UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number: 001-43037

AtaiBeckley Inc.

(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**41-3357923** **(I.R.S. Employer Identification No.)**
c/o atai Life Sciences US, Inc. **c/o Industrious NYC** **250 West 34th Street** **New York, New York** **(Address of principal executive offices)**	**10119** **(Zip Code)**

(332) 282-0507
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.01 per share	**ATAI**	**The Nasdaq Stock Market LLC (Nasdaq Global Market)**

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐ Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the Registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, as of June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $361.3 million. Solely for purposes of this disclosure, shares of common stock held by executive officers, directors and certain shareholders of the Registrant as of such date have been excluded because such holders may be deemed to be affiliates.

As of February 27, 2026, the Registrant had 364,745,985 shares of common stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s definitive proxy statement relating to its 2026 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (the "SEC") within 120 days after the end of the fiscal year ended December 31, 2025, are incorporated herein by reference in Part III where indicated.

ATAI BECKLEY INC.

FORM 10-K

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2025 (the "Form 10-K") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements contained in this Form 10-K other than statements of historical fact should be considered forward-looking statements, including without limitation statements regarding our future operating results and financial position; the success, cost, and timing of development of our product candidates, including the progress of preclinical studies and clinical trials and related milestones; the commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current product candidates and any other product candidates we may identify and pursue; the timing of and our ability to obtain and maintain regulatory approvals; our business strategy and plans, including the benefits of our corporate restructuring; potential acquisitions, partnerships and other strategic arrangements; the sufficiency of our cash and cash equivalents and short-term investments to fund our operations; and the plans and objectives of management for future operations and capital expenditures. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "initiate," "could," "would," "project," "plan," "potentially," "preliminary," "likely," and similar expressions are intended to identify forward-looking statements.

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

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

GENERAL

Unless the context otherwise requires, all references in this Form 10-K to "we," "us," "our," "atai" or the "Company" refer to ATAI Life Sciences N.V and its consolidated subsidiaries prior to the consummation of the strategic combination with Beckley Psytech (the "Beckley Psytech Transaction"), to Atai Beckley N.V. and its consolidated subsidiaries after the consummation of the Beckley Psytech Transaction and prior to the Redomiciliation Transaction (as defined below) and to AtaiBeckley Inc. and its consolidated subsidiaries after the consummation of the Redomiciliation Transaction. In addition, "AtaiBeckley" refers to AtaiBeckley Inc. and its consolidated subsidiaries after the consummation of the Redomiciliation Transaction. References to "Form 10-K" and "Annual Report on Form 10-K" herein refer to this Annual Report on Form 10-K for the fiscal year ended December 31, 2025. All references to years, unless otherwise noted, refer to our fiscal years, which end on December 31.

We were incorporated pursuant to the laws of the Netherlands as Adripa Holding B.V. on September 10, 2020 to become a holding company for ATAI Life Sciences AG, and on January 11, 2021, our name was changed to ATAI Life Sciences B.V. Prior to our initial public offering ("IPO") on June 22, 2021, we converted the legal form of ATAI Life Sciences B.V. into a public company with limited liability and our name into ATAI Life Sciences N.V. On November 5, 2025, following the completion of our acquisition of Beckley Psytech Limited, we changed our name to Atai Beckley N.V. on November 5, 2025. On December 30, 2025, we changed our corporate domicile from the Netherlands to the United States, when Atai Beckley N.V. merged with and into atai Life Sciences Luxembourg S.A., a Luxembourg public limited liability company created for the purpose of effectuating the redomiciliation, with atai Life Sciences Luxembourg S.A. surviving the merger, after which atai Life Sciences Luxembourg S.A. subsequently converted into a corporation incorporated under the laws of the State of Delaware under the name AtaiBeckley Inc.(the "Redomiciliation Transaction").

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

SUMMARY RISK FACTORS

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

- We are a clinical-stage biotechnology company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never be profitable;
- Our limited operating history may make it difficult for you to evaluate the success of our business and to assess our future viability;
- If we are unable to obtain funding when needed and on acceptable terms, we could be forced to delay, limit or discontinue our product candidate development efforts;
- Raising additional capital, such as through future sales and issuances of our common stock or rights to purchase common stock, 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;
- Our product candidates are in preclinical or clinical development, which is a lengthy and expensive process with uncertain outcomes. We cannot give any assurance that any of our product candidates will be successfully developed and/or receive regulatory approval, which is necessary before they can be commercialized;
- We may not achieve our publicly announced milestones according to schedule, or at all;
- We currently rely on qualified healthcare professionals 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 qualified healthcare professionals or effectively manage their professionals, our business, financial condition and results of operations would be materially harmed;
- Research and development of drugs targeting the central nervous system, or CNS, is particularly difficult, and it can be difficult to predict and understand why a drug has a positive effect on some patients but not others, which may reduce the likelihood our product candidates are ultimately approved and therefore may have a material adverse effect on our business and operating results;
- The production and sale of our product candidates may be considered illegal or may otherwise be restricted due to the use of controlled substances, which may also have consequences for the legality of investments from foreign jurisdictions and therefore we may not be successful in commercializing our product candidates in such jurisdictions, which will adversely affect our business, financial condition and results of operations;
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before we do or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition;
- We rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing;
- If we are unable to obtain and maintain sufficient intellectual property protection for our existing product candidates or any other product candidates that we may identify, or if the scope of the intellectual property protection we currently have or obtain in the future is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize our existing product candidates and any other product candidates that we may pursue may be impaired;
- Third parties may claim that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent or delay our development and commercialization efforts;
- Our business is subject to global financial and economic conditions and geopolitical events, including overall market volatility in the global financial markets, as well as political, trade and regulatory developments;
- Our business is subject to economic, political, regulatory and other risks associated with international operations;

- Our future success depends on our ability to retain key employees, directors, consultants and advisors and to attract, retain and motivate qualified personnel;
- A pandemic, epidemic, or outbreak of an infectious disease may materially and adversely affect our business, including our preclinical studies, clinical trials, trial sites, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results; and
- If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

PART I

Item 1. Business.

Founded in 2025 through the strategic combination of atai Life Sciences N.V. and Beckley Psytech Limited, AtaiBeckley is a clinical-stage biotechnology company on a mission to create breakthroughs for people with difficult-to-treat mental health conditions. Our work is grounded in rigorous science to deliver meaningful outcomes for the patients we serve.

Mental health disorders are highly prevalent and estimated to affect more than one billion people globally. The economic burden of these disorders is substantial and is growing rapidly. Between 2009 and 2019, spending on mental health care in the United States increased by more than 50%, reaching $225.0 billion, and a Lancet Commission report estimates that the global economic cost will reach $16.0 trillion by 2030. While current treatments, such as selective serotonin reuptake inhibitors ("SSRIs") and serotonin-norepinephrine reuptake inhibitors ("SNRIs") are well established and effective for certain patients, approximately 65% of patients do not achieve remission of their symptoms after up to four antidepressant treatment trials, translating to a significant unmet medical need.

Our Programs

We aim to create breakthroughs in mental health by developing effective, rapid-acting and convenient treatments that could transform patient outcomes. We are committed to leading a new era of mental health treatment – one that not only offers relief from symptoms, but the possibility of an improved quality of life and lasting change.

We have built a diversified pipeline of investigational psychedelic-based neuroplastogens designed to address some of the most urgent unmet needs in mental health. Our programs include:

- BPL-003: Nasal spray mebufotenin (5-MeO-DMT) benzoate for treatment-resistant depression ("TRD");
- VLS-01: Buccal film dimethyltryptamine ("DMT") for TRD;
- EMP-01: Oral formulation of a stable HCl salt form of the R-enantiomer of 3,4-methylenedioxy-methamphetamine ("R-MDMA") for social anxiety disorder ("SAD"); and
- A drug discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for TRD and Opioid Use Disorder ("OUD").

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

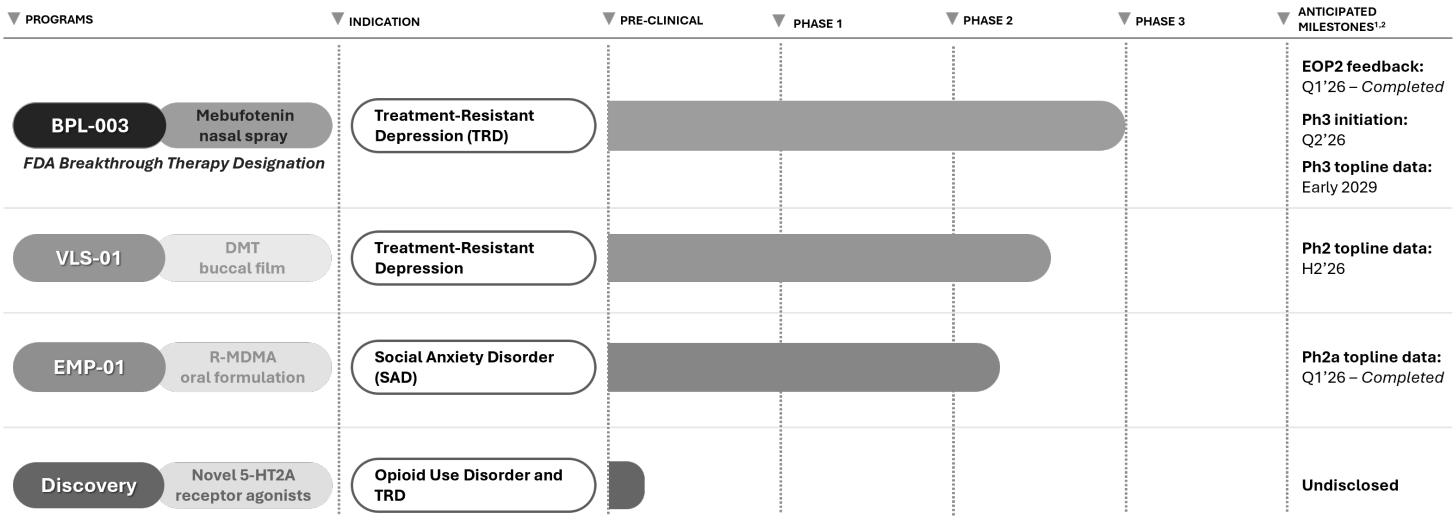
We are committed to innovation in the mental health space as exemplified by our drug discovery program and its focus on identifying new molecules with psychedelic-like pharmacology but without hallucinogenic potential. In addition to these investments in novel chemical entity ("NCE") discovery, intellectual property development has been a key strategic component since inception.

Redomiciliation

On December 30, 2025, as part of the previously announced plan to change our corporate domicile from the Netherlands to the United States via Luxembourg, as approved by our shareholders, we merged with and into atai Life Sciences Luxembourg S.A., a Luxembourg public limited liability company ("atai LuxCo"). On December 30, 2025, atai LuxCo then consummated the conversion of atai LuxCo into a corporation incorporated under the laws of the State of Delaware under the name AtaiBeckley Inc. As a result of the Redomiciliation Transaction, AtaiBeckley Inc. became the successor issuer to Atai Beckley N.V. pursuant to Rule 12g‑3(a) under the Exchange Act.

Our Pipeline

Our pipeline includes wholly owned psychedelic-based product candidates across multiple neuropsychiatric indications including depression and anxiety. The table below summarizes the status of our core product candidate portfolio as of the date of this Form 10-K.



1. All timing provided is estimated; 2. Trial initiation defined as central regulatory and ethics approval. Abbreviations: DMT = Dimethyltryptamine; FDA = Food and Drug Administration; R-MDMA = R-enantiomer of 3,4-methylenedioxy-methamphetamine; EOP2 = FDA End of Phase 2; TRD = Treatment-Resistant Depression.

The following details our psychedelic and non-psychedelic programs, recent advancements in our ongoing clinical trials and upcoming milestones:

BPL-003: Mebufotenin benzoate for TRD

- **Product Candidate Concept**: BPL-003 is a dry powder, intranasal formulation of the benzoate salt form of mebufotenin, a psychoactive indolealkylamine derivative of tryptamine. Mebufotenin is a serotonergic psychedelic due to its ability to bind to a variety of serotonin ("5-HT") receptors where it predominantly acts as an agonist. Its agonist actions at serotonin 1A ("5-HT_{1A}") and serotonin 2A ("5-HT_{2A}") receptors are considered to be the most important for the majority of its reported effects.

- **Disease Overview**: Depression is a mood disorder that affects one's thoughts, behaviors and emotions often causing a prolonged depressed mood and other symptoms severely impacting an individual's ability to live a normal life. TRD occurs when someone with depression does not experience symptom improvement, despite trying at least two different antidepressants. Of the estimated 300 million people who suffer from depression worldwide, 50% have depression which is treatment resistant.

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

- **Recent Advancements:** BPL-003 is currently being investigated as a treatment for people with TRD, with an ongoing Phase 2a open-label study and a completed Phase 2b double-blind, randomized, quadruple-masked study with open-label extension. Through an End-of-Phase 2 meeting with the FDA in February 2026, we obtained feedback from the agency on the design of the Phase 3 clinical program, which will consist of two pivotal trials each with a 12-week randomized, double-blind, placebo-controlled core study followed by a 52-week open-label extension. We remain on track to initiate the Phase 3 program in the second quarter of 2026.

  Phase 2a study in TRD: In March 2024, Beckley Psytech announced positive initial results from Part 1 of the ongoing four-part Phase 2a open-label study in patients with moderate to severe TRD. The study evaluated the safety, tolerability and efficacy of a single 10 mg dose of BPL-003 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). A single 10 mg dose induced a rapid antidepressant response (≥50% reduction in MADRS score) in 55% of patients the day after dosing. This effect was durable, with the 55% response rate maintained at weeks 4 and 12. Remission (MADRS score ≤10) was achieved by 55% of patients at Week 4 and 45% at Week 12. BPL-003 was well tolerated, with

adverse events predominantly mild or moderate; the most common (>10%) were nasal discomfort, headaches, nausea and vomiting, consistent with Phase 1 findings. No serious adverse events were reported. Acute effects resolved on the day of dosing, and patients were generally discharge-ready in less than two hours.

In May 2025, atai Life Sciences announced positive topline data from Part 2 of Beckley Psytech's Phase 2a study of BPL-003 in patients with TRD receiving a stable dose of SSRI therapy. 12 subjects were dosed and followed for 12 weeks. A single dose of BPL-003 induced rapid and durable antidepressant effects, with mean MADRS reduction of 18 points the day after dosing, 19 points at one month and 18 points at three months. All adverse events were mild or moderate, and no serious adverse events were reported. These results were consistent with the findings from Part 1 of the study.

In September 2025, atai Life Sciences and Beckley Psytech announced positive data from Part 3 of the Phase 2a study evaluating a two-dose induction regimen of BPL-003 in patients with TRD who were not on concurrent antidepressants. Patients received an 8 mg dose followed two weeks later by a 12 mg dose. Following the first (8 mg) dose, mean MADRS reductions of 13.3 points and 12.9 points were observed at day 2 and Day 8, respectively. One week after the second (12 mg) dose, the total mean reduction reached 19.0 points, with effects sustained through Week 12 (13.7 points from baseline). Remission rates were 25% one week after the initial 8 mg dose, increasing to 50% at Week 8 and 42% at Week 12. Adverse events were mild or moderate, with no serious drug-related adverse events reported. Patients generally met discharge-readiness criteria within two hours following both doses.

The data from Part 3 demonstrate that a second dose of BPL-003 at Week 2 was associated with additional reductions in MADRS score without adversely affecting the safety or tolerability profile. We believe the short-duration and time-to-discharge observed in Parts 1-3 were consistent with a potentially shorter in-clinic treatment paradigm.

In March 2026, we announced the first patient dosed in the Part 4 cohort of the Phase 2a study, evaluating a two-dose induction regimen of BPL-003 (8 mg followed by 8 mg two weeks later) in patients receiving defined antidepressants. Patients will be followed for an additional 10 weeks, and initial data are expected in the fourth quarter of 2026.

Phase 2b study in TRD: In March 2025, Beckley Psytech announced that it had completed patient enrollment in the eight-week, randomized, quadruple-masked, controlled Phase 2b study of BPL-003 for patients with TRD. The study evaluated a single 12mg or 8mg dose of BPL-003 compared to a sub-perceptual 0.3mg comparator dose in a total of 196 enrolled patients. Efficacy was assessed by masked raters using the MADRS scale at several time points, with the primary endpoint at Week 4 and the final assessment at Week 8.

In July 2025, atai Life Sciences and Beckley Psytech announced positive topline results from the Phase 2b study of BPL-003 in patients with TRD. The study was conducted across 38 sites in six countries, and 193 patients were included in the topline efficacy dataset. Patients were randomized to receive a single 12 mg (n=73), 8 mg (n=46), or 0.3 mg comparator (n=74) dose of BPL-003 and were followed for eight weeks with efficacy assessments conducted by centralized, blinded raters using the MADRS at Day 2, Day 8, Day 29, and Day 57. The trial met its primary and all key secondary endpoints. At Day 29, a single 12 mg dose of BPL-003 demonstrated a statistically significant mean reduction of 11.2 points from baseline in MADRS compared to a 5.8-point reduction with the 0.3 mg comparator ($p = 0.0033$). A single 8 mg dose produced a mean reduction of 12.0 points ($p=0.0032$ vs. comparator) at the same time point. Statistically significant differences for both the 8 mg and 12 mg doses were observed as early as Day 2 and were generally maintained through Week 8.

Durability of effect was also observed. At Day 57, the 8 mg group showed a mean change of 10.7 points from baseline and the 12 mg group showing a mean change of 10.3 points compared with a 5.2-point reduction in the 0.3 mg group. BPL-003 was generally well-tolerated across all dose arms, with approximately 99% of treatment-emergent adverse events classified as mild or moderate, and no drug-related serious adverse events or suicide-related safety signals. The majority of patients met readiness-for-discharge criteria 90 minutes post-dose, which suggests BPL-003 could fit within the existing 2-hour in-clinic interventional psychiatry treatment paradigm established by Spravato®. Based on these results, the 8 mg dose was selected for advancement into Phase 3 clinical studies.

In November 2025, we announced positive top-line results from the Phase 2b open-label extension (OLE) study of BPL-003. In the OLE, a second 12 mg dose was administered eight weeks after the initial dose received in the core trial (12 mg, 8 mg, or 0.3 mg). This second dose produced additional rapid-onset and clinically meaningful antidepressant effects that were sustained for up to eight weeks. Among patients who had received either 8 mg or 12 mg in the core study (n=60), the mean reduction in MADRS total score at Day 57 (Week 16 of the Phase 2b trial) was 19.0 points, with a response rate of 63% and a remission rate of 48%.

Patients who initially received the 0.3 mg comparator dose in the core study (n=47) demonstrated a mean reduction of 14.0 points in MADRS score at Day 57 in the OLE, consistent with the antidepressant effects observed in patients who had received a single active dose in the core study. Among patients who initially received an 8 mg dose in the core study (n=23), the mean reduction in MADRS score at Day 57 in the OLE was 22.3 points, with an 81% response rate (≥50% improvement in MADRS total score) and a 67% remission rate (MADRS ≤10) at the same time point. BPL-003 was well-tolerated with the majority of

treatment-emergent adverse events occurring on the day of the dosing. Most were classified as mild or moderate, and they were transient in nature. One serious drug-related AE was reported which resolved with additional in-patient monitoring and support.

The topline results from the OLE study were consistent with the previously announced results from the eight-week, blinded core study. Safety and efficacy data from both the core and OLE portions of the Phase 2b clinical trial supported the selection of the 8 mg dose for advancement into Phase 3 development and indicated the potential for additional benefit with repeat dosing. Following these results, AtaiBeckley completed an End-of-Phase 2 (EOP2) meeting with the FDA to obtain feedback on clinical trial designs and other key elements of the Phase 3 program.

The Phase 3 program is designed to include two pivotal studies, ReConnection 1 and ReConnection 2, conducted in parallel. Both will include a 12-week, randomized, double-blind, placebo-controlled core study followed by a 52-week open-label extension (OLE) in which participants may receive individualized retreatment with BPL-003, subject to pre-specified eligibility criteria.

- ReConnection 1: The core study will enroll approximately 350 participants and will evaluate a single-dose of BPL-003 across three treatment arms - 8 mg, 4 mg, and placebo (randomized 2:1:2). This trial is designed to replicate and extend the treatment response observed in the Phase 2b study and to further characterize the dose–response relationship for BPL-003.
- ReConnection 2: The core study will enroll approximately 300 participants and will evaluate BPL-003 administered on Day 1 and Day 15 across two arms - 8 mg BPL-003 and placebo (randomized 1:1). This trial is designed to investigate a two-dose induction model of BPL-003 as a potential treatment option to increase magnitude and durability of initial response.

The primary endpoint in both pivotal trials will be the change from baseline in the MADRS (Montgomery-Åsberg Depression Rating Scale) total score at Week 4 (Day 29) of the response in the 8 mg BPL-003 treatment arm compared to placebo.

In the OLE, participants may receive 8 mg BPL-003 at 8‑ or 12‑week intervals, subject to certain conditions for re-treatment eligibility, with the goal of maintaining remission and assessing long‑term safety, durability of effects, and treatment patterns.

Initiation of the Phase 3 program is planned for the second quarter of 2026.

VLS-01: DMT for TRD

- **Product Candidate Concept:** VLS-01 is an investigational proprietary oral transmucosal film formulation of N,N-Dimethyltryptamine (DMT) applied to the buccal surface and is being developed for the treatment of people suffering from treatment-resistant depression (TRD). Pharmacologically, VLS-01 is a partial to full agonist of the $5HT_{1/2/6/7}$ receptors and has been designed to potentially offer rapid, robust, and durable efficacy with a favorable safety profile. VLS-01 has been modeled on a short-duration interventional psychiatry treatment paradigm, positioning it for integration into existing care models. In a third-party study, intravenous ("IV") DMT has demonstrated rapid-acting antidepressant effects in patients with MDD.
- **Disease Overview:** See "— BPL-003 - Disease Overview" for an overview of TRD.
- **Recent Advancements:** VLS-01 is being developed as a potential rapid-acting treatment for people with TRD, supported by a completed Phase 1b study in healthy volunteers demonstrating favorable safety results, dose-proportional pharmacokinetics, and robust, dose-dependent subjective effects comparable to IV DMT. In March 2025, we initiated the Elumina Phase 2 randomized, double-blind, placebo-controlled trial evaluating VLS-01 in adults with TRD across two treatment periods designed to assess both rapid antidepressant effects and the contribution of repeat dosing. Topline results from this study are anticipated in the second half of 2026.

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

  Phase 2b Study in TRD: In March 2025, we announced dosing of the first patient in the Elumina trial, a randomized, double-blind, placebo-controlled Phase 2 study of VLS-01 in TRD. The study consists of two treatment periods. In the first treatment

period, approximately 142 patients were randomized 1:1 to receive a 120mg dose of VLS-01 or placebo on Day 1 and again at Week 2. The primary endpoint is change from baseline in MADRS total score at Week 4, with blinded follow-up extending to Week 14 to assess durability.

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

We anticipate reporting topline data for the Elumina study in the second half of 2026.

EMP-01: R-MDMA for SAD

- **Product Candidate Concept**: EMP-01 is a novel, investigational, oral formulation of a stable HCl salt form of R-MDMA, the R-enantiomer of 3,4-methylenedioxymethamphetamine in development for Social Anxiety Disorder (SAD). It is engineered to elicit empathogenic and psychedelic subjective effects while exhibiting reduced dopaminergic and noradrenergic activity compared with racemic MDMA. Preclinical and Phase 1 data suggest that R-MDMA showed a more selective serotonergic profile with fewer stimulant-related physiological effects than the racemic mixture. EMP-01 is designed to induce a transient, inward-focused altered-state experience characterized by heightened emotional insight and openness, consistent with engagement of 5-HT2A pathways and its entactogenic MDMA-class profile. We believe this differentiated pharmacology has the potential to enable safe, scalable outpatient administration for people with SAD.

- **Disease Overview:** SAD is one of the most prevalent psychiatric conditions worldwide, affecting an estimated 400–800 million individuals with a lifetime prevalence of approximately 12%. The disorder is characterized by persistent and debilitating fear, self-consciousness, and heightened anxiety during social interactions. SAD is frequently comorbid with major depressive disorder, generalized anxiety disorder, obsessive–compulsive disorder, attention deficit/hyperactivity disorder, bipolar disorder, and substance use disorders, contributing to substantial functional impairment and reduced quality of life. In the United States alone, roughly 30 million adults are affected by SAD; however, only about 50% of affected individuals seek treatment. Even among patients who access care, treatment adequacy remains suboptimal, and around 50% of SAD patients do not achieve adequate response to first line therapies and often deal with chronic medication side effects. These gaps in diagnosis, access, side effects and treatment response highlight a significant unmet medical need and underscore the urgency for innovative, effective therapeutic approaches for SAD.

- **Recent Advancements**: EMP-01 is being developed as a potential treatment for SAD. The program includes a completed randomized, double-blind, placebo-controlled Phase 1 study in healthy volunteers and a completed exploratory, double-blind, placebo-controlled Phase 2a study in adults with SAD. In the Phase 1 study, EMP-01 demonstrated favorable safety results, dose-proportional pharmacokinetics, and dose-dependent subjective and biomarker changes. In February 2026, we announced positive topline results from the Phase 2a trial, which met its primary endpoint of safety and tolerability and demonstrated clinically meaningful improvements across key efficacy measures.

  Phase 1 Study in Healthy Volunteers: In January 2024, we announced topline results from a randomized, double-blind, placebo-controlled, single-ascending-dose Phase 1 study conducted in 32 healthy volunteers across four dose cohorts (75 mg, 125 mg, 175 mg and 225 mg). EMP-01 was generally well tolerated, with no serious adverse events and no study discontinuations reported. Pharmacokinetics were dose-proportional, and pharmacodynamic assessments demonstrated dose-dependent changes across subjective measures and blood-based biomarkers. EMP-01 also produced a differentiated subjective profile in comparison to published reports involving racemic MDMA on standardized questionnaires, including dose-dependent increases on measures associated with emotional breakthrough phenomena and altered-state experiences.

  Phase 2a Study in SAD: In February 2026, we announced topline results from the exploratory, double-blind, placebo-controlled Phase 2a study evaluating EMP-01 in adults with SAD. The study met its primary endpoint, with EMP-01 demonstrating a favorable and manageable safety and tolerability profile, including no serious adverse events and no treatment-emergent suicidal behavior or intent. Most adverse events were mild or moderate and resolved without intervention. The multi-center study enrolled 71 adults with moderate-to-severe SAD who were randomized to receive two 225 mg doses of EMP-01 or placebo, administered 28 days apart, with psychological support but no adjunctive psychotherapy. All clinician-rated assessments were conducted by blinded central raters. The primary endpoint was safety and tolerability through Day 43, and the secondary endpoint was change in social anxiety symptoms from baseline to Day 43, using the Liebowitz Social Anxiety Scale (LSAS). An additional exploratory endpoint included changes on the CGI-I (Clinician Global Impression-Improvement) scale.

  Secondary and exploratory efficacy endpoints showed encouraging signals. EMP-01 produced a numerically greater symptom reduction than placebo, as measured by LSAS, at Day 43 relative to baseline (least squares mean: -28.53 points vs. -16.67 points, respectively). Although the study was not powered for statistical significance, the placebo-adjusted least squares mean reduction for EMP-01 of 11.85 points on the LSAS at Day 43 (Hedges' g = 0.45; p-value = 0.036, one-tailed) is consistent with a clinically meaningful improvement and a moderate treatment effect size.

On the CGI-I scale, which reflects a global impression of overall patient improvement, 49% of patients receiving EMP-01 were rated as "very much improved" or "much improved" compared to 15% in the placebo group. This 34-percentage-point difference corresponds to a Number Needed to Treat (NNT) of 2.95 (95% CI: 1.84, 7.42), indicating a clinically meaningful level of global improvement in the EMP-01 group.

The LSAS comprises two subscales - Fear and Avoidance - which often show different timelines of improvement in SAD pharmacotherapy trials, with Fear typically improving first. In this study, EMP-01 produced simultaneous gains across both domains. By Day 43, LSAS Fear improved by -13.7 points (-25.4%) in the EMP-01 group vs. -8.1 (-15.5%) on placebo, and LSAS Avoidance improved by -15.1 points (-28.6%) in the EMP-01 group vs. -8.5 (-17.1%) on placebo. Because avoidance behaviors typically change gradually and often require prolonged real-world exposure, the early, parallel improvements in both Fear and Avoidance - after two dosing sessions and without psychotherapy - suggest that EMP-01 could influence both the emotional and behavioral dimensions of social anxiety disorder.

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

- **Product Candidate Concept:** Novel 5-HT2A receptor agonists were discovered that maintain non-hallucinogenic potential based on their inability to fully-substitute for a traditional psychedelic in rodent drug discrimination studies. These differentiated 5-HT2A receptor agonists are being further optimized and studied in a series of animal models to assess therapeutic potential.
- **Recent Advancements:** In August 2025, we announced that the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health ("NIH"), awarded us a multi-year, milestone-driven grant of up to $11.4 million to support the optimization and early-stage development of the our novel 5-HT2A/2C receptor agonists with non-hallucinogenic potential for opioid use disorder. The funding is intended to support lead optimization, translational proof-of-concept studies, and the toxicology and manufacturing work needed to file an Investigational New Drug application.

Competition

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

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

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

Depression

Multiple therapies for depression exist, including common pharmacological treatments such as anti-depressants and psychosocial interventions such as cognitive based therapy. There are also non-pharmacological, somatic treatments for depression such as electroconvulsive therapy and transcranial magnetic stimulation, among others. However, these current therapies are ineffective or inadequately effective for a significant portion of patients. This treatment-resistant subset of depression is our initial therapeutic focus for several of our compounds. For TRD there are currently only two pharmacological treatments approved in the United States: (i)

SPRAVATO (S-ketamine) nasal spray, an NMDA receptor antagonist, approved by the FDA in March 2019 and marketed by Janssen Pharmaceutical Companies of Johnson & Johnson, and (ii) a fixed dose combination of olanzapine and fluoxetine hydrochloride, which are individually available generically. In addition, there have been recent developments in the treatment of MDD, including AUVELITY (dextromethorphan/bupropion), a therapeutic marketed by Axsome Therapeutics, which was approved by the FDA in August 2022 and CAPLYTA (lumateperone, a therapeutic originally developed by Intra-Cellular Therapies (now Johnson & Johnson) and approved by the FDA in November 2025. Psychosocial interventions and non-pharmacological, somatic treatments may also be used for patients. We are aware of several other biotechnology companies with therapies in development for TRD and MDD including, GH Research, Helus Pharma, Definium Therapeutics, Neumora Therapeutics, Alto Neuroscience, Xenon Pharmaceuticals, AbbVie Inc., Acadia Pharmaceuticals, as well as COMPASS, in which we hold an equity stake.

Anxiety

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

We are aware of several biotechnology companies with therapies in development for anxiety disorders including VistaGen Therapeutics, Engrail Therapeutics, Definium Therapeutics, and Helus Pharma.

Overview of our Intellectual Property

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

As of December 31, 2025, our intellectual property portfolio includes over 100 issued patents and over 200 pending applications worldwide, including 41 issued U.S. patents, 54 pending U.S. patent applications, 13 pending U.S. provisional applications, and 21 PCT applications. Our intellectual property portfolio for our key psychedelic programs are summarized in the table below. A description of our key psychedelic programs, strategic investments and non-psychedelic programs then follows. In addition, we have, and may continue to, enter into collaboration and licensing arrangements for research and development, manufacturing, and commercialization activities with counterparties for the development and commercialization of its product candidates.

BPL-003
Mebufotenin benzoate nasal spray for TRD

U.S. IP

	Issued	Pending
Drug Substance	✓	✓
Drug Product	✓	✓
Methods of Use	✓	✓
Other	✓	✓

Issued IP contemplates (non-exhaustive):

- Mebufotenin compositions for transmucosal delivery including intranasal, buccal and sublingual (Exp 2041)
- Mebufotenin benzoate salt compositions (Exp 2041)
- Methods of treating depression using mebufotenin benzoate (Exp 2041)
- Dry powder of mebufotenin & silicon dioxide (Exp 2043)
- "Other" includes alternative salt forms of mebufotenin and their methods of use (Exp 2041-43)

VLS-01
Dimethyltryptamine (DMT) buccal film for TRD

U.S. IP

	Issued	Pending
Drug Substance	–	–
Drug Product	✓	✓
Methods of Use	✓	✓
Other	✓	✓

Issued IP contemplates (non-exhaustive):

- DMT compositions for oral transmucosal delivery including buccal and sublingual (Exp 2041)
- Buccal film compositions of DMT (Exp 2042)
- Methods of treating a neurological disease or condition with a polymeric film of DMT (Exp 2042)
- "Other" includes DMT compositions for alternative RoAs including intranasal, alternative salt forms of DMT, and DMT prodrugs (Exp 2041-42)

EMP-01
R-MDMA oral formulation for SAD

U.S. IP

	Issued	Pending
Drug Substance	✓	✓
Drug Product	–	✓
Methods of Use	–	✓
Other	✓	✓

Issued IP contemplates (non-exhaustive):

- R-MDMA crystalline HCl salt composition of matter (Exp 2043)
- "Other" includes methods of manufacturing high purity R-MDMA, and MDMA prodrugs (Exp 2042)

1. Currently all in active prosecution as of 31st December 2025. Abbreviations: TRD = Treatment Resistant Depression; SAD = Social Anxiety Disorder; RoA = Route of Administration.

A description of our patents for our key psychedelic programs, strategic investments and non-psychedelic program as of December 31, 2025, follows below:

VLS-01

Atai Therapeutics, Inc. owns six issued U.S. patents, seven pending U.S. patent applications, four pending PCT patent applications, one pending U.S. provisional patent application, one granted foreign patent in Chile, and thirty-eight pending foreign patent applications in Argentina, Taiwan, Australia, Brazil, Canada, Chile, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russian Federation and UAE, covering (i) DMT compositions exhibiting unique PK profiles following transmucosal administration (ii) new DMT salts and polymorphic forms, including DMT succinate, (iii) DMT parenteral formulations, (iv) oral transmucosal films of DMT, (v) DMT intranasal and transdermal formulations, and (vi) methods of treating using DMT, including methods of treating treatment resistant depression. These issued patents and any patents issuing from these pending patent applications, if granted, are expected to expire between 2041 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. Atai Therapeutics, Inc. owns four issued U.S. patents, five pending U.S. patent applications, two pending PCT patent applications, and twenty-six pending foreign applications in Australia, Brazil, Canada, Chile, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russian Federation, UAE, Argentina, and Taiwan, covering novel analogues, prodrugs and conjugates of dimethyltryptamine, methods and pharmaceutical compositions thereof. These issued patents and any patents issuing from these pending patent applications, if granted, are expected to expire between 2042 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

EMP-01

EmpathBio, Inc. owns four issued U.S. patents, eight pending U.S. patent applications, seven pending foreign patent applications in Canada, Europe and Mexico, and one pending PCT patent applications covering MDMA enantiomers and processes for the preparation of MDMA, its enantiomers and derivatives thereof. These issued patents and any patents issuing from these pending patent applications, if granted, are expected to expire between 2042 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. EmpathBio, Inc. owns one issued U.S. patent, four pending U.S. patent applications, one pending U.S. provisional application, six pending foreign patent application in Europe and two pending PCT patent applications covering salts of R-MDMA and polymorphic forms and compositions comprising R-MDMA and methods of treating with the same, including methods of treating social anxiety disorder. Any patents issuing from these pending patent applications, if granted, are expected to expire between 2043 and 2046, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. EmpathBio, Inc. owns three pending U.S. patent applications and four pending foreign patent applications in Australia, Canada, Europe and Japan covering uses of MDMA for treating stress related disorders, increasing exposure of R-MDA, and modulating aggression responses. Any patents issuing from these pending patent applications, if granted, are expected to expire between 2043 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

EGX-A & EGX-B

Atai Therapeutics, Inc. owns five issued U.S. patents, nine pending U.S. patent applications, three pending PCT patent applications, and twenty-two pending foreign patent applications in Australia, Brazil, Canada, Chile, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia and UAE covering novel 5-HT2A agonists and methods of using the same. These issued patents and any patents issuing from these pending patent applications, if granted, are expected to expire between 2041 and 2045. Atai Therapeutics, Inc. owns, one PCT patent application covering non-hallucinogenic 5-HT2A agonists. Any patents issuing from this application, if granted, are expected to expire in 2044.

BPL-003

Through our strategic combination with Beckley Psytech Limited, we acquired four issued U.S. patents, seventeen pending U.S. patent applications, six pending PCT patent applications, nine pending U.S. provisional applications, twenty foreign granted patents in Europe, United Kingdom, China, and Japan, nineteen pending foreign patent applications in Australia, Brazil, Canada, China, Europe, Israel, Japan, South Korea and New Zealand, and eight pending United Kingdom priority applications covering (i) benzoate salt of 5-methoxy-N,N-dimethyltryptamine (mebufotenin), (ii) formulations comprising 5-methoxy-N,N-dimethyltryptamine including the benzoate salt, (iii) methods of preparing the benzoate salt of 5-methoxy-N,N-dimethyltryptamine, (iv) methods of treating using 5-methoxy-N,N-dimethyltryptamine including the benzoate salt to treat depression, (v) new polymorphic forms of the benzoate salt of 5-methoxy-N,N-dimethyltryptamine. These issued patents and any patents issuing from these pending patent applications, if granted, are expected to expire between 2041 and 2046, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

ELE-101

Amandala Neuro Limited (formerly Eleusis Holdings Limited), in which we own an 33.7% equity interest following the distribution by Beckley Psytech Limited of its interest in Eleusis Holdings Limited, owns two issued U.S. patents, one pending U.S. provisional patent application, four pending U.S. patent applications, two pending PCT patent applications and eleven pending foreign patent applications across Australia, Brazil, Canada, China, Europe, Israel, Japan, South Korea and New Zealand, covering the benzoate salt of 4-hydroxy-N,N-dimethyltryptamine (psilocin), methods of synthesis, methods of use, crystalline forms and formulations thereof. Amandala Neuro Limited also co-owns with Board of Supervisors of Louisiana State of University and Agricultural and Mechanical College one pending U.S. patent application and one pending foreign patent application in Europe covering methods of use of psilocin and 3-[2-(Dimethylamino)ethyl]-1H-indol-4-yl dihydrogen phosphate (psilocybin). Atai Therapeutics, Inc. has a strategic investment in Amandala Neuro Limited to accelerate the clinical development of short-duration psychedelics.

RL-007

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

Patents

Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. With regard to our U.S. provisional patent applications, if we do not file any corresponding non-provisional patent applications within 12

months of the provisional patent application filing date, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. All taxes, annuities or maintenance fees for a patent, as required by the United States Patent and Trademark Office ("USPTO") and certain foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product-by-product basis, from country to country and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions and the availability of legal remedies in a particular country and the validity and enforceability of the patent. Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Trade Secrets and Proprietary Information

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

Government Regulation and Product Approval

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

U.S. Drug Development Process

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

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

- completion of required non-clinical laboratory tests, animal studies and formulation studies in accordance with FDA’s good laboratory practice (“GLP”) requirements and other applicable regulations;
- submission to the FDA of an investigational new drug application ("IND") which must become effective before human clinical trials may begin;
- approval by an institutional review board (“IRB”) or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice (“GCP”) requirements to evaluate the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a new drug application (“NDA”) after completion of all pivotal trials;
- payment of user fees for the FDA review of the NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA advisory committee review, if applicable;

- potential FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice ("cGMP") requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA inspection of the non-clinical and/or clinical trial sites that generated the data in support of the NDA, and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an IND to the FDA. An IND must become effective before human clinical trials may begin. An IND is a request to the FDA for allowance to initiate a clinical trial in the United States. Once submitted, the IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA allowance to begin a clinical trial.

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

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

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

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

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

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

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Process

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

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

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

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

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

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

application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may contain limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy ("REMS") to ensure the product is distributed and used in a manner such that benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may withdraw or limit further marketing of the product based on the results of such post-marketing studies.

Expedited Development and Review Programs

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

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

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

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

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

Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are also continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which

impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

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

Marketing Exclusivity

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

The FDCA alternatively provides three years of non-patent exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential

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

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

DEA Regulation

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

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

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

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

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

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

Foreign Government Regulation

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

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries, including the European Commission or national competent authorities in the EU, as well as regulatory agencies in the APAC region such as the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, the National Medical Products Administration (NMPA) in China, and comparable authorities in other APAC jurisdictions, prior to the commencement of clinical trials or the marketing of product candidates in those countries. Failure to comply with applicable foreign regulatory requirements may result in, among other things,

fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-clinical studies and clinical trials

Similar to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice ("GLP") as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Cooperation and Development ("OECD") requirements.

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

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

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

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

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

Marketing Authorization

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

- "Centralized MA" are issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Product for Human Use ("CHMP") of the European Medicines Agency ("EMA") and are valid throughout the EU. The centralized procedure is mandatory for certain types of product candidates, such as: (i) medicinal products derived from biotechnological processes, such as genetic engineering, (ii) designated orphan medicinal products, (iii) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative diseases, diabetes, or auto-immune diseases and other immune dysfunctions and viral diseases and (iv) advanced therapy medicinal products ("ATMPs") such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure is optional for product candidates containing a new active substance not yet authorized in the EU, or for product candidates that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

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

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

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

Data and marketing exclusivity

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

Controlled Substances

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

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

The UN Conventions require signatories to require all persons manufacturing, trading (including exporting and importing) or distributing controlled substances to obtain a license from the relevant authority. Each individual export or import of a controlled substance must also be subject to an authorization. Before the relevant authority can issue an export authorization for a particular shipment, the exporter must provide the authority with a copy of the import authorization issued by the relevant authority of the importing country. Implementation of the obligations provided in the UN Conventions and additional requirements are regulated at national level and requirements may vary from one member state to another.

Post-Approval Requirements

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

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

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

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

Brexit and the Regulatory Framework in the United Kingdom

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

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

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

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from pre-existing EU legislation (as implemented into UK law, through secondary legislation). In April 2025, the UK adopted the Medicines for Human Use (Clinical Trials) Amendment Regulations. The amendment, which will take full effect from

April 2026, aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered.

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

Other Healthcare Laws

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

Coverage and Reimbursement

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

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

Healthcare Reform

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

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the

constitutionality of the ACA. Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which was temporarily suspended from May 1, 2020 through March 31, 2022. In March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, proposed and enacted legislation intended to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In 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, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began on January 1, 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs, which will first be effective in 2027. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program, although the program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated, or the impact of the IRA on our business.

The One Big Beautiful Bill Act (the "OBBBA") also included significant reforms to Medicaid, including an estimated $1.0 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations, and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our business is currently unknown, any decrease in the number of insured patients or reimbursement levels for our products, if approved, could adversely affect our revenue and commercial prospects.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our product candidates, if approved. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

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

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

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

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

On December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022, and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as

well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Environmental, Health and Safety

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

Data Privacy and Security Laws

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

Human Capital Management

As a company focused on creating new possibilities in mental health, we are working to transform patient outcomes by developing rapid-acting, durable and convenient mental health treatments. 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.

Following the strategic combination with Beckley Psytech Limited in November 2025, as of December 31, 2025, we had 99 full-time employees and 18 contractors or consultants doing regular work for us. This includes 23 employees and 2 consultants doing regular work for our Nualtis subsidiary. Of our full-time employees, 66 focus on driving forward research and development programs, either directly or through our subsidiaries. This also includes 20 employees driving forward research and development programs at Nualtis. Others provide strategic business development, finance, and executive leadership expertise, as well as operational, communications, legal and administrative services. Approximately 40% of our employees are located in the United Kingdom, 30% located in the United States, 25% located in Canada, and the reminder in various European locations. All of the Nualtis employees are located in Canada.

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

Recruiting

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

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

Professional Development and Performance Management

We have a bi-annual performance management cycle whereby employees are rated on both “what” they delivered (measured against agreed objectives and goals) and “how” they delivered (measured against the four core 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

Our core company values are: Rooted in Purpose, See Opportunities Where Others See None, Work the Problem and Keep it Simple. Our human capital philosophy is deeply rooted in these values, which form the core of everything from performance management cycle to hiring decisions.

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:

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

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

Total Rewards and Employee Engagement

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

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

Inclusion and Belonging

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

Hybrid office culture

As of December 31, 2025, we utilize coworking spaces in Oxford, Berlin, New York and Boston to support our flexible, hybrid work model. We do not require employees to work from these locations; however, these spaces are available to facilitate in-person collaboration, team interaction and connection across functions. This approach allows employees to retain flexibility in how and where they work, while providing access to shared work environments that support collaboration and engagement when in-person interaction is beneficial.

We also lease office, lab, and manufacturing spaces in Montréal, Canada through our Nualtis subsidiary

Patient Impact

AtaiBeckley develops transformative mental health therapies for individuals living with severe and often long-standing conditions, many of whom represent vulnerable communities with significant unmet needs and limited treatment options.

We believe that those most affected by mental illness deserve a meaningful role in shaping how new treatments are developed, studied, and ultimately delivered. Patient Impact reflects AtaiBeckley’s commitment to embedding lived experience at the center of our work, ensuring that patient perspectives actively inform clinical development, participant experience, community engagement, and future models of care.

Through a formal materiality assessment conducted with key internal and external stakeholders, the Company identified patient trust, ethical engagement, trial participation experience, and community readiness as material factors influencing long-term success in mental health innovation. Patient Impact was designed to address these priorities by building long-term partnerships with patients, advocacy organizations, and community leaders, and by systematically incorporating lived experience into how we design and deliver our research programs.

As part of this approach, AtaiBeckley collaborates with peer-support and patient advocacy organizations, including The Psychedelic Participant Advocacy Network (PsyPAN), to bring the voices of individuals with direct experience of psychedelic-assisted treatments into clinical design, participant support, and post-trial learning. These partnerships help strengthen ethical practice, improve trial journeys, and contribute to responsible, patient-centered standards across the evolving mental health treatment landscape.

Beyond our clinical programs, the Company supports community initiatives focused on education, stigma reduction, and the development of patient-focused models of care, reinforcing our belief that scientific progress must be matched with compassion, trust, and shared responsibility.

Patient Impact reflects our conviction that meaningful advances in mental health require not only breakthrough medicines, but deep collaboration with the people whose lives those medicines are intended to transform.

Corporate Information

Our office address and our principal executive office, or headquarters, is located at 250 West 34th Street, New York, NY 10119, and our telephone number is (332) 282-0507. Our website address is www.ataibeckley.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available for download, free of charge, through our investor relations website at *ir.ataibeckley.com* as soon as reasonably practicable after filing such material with the SEC. The information contained on, or that can be accessed from, our website does not form part of this document. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document or any other document that we file with or furnish to the SEC. Additionally, the SEC maintains a website that contains our reports, proxy and information statements, and other information. The address of the SEC's website is www.sec.gov.

Item 1A. Risk Factors

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

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

We are a clinical-stage biotechnology 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 biotechnology 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 AtaiBeckley, Inc. stockholders for the years ended December 31, 2025 and 2024 was $660.0 million and $149.3 million, respectively. We have no products that are approved for commercial sale and have not generated any commercial product revenue. We have financed operations predominantly through the sale of equity securities and debt financings. We continue to incur significant research and development, and other expenses related to ongoing operations and building our business infrastructure and expect to incur losses for the foreseeable future.

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

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

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

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

We were founded in 2018. To date, we have invested most of our resources in developing technology, establishing our platform, building our intellectual property portfolio, fostering partnerships and executing strategic transactions, including our recent acquisition of Beckley Psytech, developing our supply chain, conducting business planning, raising capital, building our management team and providing general and administrative support for these operations. We have not yet demonstrated an ability to conduct later-stage clinical trials, obtain regulatory approvals, manufacture a commercial-scale product, conduct sales and marketing activities necessary for successful product commercialization or obtain reimbursement in the countries of sale.

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

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

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

As of December 31, 2025, we had cash and cash equivalents of $85.3 million and short-term securities of $135.4 million. Based on our current operating plan, we estimate that our existing cash, including proceeds from our public offering of our common stock, marketable securities, and committed term loan funding as of the date this Annual Report on Form 10-K is filed with the SEC will be sufficient to fund operations into 2029. 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 ("CMOs");
- the costs of commercialization activities for any of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities, or entering into strategic collaborations with third parties to leverage or access these capabilities;
- the amount and timing of sales and other revenues from our product candidates, if approved, including the sales price and the availability of coverage and adequate third-party reimbursement;
- the cash requirements in purchasing additional equity from certain of our atai companies upon the achievement of specified development milestone events;
- the cash requirements of developing our programs and our ability and willingness to finance their continued development;
- the cash requirements of any future acquisitions or discovery of product candidates, including minority equity investments in third parties;
- the time and cost necessary to respond to technological and market developments, including other products that may compete with one or more of our product candidates;

- the costs of acquiring, licensing or investing in intellectual property rights, products, product candidates and businesses;
- the costs of maintaining, expanding and protecting our intellectual property portfolio;
- our ability to attract, hire and retain qualified personnel as we expand research and development and our operational and commercial infrastructure; and
- the costs of operating as a public company in the United States and maintaining a listing on the Nasdaq Stock Market LLC ("Nasdaq").

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

We may fail to realize the anticipated benefits of our strategic combination with Beckley Psytech.

The success of our strategic combination with Beckley Psytech will depend on, among other things, the combined group's ability to integrate atai's and Beckley Psytech's businesses in a manner that realizes anticipated synergies and benefits and meets or exceeds the forecasted stand‑alone cost savings anticipated by the combined group. Over time, the Company anticipates that the combined group will benefit from significant synergies, based on, among other things, increased scale. If the combined group is not able to successfully achieve these synergies, or the cost to achieve these synergies is greater than expected, then the anticipated benefits of the strategic combination may not be realized fully or at all or may take longer to realize than expected.

The success of the strategic combination will also depend on the ability of the product candidates to achieve anticipated clinical, regulatory and commercial outcomes. Clinical trials are inherently uncertain, and preliminary or early-stage results may not be predictive of final outcomes or lead to regulatory approval. Furthermore, even if regulatory approval is obtained, the combined group may face significant commercialization challenges or encounter competition sooner than expected. If Beckley Psytech's product candidates do not demonstrate safety or efficacy in later-stage trials, fail to receive regulatory approvals, encounter intellectual property challenges or face unforeseen commercial or competitive obstacles, the combined group may not realize the expected benefits of the strategic combination.

Raising additional capital, such as through future sales and issuances of our common stock or rights to purchase common stock, 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 has the authority to authorize certain offers and sales of additional securities without the vote of, or prior notice to, stockholders. 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. In February 2025, under the shelf registration statement on Form S-3 of ATAI Life Sciences N.V. on Form S-3 (File No. 333-265970) with the SEC, declared effective on July 11, 2022, (the "Shelf Registration Statement") and a prospectus supplement filed on February 13, 2025, we issued and sold 26,190,477 common stock in an underwritten offering. The common stock was sold at a public offering price of $2.10 per share, less underwriting discounts and commissions. We received aggregate net proceeds of $51.9 million. In connection with the underwritten public offering, we granted Berenberg Capital Markets LLC (the "Underwriter") an option exercisable for 30 days to purchase up to an additional 3,928,571 common stock from us at the public offering price of $2.10 per share, less underwriting discounts and commissions. The Underwriter exercised its option to purchase all additional shares February 19, 2025, and we received $7.8 million. As a result of this offering, our shareholders experienced significant dilution. In October 2025, under the Shelf Registration Statement and a prospectus supplement filed on October 16, 2025, we issued and sold 23,725,000 common shares in an underwritten offering. The common shares were sold at a public offering price of $5.48 per share, less underwriting discounts and commissions. We received aggregate net proceeds of approximately $121.7 million. In connection with the underwritten public offering, we granted underwriters an option exercisable for 30 days to purchase up to an additional 3,558,750 common shares from us at the public offering price of $5.48 per share, less underwriting discounts and commissions. The Underwriter exercised its option to purchase all additional shares on February 19, 2025, and we received $18.2 million. In November 2022, the Company entered into an Open Market Sale Agreement℠, or Sales Agreement, with Jefferies LLC ("Jefferies"), pursuant to which the Company may issue and sell its common stock having an aggregate offering price of up to $150.0 million, from time to time through an "at the market" equity offering program under which Jefferies will act as sales agent. Such additional issuances may involve the issuance of a significant number of common stock at prices less than the current market price for the common stock. We have also filed a registration

statement on Form S-8 registering the issuance of common stock 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 stock. 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 stock to decline. The incurrence of additional indebtedness would result in increased fixed payment obligations and could involve additional restrictive covenants, such as limitations on our ability to incur additional debt, limitations and liens on our assets, limitations on our ability to acquire, sell or license intellectual property rights, and other operating and financing restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term, but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses or other rights on unfavorable terms.

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

The failure to successfully integrate the businesses and operations of atai and Beckley Psytech in the expected time frame may adversely affect the combined group's future results.

atai and Beckley Psytech previously have operated independently, and their respective businesses may not be integrated successfully. It is possible that the integration process could result in the loss of suppliers, vendors, landlords, joint venture partners or other business partners, the disruption of either company's or both companies' ongoing businesses, inconsistencies in standards, controls, procedures and policies, potential unknown liabilities and unforeseen expenses or delays associated with and following completion of the strategic combination or higher than expected integration costs and an overall post‑completion integration process that takes longer than originally anticipated.

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

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

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 stock, thereby disrupting our business.

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

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

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new research and development programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such

acquisition, investment or transaction, we might incur costs in excess of what we anticipate, we might delay, limit or otherwise discontinue a program based on our ongoing assessment of our programs, and management resources and attention might be diverted from other necessary or valuable activities, any of which may have an adverse impact on our business, financial condition and results of operations.

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

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

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

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

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

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

From time to time, we may announce the timing of certain events that we expect to occur, such as the anticipated timing of results from our clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. For example, we had previously announced that Phase 2a topline results of BPL-003 in the treatment of alcohol use disorder would be expected in 2024, but ultimately those results were announced in January of 2025. The timing of events such as initiation or completion of a clinical trial, filing of an application to obtain regulatory approval, or announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. These variations in timing may occur because 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 because 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 stock.

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 euros, and potential future revenue may be earned in euros. As a result, our business and the price of our common stock may be affected by fluctuations in foreign exchange rates between the U.S. dollar and the euro, which may also have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

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

We may use our cash, cash equivalents and short-term securities to purchase bitcoin. Bitcoin is a highly volatile asset that has traded below $70,000 per bitcoin and above $120,000 per bitcoin in the 12 months preceding the date of this annual report on Form 10-K. In addition, bitcoin does not pay interest or other returns and so the ability to generate a return on investment in bitcoin will largely depend on whether there is appreciation in the market price of bitcoin following our purchases of bitcoin.

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

- Bitcoin is a highly volatile asset, and fluctuations in the price of bitcoin may influence our financial results and the market price of our common stock;
- bitcoin and other digital assets are novel assets, and are subject to significant legal, commercial, regulatory and technical uncertainty;
- our historical financial statements do not reflect the potential variability in earnings that we may experience in the future relating to bitcoin holdings;
- due to the unregulated nature and lack of transparency surrounding the operations of many bitcoin trading venues, bitcoin trading venues may experience greater fraud, security failures or regulatory or operational problems than trading venues for more established asset classes, which may result in a loss of confidence in bitcoin trading venues and adversely affect the value of the bitcoin we own;
- the emergence or growth of other digital assets, including those with significant private or public sector backing, could have a negative impact on the price of bitcoin and adversely affect our business;
- bitcoin holdings are less liquid than our existing cash and cash equivalents and may not be able to serve as a source of liquidity for us to the same extent as cash and cash equivalents;
- if we or our third-party service providers experience a security breach or cyberattack and unauthorized parties obtain access to our bitcoin, or if our private keys are lost or destroyed, or other similar circumstances or events occur, we may lose some or all of our bitcoin and our financial condition and results of operations could be materially adversely affected;
- we may face risks relating to the custody of bitcoin, including the loss or destruction of private keys required to access our bitcoin and cyberattacks or other data loss relating to our bitcoin; and
- regulatory change reclassifying bitcoin as a security could lead to our classification as an "investment company" under the Investment Company Act of 1940 and could adversely affect the market price of bitcoin and the market price of our common stock.

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

Our product candidates are in clinical (or preclinical) 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 our efforts and financial resources on identifying, acquiring, and developing product candidates, including conducting lead optimization, non-clinical studies, preclinical studies and clinical trials and providing general and administrative support for these operations. Some of our product candidates are in the preclinical stage, and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support the planned INDs in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the proposed clinical programs or if the outcome of preclinical studies will ultimately support the further development of the programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our clinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Moreover, the results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. The results of preclinical studies and clinical trials in one indication, or from preclinical studies or clinical trials that we did not lead, may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient

populations, changes in and adherence to the dosing regimen and other clinical trial protocol details. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results. Even if early-stage clinical trials are successful, we may need to conduct additional clinical trials of our product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the FDA or other comparable foreign regulatory authorities to market and sell these product candidates. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

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

Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in another 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. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue operations, which may result in dissolution, out-licensing the technology or pursuing an alternative strategy.

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

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

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

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

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

- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of product candidates that we may identify for use in clinical trials or the inability to do any of the foregoing.

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

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

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

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

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

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

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

- *DEA registration and inspection of facilities*. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control,

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

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

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

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

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

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

abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the size and nature of a patient population;
- the patient eligibility criteria defined in the applicable clinical trial protocols, which may limit the patient populations eligible for clinical trials to a greater extent than competing clinical trials for the same indication;
- the size of the study population required for analysis of the trial's primary endpoints;
- the severity of the disorder under investigation;
- the proximity of patients to a trial site;
- the inclusion and exclusion criteria for the trial in question;
- the design of the trial protocol;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the approval or concurrent enrollment of clinical trials involving competing product candidates currently under development or competing clinical trials for similar product candidates or targeting patient populations meeting our patient eligibility criteria;

- the availability and efficacy of approved medications or product candidates for the disorder or condition under investigation;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available product candidates and product candidates;
- the ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete such trials, for any reason.

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

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

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

Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or halt their clinical development, prevent their regulatory approval, cause us to suspend or discontinue clinical trials, cause us to abandon a product candidate, limit their commercial potential, if approved, or result in other significant negative consequences that could severely harm our business, prospects, financial condition and results of operations.

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

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

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

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

In addition to side effects caused by the product candidate, the administration process or related procedures also can cause adverse side effects. If any such AEs occur, our clinical trials could be suspended or terminated. If we are unable to demonstrate that any AEs were caused by the administration process or related procedures, the FDA or other regulatory authorities could order us to cease further development of, or deny approval of, a product candidate for any or all targeted indications. Even if we can demonstrate that all future

serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition, results of operations and prospects significantly.

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

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

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

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

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

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

- the efficacy and safety of the product as demonstrated in pivotal clinical trials;
- the potential and perceived advantages of the product compared to competitive and alternative products;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of dosing and administration compared to alternative treatments, including the need to have products administered in clinical settings, rather than the home, for patients who are prescribed the products;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;

- the strength of sales, marketing and distribution support;
- restrictions on how the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning these products or competing products and treatments;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

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

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

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

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

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

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

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

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

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

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

In addition, FDA and foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation has been undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published on April 26, 2023. The proposed changes were since discussed and negotiated by the European Parliament and the Council of the EU as part of the EU ordinary legislative process. A provisional agreement has been reached by the European Parliament and Council of the EU on the proposed revisions on December 11, 2025. The proposed revisions (affecting the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc.) remain to be formally adopted by the two institutions, which is not anticipated before early 2026. The proposed changes are not expected to enter into application before 2028 and may however have a significant impact on the pharmaceutical industry and our business in the long term.

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

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

From time to time, we may also disclose interim data from our clinical trials. Interim data from these trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more data becomes 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 stock.

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

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

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

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

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

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

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

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

We intend to evaluate and continue ongoing discussions with the FDA on regulatory strategies that could enable us to take advantage of expedited development pathways for certain of our product candidates in the future, although we cannot be certain that our product candidates will qualify for any designations that regulatory authorities will grant, or allow us to maintain, the relevant qualifying designations. Potential expedited FDA development and review programs 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 the fast track designation features, as well as more intensive FDA interaction and guidance. In October 2025, BPL-003 received breakthrough therapy designation for the treatment of adult patients with treatment-resistant depression.

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 where we have received such designations, they will result in any expedited review or approval or that any approved indication will not be narrower than the indication covered by the applicable designation. Therefore, even if we receive breakthrough therapy or fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, 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 programs.

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

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

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

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

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

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

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

Any regulatory approvals that we may receive for our product candidates may contain requirements for potentially costly post-marketing testing, such as additional clinical trials and surveillance to monitor the safety and efficacy of a drug product. We are required to report certain adverse reactions and production problems, if any, to the FDA, and other comparable foreign regulatory authorities. Any new

legislation addressing drug or medical safety issues could result in delays in product development or commercialization or increased costs to assure compliance.

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

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

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

If a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

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

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

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

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

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

approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition and results of operations.

Risks Related to Commercialization

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

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

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

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

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

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

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

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

indications. This trend in cost-control initiatives in the United States and other countries could cause us to decrease the price we might establish for products, and monitor and control company profits, which could result in lower than anticipated product revenues. If the prices for our drug candidates decrease or if governmental and other third-party payers do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

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

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

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

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, additional reporting requirements and

oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, diminished profits and the curtailment or restructuring of our operations. Even if we are successful in defending ourselves or asserting our rights, the existence of these actions may adversely affect market prices of our common stock.

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

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

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

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

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

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

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

Additionally, in 2024, the National Security Division of the U.S. Department of Justice (DOJ) issued a new rule—referred to as the "Data Security Program" (DSP)—to implement Executive Order 14117 aimed at preventing access to "bulk U.S. sensitive personal data" and "government-related data" by "countries of concern" (including China, Russia, Iran, North Korea, Cuba, and Venezuela) and "covered persons" (as all such terms are defined in the DSP). Effective as of April 8, 2025, and fully enforceable as of July 9, 2025, the DSP imposes stringent obligations on companies within its scope and prohibits or restricts "covered data transactions" that grant countries of concern or covered persons access to bulk U.S. sensitive personal data or any amount of government-related data. The DSP is new, complex and has yet to be enforced, and as such, there is a risk that our interpretation of its applicability, scope, and requirements is incorrect, incomplete, or misapplied. Compliance with the DSP may require us to invest heavily in data security and compliance measures, such as implementing

and complying with the Cybersecurity and Infrastructure Security Agency's guidelines and other burdensome recordkeeping, reporting, and auditing requirements. It may also require us to implement new processes, stop or restrict certain data transfers, alter the geographic scope of our operations, cease doing business with certain third parties or using certain tools or vendors, or change how data flows throughout our business, any of which could materially impact our business operations or hinder our ability to grow our business. Finally, non-compliance with the DSP could result in significant civil or criminal penalties, which could materially adversely affect our business, results of operations, and financial condition.

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

Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million/GBP 17.5 million or 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher. Since we are subject to the supervision of relevant data protection authorities under both the EU GDPR and the UK GDPR, we could be fined under each of those regimes independently in respect of the same breach. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/or civil claims (including class actions). In addition, the GDPR increases the scrutiny of transfers of personal data from the EEA or UK, including from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission or UK government does not recognize as having "adequate" data protection laws. Recent legal developments in Europe have created complexity and uncertainty regarding such transfers, in particular in relation to transfers to the United States. Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses – a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism – alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we may have to make certain operational changes and we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we operate our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

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

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

It is possible that new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit, or alter, our ability to use AI Technologies for our business. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant, which could adversely affect our business, financial condition and results of operations.

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

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

In the United States, there have been and continue to be a number of legislative initiatives and judicial challenges to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act ("ACA") was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs.

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

There have been a number of significant changes to the ACA and its implementation, as well as judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, resulted in aggregate reductions of Medicare payments to providers, which went into effect in 2013, and, due to subsequent legislative amendments, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

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 August 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs, which will first be effective in 2027. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program, although the program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated, or the impact of the IRA on our business.

The One Big Beautiful Bill Act (the "OBBBA") also included significant reforms to Medicaid, including an estimated $1.0 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations, and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment

and access to care. Although the effect on our business is currently unknown, any decrease in the number of insured patients or reimbursement levels for our products, if approved, could adversely affect our revenue and commercial prospects.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our product candidates, if approved. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We focus research and product development on treatments for mental health disorders, including depression, substance use disorder, anxiety and other neurological indications. Our projections of both the number of individuals who are affected by our target disorder indications and have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these disorders. The number of patients may turn out to be lower than expected. The effort to identify patients with these mental health disorders we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for our

product candidates that we may identify may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because the potential target populations may be small, we may never achieve profitability.

Risks Related to Reliance on Third Parties

We may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

If we enter into any collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, including the following:

- 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.

Any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could

delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

regulatory proceedings and reputational harm. If this were to occur, we may face serious setbacks for our commercialization process and our financial condition and results of operations would be materially harmed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

As is the case with other pharmaceutical and biotechnology 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 biotechnology patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and

development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, we may experience difficulties in enforcing the intellectual property rights in output generated by generative AI Technologies. The United States Copyright Office has previously denied copyright protection for content generated by AI Technologies, and the United States Patent and Trademark Office has similarly stated that an AI tool cannot be an "inventor" of a patent, rendering it impossible to obtain patent protection for inventions created solely by AI Technologies. The Supreme Court of the United Kingdom has reached a similar conclusion, stating that AI systems cannot be named as an "inventor" for UK patent law purposes.

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

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

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

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

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

We currently are reliant upon licenses of certain intellectual property rights and proprietary technology from third parties that are important or necessary to the development of our proprietary technology, including technology related to our product candidates. These licenses, and other licenses we may enter into in the future, may not provide adequate rights to use such intellectual property rights and proprietary technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize technology and product candidates in the future. Licenses to additional third-party proprietary technology or intellectual property rights that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our proprietary technology or product candidates or to develop or license replacement technology, which may not be feasible on a technical or commercial basis. If we are unable to do so, we may not be able to develop and commercialize technology and product candidates in fields of use and territories for which we are not granted rights pursuant to such licenses, which could harm our competitive position, business, financial condition, results of operations and prospects significantly. In some circumstances, we may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

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

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

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

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

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

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

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

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

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by

disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, prospects, financial condition and results of operations.

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

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

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

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

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

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

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

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

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We seek to protect our confidential proprietary information, in part, by entering into confidentiality agreements and invention assignment agreements with parties who have access to them, including our employees, consultants, scientific advisors, contractors, CROs, contract manufacturers, collaborators and other third parties, that are designed to protect our proprietary information. However, we cannot be certain that such agreements have been entered into with all relevant parties that may have or have had access to our trade secrets or proprietary technology, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets and other confidential proprietary technology, or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the

integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know, whether the steps we have taken to protect our intellectual property will be effective.

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

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

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

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

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

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

Competitors or other third parties may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and

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

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. 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 stock.

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

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

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

Our agreements with employees and contractors and our personnel policies provide that any inventions conceived by an individual in the course of rendering services to us shall be our exclusive property. Although our policy is to have all such individuals complete these

agreements assigning such intellectual property to us, we may not obtain these agreements in all circumstances, the assignment of intellectual property rights may not be self-executing and individuals with whom we have entered into these agreements may not comply with their terms. The assignment of intellectual property may not be automatic upon the creation of an invention and despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection.

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

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

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

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

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, in EU countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

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

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

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

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

Risks Related to Our Business and Industry

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

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

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

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have

commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

As we mature, we may need to realign our full-time employee base. This can include expansion or reductions in force, depending on our needs. Our management has diverted, and may need to continue, to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time toward managing these realignment activities. We may not be able to effectively manage a potential realignment of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. For example, in February 2024 and March 2025, we conducted a reduction in force of approximately 10% and 25%, respectively, of our global workforce aligning with our current business model. 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 stock; and
- the inability to commercialize our product candidates.

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

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

We could experience difficulty enforcing our contracts.

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

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

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

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

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

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

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

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

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

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

Environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. We and our third-party manufacturers and suppliers may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure by us or our third-party manufacturers and suppliers to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

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

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

The risk of a security breach or disruption to our IT Systems and Confidential Information, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, varying parts of our workforce (and that of our third-party providers') are currently working remotely on a part or full time basis. This increases our cyber security risk, creates data accessibility concerns, and makes us more susceptible to communication disruptions due to the challenges associated with managing remote computing assets and security vulnerabilities that are present in many non-corporate and home networks. Additionally, any integration of artificial intelligence in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. We cannot anticipate all types of security threats or implement preventive measures that are effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers

increasingly using tools and techniques - including artificial intelligence - that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our Confidential Information that is stored on their IT Systems. Any loss of Confidential Information, including clinical trial data from our completed or ongoing clinical trials for any of our product candidates, could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the Confidential Information.

We and certain of our service providers have experienced cyberattacks and security incidents, such as through phishing scams and ransomware. Although we do not believe that we have experienced any material system failure, accident or cybersecurity incidents to date, we cannot guarantee that material incidents in the future will not occur. Adverse impacts to the availability, integrity or confidentiality of our or third-party IT Systems or Confidential Information could result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. Any or all of the foregoing could materially adversely affect our business, results of operations, and financial condition.

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

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

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

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

In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, which have led to substantial changes in personnel, and it remains unclear the degree to which efforts to reduce or alter the federal workforce may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If funding shortages, staffing limitations or policy changes prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, such issues 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 on may be adversely affected by a natural or man-made disaster or other catastrophic event and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current business operations are conducted in our offices in New York, Berlin, London, and Montreal. 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 because 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.

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

- multiple, conflicting, and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- our failure to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, including the ongoing military conflict between Russia and Ukraine, conflict in the Middle East, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations, including taxes;
- certain expenses including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), its books and records provisions, or its anti-bribery provisions.

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

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

Our operations are subject to anti-corruption laws, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The FCPA and these other laws generally prohibit us and our employees and intermediaries from corruptly authorizing, promising, offering, or providing, directly or indirectly, anything of value, to government officials or other persons to obtain or retain business or gain some other business advantage. The FCPA also requires us to maintain accurate books and records and implement a system of internal accounting controls. In the future, we and our strategic partners may operate in jurisdictions that pose a heightened risk of potential FCPA violations, and we may participate in collaborations and relationships with third parties. We can be held liable under the FCPA or local anti-corruption laws for the corrupt or illegal activities for these third parties, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

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

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

Risks Related to Our Common Stock

The expected benefits of the Redomiciliation Transaction may not be realized.

There can be no assurance that any or all of the anticipated benefits of the Redomiciliation Transaction will be achieved. Achieving the anticipated benefits of the Redomiciliation Transaction is subject to a number of risks and uncertainties, including factors that we do not and cannot control. In addition, if the expected benefits of the Redomiciliation Transaction do not meet expectations of investors or securities analysts, the price of the Company's common stock following completion of the Redomiciliation Transaction may decline.

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

Sales of a substantial number of our common stock 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 stock. This could also impair our ability to raise additional capital through the sale of our equity securities. In addition, the stock market in general has experienced, and will continue to experience from time to time, extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors have adversely impacted, and may continue to impact, the market price of our common stock, regardless of our operating performance. For example, in February 2025, pursuant to our Shelf Registration Statement and a prospectus supplement filed with the SEC on February 13, 2025, we completed an underwritten public offering of 26,190,477 common stock. The common stock were sold at a public offering price of $2.10 per share. We received aggregate net proceeds

of $51.9 million from the offering, after deducting underwriting discounts and commissions. In connection with the offering, we also granted to the Underwriter an option exercisable for 30 days to purchase up to an additional 3,928,571 common stock from us at the public offering price, less underwriting discounts and commissions. The underwriter elected to purchase all additional shares and we received net aggregate proceeds of $7.8 million, after deducting underwriting discounts and commissions. In October 2025, under the Shelf Registration Statement and a prospectus supplement filed on October 16, 2025, we issued and sold 23,725,000 common shares in an underwritten offering. The common shares were sold at a public offering price of $5.48 per share, less underwriting discounts and commissions. We received aggregate net proceeds of approximately $121.7 million. In connection with the underwritten public offering, we granted underwriters an option exercisable for 30 days to purchase up to an additional 3,558,750 common shares from us at the public offering price of $5.48 per share, less underwriting discounts and commissions. The underwriter exercised its option to purchase all additional shares February 19, 2025, and we received $18.2 million. Following the date of these offerings, the public trading price of our common stock decreased. If we sell, or the market perceives we intend to sell, substantial amounts of our common stock under our Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly.

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

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

We are an "emerging growth company" and a "smaller reporting company," and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies will make our common stock 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 will remain an emerging growth company until December 31, 2026 (the fiscal year-end following the fifth anniversary of our IPO).

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

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

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

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

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

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

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

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

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

As a result, we do not believe our interests in such atai companies will be deemed investment securities for purposes of Section 3(a)(1)(C), Rule 3a-1 and/or Rule 3a-8. Accordingly, we believe that (i) on an unconsolidated basis less than 40% of our total assets (exclusive of U.S.

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

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

Evolving global tax legislation could increase our overall tax burden.

Global tax legislative changes could negatively impact our business. For example, the base erosion and profit shifting ("BEPS") initiative undertaken by the OECD, which contemplates changes to numerous international tax principles, as well as national tax incentives, may have adverse consequences on our tax liabilities, including the country-by-country reporting, permanent establishment rules, transfer pricing rules, tax treaties and taxation of the digital economy. The OECD BEPS initiative, which continues to evolve, focuses on two pillars. Pillar One focused on the profit allocation of certain large multinational enterprises among taxing jurisdictions based on a market-based concept rather than the historical "permanent establishment" concept. Pillar Two is focused on developing a global minimum tax rate of at least 15% applicable to multinational enterprises with revenue in excess of a specified threshold. Pillar Two remains under negotiation and subject to ongoing international political discussions. The OECD recently finalized a "side-by-side" approach, under which certain multinational enterprises may be exempt from certain Pillar Two rules. 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.

Additionally, as a U.S. corporation, we will generally be subject to U.S. income taxation on our worldwide income, the tax laws of which have changed significantly in recent years, including as a result of the enactment of the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief and Economic Security Act, the Inflation Reduction Act, and most recently, the One Big Beautiful Bill Act. Changes in laws governing non-income taxes, such was withholding taxes, value added taxes and other indirect taxes, and employment taxes may also adversely impact our business.

Any changes in tax laws or regulations, or in their interpretation by the relevant authorities, the outcome of any tax audits, or changes to our taxation as a result of any expansion or modification of our network, operations, or corporate structure, could adversely affect our business, results of operations, financial condition, and prospects.

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 stock.

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 stock. As a result, capital appreciation in the price of our common stock, if any, will be your only source of gain on an investment in our common stock. However, if we do pay dividends, we may need to withhold tax on such dividends.

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

As of December 31, 2025, we had U.S. federal NOLs of $99.7 million. Under Section 382 of the United States Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a cumulative change, by value, in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income or taxes may be limited. If an ownership change occurs and our ability to use our net operating loss carryforward is materially limited, it would

harm our future operating results by effectively increasing our future tax obligations. Our ability to utilize our NOLs and certain other tax attributes in the United States could be subject to limitation based on these provisions, or expire unused under U.S. tax law.

In addition, as of December 31, 2025, our German NOL carryforward was approximately $136.2 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.

As of December 31, 2025, our United Kingdom ("UK") NOL carryforward was approximately $65.3M. Generally, UK NOLs generated after April 1, 2017, can be carried forward indefinitely and offset against future trading profits, subject to the UK group deductions allowance which places restrictions on the quantum of NOLs that can be used in a given year. The use of UK NOLs can also be restricted if a change in ownership occurs which is coupled with a major change in the nature of trade or business if this major change occurs during a period beginning three years before the change in ownership and ending five years after the change in ownership. Broadly, a change in ownership of a company will occur where a person or a group of person acquires more than half of its ordinary share capital (assuming ownership of ordinary share capital proportionately aligns with economic return rights, and testing the proportion at the beginning and end of the relevant period such that the change can occur over a series of transactions or events). A major change of trade or business is defined by case law. Broadly, among the (non-exhaustive) factors taken into account by case law and HM Revenue & Customs published guidance are: a major change in the type of property dealt in, or the services and facilities provided in the trade, or a major change in the customers, outlets, or markets of the trade.

For the reasons set forth above, if our use of NOLs and other tax attributes is materially limited, this may restrict our ability to offset these tax assets against future taxable income, which could result in higher taxes and adversely affect our operating results.

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, 2025, Apeiron held a 15.2% 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 stock 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 stock 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.

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

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

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

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

General Risk Factors

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

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

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

If any one or more of the above risks were to materialize, we may experience an adverse impact on our business, financial condition or results of operations. See also Risk Factors –"We may fail to realize the anticipated benefits of our strategic combination with Beckley Psytech" and "The failure to successfully integrate the businesses and operations of atai and Beckley Psytech in the expected time frame may adversely affect the combined group's future results."

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

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

Furthermore, the global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, rising inflation and interest rates, and uncertainty about economic stability. A severe or prolonged economic downturn

could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all, cost increases due to high and persistent inflation and weakened demand for our product candidates. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current global economic climate and global financial market conditions could adversely impact our business.

In addition, political tensions as a result of trade policies, such as the recent tariff changes implemented by the U.S., could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. For example, IntelGenx, a Canadian company which we acquired in October 2024, is a drug delivery company focused on the development and manufacturing of novel oral thin film products for the pharmaceutical market and for our development candidate, VLS-01. These tariffs may increase the cost of such products and negatively impact our results of operations.

Moreover, persistent economic downturns may require us to undertake optimization and cost saving initiatives, including streamlining our organization and adjusting the size and structure of our workforce. For example, throughout 2022 to 2025, we implemented certain cost reduction efforts to reduce material spend and operating expenses. In February 2024 and March 2025, we conducted a reduction in force of approximately 10% and 25%, respectively, of our global workforce aligning with our current business model. 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 stock 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 stock or publishes inaccurate or unfavorable research about our business, our share price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our shares could decrease, which might cause our share price and trading volume to decline.

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

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

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

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

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

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. Such requirements and other expectations are not uniform, and in some instances policymakers have taken countervailing efforts to constrain companies' consideration of ESG matters, which can increase the complexity and cost of compliance. If we fail to comply with new laws, regulations or reporting requirements, or new interpretations of existing

standards, our reputation and business could be adversely impacted. Additionally, many of our business partners and suppliers may be subject to similar reporting and stakeholder expectations, which may augment or create additional risks, including risks that may not be known to us.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

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

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

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

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

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

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

Cybersecurity Governance

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

The Committee receives regular reports from management on our cybersecurity risks. In addition, management updates the Committee, where it deems appropriate, regarding cybersecurity incidents it considers to be significant or potentially significant.

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

Our Head of IT and Chief Operating Officer are primarily responsible for assessing and managing our material risks from cybersecurity threats and supervising both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our Head of IT has over ten years of experience leading cybersecurity teams and programs, while our Chief Operating Officer has over seven years of experience risk management and three years of cybersecurity oversight.

Our Head of IT and Chief Operating Officer help our management team to stay informed and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; reviewing threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and reporting on alerts produced by security tools deployed in the IT environment.

Item 2. Properties.

Our principal executive office is located at 250 West 34th Street, New York, NY 10119. We believe that this facility will be adequate for our near-term needs and that we will be able to renew this lease. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms. As of December 31, 2025, we utilize coworking spaces in Oxford (United Kingdom), Berlin (Germany), New York, NY and Boston, MA to support our flexible, hybrid work model.

Nualtis, a wholly owned subsidiary, leases approximately 43,000 square feet of office, lab, and manufacturing spaces in Montréal, Canada, which had an initial expiration date of February 2026. The lease terms included an option to renew for an additional 5 years, which was able to be exercised at Nualtis' sole discretion. In February 2025, Nualtis amended the lease agreement to exercise the aforementioned renewal option. As a result, the lease will now expire in February 2031. In May 2025, Nualtis subsequently sublet approximately 14,800 square feet of this office, lab, and manufacturing space. The sublease term is for three and a half years and commenced in August 2025. Nualtis has no options to extend the term of the sublease.

In November 2025, we entered into a lease termination agreement with the landlord for our leased office space in Berlin, Germany that was scheduled to end in March 2028. We and the landlord terminated the lease as of December 31, 2025.

Beckley Psytech, a wholly owned subsidiary following our November 2025 acquisition, has its registered office in Oxford, England.

Item 3. Legal Proceedings.

We are, from time to time, party to various claims and legal proceedings arising in the ordinary course of our business. Given that such proceedings are subject to uncertainty, there can be no assurance that such legal proceedings, either individually or in the aggregate, will not have a material adverse effect on our business, results of operations, financial condition or cash flows. See Note 20, *Commitments and Contingencies*, to our audited consolidated financial statements for additional information.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock trades on The Nasdaq Global Market under the symbol "ATAI".

Holders of Record

As of March 6, 2026, there were 344 holders of record of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of our common stock whose shares are held in the names of various security brokers, dealers and registered clearing agencies.

Dividend Policy

We have never paid or declared any cash dividends on our common stock in the past, and we do not anticipate paying any cash dividends on our shares of common stock in the foreseeable future. Any future determination to pay dividends or other distributions from our reserves will be at the discretion of our board and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board deems relevant.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

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

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

Business Overview

Founded in 2025 through the strategic combination of atai Life Sciences N.V. and Beckley Psytech Limited, AtaiBeckley is a clinical-stage biotechnology company on a mission to create breakthroughs for people with difficult-to-treat mental health conditions. Our work is grounded in rigorous science to deliver meaningful outcomes for the patients we serve.

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

Our Programs

We aim to create breakthroughs in mental health by developing effective, rapid-acting and convenient treatments that could transform patient outcomes. We are committed to leading a new era of mental health treatment – one that not only offers relief from symptoms, but the possibility of an improved quality of life and lasting change.

We have built a diversified pipeline of investigational psychedelic-based neuroplastogens designed to address some of the most urgent unmet needs in mental health. Our programs include:

- BPL-003: Mebufotenin (5-MeO-DMT) benzoate nasal spray for treatment-resistant depression ("TRD");
- VLS-01: Buccal film dimethyltryptamine ("DMT") for TRD;
- EMP-01: Oral formulation of a stable HCl salt form of the R-enantiomer of 3,4-methylenedioxy-methamphetamine ("R-MDMA") for social anxiety disorder ("SAD"); and
- A drug discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for TRD and Opioid Use Disorder ("OUD").

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

We are committed to innovation in the mental health space as exemplified by our drug discovery program and its focus on identifying new molecules with psychedelic-like pharmacology but without hallucinogenic potential. In addition to these investments in novel chemical entity ("NCE") discovery, intellectual property development has been a key strategic component since inception.

Redomiciliation

On December 30, 2025, as part of the previously announced plan to change our corporate domicile from the Netherlands to the United States via Luxembourg (the "Redomiciliation Transaction"), as approved by our shareholders, we merged with and into atai Life Sciences Luxembourg S.A., a Luxembourg public limited liability company ("atai LuxCo"). On December 30, 2025, atai LuxCo then consummated the conversion of atai LuxCo into a corporation incorporated under the laws of the State of Delaware under the name AtaiBeckley Inc. As a result of the Redomiciliation Transaction, AtaiBeckley Inc. became the successor issuer to Atai Beckley N.V. pursuant to Rule 12g-3(a) under the Exchange Act.

Operating Losses

We have incurred significant operating losses since our inception. Our net loss attributable to AtaiBeckley Inc. stockholders was $660.0 million and $149.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, our accumulated deficit was $1.4 billion and $700.2 million, respectively. Our ability to generate sufficient product revenue to achieve

profitability will depend substantially on the successful development and eventual commercialization of product candidates. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

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

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

Components of Our Results of Operations

Revenue

We have not generated any revenue from the sale of our core psychedelic product candidates or non-psychedelic product candidates and do not expect to unless and until such time that these 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.

As a full-service contract development and manufacturing organization, Nualtis offers services that include pharmaceutical research and development and the manufacturing of pharmaceutical products by leveraging its proprietary drug delivery technologies. Nualtis recognizes license and research and development revenue from the use of its proprietary drug delivery technologies in its customers' products.

License revenue

In January 2025, Nualtis Corp. (“Nualtis”), a wholly owned subsidiary, entered into an Amended & Restated Asset Purchase Agreement ("APA") and an Amended & Restated Supply Agreement ("Supply Agreement") with Rizafilm LLC ("Rizafilm"). Under the APA, Nualtis sold licensing and intellectual property rights of Nualtis's oral thin film technology in exchange for an upfront payment of $0.2 million and an additional $0.5 million upon completion of certain manufacturing milestones. Under the Supply Agreement, subject to approval by the FDA, Nualtis will serve as the sole manufacturer of Rizafilm's products over a five year term with an automatic renewal option for an additional five years unless either party provides sufficient written notice. Additionally, the Supply Agreement requires Rizafilm to adhere to certain firm commitments.

On March 11, 2021, we entered into a license and collaboration agreement (the “Otsuka Agreement”), with Otsuka Pharmaceutical Co., LTD (“Otsuka”). In January 2025, Otsuka provided a notice of termination pursuant to the Otsuka Agreement, effective April 2025. We did not recognize any revenue pursuant to the Otsuka Agreement in 2025, and, effective as of the termination date, we will no longer be eligible to receive any milestone payments or royalties.

Research and development services revenue

Nualtis recognizes revenue from various research and development agreements. In these agreements, Nualtis is responsible for performing research and development services for customers interested in leveraging Nualtis's novel oral thin film technology for drug delivery. Many of these agreements provide Nualtis either the option or the right to serve as the sole manufacturer of these drugs upon regulatory approval.

Operating expenses

Research and development expenses

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

- employee-related expenses, including salaries, related benefits, and stock-based compensation, for employees engaged in research and development functions;

- expenses incurred in connection with the preclinical and clinical development of our product candidates, including our agreements with third parties, such as consultants and contract research organizations ("CROs");
- expenses incurred under agreements with consultants who supplement our internal capabilities;
- the cost of laboratory supplies and acquiring, developing, and manufacturing preclinical study materials and clinical trial materials;
- costs related to compliance with regulatory requirements;
- payments made in connection with third-party licensing agreements; and
- depreciation, amortization and other direct and allocated expenses, including rent, insurance and other operating costs, incurred as a result of our research and development activities.

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

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants, CROs, contract manufacturing organizations (“CMOs”) and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under third-party license agreements.

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

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

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

Acquisition of In-Process Research and Development Expenses

Acquisition of in-process research and development (“IPR&D”) expenses consist of in-process research and development acquired in connection with an asset acquisition.

General and administrative expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries, related benefits and stock-based compensation, for personnel in our executive, finance, legal, business development and administrative functions. General and administrative expenses also include legal fees relating to corporate matters and intellectual property, professional fees for accounting, auditing, tax, human resources and administrative consulting services, insurance costs, information technology-related expenses, travel expenses and facility-related expenses, which include direct depreciation costs and allocated expenses for office rent and other operating costs. General and administrative expenses also reflect sublease income that is used to offset the cost for facility rent and other operating costs.

Other expense, net

Interest income

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

Interest expense

Interest expense consists primarily of interest expense incurred in connection with our term loan facility with Hercules Capital, Inc entered into in 2022 (“2022 Term Loan Facility”) and subsequently terminated in May 2025. See Note 14, debt, in our consolidated financial statements appearing under Part II, Item 8.

Change in fair value of assets and liabilities, net:

The Company carries various assets and liabilities at fair value and subsequent remeasurements are recorded as a Change in fair value of assets and liabilities, net as a component of Other expense, net. Assets held at fair value include securities held at fair value, investments held at fair value, and convertible notes receivable. Liabilities held at fair value include Promissory notes, convertible promissory notes, contingent considerations, derivative liability, and pre-funded warrant liabilities. The components of change in fair value of assets and liabilities, net include:

Change in fair value of securities carried at fair value

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

Change in fair value of other investments held at fair value

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

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

Changes in fair value of short-term notes receivable - related party, net, including interest, consists of subsequent remeasurement of our short-term notes receivable with IntelGenx, for which we have elected the fair value option, prior to the completion of our acquisition of Nualtis.

Change in fair value of convertible notes receivable - related party

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

Change in fair value of short-term convertible promissory notes and derivative liability - related party

Change in fair value of short-term convertible promissory notes and derivative liability consists of subsequent remeasurements of certain convertible notes issued in 2020 to a related party.

Change in fair value of short-term convertible promissory notes and derivative liability

Change in fair value of short-term convertible promissory notes and derivative liability consists of subsequent remeasurements of certain convertible notes issued in 2020.

Change in fair value of contingent consideration liability - related party

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

Change in fair value of contingent consideration liabilities

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

Change in fair value of pre-funded warrant liabilities

Change in fair value of pre-funded warrant liabilities consists of subsequent remeasurements of our pre-funded warrants issued pursuant to the June and July 2025 PIPE Financings, which we record at fair value.

Gain on other investments

Gain on other investments consists of a gain recognized on our additional investment in Beckley Psytech upon the issuance of deferred shares pursuant to the Escrow Agreement.

Gain on consolidation of Beckley Psytech, net

Gain on consolidation of Beckley Psytech consists of a non-cash gain recognized upon the acquisition of Beckley Psytech.

Change in fair value of digital assets, net

Change in fair value of digital assets, net consists of the subsequent remeasurement of our Bitcoin holding, as Bitcoin is measured at fair value based on quoted prices on active exchanges pursuant to ASC 350-60.

Foreign exchange gain (loss), net

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

Other income (expense), net

Other income (expense), net consists of the following:

Benefit from research and development tax credit

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

Pre-funded warrant issuance costs

Pre-funded warrant issuance costs consists of offering costs and commissions allocated to the pre-funded warrant liabilities issued pursuant to the June and July 2025 PIPE Financings.

Loss on sale of investment held at fair value

Loss on sale of investment held at fair value consists of non-cash loss on the sale of our ADS holdings in COMPASS.

Loss on disposal of fixed assets

Loss on disposal of fixed assets consists of non-cash losses recognized upon the disposal of fixed assets, including certain fixed assets disposed as a result of the early termination of our office lease in Berlin, Germany.

Loss on lease termination

Loss on lease termination consists of a loss recognized related an early termination fee as well as the derecognition of right-of-use assets and related lease liabilities previously recognized as a result of the early termination of our office lease in Berlin, Germany.

Loss on extinguishment of debt

Loss on extinguishment of debt represents the difference between the net carrying amount and the redemption amount related to our early repayment of all outstanding obligations under our 2022 Term Loan Facility pursuant to ASC 405-20.

Gain on settlement of pre-existing contract

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

Gain on dissolution of a variable interest entity, net

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

Gain on forgiveness accounts payable

Gain on forgiveness accounts payable consists of the forgiveness of certain accounts payable amounts associated with the dissolution of a variable interest entity.

Benefit from (provision for) income taxes

Since our inception, we have not recorded any U.S. federal, foreign, or state income tax benefits for the net losses we have incurred in each year or for our earned research and development tax credits, as it is more likely-than-not that these benefits will not be realized. We have U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards to offset future taxable income.

Income taxes are determined at the applicable tax rates adjusted for non-deductible expenses, research and development tax credits and other permanent differences. Our income tax provision may be significantly affected by changes to our estimates.

Losses from investments in equity method investees, net of tax

Losses from investments in equity method investees, net of tax consists of our share of equity method investees losses on the basis of our equity ownership percentage.

Net loss attributable to noncontrolling interests

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

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

	For the year ended December 31,			
	2025	2024	$ Change	% Change
	(in thousands, except percentages)			
License revenue	$ 202	$ 308	$ (106)	(34%)
Research and development services revenue	3,887	—	3,887	100%
Total revenue	4,089	308	3,781	1228%
Operating expenses:				
Research and development	53,062	55,455	(2,393)	(4%)
Acquisition of in-process research and development	530,000	—	530,000	100%
General and administrative	65,088	47,544	17,544	37%
Total operating expenses	648,150	102,999	545,151	529%
Loss from operations	(644,061)	(102,691)	(541,370)	527%
Other expense, net:				
Interest income	1,478	778	700	90%
Interest expense	(1,162)	(3,124)	1,962	(63%)
Change in fair value of assets and liabilities, net	(24,416)	(48,879)	24,463	(50%)
Gain on other investments	3,794	1,260	2,534	201%
Gain on consolidation of Beckley Psytech, net	6,902	—	6,902	100%
Change in fair value of digital assets, net	(1,233)	—	(1,233)	100%
Foreign exchange gain (loss), net	1,908	(1,263)	3,171	(251%)
Other income (expense), net	(3,059)	5,514	(8,573)	(155%)
Total other expense, net	(15,788)	(45,714)	29,926	(65%)
Net loss before income taxes	(659,849)	(148,405)	(511,444)	345%
Benefit from (provision for) income taxes	(298)	356	(654)	(184%)
Losses from investments in equity method investees, net of tax	—	(2,000)	2,000	(100%)
Net loss	$ (660,147)	$ (150,049)	$ (510,098)	340%
Net loss attributable to noncontrolling interests	(100)	(780)	680	(87%)
Net loss attributable to AtaiBeckley Inc. stockholders	$ (660,047)	$ (149,269)	$ (510,778)	342%

Revenue

License revenue

License revenue was $0.2 million and $0.3 million for the years ended December 31, 2025, and 2024, respectively. The revenue recognized for the year ended December 31, 2025 is related to the Rizafilm APA. The revenue recognized for the year ended December 31, 2024 is related to our license agreement with Otsuka. For the years ended December 31, 2025 and 2024, respectively, there were no milestones achieved under the Rizafilm APA or Otsuka Agreement.

Research and development services revenue

We recognized $3.9 million in research and development services revenue for the year ended December 31, 2025 related to certain research and development services performed by Nualtis for its customers. We did not recognize any research and development services revenue for the year ended December 31, 2024.

Operating expenses

Research and development expenses

The table and discussion below present our research and development expenses for the years ended December 31, 2025 and 2024:

	For the year ended December 31,			
	2025	2024	$ Change	% Change
	(in thousands, except percentages)			
Direct research and development expenses by program:				
BPL-003	$ 1,283	$ —	$ 1,283	100%
VLS-01	16,297	10,606	5,691	54%
EMP-01	7,894	1,527	6,367	417%
Discovery	2,323	2,649	(326)	(12%)
Other Programs	8,574	16,956	(8,382)	(49%)
Unallocated research and development expenses:				
Personnel expenses	14,801	20,935	(6,134)	(29%)
Professional and consulting services	276	1,052	(776)	(74%)
Rent and facilities related costs	742	152	590	388%
Depreciation and amortization	662	184	478	260%
Other	210	1,394	(1,184)	(85%)
Total research and development expenses	$ 53,062	$ 55,455	$ (2,393)	(4%)

Research and development expenses were $53.1 million for the year ended December 31, 2025 compared to $55.5 million for the year ended December 31, 2024. The decrease of $2.4 million was primarily attributable to a $6.1 million decrease in personnel expenses (inclusive of a $6.4 million decrease in stock-based compensation and a $0.7 million increase in restructuring charges), a $1.2 million decrease in other expenses primarily related to the $0.9 million impairment of certain intangible assets in 2024, and a $0.8 million decrease in professional and consulting fees. These decreases were partially offset by a $4.6 million net increase in our program's direct costs as discussed below and a $0.6 million increase in rent and facilities related costs primarily driven by Nualtis operations, and a $0.5 million increase in depreciation and amortization expense related primarily to manufacturing equipment and intangible assets associated with Nualtis.

BPL-003: Mebufotenin for TRD

The costs attributed to BPL-003 represent direct costs recognized following the completion of our strategic combination with Beckley Psytech in November 2025, and relate to the ongoing development activities of BPL-003, including $1.0 million of clinical development costs, and $0.3 million of manufacturing costs.

VLS-01: DMT for TRD

The $5.7 million net increase in direct costs for our VLS-01 program was primarily due to a $5.4 million increase in clinical development and related costs for our Elumina trial, the randomized, double-blind, placebo-controlled Phase 2 clinical trial of VLS-01, as compared to costs incurred during the year ended December 31, 2024 which were primarily for our Phase 1b trial of VLS-01, as well as $1.9 million in increased manufacturing costs. These increases were partially offset by a $1.6 million decrease in preclinical development costs.

EMP-01: MDMA for SAD

The $6.4 million increase in direct costs for our EMP-01 program was primarily due to a $6.0 million net increase in clinical development and related costs for our exploratory, randomized, double-blind, placebo-controlled Phase 2 study in the United Kingdom to assess the safety, tolerability and efficacy of EMP-01 as well as $0.5 million of increased manufacturing costs. These costs were partially offset by a $0.2 million decrease in preclinical development costs.

Discovery

The $0.3 million decrease in direct costs for our discovery programs was primarily due to a $0.3 million decrease in preclinical development costs related to our novel 5-HT2A receptor agonists. We recognized a $0.3 million reduction in our 2025 research and

development expenses related to our discovery program as certain expenses qualified for reimbursement under our National Health Institute grant

Other Programs

The $8.4 million decrease in direct costs for our other programs was primarily due to a $5.2 million decrease in direct costs for our RL-007 program due to a decrease in clinical development and related costs for our Phase 2b clinical trial for RL-007 in CIAS. The decrease also includes a $3.1 million decrease in our IBX-210 program, a $0.4 million decrease in our EGX-121 program, a $0.3 million decrease in our PCN-101 program, and a $0.5 million decrease in our enabling technologies program. These decreases were partially offset by an increase of $1.1 million of direct costs incurred by Nualtis.

Acquisition of in-process research and development

Acquisition of IPR&D expense was $530.0 million for the year ended December 31, 2025 related to our Beckley Psytech asset acquisition, as well as our Psilera (as defined below) asset acquisition and related milestone payment.

General and administrative expenses

General and administrative expenses were $65.1 million for the year ended December 31, 2025 compared to $47.5 million for the year ended December 31, 2024. The increase of $17.6 million was primarily related to a $20.7 million increase in professional services primarily in connection with our strategic combination with Beckley Psytech and our Redomiciliation Transaction and a $0.3 million increase in other administrative expenses; partially offset by a $2.6 million decrease in personnel expenses (inclusive of a $4.6 million decrease in stock-based compensation and a $0.1 million increase in restructuring) and a $0.8 million decrease in insurance related expenses.

We expect that our general and administrative expenses will decrease in the future as we incurred significant general and administrative expenses for the strategic combination with Beckley Psytech and Redomiciliation Transaction during the year ended December 31, 2025.

Other expense, net

Interest income

Interest income for the year ended December 31, 2025 primarily consisted of interest earned on our cash balances and unsecured promissory note to Beckley Psytech, prior to our strategic combination in November 2025. Interest income for the year ended December 31, 2024 consisted of interest earned on our cash balances. We recognized interest income of $1.5 million and $0.8 million for the years ended December 31, 2025 and 2024, respectively, primarily driven by higher cash holdings in 2025 from various financings and the unsecured promissory note to Beckley Psytech prior to our strategic combination.

Interest expense

Interest expense for the years ended December 31, 2025 and 2024 primarily consisted of interest expense incurred in connection with our 2022 Term Loan Facility. Interest expense decreased $2.0 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 as the 2022 Term Loan Facility was extinguished in May 2025.

Change in fair value of assets and liabilities, net:

Changes in fair value of assets and liabilities, net consisted of the following for the years ended December 31, 2025 and 2024:

	For the year ended December 31,	
	2025	2024
Change on fair value of securities carried at fair value	$ 3,144	$ 3,848
Change in fair value of other investments held at fair value	15,551	(44,297)
Change in fair value of short-term notes receivable - related party, net	—	(500)
Change in fair value of short-term convertible notes receivable - related party	—	(13,229)
Change in fair value of short-term convertible promissory notes - related party	(8,573)	2,593
Change in fair value of short-term convertible promissory notes	(11,675)	770
Change in fair value of contingent consideration liability—related party	6	510
Change in fair value of contingent consideration liabilities	7	1,426
Change in fair value of pre-funded warrant liabilities	(22,876)	—
Change in fair value of assets and liabilities, net	$ (24,416)	$ (48,879)

Gain on other investments

Gain on other investments for the year ended December 31, 2025 consists of a $3.8 million gain related to our investment in Beckley Psytech which was recognized upon the issuance of the deferred shares pursuant to the Escrow Agreement in April 2025, as compared to a $1.3 million gain related to our investment in Beckley Psytech upon the issuance of deferred shares pursuant to the Escrow Agreement during the year ended December 31, 2024.

Gain on consolidation of Beckley Psytech

Gain on consolidation of Beckley Psytech for the year ended December 31, 2025 consists of a $6.9 million gain related to our acquisition of Beckley Psytech

Change in fair value of digital assets, net

Change in fair value of digital assets, net consists of the subsequent remeasurement of our Bitcoin holding as Bitcoin is measured at fair value based on quoted prices on active exchanges pursuant to ASC 350-60. For the year ended December 31, 2025, we recognized a $1.2 million loss related to the change in fair value. We did not recognize any change in fair value for the year ended December 31, 2024.

Foreign exchange loss, net

We recognized a $1.9 million gain related to foreign currency exchange rates for the year ended December 31, 2025 and a $1.3 million loss related to foreign currency exchange rates for the year ended December 31, 2024. This was primarily due to the impact of fluctuations in the foreign currency exchange rate between the Euro, Pound Sterling, and the U.S. dollar on our foreign denominated balances.

Other income (expense), net

We recognized a $3.1 million loss and a $5.5 million gain for the years ended December 31, 2025 and 2024, respectively, in Other income (expense), net driven by the below activity:

	For the year ended December 31,	
	2025	2024
Benefit from research and development tax credit	$ 714	$ 525
Pre-funded warrant issuance costs	(1,356)	—
Loss on sale of investment held at fair value	—	(2,075)
Loss on disposal of fixed assets	(692)	—
Loss on lease termination	(408)	—
Loss on extinguishment of debt	(1,317)	—
Gain on settlement of pre-existing contract	—	5,567
Gain on dissolution of a variable interest entity, net	—	1,166
Gain on forgiveness accounts payable	—	331
Total other income (expense), net	$ (3,059)	$ 5,514

Benefit from (provision for) income taxes

We recognized a current income tax expense of $0.3 million and a current income tax benefit of $0.4 million for the years ended December 31, 2025 and 2024, respectively. The income tax expense recognized for the year ended December 31, 2025 was primarily due to tax expense of subsidiaries in the U.S. and the U.K. The income tax benefit recognized for the year ended December 31, 2024 is a result of losses generated in Germany, U.K., and the U.S. and favorable return to provision adjustments from our U.S. tax returns. We recognized no deferred tax expense for years ended December 31, 2025 and 2024, respectively. Given our early-stage development and lack of prior earnings history, we have a full valuation allowance primarily related to U.S. and foreign tax loss carryforwards, capitalized research and experimental costs, and stock-based compensation timing differences that we consider more-likely-than-not not to be realized.

Losses from investments in equity method investees

We did not recognize any losses from investment in equity method investees for the year ended December 31, 2025. Losses from investment in equity method investees for the years ended December 31, 2024 were $2.0 million. Loss from investment in equity method investees represents our share of equity method investee losses on the basis of our equity ownership percentages or based on our proportionate share of the respective class of securities in our other investments in the event that the carrying amount of our equity method investments was zero.

Net loss attributable to noncontrolling interests

Net losses attributable to noncontrolling interests for the years ended December 31, 2025 and 2024 were $0.1 million and $0.8 million, respectively which relate to the noncontrolling interests in Recognify, Perception, and Kures.

Liquidity and Capital Resources

Overview

For the years ended December 31, 2025 and 2024, we had net losses attributable to AtaiBeckley Inc. stockholders of $660.0 million and $149.3 million, respectively. As of December 31, 2025 and 2024, our accumulated deficit was $1.4 billion and $700.2 million, respectively.

We expect to continue to incur losses and operating cash outflows for the foreseeable future as we continue working towards commercializing any of our product candidates. Our primary sources of liquidity are our cash and cash equivalents, short-term securities, investments, and sales of common stock. We maintain cash balances with financial institutions in excess of insured limits.

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

Our ability to generate sufficient product revenue to achieve profitability will depend substantially on the successful development and eventual commercialization, if any, of product candidates. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings, collaboration arrangements, license agreements, other business development opportunities with third parties and government grants. The Company recognizes revenue from license and research and development arrangements through Nualtis.

Sources of Liquidity

Investments

A significant potential source of non-dilutive funding resides in our investment in COMPASS's ADS, subject to market conditions. Based on quoted market prices, the market value of our ownership in COMPASS was $35.4 million as of December 31, 2025.

Convertible Promissory Notes

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

In December 2023 and April 2024, respectively, a noteholder and a related party noteholder each entered into an agreement with us to exchange their respective Convertible Notes for New Convertible Notes issued by ATAI Life Sciences NV (which later become AtaiBeckley Inc. pursuant to the Redomiciliation Transaction). Each New Convertible Note had a face value of €1 and was convertible into 16 common shares of the Company upon the payment of €17.00.

In September 2025, the noteholder and related party noteholder each exercised the conversion feature of the New Convertible Notes and converted all of their respective New Convertible Notes into 6,185,904 common shares of the Company. Upon conversion, the Company received $7.7 million.

Digital Assets

A potential source of non-dilutive funding resides in our investment in digital assets, subject to market conditions, volatility and price fluctuations. Based on quoted market prices, the market value of our ownership in Bitcoin was $8.8 million as of December 31, 2025.

ATM Program

In November 2022, we entered into an Open Market Sale Agreement℠, (the "Sales Agreement") with Jefferies LLC ("Jefferies"), pursuant to which we may issue and sell our common stock from time to time through an "at-the-market" equity offering program under which Jefferies will act as sales agent. Subject to the terms and conditions of the sales agreement, Jefferies may sell the common stock by any method deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act. There have been no sales under the Sales Agreement through December 31, 2025, and as of the date of this Annual Report on Form 10-K, there is currently no registration statement effective with respect to offers and sales of common stock pursuant to the Sales Agreement.

February 2025 Public Offering

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

The net proceeds from the offering of our common shares were approximately $59.1 million, after deducting the underwriting discounts

and commissions and offering expenses payable by us.

PIPE Financing and Pre-Funded Warrant Subscription Agreements

On June 2, 2025, we entered into the subscription agreements, relating to the purchase (the "June 2025 PIPE Financing") by the investors party thereto of (i) 9,993,341 common shares with a nominal value of €0.10 per share for a purchase price of $1.84 per share, and (ii) a pre-funded warrant to purchase 6,311,006 common shares with an exercise price of $0.01 (the "June 2025 Pre-Funded Warrant"), for a purchase price of $1.84 per common share underlying the June 2025 Pre-Funded Warrant less the exercise price for the June 2025 Pre-Funded Warrant of $0.01 per share, resulting in aggregate net proceeds to us from the June 2025 PIPE Financing of approximately $28.1 million, after deducting placement agent fees and offering expenses payable by us. The June 2025 PIPE Financing was completed in June 2025.

On July 1, 2025, we entered into subscription agreements, relating to the purchase (the "July 2025 PIPE Financing") by the investors party thereto of (i) 18,264,840 common shares with a nominal value of €0.10 per share for a purchase price of $2.19 per share, and (ii) a pre-funded warrant to purchase 4,566,210 common shares with an exercise price of $0.01 (the "July 2025 Pre-Funded Warrant") for a purchase price of $2.19 per common share underlying the July 2025 Pre-Funded Warrant less the exercise price for the July 2025 Pre-Funded Warrant of $0.01 per share, resulting in aggregate net proceeds to us from the July 2025 PIPE Financing of approximately $46.7 million, after deducting placement agent fees and offering expenses payable by us. The July 2025 PIPE Financing was completed in August 2025.

October 2025 Public Offering

In October 2025, we entered into an underwriting agreement (the "October Underwriting Agreement") with Jefferies, as representative of the underwriters, in connection with the issuance and sale by us in a public offering of 23,725,000 common shares, at a public offering price of $5.48 per share, less underwriting discounts and commissions. The shares were offered pursuant to a registration statement on Form S-3 (File No. 333-290592) filed with the SEC on September 29, 2025, which became automatically effective upon filing with the SEC, as well as a prospectus supplement thereto. Under the terms of the October Underwriting Agreement, we granted to the underwriters an option exercisable for 30 days to purchase up to an additional 3,558,750 common shares at the public offering price, less underwriting discounts and commissions. Pursuant to the October Underwriting Agreement, the underwriters exercised the option to purchase the full amount of the additional 3,558,750 common shares.

The net proceeds from the offering of the common shares were approximately $139.1 million, after deducting the underwriting discounts and commissions and offering expenses payable by the Company.

Liquidity Risks

As of December 31, 2025, we had cash and cash equivalents of $85.3 million and short-term securities of $135.4 million. We believe our cash, cash equivalents and short-term securities will be sufficient to fund our operations for at least the next twelve months following the date of this Annual Report on Form 10-K, and, based on our current operating plan, we currently estimate that our existing cash, cash equivalents, and short-term securities will be sufficient to fund operations into 2029.

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

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

- the time and cost necessary to complete ongoing and planned clinical trials;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable foreign regulatory authorities;
- the progress, timing, scope and costs of our preclinical studies, clinical trials and other related activities for our ongoing and planned clinical trials, and potential future clinical trials;
- the costs of commercialization activities for any of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities, or entering into strategic collaborations with third parties to leverage or access these capabilities;
- the amount and timing of sales and other revenues from our product candidates, if approved, including the sales price and the availability of coverage and adequate third party reimbursement;
- the cash requirements for developing our programs and our ability and willingness to finance their continued development;
- the cash requirements for strategic transactions, including acquisitions and partnerships and integration process for our strategic combination with Beckley Psytech;

- the cash requirements for discovering and developing product candidates; and
- the time and cost necessary to respond to technological and market developments, including other products that may compete with one or more of our product candidates.

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

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

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

Cash Flows

The following table summarizes our cash flows for years ended December 31, 2025 and 2024:

	December 31,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (102,675)	$ (82,437)
Net cash provided by (used in) investing activities	(109,127)	59,172
Net cash provided by financing activities	269,481	5,374
Effect of foreign exchange rate changes on cash	116	362
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 57,795	$ (17,529)

Net Cash Used in Operating Activities

Net cash used in operating activities was $102.7 million for the year ended December 31, 2025, which consisted of a net loss attributable to stockholders of $660.1 million, adjusted by noncash charges and other adjustments of $563.9 million and net cash outflows from the change in operating assets and liabilities of $6.5 million. The noncash loss primarily consisted of $530.0 million of IPR&D expenses from the Beckley Psytech and Psilera acquisitions (defined below), $26.0 million loss related to the net change in the fair value of our assets and liabilities carried at fair value, $14.2 million of stock-based compensation, $1.4 million related to issuance costs allocated to pre-funded warrant liabilities issued pursuant to the June and July 2025 PIPE Financings, $1.3 million related to the loss on the extinguishment of the Company's debt, $1.2 million of the change in fair value of the Company's digital assets, $1.0 million of depreciation and amortization, $0.7 million noncash loss on the disposal of fixed assets, $0.4 million of noncash lease expense, $0.4 million noncash loss on lease termination, and $0.2 million of amortization of debt discount. These losses were partially offset by a $6.9 million gain on the acquisition of Beckley Psytech, $3.8 million gain on other investments related to our investment in Beckley Psytech which was recognized upon the issuance of the deferred shares pursuant to the Escrow Agreement, $2.0 unrealized foreign exchange gain, and $0.2 million gain of other income (expense), net. The cash outflow from the change in operating assets and liabilities of $6.5 million was primarily due to a $6.2 million decrease in accrued liabilities and other liabilities and a $1.7 million decrease in accounts payable; partially offset by a $0.7 million decrease in prepaid expenses and other current assets and a $0.8 million increase in deferred revenue.

Net cash used in operating activities was $82.4 million for the year ended December 31, 2024, which consisted of a net loss attributable to stockholders of $150.0 million, adjusted by noncash benefit of $76.8 million and net cash inflows from the change in operating assets and liabilities of $9.2 million. The noncash benefit primarily consisted of $51.6 million loss related to the net change in the fair value of our assets and liabilities carried at fair value, $25.5 million of stock-based compensation, $2.1 million of loss on sale of investment held at fair value, $2.0 million of losses from our equity method investments, $1.1 unrealized foreign exchange losses, $1.0 million of depreciation and amortization, $0.9 million impairment of intangible assets, and $0.4 million of noncash lease expense. These losses were partially offset by a $5.6 million gain on settlement of pre-existing contract, a $1.2 million gain on dissolution of a variable interest entity, and $1.0 million of other income (expense), net. The cash outflow from the change in operating assets and liabilities of $9.2 million was primarily due to a $7.0

million decrease in accrued liabilities and other liabilities, a $1.9 million decrease in accounts payable, and a $1.1 million increase in prepaid expenses and other current assets; partially offset by an increase in deferred revenue of $0.7 million.

Net Cash Provided by (Used in) Investing Activities

Net cash used in investing activities was $109.1 million for the year ended December 31, 2025, primarily driven by $88.9 million of cash paid for securities carried at fair value, $10.0 million cash paid to Beckley Psytech pursuant to the Secondary Sale and the Escrow Agreement, $10.0 million of cash paid for the Beckley Psytech promissory note prior to our strategic combination, $10.0 million of cash paid for digital assets, $3.0 million of cash paid for Psilera (defined below) asset acquisition, and $0.9 million of cash paid for property plant and equipment. These cash outflows were partially offset by $9.1 million of proceeds from the sale of ADSs of COMPASS and $4.6 million of cash received in the acquisition of Beckley Psytech.

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

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $269.5 million for the year ended December 31, 2025 consisted of $258.1 million of proceeds from equity offerings, net of commissions, $21.5 million of proceeds from the issuances of pre-funded warrants, $10.4 million of proceeds from stock option exercises, $7.7 million of proceeds from the conversion of convertible notes to common stock, and $0.2 million of proceeds from other financings. These inflows were partially offset by $21.8 million of cash paid for the extinguishment of our 2022 Term Loan Facility and $6.6 million of cash paid for common stock and pre-funded warrant issuance costs.

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

Material Cash Requirements from Known Contractual and Other Obligations

We are a party to many contractual obligations involving commitments to make payments to third parties. These obligations impact our short-term and long-term liquidity and capital resource needs. Certain contractual obligations are reflected on the consolidated balance sheets as of December 31, 2025, while others are considered future commitments. Our contractual obligations primarily consist of milestone payments under existing license agreements. For additional information regarding our other contractual obligations, refer to Note 13, Leases, Note 20, Commitments and Contingencies, and Note 21, License Agreements in our consolidated financial statements appearing under Part II, Item 8.

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

In addition, under various licensing and related agreements to which we are a party, we are obligated to pay annual license maintenance fees and may be required to make milestone payments and to pay royalties and other amounts to third parties. The payment obligations under these agreements are contingent upon future events, such as our achievement of specified milestones or generating product sales, and the amount, timing and likelihood of such payments are not known. Such contingent payment obligations are described below. For additional information regarding our license agreements described below, see Note 21, License Agreements, to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. For additional information regarding our contingent commitments and future put rights or options associated with our investments, see Note 5, Variable Interest Entities, in our consolidated financial statements appearing under Part II, Item 8.

National University Corporation Chiba University License Agreement

In August 2017, Perception entered into a license agreement (the "CHIBA License"), with the National University Corporation Chiba University ("CHIBA"), relating to Perception's drug discovery and development initiatives. Under the CHIBA License, Perception has been granted a worldwide exclusive license under certain patents and know-how of CHIBA to research, develop, manufacture, use and commercialize therapeutic products. Perception paid an upfront license fee and is required to pay an annual maintenance fee until the filing of a new drug application with the Food and Drug Administration. In addition, Perception is also required to pay tiered royalties ranging in the low to mid-single-digit on future net sales of licensed products that are covered by a valid claim of a licensed patent, if any. Perception is also obligated to make contingent milestone payments totaling up to $1.2 million upon the achievement of certain clinical or regulatory

milestones for each of the first two licensed products and $1.0 million upon the achievement of certain clinical or regulatory milestones for each additional licensed product. The CHIBA License will remain in effect until terminated by the parties according to their rights.

During the years ended December 31, 2025 and 2024, the Company did not make any material payments pursuant to the CHIBA License.

Allergan License Agreement

In February 2020, Recognify entered into an amended and restated license agreement (the "Allergan License Agreement"), with Allergan Sales, LLC, or Allergan, under which Allergan granted Recognify an exclusive (non-exclusive as to know-how), sublicensable and worldwide license under certain patent rights and know-how controlled by Allergan to develop, manufacture and commercialize certain products for use in all fields including the treatment of certain diseases and conditions of the central nervous system. Recognify paid Allergan an upfront payment of $0.5 million and will pay Allergan a mid-single-digit royalty on the net sales of the licensed products. In addition, Recognify is obligated to pay Allergan a low teen percentage of the non-royalty sublicense payments it receives from a third party receiving a sublicense to practice the rights licensed to Recognify under the Allergan License Agreement. Upon the occurrence of certain change of control transactions involving Recognify, or sale, assignment or transfer (other than sublicense) to a third party of any rights licensed to Recognify under the Allergan License Agreement, Recognify is required to share with Allergan a low teen percentage of the proceeds it receives from such transactions. The Allergan License Agreement will remain in effect until terminated by the parties according to their rights.

During the years ended December 31, 2025 and 2024, Recognify did not make any material payments pursuant to the Allergan License Agreement.

Dalriada License Agreement

In December 2021, Invyxis, Inc. (“Invyxis”), now merged with atai Therapeutics, Inc., a wholly owned subsidiary, entered into an exclusive services and license agreement (the “Invyxis ESLA”) with Dalriada Drug Discovery Inc. (“Dalriada”). Under the Invyxis ESLA, Dalriada is to exclusively collaborate with Invyxis to develop products, services and processes with the specific purpose of generating products consisting of new chemical entities. Under the original agreement, Invyxis was obligated to pay Dalriada up to $12.8 million in service fees for research and support services. In May 2023, we executed an amendment to the Dalriada License Agreement, which reduced the amount Invyxis will pay Dalriada in service fees to $7.4 million. In addition, Invyxis will pay Dalriada development milestone payments and low single digit royalty payments based on net product sales. We have the right, but not the obligation, to settle future royalty payments based on net product sales with the our common shares. Invyxis, our wholly-owned subsidiary, and Dalriada will determine the equity settlement based on a price per share determined by both parties.

In December 2022, we executed an amendment to the Dalriada License Agreement, which reduced the upfront deposit from $1.1 million to $0.5 million. As such, the remaining $0.6 million was applied against research and development expense incurred. We will expense the remaining deposit as the services are performed as a component of research and development expense in the consolidated statements of operations.

For the year ended December 31, 2025, the Company did not make any material payments pursuant to the Dalriada License Agreement. For the year ended December 31, 2024, the Company recognized $0.4 million in payments as research and development expense. During the years ended December 31, 2025 and 2024 Invyxis made no other service fee payments to Dalriada.

Psilera Acquisition

In February 2025, we entered into an Intellectual Property Assignment & License Agreement with Psilera, Inc. (“Psilera”) under which we acquired Psilera's dimethyltryptamine (“DMT”) patent portfolio, including all granted and pending patents related to DMT and other related psychedelics. In return, we paid Psilera an upfront fee of $0.8 million upon execution of the agreement and may also be required to pay Psilera additional consideration upon the achievement of certain regulatory and sales milestones, in addition to certain sales-based royalties over a ten-year period. We recognized the upfront fee of $0.8 million as acquired IPR&D expenses in the consolidated statement of operations when incurred during the three months ended March 31, 2025. In August 2025, Psilera achieved a milestone related to the grant of certain patents by the United States Patent Office. Upon completion of the milestone, the Company paid Psilera $2.3 million, which is also recognized as acquired IPR&D expenses in the consolidated statement of operations for the year ended December 31, 2025. The Company may be required to pay Psilera up to an additional $80.0 million upon the completion of certain sales milestones.

During the year ended December 31, 2025, the Company did not make any other payments to Psilera in connection with the Psilera Agreement. Additionally, as of December 31, 2025, the Company did not record any contingent liabilities in connection with the Psilera Agreement.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets and liabilities, costs and expenses and the disclosure of contingent liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are

reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2, Basis of Presentation, Consolidation and Summary of Significant Accounting Policies, in our consolidated financial statements appearing under Part II, Item 8, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred.

We accrue expense for preclinical studies and clinical trial activities performed by vendors based upon estimates of the proportion of work completed. We determine such estimates by reviewing contracts, vendor agreements, and through discussions with our internal personnel and external service providers as to the progress or stage of completion and the agreed-upon fee to be paid for such services. However, actual costs and timing of preclinical studies and clinical trials are highly uncertain, subject to risks, and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the accrual is adjusted accordingly. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Acquisitions and Dispositions

We evaluate each of our acquisitions under the accounting framework in ASC 805, Business Combinations, to determine whether the transaction is a business combination or an asset acquisition. In determining whether an acquisition should be accounted for as a business combination or an asset acquisition, we first perform a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this is the case, the acquired set is not deemed to be a business and is instead accounted for as an asset acquisition. If this is not the case, we further evaluate whether the acquired set includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. If so, we conclude that the acquired set is a business. During the year ended December 31, 2025, we did not have any acquisitions that were accounted for as business combinations. During the year ended December 31, 2024, we completed the acquisition of IGX, that was accounted for as a business combination. Refer to Note 4, Acquisitions, to our audited consolidated financial statements for additional information. We account for business acquisitions using the acquisition method of accounting. Under this method of accounting, assets acquired and liabilities assumed are recorded at their respective fair values at the date of the acquisition. When determining the fair values of assets acquired and liabilities assumed, we make significant estimates and assumptions. Our estimates of fair value are based upon assumptions believed to be reasonable, but these assumptions are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Any excess of the purchase price over the fair value of the net assets acquired is recognized as goodwill.

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

Upon the occurrence of certain events and on a regular basis, we evaluate whether we no longer have a controlling interest in our consolidated VIEs. If we determine that we no longer have a controlling interest, the subsidiary is deconsolidated. We will record a gain or loss on deconsolidation based on the difference on the deconsolidation date between (i) the aggregate of (a) the fair value of any consideration received, (b) the fair value of any retained noncontrolling investment in our former subsidiary and (c) the carrying amount of any noncontrolling interest in the subsidiary being deconsolidated, less (ii) the carrying amount of the former subsidiary's assets and liabilities.

Stock-Based Compensation

We recognize compensation costs related to stock-based awards granted to employees, directors, and consultants based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation expense, for stock options that only have service vesting requirements or performance-based vesting requirements without market conditions using the

Black-Scholes option-pricing model. The grant date fair value of the stock-based awards with service vesting requirements is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. Determining the appropriate amount to expense for performance-based awards based on the achievement of stated goals requires judgment. We recognize expense for performance-based awards if the stated goals are determined to be probable of being met as of the period end. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed. For performance-based awards with market conditions, we determine the fair value of awards as of the grant date using a Monte Carlo simulation model. We have elected to recognize forfeitures of stock-based compensation awards as they occur.

We estimate the fair value of stock options using the Black-Scholes option-pricing model, which requires assumptions, including the fair value of our common stock 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 stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. We also included our own historical volatility in the determination of expected volatility.

Risk-free interest rate—The risk-free rate assumption is based on the implied yield with an equivalent expected term at the grant date.

Expected dividend yield—We have not issued any dividends in our history and do not expect to issue dividends over the life of the options; therefore, we have estimated the dividend yield to be zero.

As part of the valuation of stock-based compensation under the Black-Scholes option-pricing model, it is necessary for us to estimate the fair value of our common stock. Prior to our IPO, we were required to periodically estimate the fair value of our common stock when issuing options and in computing our estimated stock-based compensation expense. Given the absence of a public trading market prior to the completion our initial public offering, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, we exercised reasonable judgment and considered numerous objective and subjective factors to determine our best estimate of the fair value of our common stock. The estimation of the fair value of our common stock 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 stock; industry information such as market size and growth; market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and macroeconomic conditions. We apply similar methodology to estimate the fair value of our privately held subsidiaries' common stock. After the closing of the IPO, our board of directors determined the fair value of each common share underlying stock-based awards based on the closing price of our common stock as reported on Nasdaq on the date of grant.

Recently Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, Basis of Presentation, Consolidation and Summary of Significant Accounting Policies, in our consolidated financial statements appearing under Part II, Item 8.

JOBS Act

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We will remain an emerging growth company until December 31, 2026 (the fiscal year-end following the fifth anniversary of our IPO).

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of fluctuations in

interest rates and foreign currency exchange rates. In addition, our portfolio of notes receivables is exposed to credit risk in the form of non-payment or non-performance. In mitigating our credit risk, we consider multiple factors, including the duration and terms of the note and the nature of and our relationship with the counterparty. The following analysis provides quantitative information regarding these risks.

Interest Rate Sensitivity

Interest rate risk is highly sensitive due to many factors, including U.S. monetary and tax policies, U.S. and international economic factors and other factors beyond our control. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of December 31, 2025, we had cash and cash equivalents of $85.3 million and short-term securities of $135.4 million. We generally hold our cash in interest-bearing demand deposit accounts and short-term securities. Due to the nature of our cash and investment portfolio, a hypothetical 100 basis point change in interest rates would not have a material effect on the fair value of our cash. Our cash is held for working capital purposes. We purchase treasury bills and money-market funds which are rated by nationally recognized statistical credit rating organizations in accordance with its investment policy. This policy is designed to minimize our exposure to credit losses and to ensure that the adequate liquidity is maintained at all times to meet anticipated cash flow needs.

Foreign Currency Exchange Risk

Our reporting and functional currency is the U.S. dollar, and the functional currency of our foreign subsidiaries is generally the respective local currency. The assets and liabilities of each of our foreign subsidiaries are translated into U.S. dollars at exchange rates in effect at each balance sheet date. Adjustments resulting from translating foreign functional currency financial statements into U.S. dollars are recorded as a separate component on the consolidated statements of comprehensive loss. Equity transactions are translated using historical exchange rates. Expenses are translated using the average exchange rate during the previous month. Gains or losses due to transactions in foreign currencies are included in interest and other income, net in our consolidated statements of operations.

The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. We have experienced and will continue to experience fluctuations in foreign exchange gains and losses related to changes in foreign currency exchange rates. In the event our foreign currency denominated assets, liabilities, revenue, or expenses increase, our results of operations may be more greatly affected by fluctuations in the exchange rates of the currencies in which we do business, resulting in unrealized foreign exchange gains or losses. We have not engaged in the hedging of foreign currency transactions to date, although we may choose to do so in the future. No strategy can completely insulate us from risks associated with such fluctuations and our currency exchange rate risk management activities could expose us to substantial losses if such rates move materially differently from our expectations.

A hypothetical 10% change in the relative value of the U.S. dollar to other currencies during any of the periods presented would not have had a material effect on our consolidated financial statements, but could result in significant unrealized foreign exchange gains or losses for any given period.

Item 8. Financial Statements and Supplementary Data.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the shareholders and the Board of Directors of AtaiBeckley, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of AtaiBeckley Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ DELOITTE & TOUCHE LLP

Morristown, New Jersey
March 6, 2026

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

ATAIBECKLEY INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 85,300	$ 17,505
Securities carried at fair value	135,351	44,825
Short-term restricted cash for other investments	—	10,000
Other current investments held at fair value	35,389	—
Prepaid expenses and other current assets	19,644	7,795
Total current assets	275,684	80,125
Property and equipment, net	2,166	2,535
Operating lease right-of-use assets, net	1,846	1,334
Other investments held at fair value	—	28,887
Other investments	—	42,079
Intangible assets, net	2,851	3,246
Goodwill	331	331
Digital assets	8,735	—
Other assets	1,110	850
Total assets	$ 292,723	$ 159,387
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,906	$ 2,616
Accrued liabilities	14,168	9,847
Current portion of lease liabilities	271	477
Short-term convertible promissory notes and derivative liability - related party	—	1,150
Short-term convertible promissory notes and derivative liability	—	1,840
Current portion of long-term debt	—	6,374
Deferred revenue	1,524	721
Other current liabilities	2,610	1,926
Total current liabilities	23,479	24,951
Contingent consideration liability - related party	104	110
Contingent consideration liabilities	205	212
Noncurrent portion of lease liabilities	1,801	732
Pre-funded warrant liabilities	44,379	—
Long-term debt, net	—	14,133
Other liabilities	754	2,695
Total liabilities	$ 70,722	$ 42,833
Commitments and contingencies (Note 20)		
Stockholders' equity:		
Preferred stock, $0.01 par value, 37,500,000 and zero shares authorized at December 31, 2025 and December 31, 2024, respectively; no shares issued or outstanding at December 31, 2025 and December 31, 2024	—	—
Common stock, $0.01 par value at December 31, 2025 and €0.10 ($0.10) par value as of December 31, 2024; 750,000,000 shares authorized at December 31, 2025 and December 31, 2024, respectively; 363,280,522 and 167,959,752 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	3,633	18,785
Additional paid-in capital	1,599,421	816,185
Accumulated other comprehensive loss	(20,926)	(18,466)
Accumulated deficit	(1,360,254)	(700,207)
Total stockholders' equity attributable to AtaiBeckley Inc. stockholders	221,874	116,297
Noncontrolling interests	127	257
Total stockholders' equity	222,001	116,554
Total liabilities and stockholders' equity	$ 292,723	$ 159,387

See accompanying notes to the consolidated financial statements.

ATAIBECKLEY INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

	For the year ended December 31,	
	2025	2024
License revenue	$ 202	$ 308
Research and development services revenue	3,887	—
Total revenue	4,089	308
Operating expenses:		
Research and development	53,062	55,455
Acquisition of in-process research and development	530,000	—
General and administrative	65,088	47,544
Total operating expenses	648,150	102,999
Loss from operations	(644,061)	(102,691)
Other expense, net:		
Interest income	1,478	778
Interest expense	(1,162)	(3,124)
Change in fair value of assets and liabilities, net	(24,416)	(48,879)
Gain on other investments	3,794	1,260
Gain on consolidation of Beckley Psytech	6,902	—
Change in fair value of digital assets, net	(1,233)	—
Foreign exchange gain (loss), net	1,908	(1,263)
Other income (expense), net	(3,059)	5,514
Other expense, net:	(15,788)	(45,714)
Net loss before income taxes	(659,849)	(148,405)
Benefit from (provision for) income taxes	(298)	356
Losses from investments in equity method investees, net of tax	—	(2,000)
Net loss	(660,147)	(150,049)
Net loss attributable to noncontrolling interests	(100)	(780)
Net loss attributable to AtaiBeckley Inc. stockholders	$ (660,047)	$ (149,269)
Net loss per share attributable to AtaiBeckley Inc. stockholders — basic and diluted	$ (2.91)	$ (0.93)
Weighted average common shares outstanding attributable to AtaiBeckley Inc. stockholders — basic and diluted	226,532,786	160,159,983

See accompanying notes to the consolidated financial statements.

ATAIBECKLEY INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	For the year ended December 31,	
	2025	**2024**
Net loss	$ (660,147)	$ (150,049)
Other comprehensive loss:		
Foreign currency translation adjustments, net of tax	(2,460)	994
Comprehensive loss	$ (662,607)	$ (149,055)
Net loss attributable to noncontrolling interests	(100)	(780)
Foreign currency translation adjustments, net of tax attributable to noncontrolling interests	(30)	32
Comprehensive loss attributable to noncontrolling interests	(130)	(748)
Comprehensive loss attributable to AtaiBeckley Inc. stockholders	$ (662,477)	$ (148,307)

See accompanying notes to the consolidated financial statements.

ATAIBECKLEY INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity Attributable to AtaiBeckley Inc. Stockholders	Noncontrolling Interests	Total Stockholders' Equity
	Shares	Amount						
Balances at December 31, 2023	166,026,396	$ 18,573	$ 794,787	$ (19,460)	$ (550,938)	$ 242,962	$ 1,354	$ 244,316
Issuance of shares upon exercise of stock options	453,043	49	485	—	—	534	—	534
Issuance of shares upon restricted stock units vest	1,480,313	163	(163)	—	—	—	—	—
Adjustment to additional paid in capital upon acquiring additional interest in variable interest entity	—	—	(115)	—	—	(115)	—	(115)
Adjustment to additional paid in capital upon debt modification	—	—	(3,590)	—	—	(3,590)	—	(3,590)
Adjustment to additional paid in capital upon dissolution of variable interest entity	—	—	(709)	—	—	(709)	(349)	(1,058)
Foreign currency translation adjustment, net of tax	—	—	—	994	—	994	32	1,026
Stock-based compensation expense	—	—	25,490	—	—	25,490	—	25,490
Net loss	—	—	—	—	(149,269)	(149,269)	(780)	(150,049)
Balances at December 31, 2024	167,959,752	$ 18,785	$ 816,185	$ (18,466)	$ (700,207)	$ 116,297	$ 257	$ 116,554
Issuance of shares upon exercise of stock options	7,923,098	910	9,529	—	—	10,439	—	10,439
Issuance of shares upon restricted stock units vest	1,069,057	118	(118)	—	—	—	—	—
Issuance of common shares related to equity offerings, net of issuance costs of $18.3 million	85,660,979	9,547	243,299	—	—	252,846	—	252,846
Conversion of convertible notes to common shares	6,185,904	725	30,222	—	—	30,947	—	30,947
Shares issued in the acquisition of Beckley Psytech	93,580,831	11,555	444,048	—	—	455,603	—	455,603
Shares issued for the settlement of Beckley Psytech's transaction costs	900,901	106	3,930	—	—	4,036	—	4,036
Change in par value and equity related transaction costs	—	(38,113)	38,113	—	—	—	—	—
Foreign currency translation adjustment, net of tax	—	—	—	(2,460)	—	(2,460)	(30)	(2,490)
Stock-based compensation expense	—	—	14,213	—	—	14,213	—	14,213
Net loss	—	—	—	—	(660,047)	(660,047)	(100)	(660,147)
Balances at December 31, 2025	363,280,522	$ 3,633	$ 1,599,421	$ (20,926)	$ (1,360,254)	$ 221,874	$ 127	$ 222,001

See accompanying notes to the consolidated financial statements.

ATAIBECKLEY INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the year ended December 31,	
	2025	2024
Cash flows from operating activities		
Net loss	$ (660,147)	$ (150,049)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of long-term assets	1,012	473
Noncash lease expense	413	416
Amortization of debt discount	176	515
Stock-based compensation expense	14,213	25,490
Noncash change in the fair value of assets and liabilities, net	25,995	51,579
Acquisition of in-process research and development	530,000	—
Gain on consolidation of Beckley Psytech	(6,902)	—
Loss on disposal of fixed assets	692	—
Loss on lease termination	408	—
Loss on sale of investment held at fair value	—	2,075
Gain on dissolution of a variable interest entity	—	(1,166)
Gain on settlement of pre-existing contract	—	(5,567)
Impairment of intangible assets	33	919
Gain on other investments	(3,794)	(1,260)
Noncash change in the fair value of digital assets, net	1,233	—
Loss on extinguishment of debt	1,317	—
Unrealized foreign exchange (gain)	(2,024)	1,078
Losses from investments in equity method investees, net of tax	—	2,000
Issuance costs allocated to pre-funded warrants	1,357	—
Noncash loss on sale of investment held at fair value	—	2,660
Other income, net	(182)	(2,400)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	691	(1,091)
Accounts payable	(1,695)	(1,872)
Accrued liabilities	(6,237)	(6,958)
Deferred revenue	766	721
Net cash used in operating activities	(102,675)	(82,437)
Cash flows from investing activities		
Proceeds from sale and maturities of securities carried at fair value	—	65,560
Proceeds from sale of other investment held at fair value	9,050	16,093
Cash received in acquisition of IntelGenx Corp.	—	359
Cash received in acquisition of Beckley Psytech Limited	4,636	—
Cash paid for securities carried at fair value	(88,945)	—
Cash paid for other investments	(10,000)	(15,000)
Cash paid for digital assets	(9,967)	—
Cash paid for Psilera asset acquisition	(3,000)	—
Cash paid for short-term convertible notes receivable and warrant - related party	—	(2,000)
Cash paid for short term notes receivable - related party	(10,000)	(5,745)
Cash paid for capitalized internal-use software development costs	—	(6)
Cash paid for intangible asset	—	(83)
Cash paid for property and equipment	(901)	(6)
Net cash provided by (used in) investing activities	(109,127)	59,172
Cash flows from financing activities		
Proceeds from equity offerings, net of commissions	258,128	—
Proceeds from issuance of pre-funded warrants	21,503	—
Cash paid for common stock and pre-funded warrant issuance costs	(6,635)	—
Proceeds from conversion of convertible notes to common shares	7,711	—
Proceeds from issuance of shares upon exercise of stock options	10,437	535
Proceeds from debt financing	—	5,000
Cash paid for debt financing costs	—	(161)
Proceeds from other financing	148	—
Cash paid for debt extinguishment	(21,811)	—
Net cash provided by financing activities	269,481	5,374
Effect of foreign exchange rate changes on cash	116	362
Net increase (decrease) in cash, cash equivalents and restricted cash	57,795	(17,529)
Cash, cash equivalents and restricted cash – beginning of the period	27,505	45,034
Cash, cash equivalents and restricted cash – end of the period	$ 85,300	$ 27,505
Supplemental disclosures:		
Cash paid for interest	$ 793	$ 2,159
Cash paid for taxes	$ 589	$ 411
Supplemental disclosures of noncash investing and financing information:		
Right of use asset obtained in exchange for operating lease liabilities	$ 1,709	$ —
Common stock issuance costs in accounts payable and accrued liabilities	$ 6	$ —
Noncash exchange of convertible promissory note modification	$ —	$ 3,586
Discharge of notes receivable	$ —	$ 5,356
Noncash consideration for acquisition of Beckley Psytech	$ 519,591	$ —
Noncash transaction costs for services rendered to Beckley Psytech	$ 4,036	$ —
Noncash consideration for variable interest deconsolidation	$ —	$ 115

See accompanying notes to the consolidated financial statements.

ATAIBECKLEY INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of Business

AtaiBeckley Inc. ("AtaiBeckley", "atai", or, the "Company"), headquartered in New York, New York, was founded in 2025 through the strategic combination of atai Life Sciences N.V. and Beckley Psytech Limited and is the parent company of ATAI Life Sciences GmbH (formerly ATAI Life Sciences AG). AtaiBeckley, along with its subsidiaries, is a clinical-stage biotechnology company aiming to create breakthroughs for people with difficult-to-treat mental health conditions. The Company is advancing a pipeline of interventional psychiatric product candidates designed to address the complex nature of mental health disorders. The Company believes that these investigational compounds have the potential to become fast-acting, durable, and commercially scalable therapies for mental health patients in need of new treatment options.

On November 5, 2025, in connection with the Company's strategic combination with Beckley Psytech Limited ("Beckley Psytech"), as described further under Note 4, Acquisitions, the Company changed its name from ATAI Life Sciences N.V. to Atai Beckley N.V. On December 30, 2025, in connection with the Company's redomiciliation to the United States, as further described below, the Company changed its name to AtaiBeckley Inc.

Unless the context suggests otherwise, references to the "AtaiBeckley", "atai", or the "Company" refer to ATAI Life Sciences N.V and its consolidated subsidiaries prior to the consummation of the Beckley Psytech Acquisition (as defined below), to Atai Beckley N.V. and its and its consolidated subsidiaries after the consummation of the Beckley Psytech Acquisition and prior to the Redomiciliation Transaction (as defined below) and to AtaiBeckley Inc. and its consolidated subsidiaries after the consummation of the Redomiciliation Transaction.

The Company's research is focused on developing rapid-acting, effective and durable mental health treatments that can deliver large-scale patient impact. The Company is committed to leading a new era of mental health treatment – one that not only offers relief from symptoms, but the possibility of an improved quality of life and lasting change.

The Company has built a diversified pipeline of drug and discovery development programs, including psychedelic and non-psychedelic compounds. Psychedelics are emerging as novel therapies for mental health disorders, such as depression and, with growing scientific support, recent regulatory advancements and increasing patient and physician acceptance. There is a growing body of clinical evidence that supports the development of psychedelics, which the Company believes may have potential therapeutic benefits, such as a rapid onset of effect and sustained efficacy after a short-course of administration. The Company believes these programs, which include new molecular entities as well as variants of known compounds with unique pharmacology, have the potential to address unmet needs in mental health disorders. These programs vary across stages of development, targeted indication and proposed mechanism of action, which the Company believes will improve the commercial potential and risk profile of our pipeline in the aggregate.

The Company is subject to risks and uncertainties common to clinical stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, third-party clinical research organizations and manufacturers, protection of proprietary intellectual property and technology, compliance with government regulations and the ability to secure additional capital to fund operations. Therapeutic candidates currently under development will require significant additional Research and development ("R&D") efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's therapeutic development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from sales.

Redomiciliation

On December 30, 2025, as part of the previously announced plan to change the Company's corporate domicile from the Netherlands to the United States via Luxembourg (the "Redomiciliation Transaction"), Atai Beckley N.V. merged with and into atai Life Sciences Luxembourg S.A., a Luxembourg public limited liability company ("atai LuxCo"). On December 30, 2025, atai LuxCo then consummated the conversion (the "Delaware Conversion") of atai LuxCo into a corporation incorporated under the laws of the State of Delaware under the name AtaiBeckley Inc. As a result of the Redomiciliation Transaction, AtaiBeckley Inc. became the successor issuer to Atai Beckley N.V. pursuant to Rule 12g-3(a) under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Liquidity and Going Concern

The Company has incurred significant losses and negative cash flows from operations since its inception. As of December 31, 2025, the Company had cash and cash equivalents of $85.3 million and short-term securities of $135.4 million, and its accumulated deficit was $1.4 billion. The Company has historically financed its operations through the sale of equity securities, sale of convertible notes, and revenue generated from licensing and collaboration arrangements. The Company has not generated any revenues to date from the sale of its core product candidates and does not anticipate generating any revenues from the sale of either unless and until it successfully completes development and obtains regulatory approval to market its product candidates. The Company recognizes revenue from license and research and development arrangements through Nualtis Corp.

The Company currently expects that its existing cash and cash equivalents and short-term securities as of December 31, 2025 will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date the consolidated financial statements are issued.

2. Basis of Presentation, Consolidation and Summary of Significant Accounting Policies

Basis of Presentation

The Redomiciliation Transaction has been accounted for as a transaction between entities under common control. Accordingly, the Company recorded the assets and liabilities transferred at their carrying amounts at the date of transfer. All common shares in atai Life Sciences N.V., at par value €0.10, were canceled and exchanged for common stock in AtaiBeckley Inc., at par value $0.01, on a one-for-one basis. AtaiBeckley Inc.'s common stock par value was decreased by $38.1 million for the difference between the total par value of common stock of AtaiBeckley Inc. and the total par value of common shares of atai Life Sciences N.V. at the date of transfer, with an offset to additional paid in capital. There is no difference between the combined separate entities prior to the Redomiciliation Transaction and the combined separate entities after the Redomiciliation Transaction, therefore, these financial statements and comparative information do not differ from amounts previously reported under atai Life Sciences N.V.'s consolidated financial statements. These financial statements should be read in conjunction with atai Life Sciences N.V.'s Annual Report on Form 10-K for the year ended December 31, 2024, including Note 2, Basis of Presentation, Consolidation and Summary of Significant Accounting Policies.

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

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

Reclassifications

Certain reclassifications were made to prior period amounts in the consolidated financial statements and accompanying notes to conform with current year presentation. Reclassifications were made to the prior year presentation of Deferred revenue, which was presented as a component of Other current liabilities in the prior year consolidated balance sheets. Reclassifications were also made to the prior year presentation of Gain on other investments, which was presented as a component of Other income (expense), net in the prior year consolidated statement of operations. Reclassifications were further made to the prior year presentation of Benefit from research and development tax credits, Gain on settlement of a pre-existing contract, and Gain on dissolution of a variable interest entity, which are now recognized as a component of Other income (expense), net in the current year.

Consolidation

The Company's consolidated financial statements include the accounts of AtaiBeckley and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The Company's reporting currency is the U.S. dollar.

The Company's policy is to consolidate all entities that it controls by ownership of a majority of the outstanding voting stock. In addition, entities that meet the definition of a variable interest entity ("VIE") for which AtaiBeckley is the primary beneficiary are consolidated. The primary beneficiary is the party who has the power to direct the activities of a VIE that most significantly impact the entity's economic performance and who has an obligation to absorb losses of the entity or a right to receive benefits from the entity that could potentially be significant to the entity. For consolidated entities that are less than wholly owned, the third-party's holding of equity interest is presented as Noncontrolling interests in the Company's consolidated balance sheets and consolidated statements of stockholders' equity. The portion of net earnings attributable to the noncontrolling interests is presented as Net loss attributable to noncontrolling interests in the Company's consolidated statements of operations.

Ownership interests in entities over which the Company has significant influence, but not a controlling financial interest, are accounted for under either the alternative measurement under ASC Topic 321: *Investments - Equity Securities* ("ASC 321") or as an equity method investment. Investments eligible for the measurement alternative under ASC 321 are carried at its initial cost, with remeasurements to fair value upon impairment or upon a price change observed in an orderly transaction of the same or similar investment of the same issuer. For equity method investments where the Company has not elected the fair value option, it records gains (losses) from investments in equity method investees, net of tax, for its proportionate share of the underlying company's net results until the investment balance is adjusted to zero. If the Company makes subsequent additional investments in that same company, it may record additional gains (losses) based on changes to its investment basis and also may record additional income (loss) in equity method investments.

If the Company has elected the fair value option for an equity investment, the fair value of the investment will be recorded upon acquisition and any changes in fair value will be recorded as a component of other expense, net.

Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to the fair value of securities carried at fair value, definite-lived intangible assets, accruals for research and development costs, the fair value of contingent consideration liabilities, the fair value of assets acquired and liabilities assumed in acquisitions, noncontrolling interests recognized in acquisitions, revenue recognition, the valuation of stock-based awards, impairment of long-lived assets, including goodwill, income taxes, including uncertain tax positions, and the valuation allowance of deferred tax assets.

The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates. Changes in estimates are recorded in the period in which they become known.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, and short-term investments. The Company’s cash is mainly held in financial institutions in the United States. Amounts on deposit may at times exceed federally insured limits. The Company does not believe that it is exposed to any significant credit risk related to these instruments.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. As of December 31, 2025 and 2024, cash and cash equivalents consisted of cash on deposit and cash held in high-yield savings accounts and money market funds, and at times in excess of federally insured limits.

Investment Securities Portfolio

The Company maintains an investment portfolio, which is comprised of money market funds and U.S. treasury securities. The Company classified securities in the investment portfolio as available-for-sale securities. Furthermore, the Company elected the fair value option for the available-for-sale securities in the investment portfolio. The decision to elect the fair value option, which is irrevocable once elected, is determined on an instrument-by-instrument basis and applied to an entire instrument. The net gains or losses, if any, on an investment for which the fair value option has been elected are recognized as a Change in fair value of assets and liabilities, net on the consolidated statements of operations and the amortized cost of investments approximates their fair value. The Company's securities in the investment portfolio will mature within one year.

Accounts Receivable

The Company's accounts receivable relates to licensing and collaboration agreements, including agreements for product development, licensing, and supply agreements assumed through its acquisition of IGX in October 2024. These accounts receivable are short-term in nature. The Company estimates expected credit losses over the life of the financial assets as of the reporting date based on relevant information about past events, current conditions, and reasonable and supportable forecasts. For the years ended December 31, 2025 and 2024, the Company recognized its accounts receivable in Other current assets within its consolidated balance sheets. For the years ended December 31, 2025 and 2024, the Company had no allowance for credit losses.

Convertible Notes Receivable

Prior to the Company's acquisition of IGX in October 2024, as permitted under ASC 825, the Company elected the fair value option to account for its IntelGenx convertible notes, which otherwise would have been subject to ASC 320. In accordance with ASC 825, the Company recorded this investment at fair value under Convertible notes receivable - related party in the Company's consolidated balance sheets and changes in fair value are recognized as Change in fair value of assets and liabilities, net, a component of other expense, net in the consolidated statements of operations.

Notes Receivable

The Company has certain notes receivable that are carried at cost, which included the principal value of the note receivable, accrued interest and net of any payments received and expected credit losses. Management utilized an undiscounted probability-of-default (“PD”) and loss-given-default (“LGD”) method for estimating credit losses on its assets pool, which was comprised of loans to other companies. Under the PD and LGD method, the expected credit loss percentage (or “loss rate”) is calculated as the probability of default (i.e., the probability the asset will default within the given time frame) multiplied by the loss given default (i.e., the percentage of the asset not expected to be collected because of default).

Property and Equipment

The Company's property and equipment consists of manufacturing equipment, laboratory and office equipment, furniture and fixtures, and computer equipment and is recorded at cost, less accumulated depreciation. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon disposal, retirement or sale, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation of property and equipment is recorded using the straight-line method over the estimated useful lives of the related assets once the asset has been placed in service. Leasehold improvements are amortized using the straight-line method over the estimated useful life or remaining lease term, whichever is shorter. The Company estimates useful lives by asset class based on the below useful lives:

Asset	Estimated useful lives used
Manufacturing equipment	5 to 20 years
Laboratory and office equipment	5 to 10 years
Furniture and fixtures	7 years
Computer equipment	5 years

Leases

The Company accounts for its leases in accordance with ASC Topic 842, *Leases* (“ASC 842”). At the inception of an arrangement, the Company determines if an arrangement is, or contains, a lease based on the unique facts and circumstances present in that arrangement. Lease classification, recognition, and measurement are then determined at the lease commencement date. For arrangements that contain a lease the Company (i) identifies lease and non-lease components, (ii) determines the consideration in the contract, (iii) determines whether the lease is an operating or financing lease; and (iv) recognizes lease right-of-use (ROU) assets and liabilities. Lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable and as such, the Company uses its incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment. For lease arrangements with an initial term of 12 months or less, the Company does not recognize a lease liability and ROU asset; instead, the Company recognizes the related lease payments as lease expense on a straight-line basis over the lease term.

The Company presents operating leases on the consolidated balance sheets within Operating lease right-of-use assets, net, Current portion of lease liabilities, and Noncurrent portion of lease liabilities. On the consolidated statements of operations, the Company presents amortization of operating leases as lease expense within Research and development expenses or General and administrative based on operating lease use.

Most leases include options to renew or terminate the lease, which can impact the lease term. The exercise of these options is at the Company's discretion. The Company does not include any of these options within the expected lease term, as it is not reasonably certain it will exercise these options.

In the event the Company and its landlord enter into an agreement to end the lease, the Company determines if the agreement is a termination or modification of the original lease agreement. For terminated leases, the Company derecognizes the ROU asset and corresponding liability with profit or loss recognized for the difference. Any termination penalty paid as part of a full termination of a lease are included in the determination of the gain or loss upon termination.

Where feasible and allowed under the lease agreement, the Company may sublet their leased space to third party tenants. Under ASC 842, the Company must first assess whether their obligation to the head landlord is relieved based on the terms of the head lease. If the Company is relieved of their obligation to the landlord under the head lease, the sublease transaction is considered to be a termination of the head lease, where the right-of-use asset and lease liability is derecognized, with the difference recorded to profit or loss on the Company's consolidated statements of operation. If the Company is not relieved of their primary obligation to the landlord, the Company determines the subleases' lease classification as either a sales-type, direct-financing, or operating lease from the perspective of the lessor. As of December 31, 2025, the Company has entered into one sublease agreement which is classified as an operating lease. Operating subleases under ASC 842 are treated as separate contracts, with the Company continuing to account for their obligation as lessee in the head lease agreement. The Company records sublease income on a net basis, which is recorded against rent expense within either Research and development expense or General and administrative expense in the Company's consolidated statements of operations.

Other Investments Held at Fair Value

The Company holds various investments that are recognized at fair value on the consolidated balance sheet as described below:

The Company's investment in COMPASS Pathways plc is accounted for at fair value under ASC 321, *Investments-Equity Securities* (“ASC 321”) and recorded in Other investments held at fair value on the consolidated balance sheets and changes in fair value are recognized as Change in fair value of assets and liabilities, net, a component of other expense, net in the consolidated statements of operations.

Prior to the Company's acquisition of IGX in October 2024, as permitted under ASC 825, *Financial Instruments* (“ASC 825”), the Company elected the fair value option to account for its investment in IntelGenx, which otherwise would have been subject to ASC 323, *Equity method investments and joint ventures* (“ASC 323”). In accordance with ASC 825, the Company recorded this investment at fair value under the Other investments held at fair value in the Company's consolidated balance sheets and changes in the fair value were recognized as Change in fair value of assets and liabilities, net, a component of other expense, net in the consolidated statements of operations. The Company continued to hold certain IntelGenx investments as IntelGenx continues its bankruptcy proceedings.

In January 2024, the Company received Additional Warrants (defined in Note 6, Investments) pursuant to the Beckley Psytech subscription and shareholders' agreement. Prior to the Company’s acquisition of Beckley Psytech in November 2025, the Company determined that the Additional Warrants meet the definition of a derivative instrument under ASC 815, *Derivatives and Hedging* (“ASC 815”), and recorded the Additional Warrants under the Other investments held at fair value in the consolidated balance sheets, with subsequent changes in fair value being reflected through the consolidated statements of operations in the Change in fair value of assets and liabilities, net, a component of other expense, net in the consolidated statements of operations.

Other Investments

The Company holds investments in various equity securities that do not have a readily available fair value. The Company records these investments under either the alternative measurement under ASC 321 or as an equity method investment within Other investments on the Company's consolidated balance sheets.

Alternative Measurement

Other investments include ownership rights that either (i) do not provide the Company with control or significant influence, or (ii) do not have risk and reward characteristics that are substantially similar to an investment in the investee’s common stock. The Company records such investments under the measurement alternative method pursuant to ASC 321 as these investments do not have readily determinable fair values. Under the measurement alternative method, the Company records the investment at cost or the fair value (if there is no cost basis) less impairment losses, if any, unless it identifies observable price changes in orderly transactions for the identical or a similar investment of the same issuer, in which case the Company will measure its investments at fair value as of the date that the observable transaction occurred. Such investments are presented as Other Investments on the consolidated balance sheets and any impairment recognized related to these investments are presented as Impairment of other investments, a component of other expense, net in the consolidated statements of operations. There has not been any impairment for Other investments for the years ended December 31, 2025 and 2024.

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

Equity Method Investments

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

In applying the equity method, the Company’s investments are initially recorded at cost in Other investments on the consolidated balance sheets. Upon recording an equity method investment, the Company evaluates whether there are basis differences between the carrying value and fair value of the Company’s proportionate share of the investee’s underlying net assets. Typically, the Company amortizes basis differences identified on a straight-line basis over the underlying assets’ estimated useful lives when calculating the attributable earnings or losses, excluding the basis differences attributable to in-process research and development (“IPR&D”) that had no alternative future use. To the extent a basis difference relates to IPR&D and the investee is not a business as defined in ASC 805, the Company immediately expenses such basis difference related to IPR&D. If the Company is unable to attribute all the basis difference to specific assets or liabilities of the investee, the residual excess of the cost of the investment over the proportional fair value of the investee’s assets and liabilities is recognized within the equity investment balance.

The Company subsequently adjusts the carrying amount of the investment by the Company's proportionate share of the net earnings or losses and other comprehensive income or loss of the investee based on the Company's percentage of common stock or in-substance common stock ownership during the respective reporting period. The Company records its share of the results of equity method investees and any impairment related to equity method investments as earnings or losses from investments in equity method investees, net of tax in the consolidated statements of operations. In the event that net losses of the investee reduce the carrying amount to zero, additional net losses may be recorded if the Company has other investment or other outstanding loans and advances to the investee and would be determined based on the Company's proportionate share of the respective class of securities.

Currently the Company is not obligated to make additional capital contributions for its equity method investments, and therefore only records losses up to the amount of its total investment, inclusive of other investments in and loans to the investee, which are not accounted for as equity method investments. To the extent that the Company's share of losses of the equity method investee on a cumulative basis exceeds its total investment amount, inclusive of its equity method investment, other investments, and loans, the Company will discontinue equity method loss recognition as the Company does not have guaranteed obligations of the investee nor has the Company otherwise committed to provide further financial support for the investee. The Company will resume recording its share of losses in future periods only after its share of the earnings of the equity method investee equals the Company's share of losses not recognized during the suspended period. The Company evaluates additional equity method investments made after the suspension of loss recognition to determine whether such investments represent the funding of prior suspended losses of the equity method investee.

Equity method investments are reviewed for indicators of other-than-temporary impairment at each reporting period. Equity method investments are written down to fair value if there is evidence of a loss in value that is other-than-temporary. Methodologies that the Company may use to estimate the fair value of its equity method investments include, but are not limited to, considering recent investee equity transactions, discounted cash flow analysis, recent operating results, comparable public company operating cash flow multiples and in certain situations, balance sheet liquidation values. If the fair value of the investment has declined below the carrying amount, management considers several factors when determining whether an other-than-temporary decline has occurred, such as the length of the time and the extent to which the estimated fair value or market value has been below the carrying value, the financial condition and the near-term prospects of the investee, the intent and ability of the Company to retain its investment in the investee for a period of time sufficient to allow for any anticipated recovery in market value and general market conditions. The estimation of fair value and whether an other-than-temporary impairment has occurred requires the application of significant judgment and future results may vary from current assumptions. If declines in the value of the equity method investments are determined to be other-than-temporary, a loss is recorded in earnings in the current period as a component of losses from investments in equity method investees, net of tax on the consolidated statements of operations. Evidence of a loss in value might include, but would not necessarily be limited to, absence of an ability to recover the carrying amount of the investment or inability of the investee to sustain an earnings capacity that would justify the carrying amount of the investment. This evaluation consists of several qualitative and quantitative factors including recent financial results and operating trends of the investee, implied values in recent transactions of investee securities, or other publicly available information that may affect the value of the Company's investments. The Company presents income/losses from equity investments and any impairment related to equity method investments as Income (losses) from investments in equity method investees, net of tax on the consolidated statements of operations.

Business Combinations

The Company evaluates each of its acquisitions under the accounting framework in ASC 805, *Business Combinations* ("ASC 805"), to determine whether the transaction is a business combination or an asset acquisition. In determining whether an acquisition should be accounted for as a business combination or an asset acquisition, the Company first performs a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this is the case, the acquired set is not deemed to be a business and is instead accounted for as an asset acquisition. If this is not the case, the Company then further evaluates whether the acquired set includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. If so, the Company concludes that the acquired set is a business.

The Company accounts for business acquisitions using the acquisition method of accounting. Under this method of accounting, assets acquired and liabilities assumed are recorded at their respective fair values at the date of the acquisition. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions. The Company's estimates of fair value are based upon assumptions believed to be reasonable, but these assumptions are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Any excess of the purchase price over the fair value of the net assets acquired is recognized as goodwill.

During the measurement period, which may be up to one year from the acquisition date, the Company adjusts the provisional amounts of assets acquired and liabilities assumed with the corresponding offset to goodwill to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized as of that date. Upon the conclusion of the measurement period or final determination of the values of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded within the Company's consolidated statements of operations.

The Company allocates the purchase price of acquired entities to the underlying tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values, with any excess recorded as goodwill. The valuations of the acquired assets and

liabilities will impact the determination of future operating results. Determining the fair value of assets the Company acquires and liabilities assumed requires management's judgment and often involves the use of significant estimates and assumptions, including assumptions with respect to future cash inflows and outflows, discount rates, asset lives and market multiples, among other items. The Company determines the fair values of intangible assets acquired generally in consultation with third-party valuation advisors. Fair value adjustments to the assets and liabilities are recognized and the results of operations of the acquired business are included in the Company's consolidated financial statements from the effective date of the acquisition. For the year ended December 31, 2025, the Company did not have any acquisitions that were accounted for as business combinations. For the year ended December 31, 2024, the Company completed the acquisition of Nualtis Corp. as a business combination.

If the Company's screen test determines the fair value of gross assets acquired is concentrated into a single identifiable asset, the entity being acquired is a VIE, and the Company is the primary beneficiary, the transactions are accounted for under ASC 810, *Consolidation*, and no goodwill is recognized. Rather, the Company recognizes the identifiable assets acquired (excluding goodwill), the liabilities assumed, and any noncontrolling interests as though the VIE was a business and subject to the guidance on recognition and measurement in a business combination under ASC 805, and recognizes a gain or loss calculated by taking (a) the sum of the fair values of consideration paid (including any contingent consideration) and noncontrolling interests, plus (b) the fair value of the VIE's identifiable assets and liabilities, less (c) the reported amounts of any previously held interests. Acquisition-related expenses incurred by the Company in asset acquisitions that involve the initial consolidation of a VIE that is not a business, are not included as a component of consideration transferred, but are accounted for as an expense in the period in which the costs are incurred. In an asset acquisition, including the initial consolidation of a VIE that is not a business, acquired IPR&D with no alternative future use is expensed immediately as a component of in-process Research and development expense in the consolidated statements of operations and comprehensive loss.

Variable Interest Entities and Voting Interest Entities

The Company consolidates those entities in which it has a direct or indirect controlling financial interest based on either the variable interest model (the "VIE model") or the voting interest model (the "VOE model") as prescribed under ASC 810, *Consolidation*.

VIEs are entities that, by design, either (i) lack sufficient equity to permit the entity to finance its activities without additional subordinated financial support from other parties; or (ii) have equity investors that do not have the ability to make significant decisions relating to the entity's operations through voting rights, or do not have the obligation to absorb the expected losses, or do not have the right to receive the residual returns of the entity.

The primary beneficiary of a VIE is required to consolidate the assets and liabilities of the VIE. The primary beneficiary is the party that has both (i) the power to direct the activities of the VIE that most significantly impact the VIE's economic performance; and (ii) the obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE through its interest in the VIE.

To assess whether the Company has the power to direct the activities of a VIE that most significantly impact the VIE's economic performance, the Company considers all the facts and circumstances, including its role in establishing the VIE and its ongoing rights and responsibilities. This assessment includes identifying the activities that most significantly impact the VIE's economic performance and identifying which party, if any, has power over those activities. In general, the parties that make the most significant decisions affecting the VIE (management and representation on the board of directors) and have the right to unilaterally remove those decision-makers are deemed to have the power to direct the activities of a VIE.

To assess whether the Company has the obligation to absorb losses of the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE, the Company considers all of its economic interests, which primarily include equity investments in preferred and common stock and notes receivable that are convertible into preferred stock, that are deemed to be variable interests in the VIE. This assessment requires the Company to apply judgment in determining whether these interests, in the aggregate, are considered potentially significant to the VIE. Factors considered in assessing the significance include: the design of the VIE, including its capitalization structure; subordination of interests; payment priority; relative share of interests held across various classes within the VIE's capital structure; and the reasons why the interests are held by the Company.

At the VIE's inception, the Company determines whether it is the primary beneficiary and if the VIE should be consolidated based on the facts and circumstances. The Company then performs on-going reassessments of the VIE based on reconsideration events and reevaluates whether a change to the consolidation conclusion is required each reporting period. If the Company is not deemed to be the primary beneficiary in a VIE, the Company accounts for the investment or other variable interests in a VIE in accordance with the applicable GAAP.

Upon the occurrence of certain events and on a regular basis, the Company evaluates whether it no longer has a controlling interest in its consolidated VIEs. If the Company determines it no longer has a controlling interest, the subsidiary is deconsolidated. The Company records a gain or loss on deconsolidation based on the difference on the deconsolidation date between (i) the aggregate of (a) the fair value of any consideration received, (b) the fair value of any retained noncontrolling investment in the former subsidiary and (c) the carrying amount of any noncontrolling interest in the subsidiary being deconsolidated, less (ii) the carrying amount of the former subsidiary's assets and liabilities.

Entities that do not qualify as a VIE are assessed for consolidation under the VOE model. Under the VOE model, the Company consolidates the entity if it determines that it, directly or indirectly, has greater than 50% of the voting shares and that other equity holders do not have substantive voting, participating or liquidation rights.

Intangible Assets

The Company has definite-lived intangible assets that are amortized on a straight-line basis over the period in which the Company expects to receive economic benefit and are reviewed for impairment when facts and circumstances indicate that the carrying value of the asset may not be recoverable. The determination of the expected life will be dependent upon the use and underlying characteristics of the intangible asset. In the Company's evaluation of the intangible assets, it considers the term of the underlying asset life and potential limitations to its useful life, including any legal, regulatory, contractual, or economic factors.

The Company also owns certain developed and acquired IPR&D intangible assets. These IPR&D assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. These IPR&D assets are not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. Acquired IPR&D pursuant to an asset acquisition that has no alternative future use is expensed immediately as a component of Research and development expense in the consolidated statements of operations.

The Company presents definite- and indefinite-lived intangible assets on the consolidated balance sheets within Intangible assets, net. On the consolidated statements of operations, the Company presents amortization of definite-lived intangible assets as amortization expense within General and administrative or Research and development based on intangible asset use.

Goodwill

Goodwill represents the amount of consideration paid in excess of the fair value of net assets acquired as a result of the Company's business acquisitions accounted for using the acquisition method of accounting. Goodwill is not amortized and is subject to impairment testing on an annual basis or when a triggering event occurs that may indicate the carrying value of the goodwill is impaired.

Digital Assets

The Company recognizes its investment in Bitcoin in accordance with ASC 350-60 (as defined below). Under the guidance, Bitcoin and other crypto assets ("digital assets") are accounted for as indefinite-lived intangible assets, are initially measured at cost, and are adjusted to fair value at the end of each reporting period. The Company measures gains or losses on the disposition of digital assets in accordance with the first-in-first-out ("FIFO") method of accounting. Additionally, changes in fair value will be recorded in Change in fair value of digital assets on the Company's consolidated statements of operations. The Company expects to hold its digital assets as a long-term investment, and, therefore, they are classified as non-current assets as of December 31, 2025 on the consolidated balance sheets.

Impairment of Long-Lived Assets

The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful lives of its long-lived assets, including goodwill, identifiable intangible assets subject to amortization, and property plant and equipment, may warrant revision or that the carrying value of the assets may be impaired. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheets. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss in the statements of operations if the carrying value of the intangible asset exceeds its fair value. Fair value is generally estimated based on either appraised value or other valuation techniques. Events that could result in an impairment, or trigger an interim impairment assessment, may include actions by regulatory authorities with respect to the Company or its competitors, new or better products entering the market, changes in market share or market pricing, changes in the economic lives of the assets, changes in the legal framework covering patents, rights or licenses, and other market changes which could have a negative effect on cash flows and which could result in an impairment. For the year ended December 31, 2025, the Company did not recognize impairment charges for any of their long-lived assets. For the year ended December 31, 2024, the Company recognized impairment charges for certain indefinite-lived intangible assets. Refer to Note 11, Intangible Assets, Goodwill, and Digital Assets, for more information.

The Company evaluates the recoverability of goodwill annually or more frequently if events or changes in circumstances indicate that the carrying value of the reporting unit exceeds the fair value of the reporting unit, in accordance with Other (Topic 350): Simplifying the Accounting for Goodwill Impairment. Goodwill is first qualitatively assessed to determine whether further impairment testing is necessary. Factors that management considers in this assessment include macroeconomic conditions, industry and market considerations, overall financial performance (both current and projected), changes in management and strategy and changes in the composition or carrying amount of net assets. If this qualitative assessment indicates that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a one-step test is then performed in accordance with ASC 350. Under the simplified model, a goodwill impairment is calculated as the difference between the carrying amount of the reporting unit and its fair value.

Changes in these assumptions and resulting valuations could result in future long-lived asset impairment charges. Management will continue to monitor any changes in circumstances for indicators of impairment. Any write‑downs are treated as permanent reductions in the carrying amount of the assets.

Contingent Consideration Liabilities

The Company may record contingent consideration as part of the cost of either business combinations or asset acquisitions. For contingent consideration recognized as part of a business combination, the Company recognizes the contingent consideration in accordance with ASC 805 which is measured at the fair value as of the date of acquisition and accounted for under Contingent consideration liabilities or Contingent consideration liability - related party on the consolidated balance sheets. Contingent considerations from business combinations are remeasured on a quarterly basis, as appropriate, using a discounted cash-flow valuation technique until fulfillment of the contingency. Changes in the fair value of the contingent consideration are recognized as Change in fair value of assets and liabilities, net, a component of other expense, net in the consolidated statements of operations.

For contingent consideration recognized as part of an asset acquisition, the Company must first assess whether the contingent consideration should be accounted for as either an embedded derivative under ASC 815, or in accordance with an acquisition of an equity-method investment under Subtopic ASC 323-10 (“ASC 323-10”). Contingent consideration under the guidance of ASC 815 will be recorded as a derivative liability, which is measured at fair value and remeasured on a quarterly basis. Under the guidance of ASC 323-10, contingent consideration is recorded as a liability at the lesser of either the maximum amount of contingent consideration or the excess of the Company's share of the equity method investee's net assets over the initial cost measurement. If the contingent consideration does not fall under the guidance of either ASC 815 or ASC 323-10, the Company elects the practical expedient under FASB's Statement 141, in which no contingent consideration liability is recognized on the acquisition date, and recognition does not occur unless the contingency is resolved and the consideration is issued or become issuable.

Warrants

The Company determines the accounting classification of warrants that are issued, as either liability or equity, by first assessing whether the warrants meet liability classification in accordance with ASC 480, *Distinguishing Liabilities from Equity* (“ASC 480”), and then in accordance with ASC 815, depending on the specific terms of the warrant agreement. Under ASC 480, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate the issuer to settle the warrants or the underlying shares by paying cash or other assets, or must or may require settlement by issuing variable number of shares. If warrants do not meet liability classification under ASC 480, the Company assesses the requirements under ASC 815, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815, in order to conclude equity classification, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815 or other applicable GAAP. After all relevant assessments are made, the Company concludes whether the warrants are classified as liability or equity. Liability classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded in the statements of operations as a gain or loss. For equity classified warrants, no changes in fair value are recognized after the issuance date. Transaction costs associated with the warrant liabilities are recognized as other expenses when incurred.

Debt Issuance Costs and Debt Discount

Debt issuance costs include incremental and direct costs incurred in relation to debt, such as legal fees, accounting fees, and other direct costs of the financing. Amounts paid to the lender are a reduction in the proceeds received by the Company and are generally considered a component of issuance discount, unless it is paid to compensate the lender for the services rendered or as a reimbursement of direct costs incurred by them in relation to the debt, in which case it would be akin to a debt issuance cost.

Debt issuance costs related to a recognized debt liability are presented in the consolidated balance sheets as a direct deduction from the carrying amount of the debt liability rather than as an asset, consistent with the presentation of debt discounts, and are amortized to interest expense over the term of the related debt using the effective interest method.

Debt Extinguishments

When the Company modifies or extinguishes debt, it first evaluates whether the modification qualifies as a troubled debt restructuring (TDR) under ASC Topic 470-60, which requires debt modifications to be evaluated to determine if (1) the borrower is experiencing financial difficulty, and (2) the lender grants the borrower a concession. If a TDR is determined not to have occurred, the Company evaluates the modification in accordance with ASC Topic 470-50-40, which requires modification to debt instruments to be evaluated to assess whether debt modification or debt extinguishment accounting is applicable. This evaluation includes analyzing whether there are significant and consequential changes to the economic substance of the note. If the change is deemed insignificant then the change is considered a debt modification, whereas if the change is substantial the change is reflected as a debt extinguishment.

If debt extinguishment guidance applies, the previous debt principal amount is removed, the previously capitalized debt issuance costs are expensed, the value of instruments exchanged are recorded, including cash, new debt, warrants and common stock, and a gain or loss on

extinguishment of debt is recorded. If debt modification guidance applies, no gain or loss is recorded and the effective interest rate of the debt is updated based on the carrying value of the debt and the revised future cash flows. Any previously capitalized debt issuance costs in a debt modification are amortized as interest expense over the term of the new debt instrument.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development consist of salaries, benefits and other personnel related costs including equity-based compensation expense, laboratory supplies, preclinical studies, clinical trials and related clinical manufacturing costs, costs related to manufacturing preparations, fees paid to other entities to conduct certain research and development activities on the Company's behalf and allocated facility and other related costs. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed.

Preclinical and clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as Research and development expense.

Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses any litigation or other claims it may confront to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. The Company will accrue for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company will accrue the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company will disclose the facts and circumstances of the litigation, including an estimable range, if possible.

Revenue Recognition

The Company accounts for its revenue in accordance with ASC 606, *Revenue Recognition.* ASC 606 outlines a five-step process for recognizing revenue from contracts with customers: i) identify the contract with the customer, ii) identify the performance obligations in the contract, (iii) determine the transaction price, iv) allocate the transaction price to the separate performance obligations in the contract, and (v) recognize revenue associated with the performance obligations as they are satisfied.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606, the Company determines the performance obligations that are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to each respective performance obligation when the performance obligation is satisfied or as it is satisfied. Payments received in advance of the Company satisfying performance obligations will be recognized as Deferred revenue within the consolidated balance sheets. As noted above, the Company has not generated any revenues to date from the sale of its product candidates and does not anticipate generating any revenues from the sale of its product candidates unless and until it successfully completes development and obtains regulatory approval to market its product candidates. The Company does recognize revenue through their licenses of intellectual property and manufacturing contracts.

Licenses of Intellectual Property

The Company may enter into collaboration and out-licensing arrangements for research and development, manufacturing, and commercialization activities with counterparties for the development and commercialization of its product candidates. The agreements may have units of account within the scope of ASC 606 where the counterparties meet the definition of a customer as well as units of account within the scope of ASC 808 where both parties are determined to be active participants exposed to significant risk and rewards.

The arrangements may contain multiple components, which may include (i) licenses, or options to obtain licenses to the Company's intellectual property or sale of the Company's license, (ii) research and development activities, (iii) participation on joint steering committees, and (iv) the manufacturing of commercial, clinical or preclinical material. Payments pursuant to these arrangements may include non-refundable, upfront payments, milestone payments upon the achievement of significant development events, research and development reimbursements, sales milestones, and royalties on product sales. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period. The contracts into which the Company enters generally do not include significant financing components.

As part of the accounting for these arrangements, the Company must use significant judgment to determine: a) the number of performance obligations; b) the transaction price; c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price; and d) the measure of progress. The Company uses judgment to determine whether milestones or other

variable consideration, except for sales-based milestones and royalties on license arrangements, should be included in the transaction price as described further below.

If a license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from consideration allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other elements, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the counterparties and the availability of its associated expertise in the general marketplace. In addition, the Company considers whether the counterparties can benefit from a promise for its intended purpose without the receipt of the remaining elements, whether the value of the promise is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is separately identifiable from the remaining promise. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress as of each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, is subject to estimates by management and may change over the course of the arrangement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Customer Options: If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services such as research and development services or manufacturing services, the goods and services underlying the customer options are not considered to be performance obligations at the inception of the arrangement unless a material right is provided to the customer. If the customer option does not represent a material right, the obligation to provide such goods and services is contingent on exercise of the option, and the associated consideration is not included in the transaction price. If a customer option is determined to include a significant and incremental discount and, therefore, represents a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price.

Milestone Payments: At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most-likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties: For license arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Government Grants

The Company accounts for its government grant by first determining if the grant is a grant related to an asset or a grant related to income. A grant related to an asset is a grant that is conditioned on the purchase, construction, or acquisition of an asset while a grant related to income is a grant other than a grant related to an asset, such as a grant that reimburses expenses. The Company has received a grant related to income in 2025. The Company recognizes the grant in earnings on a systematic and rational basis over the periods in which the entity recognizes as expenses the related costs for which the grant is intended to compensate. The Company recognizes the grant as a reduction to Research and development costs in the Consolidated statement of operations.

Stock-Based Compensation

The Company accounts for all stock-based payment awards granted to employees, directors and non-employees as stock-based compensation expense based on their grant date fair value. The stock-based payment awards are measured at fair value on the date of the grant and that fair value is recognized as stock-based compensation expense in the Company's consolidated statements of operations over the requisite service period of the respective award. The estimated fair value of awards that contain performance conditions is expensed when the Company concludes that it is probable that the performance condition will be achieved. The Company may grant awards with graded-vesting features. When such awards have only service vesting requirements, the Company elected to record stock-based compensation expense on a straight-line basis.

The Company measures the fair value of its stock options that only have service vesting requirements or performance-based options without market conditions using the Black-Scholes option pricing model. For performance-based awards with market conditions, the Company determines the fair value of the awards as of the grant date using a Monte Carlo simulation model.

Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate and the fair value of the Company's common stock. Since the Company has limited option exercise history, it has generally elected to estimate the expected life of an award based upon the "simplified method" with the continued use of this method extended until such time the Company has sufficient exercise history. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the equity award. Because the Company did not have an extended trading history for its common stock, the expected volatility was estimated using weighted average measures of the Company's historical volatility and the historical volatility of a peer group of companies for a period equal to the expected life of the stock options. The Company's peer group of publicly traded biopharmaceutical or biotechnology companies was chosen based on their similar size, stage in the life cycle or area of specialty. The Company has elected to recognize forfeitures of stock-based compensation awards as they occur.

As part of the valuation of stock-based compensation under the Black-Scholes option pricing model, it is necessary for the Company to use the fair value of its common stock as a valuation input. Prior to the closing of the IPO, the fair value of the Company's common stock was estimated on each grant date. The fair value of the Company's privately held subsidiaries' common stock was also estimated on each grant date. Given the absence of a public trading market, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, the Company exercised reasonable judgment and considered numerous objective and subjective factors to determine its best estimate of the fair value of its common stock. The estimation of the fair value of the common stock considered factors including the following: the estimated present value of the Company's future cash flows; the Company's business, financial condition and results of operations; the Company's forecasted operating performance; the illiquid nature of the Company's common stock; industry information such as market size and growth; market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and macroeconomic conditions. The Company recognized stock-based compensation related to awards granted prior to the closing of the IPO for the year ended December 31, 2025. As of December 31, 2025, there are no unvested pre-IPO awards.

After the closing of the IPO in June 2021, the Company's board of directors determined the fair value of each share of common stock underlying stock-based awards based on the closing price of the Company's common stock as reported by Nasdaq on the date of grant.

Noncontrolling Interests

The Company recognizes noncontrolling interests related to its consolidated VIEs in the consolidated balance sheets as a component of equity, separate from AtaiBeckley stockholders' equity. Changes in the Company's ownership interest in a consolidated VIE that do not result in a loss of control are accounted for as equity transactions. The noncontrolling interests related to its consolidated VIEs are initially recorded at fair value. Net losses in consolidated VIEs are attributed to noncontrolling interests considering the liquidation preferences of the different classes of equity held by the shareholders in the VIE and their respective interests in the net assets of the consolidated VIE in the event of liquidation, and their pro rata ownership.

In addition, the Company evaluates the classification of noncontrolling interests based upon a review of the legal provisions governing the redemption of such interests as the obligation to redeem these shares are triggered by events that are within the control of the Company. The Company evaluates individual noncontrolling interests for the ability to recognize the noncontrolling interest as permanent equity on the consolidated balance sheets at the time such interests are issued and on a continual basis. Any noncontrolling interest that fails to qualify as permanent equity are considered redeemable noncontrolling interests and reclassified as temporary equity.

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

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded when, after consideration of all positive and negative evidence, it is not more likely than not that the Company's deferred tax assets will be realizable. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits

of the tax position as well as consideration of the available facts and circumstances. The Company recognizes interest and penalties related to the underpayment of income taxes as a component of the Provision for income taxes in its consolidated statements of operations.

Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active; and

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amount reflected in the accompanying consolidated balance sheets for cash and cash equivalents, committed investment funds, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

Foreign Currency

Assets and liabilities of foreign operations are translated using exchange rates in effect at the balance sheet date and their results of operations are translated using average exchange rates for the year. Investments accounted for under the equity method and stockholders' equity are translated based on historical exchange rates. Certain transactions of the Company and its subsidiaries are denominated in currencies other than their functional currency. Adjustments resulting from the translation of the financial statements of the Company's foreign functional currency subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of stockholders' equity. Foreign exchange transaction gains and losses are recognized as a component of other expense, net in the consolidated statements of operations.

Basic and Diluted Net Loss Per Share of Common Stock

Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders for the year by the weighted average number of common stock outstanding during the year. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders for the year by the weighted average number of common stock, including potential dilutive shares of common stock assuming the dilutive effect of potential dilutive securities. The Company uses the treasury stock method to calculate diluted net loss per share. For years in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share because their impact would be anti-dilutive to the calculation of net loss per share. For the years ended December 31, 2025 and 2024, the Company reports a combined basic net loss and diluted loss per share of common stock.

Segment Reporting

The Company's operations are organized into one operating and reportable segment dedicated to the global discovery, research, development, and commercialization of highly effective mental health treatments to transform patient outcomes. The Company's Chief Executive Officer is the Company's Chief Operating Decision Maker ("CODM") and makes key operating decisions and assesses performance on a consolidated basis. The Company's determination that it operates as a single operating segment is consistent with the financial information regularly reviewed by the CODM. See Note 26, Segment Reporting, for details.

Subsequent Events

Subsequent events are defined as those events or transactions that occur after the balance sheet date, but before the financial statements are filed with the Securities and Exchange Commission. The Company completed an evaluation of the impact of any subsequent events through the date these financial statements were issued, and determined there were no subsequent events that required disclosure or adjustment in these financial statements.

Emerging Growth Company Status

For the years ended December 31, 2025 and 2024, the Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Adopted Accounting Pronouncements

ASU 2023-08 Intangibles: Accounting for and Disclosure of Crypto Assets

In December 2023, the FASB issued ASU 2023-08, *Accounting for and Disclosure of Crypto Assets*, which is codified as ASC subtopic 350-60 ("ASC 350-60"). The new guidance is designed to streamline the accounting treatment of crypto assets. ASC 350-60 requires that an entity measure crypto assets at fair value with changes recognized in net income at each reporting period and present crypto assets separately from other intangible assets in the balance sheet and changes from the remeasurement of crypto assets separately from changes in the carrying amounts of other intangible assets in the income statement. The guidance is effective for annual periods beginning after December 15, 2024 and interim periods within annual periods beginning after December 15, 2024. The Company adopted ASC 350-60 as of January 1, 2025 resulting in certain expanded disclosures about its digital assets. Refer to Note 11, Intangible Assets, Goodwill, and Digital Assets, for more information.

ASU 2023-09 Income taxes: Improvements to Income Tax Disclosures

In December 2023, the FASB issued ASU 2023-09, *Income Taxes: Improvements to Income Tax Disclosures*, which is designed to improve income tax disclosure requirements, primarily through increased disaggregation disclosures within the effective tax rate reconciliation as well as enhanced disclosures on income taxes paid. The guidance is effective for all fiscal years beginning after December 15, 2024 and interim periods within annual periods beginning after December 15, 2024. The new standard can be adopted on a prospective basis with an option to be adopted retrospectively and early adoption is permitted. The Company adopted the new disclosure requirements effective December 31, 2025. Refer to Note 17, Income Taxes, for more information.

ASU 2025-10 Government Grants: Accounting for Government Grants Received by Business Entities

In December 2025, the FASB issued ASU 2025-10, *Accounting for Government Grants Received by Business Entities*. The new guidance is designed to provide authoritative guidance on the accounting for government grants received by business entities. The guidance is effective for annual periods beginning after December 15, 2028 and interim periods within annual periods beginning after December 15, 2028. The Company elected to early adopt this standard as of December 31, 2025 on a prospective basis, resulting in certain expanded disclosures about its government grant. Refer to Note 21, Government Grant, for more information. This standard has no impact on any prior periods presented in the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures*, which is designed to improve income statement expense disclosures, primarily by requiring new financial statement disclosures in tabular format and disaggregating information about prescribed categories underlying any relevant income statement captions. The standard is effective for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. Upon adoption, the new standard may be applied prospectively or retrospectively. The Company is currently evaluating the impact that the adoption may have on its disclosures in its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-04, *Debt - Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments*, which clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. The standard is effective for annual periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods. Early adoption is permitted for all entities. Adoption can be on a prospective or retrospective basis. The Company is currently in the process of evaluating the impact of adoption on the consolidated financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles (Subtopic 450-40): Targeted Improvements to the Accounting for Internal-Use Software*, which amends certain aspects of the accounting for and disclosure of software costs under ASC Subtopic 350-40, *Internal Use Software*. The standard is effective for fiscal years beginning after December 15, 2027 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. Entities may elect to apply the guidance prospectively, retrospectively, or through a modified prospective transition method. The Company is currently evaluating the impact that the adoption may have on its disclosures in its consolidated financial statements.

In September 2025, the FASB issued ASU 2025-07, *Derivatives and Hedging (subtopic 815): Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract,* which expands the scope exceptions within ASC Topic 815, Derivatives and Hedging, to include certain nonexchange-traded contracts with underlyings that are based on operations or activities specific to one of the parties to the contract, including research and development funding arrangements. The standard is effective for annual fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2026, with early adoption permitted. Entities should apply the amendments either prospectively for contracts entered into on or after the date of adoption or on a modified retrospective basis through a cumulative-effect adjustment to the opening balance of retained earnings for contracts that exist as of the beginning of the annual reporting period of adoption. The Company is currently evaluating the impact that the adoption may have on its disclosures in its consolidated financial statements.

3. Revenue

As described in Note 1, Organization and Description of Business, above, the Company's primary operations are inclusive of the research and development of several product candidates. The Company's ability to generate revenue will depend substantially on the successful development and eventual commercialization of product candidates. For the years ended December 31, 2025 and 2024, the Company has not recognized revenue from its primary operations and does not expect to do so for at least the next several years. The Company does generate revenue from license agreements and research and development agreements through certain subsidiaries, which is further explained below:

License Revenue

Otsuka License and Collaboration Agreement

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

In January 2025, Otsuka provided a notice of termination pursuant to the Otsuka Agreement, effective as of April 2025. As of the termination date, the Company is no longer eligible to receive any milestone payments or royalties pursuant to the Otsuka Agreement. For the years ended December 31, 2025 and 2024 there were no milestones achieved under the Otsuka Agreement. For the year ended December 31, 2025 and 2024, the Company did not recognize any license revenue and recognized $0.3 million or license revenue, respectively, pursuant to the Otsuka Agreement.

Rizafilm LLC License and Supply Agreement

In January 2025, the Company, through its wholly owned subsidiary Nualtis, entered into an Amended & Restated Asset Purchase Agreement ("APA") and an Amended & Restated Supply Agreement ("Supply Agreement") with Rizafilm LLC ("Rizafilm"). Under the APA, Nualtis sold licensing and intellectual property rights of Nualtis's oral thin film technology in exchange for an upfront payment of $0.2 million and an additional $0.5 million upon completion of certain manufacturing milestones. Under the Supply Agreement, subject to approval by the FDA, Nualtis will serve as the sole manufacturer of Rizafilm's products over a five year term with an automatic renewal option for an additional five years unless either party provides sufficient written notice. Additionally, the Supply Agreement requires Rizafilm to adhere to certain firm commitments.

During the year ended December 31, 2025, the Company recognized $0.2 million of license revenue pursuant to the Rizafilm APA.

Research and Development Services Revenue

In addition to the Company's license revenue, the Company recognizes revenue through various research and development agreements through Nualtis. In these agreements, Nualtis is responsible for performing research and development services for customers interested in leveraging Nualtis's novel oral thin film technology for drug delivery. Many of these agreements provide Nualtis either the option or the right to serve as the sole manufacturer of these drugs upon regulatory approval. For the year ended December 31, 2025 the Company has recognized $4.0 million in revenue from research and development services. For the year ended December 31, 2024, the Company did not recognize revenue from research and development services.

For the years ended December 31, 2025 and 2024, the Company had contract liabilities of $1.5 million and $0.7 million, respectively, which is recorded within Deferred revenue on the Company's consolidated balance sheets, and consists of the upfront payments received as part of the various research and development agreements discussed above. As of December 31, 2025, approximately $1.5 million of the contract liability balance is expected to be recognized as revenue from the remaining performance obligations over the next 12 months as performance obligations are satisfied. The Company will re-evaluate the transaction price in each reporting period and as certain events are resolved or other changes in circumstances occur.

For the year ended December 31, 2025, the Company's license revenue and research and development revenue has been recognized entirely in Canada. Nualtis recognized a significant amount of research and development service revenue from three customers that individually represent more than 10% of total research and development service revenue. Total research and development service revenue from the three vendors are $1.6 million, $1.5 million, and $0.7 million, respectively.

4. Acquisitions

2025 Acquisitions

Beckley Psytech Limited

Beckley Psytech is a clinical stage biotechnology company dedicated to improving the lives of people suffering from neuropsychiatric disorders by transforming psychedelics into effective and rapid-acting clinical medicines. Its most advanced programs are focused on the development of psychedelic-based medicines to treat people with treatment resistant depression and major depressive disorder. Prior to the Company's acquisition of Beckley Psytech, the Company had an existing investment in Beckley Psytech's preferred shares. See Note 6, Investments, for details over the Company's investment in Beckley Psytech prior to the acquisition.

On June 2, 2025, the Company executed a share purchase agreement with Beckley Psytech and certain other parties thereto (the "SPA"), pursuant to which the Company agreed to acquire from the shareholders of Beckley Psytech (the "Sellers") the entire issued share capital of Beckley Psytech not already owned by the Company (refer to Note 6, Investments, for more information) in exchange for an aggregate of 105,044,902 common stock of the Company issued directly as share consideration or underlying replacement awards in each case, as set forth in the SPA (the "Beckley Psytech Acquisition"). Subsequently, on October 23, 2025, the Company and Beckley Psytech entered into a side letter deed to the SPA (the "SPA Amendment"), pursuant to which the number of Company common shares to be issued to the Sellers was reduced, on a pro-rata basis, to 103,823,190 common shares. The SPA Amendment also provided for a cash payment of $5.3 million and the issuance of 900,901 common shares, which is included in the SPA Amendment's reduction in common shares, by the Company to a third party in connection with financial advisory services rendered to Beckley Psytech. The liability recognized by Beckley Psytech for such financial advisory services was assumed by the Company upon completion of the Beckley Psytech Acquisition.

In October 2025, prior to the Company's acquisition of Beckley Psytech and pursuant to the terms of the SPA, Beckley Psytech distributed its 100% equity ownership of Eleusis Holdings Limited as a dividend in specie pro rata among existing Beckley Psytech shareholders based on their current ownership stakes in Beckley Psytech. The Company recognized its investment of 33.7% of the outstanding common shares of Eleusis Holdings Limited as Other investments in the consolidated balance sheets. Subsequent to the Beckley Psytech's distribution of Eleusis Holdings Limited, Eleusis Holdings Limited rebranded to Amandala Neuro Limited ("Amandala"). See Note 6, Investments, for details.

On November 5, 2025 (the "Acquisition Date"), the Beckley Psytech Acquisition was completed and the Company issued an aggregate of 103,823,021 common shares to the Sellers in the form of share consideration or shares underlying replacement awards pursuant to the SPA, reflecting a round down to the nearest whole share at the individual issuance level, which was comprised of 93,580,831 common shares issued directly to the Sellers as share consideration for Beckley Psytech, 8,695,937 RSUs and 1,546,258 stock options issued as replacement awards to the shareholders of Beckley Psytech, certain consultants of Beckley Psytech and certain equity award holders in Beckley Psytech. Additionally, 900,901 common shares were issued to a third party pursuant to the SPA Amendment. Certain RSUs issued as replacement awards were issued net of the exercise price of the Beckley option awards to which they correspond, resulting in the issuance of 6,971,912 RSUs on the Acquisition Date. The shares underlying the options and RSUs issued as replacement awards are subject to a lock-up period whereby $1/12^{th}$ of the underlying shares will be released from the lock-up each calendar month beginning January 2026, resulting in all shares underlying the options and RSUs being freely transferable in January 2027. Under the original terms of the agreements for the Beckley Psytech options awards for which the holders received replacement awards, the Beckley Psytech Acquisition represented an exit event that triggered the automatic acceleration of all unvested awards prior to the Acquisition Date, which was recognized in the pre-combination financial results of Beckley Psytech.

The Beckley Psytech Acquisition was accounted for as an asset acquisition involving the initial consolidation of a VIE that is not a business for which the Company was determined to be the primary beneficiary on the Acquisition Date. The Beckley Psytech Acquisition was determined to be an asset acquisition because substantially all of the fair value of the gross assets acquired was concentrated in an IPR&D asset, an intangible asset. Accordingly, the Beckley Psytech Acquisition was accounted for under ASC 810 and no goodwill was recognized. Under ASC 810, upon initial consolidation of a VIE the acquirer shall recognize a gain or loss for the difference between the sum of (a) the sum of the fair values of consideration paid (including any contingent consideration) and noncontrolling interests and (b) the reported amounts of any previously held interests; less (c) the fair value of the VIE's identifiable assets and liabilities. In accordance with ASC 810, a gain of $6.9 million was recognized on the Beckley Psytech Acquisition.

The net amount of the VIE's identifiable assets and liabilities recognized with respect to the Beckley Psytech Acquisition is based upon management's preliminary estimates of and assumptions related to the fair values of assets acquired and liabilities assumed, using currently available information and subject to the guidance on recognition and measurement in a business combination under ASC 805.

The following table presents, in accordance with ASC 810, the sum of the (i) fair values of consideration paid, and (ii) the reported amount of previously held interests in Beckley Psytech (in thousands). There were no noncontrolling interests in Beckley Psytech upon completion of the Beckley Psytech Acquisition as the Company acquired all of the outstanding share capital of Beckley Psytech not already owned by the Company.

Share consideration issued to the Sellers [1]	$	450,476
Settlement of the unsecured promissory note [2]		10,280
Settlement of payable to Beckley Psytech [3]		(238)
Estimated fair value of stock options issued as replacement awards [4]		5,455
Incremental fair value of atai restricted stock units issued for consideration at closing that is attributable to the post-combination entity [5]		(328)
(i) Total fair value of consideration paid		465,645
(ii) Reported value of atai's previously held interest in Beckley Psytech [6]		53,947
	$	519,592

[1] Represents the aggregate fair value of 93,580,831 common shares of the Company issued directly to the Sellers as equity consideration and 6,971,912 RSUs issued as replacement awards on the Acquisition Date, based on the closing trading price of the Company's common share of $4.48 per share on the Acquisition Date.

[2] Represents the settlement of an unsecured promissory note issued by the Company to Beckley Psytech and related accrued interest of $10.3 million (refer to Note 7, Notes Receivable, for more information).

[3] Represents the settlement of accounts payable to Beckley Psytech of $0.2 million on the Acquisition Date, as these pre-existing relationships became intercompany and were effectively settled upon completion of the Beckley Psytech Acquisition.

[4] Represents the fair value of 1,546,258 stock options issued at replacement awards on the Acquisition Date. The Company estimated the fair value of the stock options using the Black-Scholes option-pricing model on the Acquisition Date. The assumptions used in the Black-Scholes option pricing model were as follows:

Weighted average expected term in years	2.16
Weighted average expected stock price volatility	89.5%
Risk-free interest rate	3.63% - 3.79%
Expected dividend yield	0%

[5] Represents the incremental fair value of 6,971,912 atai restricted stock units issued as replacement awards that is attributable to the post-combination entity.

[6] Represents the reported amount of the Company's previously held interests in Beckley Psytech, including the carrying value of the Company's pre-existing investment in Series C Shares of $45.5 million and the carrying value of the Company's outstanding Series C Warrants of $8.5 million on the Acquisition Date. Refer to Note 6, Investments, for more information.

The following table presents, in accordance with ASC 810, the net amount of the VIE's identifiable assets and liabilities recognized and measured in accordance with ASC 805 (in thousands):

Assets acquired and liabilities assumed		
Cash and cash equivalents	$	4,636
Prepaid expenses and other current assets		11,848
Acquired in-process research and development		527,000
Property and equipment		14
Other assets		825
Accounts payable		(3,602)
Accrued liabilities		(12,103)
Other current liabilities		(2,124)
Total assets acquired and liabilities assumed	$	526,494

In accordance with ASC 810, a gain of $6.9 million was recognized on the initial consolidation of Beckley Psytech within Gain on consolidation of Beckley Psytech in the accompanying consolidated statements of operations. The Company incurred transaction costs of $14.3 million in connection with the Beckley Psytech Acquisition for consulting, legal, accounting and other professional fees, which have been expensed as incurred as General and administrative expenses within the consolidated statements of operations.

The fair value of the remaining net assets of Beckley Psytech acquired by the Company approximated their carrying values on the Acquisition Date. The fair value of acquired IPR&D was determined primarily using the income approach, which requires a forecast of all of the expected future cash flows with the following assumptions: net revenue attributable to Beckley Psytech's IPR&D, operating expenses, and contributory asset charges resulting from applying a terminal growth rate at the end of the discrete period. An estimated discount rate of 17.8% was applied to the projected cash flows of Beckley Psytech's IPR&D based on the rate of return used by a similar market participant. Immediately subsequent to the consummation of the Beckley Psytech Acquisition, the acquired IPR&D of $527 million, which was determined to have no alternative future use, was charged to Acquisition of in-process research and development within the consolidated statements of operations.

Beckley Psytech results from the Acquisition Date through December 31, 2025, which are included in the consolidated statements of operations, are as follows (in thousands):

Classification in Consolidated Statements of Operations	Acquisition Date through December 31, 2025
Total revenues	$ —
Net loss	4,812

Unaudited Pro Forma Summary of Operations

Supplemental information on an unaudited pro forma basis is presented below as if the Beckley Psytech Acquisition occurred at the beginning of fiscal year 2024. The pro forma information for the years ended December 31, 2025 and 2024 presented below is based on estimates and assumptions, which the Company believes are reasonable and not necessarily indicative of the consolidated financial position or results of operations in future periods or the results that actually would have been realized had the Beckley Psytech Acquisition been completed at the beginning of fiscal year 2024 (in thousands).

	For the years ended December 31,	
	2025	2024
Total revenues	$ 4,089	$ 308
Net loss	$ (704,379)	$ (700,788)

The unaudited pro forma information was prepared using the acquisition method of accounting and was based on the historical information of the Company and Beckley Psytech. The summary pro forma financial information primarily reflects the following pro forma adjustments:

- Derecognition of the change in fair value of Additional Warrants held by the Company for the years ended December 31, 2025 and 2024.
- Derecognition of the change in fair value of warrant liabilities incurred by Beckley Psytech for the years ended December 31, 2025 and 2024.
- Derecognition of the change in fair value of the contingent consideration liability recognized by Beckley Psytech for the years ended December 31, 2025 and 2024.
- Conversion of Beckley Psytech's accounting for share-based compensation from IFRS to US GAAP for the years ended December 31, 2025 and 2024.
- Derecognition of the interest income earned by the Company and the interest expense incurred by Beckley Psytech related to the unsecured promissory note for the year ended December 31, 2025.

2024 Acquisitions

Nualtis Corp.

In October 2024, the Company acquired all of the issued and outstanding shares of IntelGenx Corp. ("IGX"), a subsidiary of IntelGenx Technologies Corp. ("IntelGenx"). In June 2025, IGX rebranded to Nualtis Corp. ("Nualtis") as part of the subsidiary's transformation and long-term strategic vision. Nualtis is a novel drug delivery company focused on the development and manufacturing of novel oral thin film products for the pharmaceutical market. In March 2021, IntelGenx and the Company entered into the Strategic Development Agreement and Purchaser Rights Agreement ("PPA"), (described in Note 6, investments). In May 2021, IntelGenx and the Company executed a Securities Purchase Agreement (the "2021 IntelGenx SPA"), (described in Note 6, investments), under which the Company held a 25% voting interest in IntelGenx. Pursuant to the PPA, the Company is entitled to designate a number of directors to the IntelGenx's board of directors in the same proportion as the shares of common stock held by the Company to the outstanding IntelGenx common shares.

The Company and IntelGenx also entered into certain loan agreements and convertible promissory note agreements, including the IntelGenx Term Loan, 2023 Initial Notes, 2023 Subsequent Notes, 2023 Term Loan, and the DIP Loan (as defined and described in Note 7, Notes Receivable).

In May 2024, IntelGenx announced that its board of directors authorized IntelGenx to bring an application in the Quebec Superior Court to seek protection from creditors under the Companies' Creditors Arrangement Act (“CCAA”) to allow time to review its strategic alternatives. IntelGenx was granted protection pursuant to an initial order ("Initial Order"), which also authorized interim debtor-in-possession financing ("DIP Financing") provided by the Company in order to allow IntelGenx to continue its operations during a restructuring process. Subsequently, IntelGenx obtained approval to implement a sale and investment solicitation process (the "SISP" and the approval, the "SISP Approval Order"). As part of the SISP Approval Order, the Court approved the agreement of a purchase and sale between IntelGenx and the Company, solely for the purpose of constituting the “Stalking Horse Bid" under the SISP. The Stalking Horse Bid established a baseline price and deal structure for the solicitation of superior bids from qualified interested parties.

On September 30, 2024, the Superior Court of Quebec issued an Approval and Vesting Order, sanctioning the transactions contemplated in ATAI’s stalking horse bid, which consisted of the Company acquiring IGX, the operating company and a subsidiary of IntelGenx. The acquisition closed on October 2, 2024.

The Company did not exchange any equity or cash in this transaction. Rather, the transaction was structured as a credit bid, which resulted in the Company receiving all issued and outstanding shares of IGX in exchange for the discharge of all senior secured debt payable to the Company by IntelGenx, which included solely the DIP Loan and the IntelGenx Term Loan (described in Note 7, Notes Receivable). The transaction was further structured to include only the assumption of the assets and liabilities which the Company designated within their Stalking Horse Bid (the “Purchase Transaction”). All remaining unsecured debt payable by IntelGenx, and any remaining assets and liabilities not assumed by the Company in the Purchase Transaction, continue to be held by IntelGenx, and IntelGenx continues its bankruptcy proceedings.

The Company continues to hold investments in IntelGenx's common shares, Warrants, and Call Option as well as various notes receivable, as defined and discussed further in Note 6, Investments, and Note 7, Notes Receivable.

The Company determined that the transaction met the definition of a business under ASC 805; therefore, the Company accounted for the transaction as a business combination and applied the acquisition method of accounting. The purchase consideration transferred at the acquisition date was $5.7 million, which was the fair value of the aforementioned discharged senior secured debt. The Company did not include any cash or equity as part of the consideration transferred.

The following table sets forth the allocation of the IGX purchase price to the estimated fair value of the net assets acquired at the acquisition date (in thousands):

	Amounts Recognized at the Acquisition Date
Assets acquired:	
Cash	$ 359
Accounts receivable	46
Prepaid expenses and other current assets	971
Property and Equipment	1,892
Right-of-use assets, net	527
Definite-lived intangible assets	2,625
Other assets	275
Total assets	$ 6,695
Liabilities assumed:	
Accounts payable	$ 214
Deferred revenue	575
Accrued liabilities	136
Right-of-use liabilities	327
Other current liabilities	59
Total liabilities	$ 1,311
Total identifiable net assets acquired	5,384
Goodwill	331
Total consideration transferred	$ 5,715

Nualtis’s results from the acquisition date of October 2, 2024 through December 31, 2024, which are included in the consolidated statements of operations, are as follows (in thousands):

Classification in Consolidated Statements of Operations		Acquisition Date Through December 31, 2024
Total revenues	$	12
Net loss	$	(960)

Unaudited Pro Forma Summary of Operations

The following table shows the unaudited pro forma summary of operations for the year ended December 21, 2024, as if the Nualtis acquisition had occurred on January 1, 2024. This pro forma information does not purport to represent what the Company's actual results would have been if the acquisition had occurred as of January 1, 2024, and is not indicative of what such results would be expected for any future period (in thousands):

		For the year ended December 31, 2024
Total revenues	$	457
Net loss	$	(138,803)

The unaudited pro forma financial information was prepared using the acquisition method of accounting and was based on the historical financial information of the Company and Nualtis. The summary pro forma financial information primarily reflects the following pro forma adjustments:

- Removal of the acquisition-related transaction fees and costs;
- Removal of any revenue recognized by Nualtis in connection with services performed for the Company;
- Removal of Nualtis’s interest expense and the Company's interest income in connection with certain notes receivable instruments;
- Derecognition of any fair value adjustments recognized by the Company for their equity and notes receivable instruments;
- Additional amortization expense from the acquired intangible assets;
- Additional depreciation of fixed assets; and
- Additional lease expense on the ROU assets.

5. Variable Interest Entities ("VIE")

Consolidated VIEs

At each reporting period, the Company reassesses whether it remains the primary beneficiary for VIEs consolidated under the VIE model.

The entities consolidated by the Company are comprised of wholly and partially owned entities for which the Company is the primary beneficiary under the VIE model as the Company has (i) the power to direct the activities that most significantly impact the VIE's economic performance and (ii) the obligation to absorb losses that could potentially be significant to the VIE, or the right to receive benefits from the VIE that could potentially be significant to the VIE. The results of operations of the consolidated entities are included within the Company's consolidated financial statements from the date of acquisition to December 31, 2025.

As of December 31, 2025 and 2024, the Company has accounted for the following consolidated investments as VIEs:

Consolidated Entities	Relationship as of December 31, 2025	Relationship as of December 31, 2024	Date Control Obtained	Ownership % December 31, 2025	Ownership % December 31, 2024
Perception Neuroscience Holdings, Inc.	Controlled VIE	Controlled VIE	November 2018	59.2%	59.2%
Recognify Life Sciences, Inc.	Controlled VIE	Controlled VIE	November 2020	51.9%	51.9%

As of December 31, 2025 and 2024, the assets of the consolidated VIEs can only be used to settle the obligations of the respective VIEs. The liabilities of the consolidated VIEs are obligations of the respective VIEs and their creditors have no recourse to the general credit or assets of atai.

Consolidated VIE Balance Sheets

The following table presents the assets and liabilities (excluding intercompany balances that were eliminated in consolidation) for all VIEs as of December 31, 2025 (in thousands):

	Perception	Recognify
Assets:		
Current assets:		
Cash	$ 43	$ 560
Accounts receivable	—	—
Prepaid expenses and other current assets	86	60
Total current assets	129	620
Total assets	$ 129	$ 620
Liabilities:		
Current liabilities:		
Accounts payable	$ 875	$ 107
Accrued liabilities	45	243
Other current liabilities	14	1
Total current liabilities	934	351
Total liabilities	$ 934	$ 351

The following table presents the assets and liabilities (excluding intercompany balances that were eliminated in consolidation) for all consolidated VIEs as of December 31, 2024 (in thousands):

	Perception	Recognify
Assets:		
Current assets:		
Cash	$ 31	$ 819
Accounts receivable	261	—
Prepaid expenses and other current assets	88	40
Total current assets	380	859
Total assets	$ 380	$ 859
Liabilities:		
Current liabilities:		
Accounts payable	$ 276	$ 221
Accrued liabilities	195	961
Other current liabilities	83	4
Total current liabilities	554	1,186
Total liabilities	$ 554	$ 1,186

Non-consolidated VIEs

The Company evaluated the nature of its investments in Innoplexus AG ("Innoplexus") and Amandala and determined that Innoplexus and Amandala are not consolidated VIEs as of the date of the Company's initial investment through December 31, 2025. The Company is not the primary beneficiary of Innoplexus or Amandala as the Company does not have the power to direct the activities of Innoplexus or Amandala that most significantly impact their respective economic performance. Therefore, the Company concluded that it did not have a controlling financial interest in Innoplexus or Amandala that would require consolidation as of December 31, 2025 and 2024.

The Company will reevaluate if Innoplexus and Amandala meet the definition of a VIE upon the occurrence of specific reconsideration events. The Company accounted for these investments under the measurement alternative included within ASC 321 (see Note 6, Investments). As of December 31, 2025, the Company's maximum exposure for its investment in Innoplexus and Amandala is zero.

As of December 31, 2024, the Company held the investments in Innoplexus and Beckley Psytech (collectively "non-consolidated VIEs"), and the Company's maximum exposure for its non-consolidated VIEs was $10.0 million of Short-term restricted cash, reflected in the consolidated balance sheets, for the purchase of Beckley Psytech Deferred Shares (as defined and described in Note 6, Investments).

Non-Consolidated VIEs as of December 31, 2024

The following investments no longer met the requirements to consolidate as VIEs as of December 31, 2024 but were previously consolidated VIEs:

Kures, Inc.

Kures Inc. ("Kures") was a pre-clinical stage biotech company focusing on developing new opioid-based therapeutics for mood disorders and psychiatry or physical pain using mitragynine and tianeptine derivatives. In August 2019, through a series of transactions, the Company acquired a controlling financial interest in Kures through its purchase of Kures' Series A-1 preferred stock. Immediately following the closing of these transactions, the Company's ownership in Kures was approximately 57.1%. Based on the Company's assessment of the transaction at the time of acquisition, the Company concluded that Kures was not a business and accounted for the Company's investment as an initial consolidation of a VIE that is not a business under ASC 810.

In July 2024, the Board of Directors for Kures determined it was in the best interests of the company to wind up operations and dissolve Kures through a Plan of Liquidation and Dissolution ("the Plan"). The Plan consisted of several components, including (i) the dissolution of Kures, (ii) transfer of all outstanding shares of Kures Australia Pty Ltd, a wholly owned subsidiary of Kures, to the Company, and (iii) transfer of all clinical trial data relating to the clinical safety and activity of KUR-101 to the Company.

In October 2024, in connection with the dissolution of Kures, Kures and Columbia mutually agreed to terminate the existing License Agreement (the "Termination Agreement"). Under the Termination Agreement, Kures assigned to Columbia all of Kures' intellectual property rights that were filed during the term of the License Agreement and agreed that all licenses granted to Kures by Columbia are terminated. In exchange, Kures received consideration through the relief and discharge of an immaterial amount of outstanding payment obligations due to Columbia.

Immediately prior to the transaction the Company's ownership in Kures was approximately 64.5%. The transaction and dissolution closed in November 2024, with the purchase consideration transferred on the acquisition date of $0.1 million. The Company determined the dissolution of Kures in November 2024 meant the Company no longer held a controlling financial interest, and, therefore, accounted for the dissolution as a deconsolidation of a VIE under ASC 810. The Company derecognized all of Kures's assets and liabilities, with the exception of the retained intellectual property from its consolidated balance sheets and recognized a gain of $1.2 million, which was reported as Gain on dissolution of a variable interest entity, a component of other income (expense), net in the consolidated statements of operations for the year ended December 31, 2024. Pursuant to the Plan, the Company recognized $0.1 million of intellectual property from the transaction within Intangible assets, net on the consolidated balance sheets.

PsyProtix, Inc.

On February 3, 2021, PsyProtix, Inc. ("PsyProtix") was created as a joint venture between the Company and Chymia (the “Founders”), with the intent of PsyProtix becoming a newly formed corporate subsidiary of the Company. PsyProtix was created for the purpose of exploring and developing a metabolomics-based precision psychiatry approach. Based on the Company's assessment of the transaction at the time of acquisition, the Company concluded that PsyProtix was not a business and accounted for the Company's investment as an initial consolidation of a VIE that is not a business under ASC 810.

In April 2024, the Company and Chymia entered into a Framework Agreement which resulted in the Company's acquisition of Chymia's 25% equity ownership of PsyProtix (the “Stock Transfer”). As a result of the Stock Transfer, the Company owned 100% of the outstanding common stock of PsyProtix, and PsyProtix became a wholly owned subsidiary of the Company. The Stock Transfer was accounted for as an equity transaction with no gain or loss recognized. The difference between the carrying amount of Chymia's non-controlling interest and the note receivable forgiven in the acquisition of the additional equity interest was recorded as a reduction in additional paid-in capital in the consolidated balance sheets and consolidated statements of stockholders' equity.

In December 2024, PsyProtix entered into an Agreement and Plan of Merger ("Merger Agreement") with atai Therapeutics Inc., a wholly owned atai subsidiary. Pursuant to the Merger Agreement, all common stock issued and outstanding of PsyProtix was automatically canceled and retired and ceased to exist. Upon the merger, all assets and liabilities were transferred to atai Therapeutics Inc., and the Company recognized no gain or loss from the transaction in its consolidated statements of operations.

Noncontrolling Interests

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

	Perception	Kures	Recognify
Balance as of December 31, 2023	$ 428	$ 369	$ 557
Net loss attributable to noncontrolling interests - preferred	(207)	(16)	(557)
Adjustment to noncontrolling interests upon dissolution of variable interest entity	—	(349)	—
Comprehensive loss attributable to noncontrolling interests	35	(3)	—
Balance as of December 31, 2024	$ 257	$ 0	$ —
Net loss attributable to noncontrolling interests - preferred	(100)	—	—
Comprehensive loss attributable to noncontrolling interests	(30)	—	—
Balance as of December 31, 2025	$ 127	$ 0	$ —

6. Investments

Other investments held at fair value

As of December 31, 2025 and 2024, the carrying values of Other Current investments held at fair value and Other investments held at fair value were as follows (in thousands):

	December 31, 2025	December 31, 2024
Other current investments held at fair value		
COMPASS Pathways plc	$ 35,389	$ —
Other investments held at fair value		
COMPASS Pathways plc	—	26,104
Beckley Psytech Additional Warrants	—	2,783
Total	$ 35,389	$ 28,887

COMPASS Pathways plc

COMPASS Pathways plc ("COMPASS") is a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. The Company is developing its investigational COMP360 psilocybin treatment through late-stage clinical trials in Europe and North America for patients with treatment-resistant depression. The Company accounts for its COMPASS investment under ASC 321 at fair value. Any changes in fair value of the Company's investment in COMPASS are recognized as a Change in fair value of assets and liabilities, net in its consolidated statements of operations.

During the year ended December 31, 2025, the Company sold 1,777,000 American Depositary shares ("ADS") of COMPASS at an average price of $5.38 per ADS in an open market transaction, resulting in net proceeds received of $9.0 million. The Company recorded the sales of the ADS shares as a reduction in its COMPASS investment under ASC 321. The Company recognized an immaterial commission expense related to the sale, which is recognized as a General and administrative expense in its consolidated statements of operations.

During 2024, the Company sold 2,660,000 American Depositary shares ("ADS") of COMPASS at a price of $6.05 per ADS in an open market transaction, resulting in net proceeds received of $16.1 million. The Company recognized a non-cash loss of $2.1 million on the sales during the year ended December 31, 2024, which is recorded as a component of Other income (expense), net in its consolidated statements of operations.

Based on quoted market prices, for the years ended December 31, 2025 and 2024, the fair value of the Company's COMPASS investment was $35.4 million and $26.1 million, respectively. For the years ended December 31, 2025 and 2024, the Company recorded a $18.3 million gain and a $39.4 million loss related to changes in the fair value of the Company's investment in Compass within Change in fair value of assets and liabilities, net in its consolidated statements of operations, respectively.

IntelGenx Technologies Corp.

In October 2024, the Company acquired all issued and outstanding shares of Nualtis (see Note 4, Acquisitions). As of December 31, 2025, the Company continues to hold equity instruments in IntelGenx, the former parent company of Nualtis, which consists of IntelGenx Common Stock, 2023 Initial Warrants, 2023 Subsequent Warrants, and 2024 Warrants, (the 2023 Initial Warrants, 2023 Subsequent Warrants, and 2024 Warrants are collectively referred to as the "Warrants"), and Call Option Units, all of which are measured at fair value as the Company had qualified for and elected the fair value option (all IntelGenx equity investments defined below). As of December 31, 2025 and 2024 the Company's equity instruments were all determined to have a carrying value of zero as IntelGenx continues its bankruptcy proceedings. For the year ended December 31, 2024, the Company recognized losses of $5.2 million and $1.4 million within Change in fair value of assets and liabilities, net relating to the Call Option Units and the Warrants, respectively, in its consolidated statements of operations. The Company's holding in IntelGenx Common Stock was written down to zero in 2021.

2021 Securities Purchase Agreement

In May 2021, IntelGenx and the Company executed a Securities Purchase Agreement (the "IntelGenx SPA") after obtaining IntelGenx shareholder approval, whereby IntelGenx issued shares of its common stock (the "IntelGenx Common Stock") and warrants to the Company at a price of approximately $12.3 million.

2023 Subscription Agreement, as Amended

In August 2023, IntelGenx and the Company entered into a subscription agreement (the "Subscription Agreement"), under which the Company paid IntelGenx $2.2 million for 2,220 convertible debenture units (the "2023 Initial Units") with each convertible debenture unit consisting of:

i. $1,000 principal amount convertible promissory notes (the "2023 Initial Notes") bearing interest at a rate of 12.0% per annum, payable quarterly in arrears beginning September 30, 2023, with all principal and accrued interest convertible into common

shares of IntelGenx, at any time from the date that is six months following their issuance up to and including August 31, 2026 at a conversion price equal to $0.185 per common share; and

ii. 5,405 common share purchase warrants of IntelGenx (the “2023 Initial Warrants”), each exercisable at an exercise price of $0.26 per common share for a period of three years following their issuance.

Pursuant to the Subscription Agreement, the Company agreed to subscribe for an additional 750 convertible debenture units (the “2023 Subsequent Units”) at a price of $750,000 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, which had an initial fair value of $5.1 million, 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.

As the Call Option was additional value conveyed to the Company relating to its investment in and Strategic Development Agreement with IntelGenx, the Call Option was recognized by the Company as a $5.1 million deferred credit with IntelGenx. The Company accounted for the deferred credit as a reduction of research and development expense in its consolidated statements of operations until the credit is exhausted or until the Company is no longer receiving goods or services from IntelGenx. Pursuant to the acquisition of Nualtis, the Company has determined that it is no longer a customer of IntelGenx. As such, the Company released the $5.1 million deferred credit and recognized a $5.1 million gain, which is included in Gain on settlement of pre-existing contract in the consolidated statements of operations.

2024 Term Loan Warrants

In March 2024, the Company and IntelGenx entered into a Third Amendment to the IntelGenx Term Loan as further described in Note 7, Notes Receivable, below. In connection with the Third Amendment, the Company received warrants to purchase up to 4.0 million shares of IntelGenx Common Stock ("2024 Warrants"), which had an initial value of $0.4 million. As the 2024 Warrants were additional value conveyed to the Company relating to its investment in and Strategic Development Agreement with IntelGenx, the 2024 Warrants were recognized by the Company as a $0.4 million deferred credit with IntelGenx. The Company accounted for the deferred credit as a reduction of research and development expense in its consolidated statements of operations until the credit is exhausted or until the Company is no longer receiving goods or services from IntelGenx. Pursuant to the acquisition of Nualtis, the Company has determined that it is no longer a customer of IntelGenx. As such, the Company released the $0.4 million deferred credit and recognized a $0.4 million gain, which is included in Gain on settlement of pre-existing contract in the consolidated statements of operations.

Strategic Development Agreement

Prior to the Company's acquisition of Nualtis in October 2024 and pursuant to the Strategic Development Agreement, the Company engaged IntelGenx to conduct research and development projects (“Development Projects”) using IntelGenx’s proprietary oral thin film technology. Under the terms of the Strategic Development Agreement, the Company could select four program products. As of the effective date of the Strategic Development Agreement, the Company nominated two 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 was eligible to receive a total credit of $2.5 million. For the year ended December 31, 2024, research and development expense relating to the Strategic Development Agreement was $0.6 million, respectively, which was applied as a reduction in research and development expenses in accordance with the Strategic Development Agreement. After the Company's acquisition of Nualtis in October 2024, any work performed with respect to the Development Projects is recorded as an intercompany transaction and eliminated upon consolidation in accordance with the Company's accounting policies.

Other investments

The Company’s investments in the preferred stock of Innoplexus, GABA Therapeutics, Inc. (“GABA”), and Beckley Psytech, prior to the Company’s acquisition of Beckley Psytech in November 2025, are not considered as in-substance common stock due to the existence of substantial liquidation preferences, and, therefore, did not have subordination characteristics that were substantially similar to common stock. Accordingly, these investments do not fall under the guidance in ASC 323, and the Company records these investments under the measurement alternative method pursuant to ASC 321 as these investments do not have readily determinable fair values.

As described in Note 4, Acquisitions, the Company holds approximately 33.7% of the outstanding common stock of Eleusis Holdings Limited. The Company does not have the ability to exercise significant influence over Amandala’s operating and financial policy as the Company does not have board representation and has contractually agreed to voting restrictions. Accordingly, the Company determined that the investment does not fall under the guidance on ASC 323 and the Company records these investments under the measurement alternative method pursuant to ASC 321 as these investments do not have readily determinable fair values.

During the years ended December 31, 2025 and 2024 and prior to the Company's acquisition of Beckley Psytech in November 2025, the Company evaluated all of its Other investments to determine if certain events or changes in circumstance had a significant adverse effect on the fair value of any of its investments in non-consolidated entities. Based on this analysis, the Company did not note any impairment indicators associated with the Company's Other investments.

During the years ended December 31, 2025 and 2024 there were no observable changes in price recorded related to the Company's Other investments.

As of December 31, 2025 and 2024, the carrying values of Other investments, which consisted of investments in the investee's preferred stock not in the scope of ASC 323 as well as investments in the investees common stock not in scope of ASC 323, was zero and $42.1 million, respectively. The 2024 balance relates solely to the Company's investment in Beckley Psytech.

Beckley Psytech Limited

Beckley Psytech Acquisition

As discussed in Note 4, Acquisitions, the Company acquired all outstanding shares of Beckley Psytech in November 2025. On the Acquisition Date, the Company derecognized its carrying amount of $53.9 million under Other investments in the consolidated balance sheet related to the Initial Shares, Deferred Shares, and Secondary Shares as Beckley Psytech is a consolidated entity after the completion of the transaction. Further, as part of the SPA, the Company no longer has rights to receive the Additional Warrants as of the Acquisition Date. The Company's investment in Beckley Psytech prior to the acquisition is described below.

Subscription and shareholders' agreement

On January 3, 2024, the Company entered into a subscription and shareholders' agreement with Beckley Psytech and certain other shareholders as identified in the agreement (the "SSA"). Pursuant to the terms of the SSA, the Company (a) has the right to acquire 24,096,385 newly issued series C preferred shares, par value £0.0001 per share, of Beckley Psytech (the "Series C Shares") for a total purchase price of $40 million (the "Primary Investment"); and (b) undertakes to enter into a Share Purchase Deed (the "Secondary Sale SPA") within 10 business days, pursuant to which the Company will acquire a total of 11,153,246 shares of Beckley Psytech from certain existing shareholders of Beckley Psytech (the "Secondary Sale" and together with the Primary Investment, the "Investment"), all of which will be re-designated into Series C Shares immediately prior to completion of the Secondary Sale, for a total purchase price of $10.0 million.

In connection with the SSA, the Company acquired, pursuant to an equity warrant instrument between the Company and Beckley Psytech, 24,096,385 warrants to purchase an amount of Series C shares equal to the lesser of (i) 24,096,385 Series C Shares; or (ii) such number of Series C Shares (rounded up to the nearest whole number) as immediately after their issuance would, together with all shares held by the Company in the issued share capital of Beckley Psytech, equal to less than 50% of Beckley Psytech's fully diluted share capital, and each such warrant is exercisable at an exercise price of $2.158 per share ("Series C Warrants").

Also under the SSA, prior to the Acquisition Date, the Company had the right to receive additional warrants to purchase Series C Shares in the event Beckley Psytech issued equity or equity linked securities pursuant to a deferred equity arrangement in connection with a prior acquisition made by Beckley Psytech, with each such warrant exercisable at an exercise price of $1.66 per share ("Additional Warrants"). Each of the warrants described above was exercisable upon delivery of a written notice to Beckley Psytech.

Initial Subscription

On January 3, 2024, the Company made the initial payment of $25 million for 15,060,241 Series C Shares at a subscription share price of $1.66 ("Initial Shares") and delivered the executed deferred payment escrow agreement ("Escrow Agreement") to Beckley Psytech which was a condition for the closing or completion of the transaction ("Initial Subscription").

Deferred Shares

On January 5, 2024, subject to the terms of the Escrow Agreement, the Company deposited $15.0 million into an escrow account. Prior to April 1, 2025, Beckley Psytech could, at its sole discretion, draw down up to $5.0 million from the escrow account, with the remaining balance to be paid to Beckley Psytech on April 1, 2025. Beckley Psytech was required credit as fully-paid such corresponding number of Series C Shares as corresponds with the value of each draw-down. The total number of deferred payment shares ("Deferred Shares") is 9,036,144 with a share price of $1.66.

Secondary Sale

On January 18, 2024, the Company and Beckley Psytech entered into the Secondary Sale SPA pursuant to which the Company agreed to purchase 11,153,246, £0.0001 par value, re-designated Series C shares (the "Secondary Sale Shares") at a price of $0.8966 per share from the existing shareholders for an aggregate consideration of $10.0 million. On January 18, 2024, the Secondary Sale Shares were acquired by the Company.

Upon closing of the Initial Subscription, executed Escrow Agreement, and acquisition of the Secondary Sale Shares, the Company recognized a fair value of $35.3 million in Other Investments in the consolidated balance sheets related to the Initial Shares, Secondary Shares, and Series C Warrants and a fair value of $2.6 million in Other investments held at fair value related to the Additional Warrants.

The Company qualified for and elected to account for the investment acquired per the SSA using the measurement alternative under ASC 321, and is included in Other investments in the consolidated balance sheets. The Company applied a calibrated model for the $35.3 million investment, to account for the Initial Shares, option to purchase the Deferred Shares, Secondary Shares, and Series C Warrants, on a relative fair value basis resulting in no initial gain or loss recognized in the consolidated statements of operations.

Pursuant to the Escrow Agreement, the Company recognized the fair value of the Deferred Shares as additional consideration for its initial investment in Beckley Psytech as the fair value of the Deferred Shares was less than the purchase price of $1.66 per share. The Company recognized a $2.9 million liability for the Deferred Shares recorded within Other current liabilities in its consolidated balance sheets. Upon Beckley Psytech drawing on the Escrow Agreement, the Company will reduce its liability related to the Deferred Shares and recognize gain or loss based on the fair value of the Series C shares as Other income (expense), net in the consolidated statements of operations.

Escrow Agreement Draw

In October 2024, pursuant to the terms of the Escrow Agreement, Beckley Psytech, at its sole discretion, drew $5.0 million from the escrow account and the Company was credited 3,012,048 Series C shares. The Company determined that the fair value of the shares received was $5.3 million, which is recorded as Other investments in the consolidated balance sheets. The Company recognized a gain of $1.3 million related to the investment for the year ended December 31, 2024, which is recognized as Gain on other investments in the consolidated statements of operations.

In April 2025, pursuant to the terms of the Escrow Agreement, Beckley Psytech, at its sole discretion, drew the remaining $10.0 million from the escrow account and the Company was credited 6,024,096 Series C shares. The Company determined that the fair value of the shares received was $11.9 million, which is recorded as Other investments in the consolidated balance sheets. The Company recognized a gain of $3.8 million related to the investment for the year ended December 31, 2025, which is recognized as Gain on other investments in the consolidated statements of operations.

As of the April 2025 escrow draw, the Company has satisfied its obligations under the Escrow Agreement. As of December 31, 2024, The Company reflected the remaining $1.9 million liability related to the Deferred Shares in Other current liabilities within the consolidated balance sheets.

Additional Warrants

Prior to the acquisition of Beckley Psytech, the Company determined that the Additional Warrants meet the definition of a derivative instrument under ASC 815 and recorded the $2.6 million fair value at the transaction date in Other investments held at fair value in the consolidated balance sheets, with subsequent changes in fair value being reflected through the consolidated statements of operations in the Change in fair value of assets and liabilities, net.

In May 2024, Beckley Psytech issued equity pursuant to the deferred equity arrangement, and, per the SSA, the Company received 4,393,400 warrants. The Company determined that once received the Additional Warrants will no longer meet the definition of a derivative instrument under ASC 815. The Company qualified for and elected to account for the warrants under ASC 321, and recorded the warrants received in Other Investments in the consolidated balance sheets. At the time of receipt, the warrants had a fair value of $1.5 million.

As a result of the Beckley Psytech Acquisition, the Additional Warrants no longer exist as Beckley Psytech is a wholly owned subsidiary as of the Acquisition Date. Accordingly, the Additional Warrants have a fair value of zero as of December 31, 2025 and the Company recognized a $2.8 million loss in the Change in fair value of assets and liabilities, net in its consolidated statements of operations for the year ended December 31, 2025.

As of December 31, 2024, the remaining Additional Warrants had a fair value of $2.8 million recorded in Other investments held at fair value in the consolidated balance sheets.

For the years ended December 31, 2025 and 2024, the Company recognized a $2.8 million loss and a$1.7 million gain, respectively, in the Change in fair value of assets and liabilities, net in its consolidated statements of operations.

Amandala Neuro Limited

Amandala (formerly Eleusis Holdings Limited) was previously a wholly owned subsidiary of Beckley Psytech and operated Beckley Psytech's ELE-101 program, a novel intravenous formulation of psilocin, the active metabolite of psilocybin, that is being developed to address certain neuropsychiatric disorders such as treatment resistant depression and major depressive disorder.

In October 2025, prior to the Company's acquisition of Beckley Psytech and pursuant to the terms of the SPA (defined in Note 4, Acquisitions), Beckley Psytech distributed the equity ownership of Amandala as a dividend in specie pro rata among existing Beckley Psytech shareholders based on their current ownership stakes in Beckley Psytech. In October 2025, Beckley Psytech distributed

297,653,598 ordinary shares of Amandala to its shareholders, and the Company received 100,208,918 ordinary shares, which is equivalent to approximately 33.7% of the total shares distributed.

The Company determined that it does not have the ability to exercise significant influence over Amandala's operating and financial policy, and, therefore, accounted for its investment in Amandala using the measurement alternative under ASC 321. The Company recognized the fair value of the Amandala common stock as Other investments in the consolidated balance sheet upon receipt as there is no cost basis for dividend in specie. There was no gain or loss recognized upon the receipt of the common stock. The carrying value of the Company's investment in Amandala was zero as of December 31, 2025.

GABA Therapeutics, Inc.

GABA is a California based biotechnology company focused on developing GRX-917 for the treatment of anxiety, depression and a broad range of other 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 common and preferred stock, and the Company's noncontrolling representation on GABA's board of directors.

The Company's investment in GABA's common stock was accounted for in accordance with the equity method, and the carrying value of the investment in GABA common stock was reduced to zero as of December 31, 2020 due to IPR&D charges with no alternative future use and remained zero as of December 31, 2025.

The Company's investment in GABA's preferred stock did not meet the criteria for in-substance common stock. As such, the investment in GABA's preferred stock is accounted for under the measurement alternative pursuant to ASC 321.

As of December 31, 2025, the Company's remaining obligation to purchase additional shares of Series A preferred stock from GABA is for up to $0.9 million at the same price per share as its initial investment upon the achievement of specified contingent milestones. As of December 31, 2025, the contingent milestones have not been met.

GABA's net losses attributable to the Company were determined based on the Company's ownership percentage of preferred stock in GABA and recorded to the Company's investments in GABA preferred stock. As of December 31, 2025 and December 31, 2024, the investment in GABA's preferred stock had a carrying value of zero. For the years ended December 31, 2025 and 2024, the Company recognized its proportionate share of GABA's net loss of zero and $2.0 million, respectively, as Losses from investments in equity method investees, net of tax on the consolidated statements of operations.

Innoplexus AG

Innoplexus 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 with an additional investment in December 2020, bringing its aggregate ownership percentage to 35%. The Company's ownership percentage remains at 35% as of December 31, 2025.

The Company had significant influence over Innoplexus through its noncontrolling representation on the investee's 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 under ASC 321. The carrying value of the Company's investment in Innoplexus was zero as of December 31, 2025 and December 31, 2024.

In February 2021, the Company entered into a Share Purchase and Assignment Agreement (the "Innoplexus SPA") to sell its shares of common and preferred stock held in Innoplexus to a current investor of Innoplexus (the "Purchaser") in exchange for an initial purchase price of approximately $2.4 million. In addition, the Company is entitled to receive contingent payments based on the occurrence of subsequent equity transactions or liquidity events at Innoplexus as determined under the Innoplexus SPA.

Pursuant to the Innoplexus SPA, the Purchaser is required to hold a minimum number of shares equivalent to the number of shares purchased from the Company through December 31, 2026. In the event that the Purchaser is in breach of this requirement, the Purchaser is required to pay the Company an additional purchase price of approximately $9.6 million. The transaction was accounted for as a secured financing as it did not qualify for sale accounting under ASC 860, Transfers and Servicing ("ASC 860"), due to the provision under the Innoplexus SPA which constrained the Purchaser from its right to pledge or exchange the underlying shares and provided more than a trivial benefit to the Company. The initial proceeds from the transaction are reflected as a secured borrowing liability of $2.5 million and $2.2 million as of December 31, 2025 and December 31, 2024, respectively, of which the December 31, 2025 balance is included in Other current liabilities in the Company's consolidated balance sheets and the December 31, 2024 balance is included in Other liabilities in the Company's consolidated balance sheet.

In addition, the Innoplexus SPA also provides the right 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, 2025.

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, 2025	December 31, 2024
	GABA	GABA
Current assets	$ 443	$ 112
Noncurrent assets	—	—
Total assets	$ 443	$ 112
Current liabilities	$ 3,910	$ 2,805
Noncurrent liabilities	—	—
Total liabilities	$ 3,910	$ 2,805

Statements of Operations

	For the year ended December 31, 2025	For the year ended December 31, 2024
	GABA	GABA
Loss from continuing operations	$ (724)	$ (3,227)
Net loss	$ (724)	$ (3,227)

7. Notes Receivable

IntelGenx Technologies Corp.

Prior to the Company's acquisition of Nualtis in October 2024, the Company had outstanding loan agreements and convertible notes with IntelGenx, which are measured at fair value as the Company had qualified for and elected the fair value option. The Company discharged its secured debt it held with IntelGenx, which included the DIP Loan and the IntelGenx Term Loan, in consideration of its acquisition of Nualtis (see Note 4, Acquisitions). The Company continues to hold the 2023 Initial Notes, the 2023 Subsequent Notes, and the IntelGenx 2023 Term Loan Note with IntelGenx (collectively the "IntelGenx Unsecured Debt"); however, IntelGenx continues its bankruptcy proceedings. Accordingly, the Company determined that the fair value of IntelGenx Unsecured Debt was zero as of December 31, 2025 and 2024. respectively. For the year ended December 31, 2024, the Company recognized losses of $10.9 million, an immaterial amount, and $2.8 million in Change in fair value of assets and liabilities, net in its consolidated statements of operations relating to the IntelGenx Term Loan, the DIP Loan, and the IntelGenx Unsecured Debt, respectively.

IntelGenx Term Loan

In March 2021, the Company and IntelGenx entered into a loan agreement (the "Original Loan Agreement") under which the Company provided a loan to IntelGenx for an aggregate principal amount of $2.0 million. In May 2021, the Company paid an additional advance of $0.5 million as an additional term loan. In September 2021, the Company entered into an amended and restated loan agreement which, among other things, increased the principal amount of loans available to IntelGenx by $6.0 million, for a total of up to $8.5 million. The additional $6.0 million loan amount was funded via two separate $3.0 million tranches. The first $3.0 million tranche was funded in January 2022 and the second $3.0 million tranche was funded in January 2023. The loan bears an annualized interest rate of 8% and such interest is accrued daily.

In August 2023 and September 2023, the Company and IntelGenx amended and restated the Original Loan Agreement. The August 2023 amendment, among other things, extended the maturity date from January 5, 2024 to January 5, 2025 and granted the Company additional security over any non-licensed intellectual property owned or controlled by IntelGenx (the "First Amendment"). The September 2023 amendment, among other things, entitles the Company to convert any portion of the outstanding and unpaid principal and accrued interest into common stock of IntelGenx at a conversion price per share of $0.185 (the "Second Amendment").

Further, in March 2024, the Company and IntelGenx entered into a third amendment to the amended and restated loan agreement (the "Third Amendment", together with the Original Loan Agreement, the First Amendment, and the Second Amendment, the "IntelGenx Term Loan"), under which, among other things, the Company provided an additional $2.0 million term loan, with $1.0 million tranches paid in March 2024 and May 2024, respectively. The Company also received the 2024 Warrants pursuant to the Third Amendment, further described on Note 6, Investments. As described above, the IntelGenx Term Loan was discharged in consideration of the Company's acquisition of Nualtis.

IntelGenx Convertible Notes

On August 30, 2023, the Company and IntelGenx entered into the Subscription Agreement (as further described in Note 6, Investments), under which the Company paid IntelGenx $2.2 million for the 2023 Initial Units, which included the 2023 Initial Notes. In November 2023, the Company paid $750,000 for the 2023 Subsequent Units, which included the 2023 Subsequent Notes.

IntelGenx 2023 Term Loan Note

In December 2023, the Company and IntelGenx entered into a new term loan agreement under which the Company provided the aggregate principal amount of $500,000 (the "IntelGenx 2023 Term Loan Note").

Debtor-in-Possession Loan

In May 2024, pursuant to the Initial Order authorizing the DIP Financing, the Company and IntelGenx entered into a senior secured super-priority, interim, non-revolving multiple draw credit facility ("DIP Loan") up to a maximum of CDN $8.0 million. Prior to the Company's acquisition of IGX in October 2024, IntelGenx drew CDN $7.8 million (USD $5.7 million) pursuant to the DIP Loan. As described above, the IntelGenx Term Loan was discharged in consideration of the Company's acquisition of Nualtis.

Beckley Psytech

In August 2025, the Company issued an unsecured promissory note (the ''Promissory Note'') to Beckley Psytech in the principal amount of $10.0 million, with net proceeds to be used for the achievement of specified product development milestones. The Promissory Note bore interest at a rate equal to the lesser of 12% per annum and the highest rate permitted by applicable law.

As described in Note 4, Acquisitions, the Promissory Note was settled in connection with the completion of the Beckley Psytech Acquisition as Beckley Psytech became a wholly owned subsidiary and the Promissory Note became an intercompany transaction that is eliminated in consolidation as of the Acquisition Date. The $10.3 million fair value of the Promissory Note, which included principal and interest, was included as consideration in the Beckley Psytech Acquisition as a settlement of a preexisting contract.

Prior to the Company's acquisition of Beckley Psytech, the Promissory Note was accounted for under amortized cost, which includes the principal value of the note receivable and accrued interest, and was recognized in Short-term notes receivable - related party, net within the consolidated balance sheet.

For the year ended December 31, 2025, and prior to the Company's acquisition of Beckley Psytech, the Company recognized $0.3 million of interest income related to the Promissory Note in its consolidated statements of operations.

Amandala Neuro Limited Notes Receivable

As noted above in Note 4, Acquisitions, and Note 6, Investments, prior to the Company's acquisition of Beckley Psytech in November 2025 and pursuant to the terms of the SPA (defined in Note 4, Acquisitions), Beckley Psytech distributed its 100% equity ownership of Amandala, a subsidiary of Beckley Psytech, as a dividend in specie pro rata among existing Beckley Psytech shareholders based on their current ownership stakes in Beckley Psytech. Upon the acquisition and consolidation of Beckley Psytech in November 2025, the Company recognized $1.5 million of loans receivable Beckley Psytech holds from Amandala ("Amandala Notes Receivable"). The Amandala Notes Receivable are non-interest bearing are recognized at costs net of expected credit losses with $0.6 million recognized as Prepaid expenses and other current assets and $0.9 million recognized as Other assets within the consolidated balance sheet, respectively.

8. Fair Value Measurement

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

	Fair Value Measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 65,423	$ —	$ —	$ 65,423
Investment in securities at fair value:				
U.S. treasuries	—	135,351	—	135,351
Other current investments held at fair value	35,389	—	—	35,389
Digital assets	8,735	—	—	8,735
	$ 109,547	$ 135,351	$ —	$ 244,898
Liabilities:				
Contingent consideration liability - related party	$ —	$ —	$ 104	$ 104
Contingent consideration liabilities	—	—	205	205
Pre-funded warrant liabilities	44,379	—	—	44,379
	$ 44,379	$ —	$ 309	$ 44,688

	Fair Value Measurements as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 6,196	$ —	$ —	$ 6,196
Investment in securities at fair value:				
U.S. treasuries	—	44,825	—	44,825
Other investments held at fair value	26,104	—	2,783	28,887
	$ 32,300	$ 44,825	$ 2,783	$ 79,908
Liabilities:				
Short-term convertible promissory note conversion option - related party	$ —	$ —	$ 995	$ 995
Short-term convertible promissory note conversion option	—	—	1,616	1,616
Contingent consideration liability - related party	—	—	110	110
Contingent consideration liabilities	—	—	212	212
	$ —	$ —	$ 2,934	$ 2,934

Investment in Securities at Fair Value

The Company elected the fair value option for the securities in its investment portfolio. The fair value is based on quoted market prices, when available. When a quoted market price is not readily available, the Company uses the market price from its last sale of similar assets. The cash and cash equivalents held by the Company are categorized as Level 1 investments as quoted market prices are readily available for these investments. All other investments in the investment portfolio are categorized as Level 2 investments as inputs utilized to fair value these securities are either directly or indirectly observable, such as the market price from the last sale of similar assets.

The unrealized gains and losses on the available-for-sale securities, represented by change in the fair value of the investment portfolio, are 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, 2025 and 2024, the Company recognized a $3.1 million and $3.8 million gain related to the change in fair value in its available for sale securities recorded as a Change in fair value of assets and liabilities, net in its consolidated statements of operations.

Other Investments Held at Fair Value

COMPASS Pathways plc

The Company determines the fair value of its COMPASS investment by taking the publicly available share price as of the balance sheet date multiplied by the number of shares the Company holds. There are no non-observable inputs in determining the fair value. For the years ended December 31, 2025 and 2024, the Company recognized a $18.3 million gain and a $39.4 million loss within Change in fair value of assets and liabilities, net, respectively.

Beckley Psytech Additional Warrants

Prior to the Company's acquisition of Beckley Psytech and as described in Note 6, Investments, the Company determined that the Additional Warrants meet the definition of a derivative instrument under ASC 815 and recorded the Additional Warrants at fair value with subsequent changes in fair value being reflected through the consolidated statements of operations in Change in fair value of assets and liabilities, net.

At the Acquisition Date, Beckley Psytech became a wholly owned subsidiary and the Additional Warrants no longer exist, resulting in the Additional Warrants having no value as of December 31, 2025. As of December 31, 2024, the Additional Warrants had a fair value of $2.8 million recognized in Other investments held at fair value in the consolidated balance sheet.

The significant unobservable inputs that are included in the valuation of the Additional Warrants as of December 31, 2024 are (i) probability of issuances under the deferred equity arrangement of 55%-80%, and (ii) volatility of 95%.

IntelGenx Technologies Corp.

IntelGenx Equity Investments

As described in Note 6, Investments, prior to the completion of the Company's acquisition of IGX in October 2024, the Company's investment in IntelGenx included IntelGenx Common Stock, Warrants, and Call Option Units for which it qualified for and elected the fair value option. The Company determined that the Warrants and the Call Option Units did not meet the definition of a derivative instrument under ASC 815. The Company classified the IntelGenx Common Stock as Level 2 assets and the Warrants and the Call Option as Level 3 assets in the fair value hierarchy. The Warrants and Call Option were measured at fair value on a quarterly basis and any changes in the fair value were recorded as Change in fair value of assets and liabilities, net, a component of other expense, net in the consolidated statements of operations.

Considering the aforementioned facts and circumstances in Note 4, Acquisitions, and Note 6, Investments, the Company estimated zero fair value attributable to the IntelGenx Common Stock, Warrants, and Call Option Units as of December 31, 2025 and 2024. For the year ended December 31, 2024, the Company recognized losses of $5.2 million and $1.4 million within Change in fair value of assets and liabilities, net relating to the Call Option Units and the Warrants, respectively, in its consolidated statements of operations.

IntelGenx Notes Receivable

As described in Note 7, Notes Receivable, prior to October 2024, the Company's notes receivable with IntelGenx included the IntelGenx Term Loan, the DIP Loan, and the IntelGenx Unsecured Debt for which it qualified for and elected the fair value option. The fair value of these instruments were estimated based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

As described in Note 4, Acquisitions, above, the Company made a Stalking Horse bid for IntelGenx as they sought protection from creditors under the CCAA. The Company's bid was to acquire certain assets and liabilities of IntelGenx in exchange for the discharge of all senior secured debt payable by IntelGenx, which included the DIP Loan and the IntelGenx Term Loan. The underlying collateral of such senior secured debt was determined to be the net assets and liabilities of IGX as acquired by the Company and as included in the Company's Stalking Horse bid. Accordingly, the Company has estimated the fair value of the underlying collateral, which included the fair value of the acquired intangible assets, based on a probability adjusted forecasted revenue and expenses and a discount rate of 12.5%. The Company adjusted the fair value of the DIP Loan to agree to this determined fair value of the net assets and liabilities acquired. As of the Company's acquisition date of IGX in October 2024, the fair value of the DIP Loan was $5.7 million and the fair value of the IntelGenx Term Loan was zero immediately prior to these receivables being discharged as consideration.

Considering relevant facts and circumstances, the Company estimated the fair value attributable to the various notes receivables with IntelGenx based on the remaining fair value of the underlying collateral. As the IntelGenx Unsecured Debt was not secured by the underlying collateral and IntelGenx continues to go through bankruptcy, the Company determined the fair value of IntelGenx Unsecured Debt to be zero as of December 31, 2025 and 2024, respectively.

For the year ended December 31, 2024, the Company recognized losses of $2.9 million, an immaterial amount, and $10.9 million in Change in fair value of assets and liabilities, net in its consolidated statements of operations relating to the IntelGenx Term Loan, the DIP Loan, and the IntelGenx Unsecured Debt, respectively.

Digital Assets

In 2025, the Company invested in Bitcoin to diversify its treasury investment strategy. Under ASC 350-60, the Company's digital assets are measured at fair value based on quoted prices on active exchanges, and are therefore categorized as Level 1 investments in the fair value hierarchy. The Company recognizes changes in the fair value of its digital assets as gains or losses in Change in fair value of digital assets on the Company's consolidated statements of operations during the period in which they occur.

For the year ended December 31, 2025, the Company recognized a $1.2 million loss, related to the change in fair value in its Bitcoin holding, which is recognized as a Change in fair value of digital assets, net in its consolidated statements of operations.

Convertible Promissory Note

As described in Note 14, Debt, in December 2023 and April 2024, the Company entered into subscription agreements with each of a noteholder and a related party noteholder, respectively, (together the "Subscription Agreements") whereby each of the noteholder and the related party noteholder exchanged their ATAI Life Sciences AG (now known as ATAI Life Sciences GmbH) notes, into the same principal amount of new convertible notes issued by the Company (the "New Convertible Notes"). The exchange resulted in the New Convertible Notes conversion option no longer meeting the equity classification criteria. Accordingly, at the time of the exchange modification, the Company bifurcated the conversion option and reclassified the conversion option fair value from equity to a liability, which was included in Short-term convertible promissory notes and derivative liability and Short-term convertible promissory notes and derivative liability - related party, respectively, in the consolidated balance sheets. In September 2025 the noteholder and related party noteholder each exercised the conversion feature of the New Convertible Notes and converted all of their respective New Convertible Notes into common stock of the Company.

The conversion option was measured at fair value on a quarterly basis as well as immediately prior to conversion with any changes in the fair value recognized as Change in fair value of assets and liabilities, net, a component of other expense, net in the consolidated statements of operations. For the years ended December 31, 2025 and 2024, the Company recorded losses of $20.3 million and $3.4 million, respectively, as a result of the change in fair value of the New Convertible Notes.

Immediately prior to conversion, the conversion option fair value was estimated utilizing the Company's stock price on the date of conversion. Prior to conversion, the fair value of the conversion option was estimated utilizing the Black-Scholes option pricing model and was classified as Level 3 in the fair value hierarchy based on the nature of the inputs and valuation techniques. The Black-Scholes option pricing model was based on the estimated market value of the underlying common stock at the valuation measurement date, the remaining contractual term of the conversion feature, risk-free interest rates, expected dividends, and expected volatility of the price of the underlying common stock. The expected volatility was based upon the historical volatility of daily lognormal returns on atai shares.

A significant input that was included in the valuation of the conversion feature as of December 31, 2024 was volatility of 75%.

Contingent Consideration Liability - Related Party

The contingent consideration liability - related party in the fair value measurement table above relates to milestone and royalty payments in connection with the acquisition of Perception Neuroscience Holdings, Inc. ("Perception") in 2018. The fair value of the contingent consideration liabilities—related parties was determined based on significant inputs not observable in the market, which represent Level 3 measurements within the fair value hierarchy. The fair value of the contingent milestone and royalty liabilities was estimated based on the discounted cash flow valuation technique. The technique considered the following unobservable inputs:

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

The fair value of the Perception contingent milestone and royalty liabilities could change in future periods depending on prospects for the outcome of R-Ketamine milestone meetings with the FDA or other regulatory authorities, and whether the Company realizes a significant increase or decrease in sales upon commercialization.

The most significant assumptions in the discounted cash flow valuation technique that impacts the fair value of the milestone contingent consideration are the projected milestone timing and the probability of the milestone being met. Further, significant assumptions in the discounted cash flow that impacts the fair value of the royalty contingent consideration are the projected revenue over ten years, the timing of royalties on commercial revenue, and the probability of success rate for a commercial R-Ketamine product. As of December 31, 2025, the Company expects that the revenue projection over the ten year term is de minimis and no longer includes the contingent royalty payment in the total fair value of the contingent consideration.

The valuations as of December 31, 2025 and 2024, respectively, used inputs that were unobservable inputs with the most significant being the discount rates for clinical milestones and probability of success estimates over the following ten years, which represent Level 3

measurements within the fair value hierarchy. The discount rates used for clinical milestones were 13% and 11.6% for the valuations as of December 31, 2025 and 2024, respectively, and the probability of success for the milestones was 5% for December 31, 2025 and 2024.

A significant input that was included in the valuation of the Contingent consideration liability - related party as of December 31, 2024 was the discount rate for royalties on projected commercial revenue of 3.8%-4.3% and a probability of success rate of 5%.

The fair value of the contingent milestone and royalty liabilities for Perception was estimated to be $0.1 million and $0.1 million as of December 31, 2025 and 2024, respectively.

Contingent Consideration Liabilities

The contingent consideration liabilities in the fair value table above relates to milestone payments in connection with the acquisition of DemeRx IB, Inc. ("DemeRx"), and TryptageniX. The fair value of the contingent consideration liabilities were determined based on significant inputs not observable in the market, which represent Level 3 measurements within the fair value hierarchy. The fair value of the contingent milestone and royalty liabilities was estimated based on the discounted cash flow valuation technique. The technique considered the following unobservable inputs:

- market-based discount rates, and
- the probability and timing of achieving the specified milestones as of each valuation date

DemeRx

In October 2023, the Company and DemeRx, Inc. entered into a Stock Purchase and Framework Agreement which resulted in the Company's acquisition of DemeRx, Inc.’s equity ownership of DemeRx IB (the “Stock Purchase”), in exchange for consideration that included, among other items, earn-out consideration of up to an additional $8.0 million payable to DemeRx, Inc. contingent upon the achievement of certain development milestones directly related to DemeRx’s oral capsule formulation of ibogaine (“DMX-1002”) program. The earn-out consideration was recorded at fair value in contingent consideration as a liability under ASC 480 and the fair value is adjusted each quarter and reflected in other income and expense in the statements of operations.

The fair value of the DemeRx contingent milestone could change in future periods depending on prospects for the outcome of ibogaine milestone meetings with the FDA or other regulatory authorities. The most significant assumptions in the discounted cash flow valuation technique that impacts the fair value of the milestone contingent consideration are the projected milestone timing and the probability of the milestone being met. The valuations as of December 31, 2025 and 2024 used inputs that were unobservable inputs with the most significant being the discount rates clinical milestones and probability of success, which represent Level 3 measurements within the fair value hierarchy.

For the years ended December 31, 2025 and 2024, the fair value of the contingent milestone for DemeRx was estimated to be $0.2 million and $0.2 million, respectively.

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

		December 31, 2025	December 31, 2024
Valuation Technique	**Significant Unobservable Inputs**	**Input Range**	**Input Range**
Discounted cash flow	Milestone contingent consideration:		
	Discount rate	12.4%-12.6%	11.7%-11.8%
	Probability of the milestone	4.0% - 5.0%	4.0% - 5.0%

TryptageniX

The fair value of the contingent liability for TryptageniX was estimated to be an immaterial amount as of both December 31, 2025 and 2024, respectively. The contingent liability is comprised of research and development milestone success fee payments and royalties payments. The fair value of the success fee liability was estimated based on the scenario-based method within the income approach. The fair value of the contingent liability for TryptageniX was determined based on significant unobservable inputs, including the discount rate, estimated probabilities of success, and timing of achieving certain clinical milestones. The fair value of the royalties liability was determined to be de minimis as the products are in the early stages of development. The Company will continue to assess the appropriateness of the fair value of the contingent liability as the products continue through development.

Pre-funded Warrant Liabilities

On June 2, 2025, the Company entered into the subscription agreements, dated as of June 2, 2025 (the “June 2025 Subscription Agreements”) relating to the purchase (the “June 2025 PIPE Financing”) by the investors party thereto of (i) 9,993,341 common stock of the Company with a nominal value of €0.10 per share for a purchase price of $1.84 per share, and (ii) a pre-funded warrant to purchase

6,311,006 common stock with an exercise price of $0.01 (the "June 2025 Pre-Funded Warrants"), for a purchase price of $1.84 per common share underlying the June 2025 Pre-Funded Warrants less the exercise price for the June 2025 Pre-Funded Warrants of $0.01 per share, resulting in aggregate gross proceeds to the Company from the June 2025 PIPE Financing of approximately $29.9 million. See Note 15, Stockholders' Equity, for further details regarding the June 2025 PIPE Financing.

On July 1, 2025, the Company entered into subscription agreements, dated as of July 1, 2025 ("July 2025 Subscription Agreements"), relating to the purchase (the "July 2025 PIPE Financing") by the investors party thereto of 18,264,840 common stock in the capital of the Company with a nominal value of €0.10 per share for a purchase price of $2.19 per share and a pre-funded warrant to purchase 4,566,210 common stock with an exercise price of $0.01 (the "July 2025 Pre-Funded Warrant") for a purchase price of $2.19 per common share underlying the July 2025 Pre-Funded Warrant less the exercise price for the July 2025 Pre-Funded Warrant of $0.01 per share, resulting in aggregate gross proceeds to the Company from the July 2025 PIPE Financing of approximately $50.0 million. See Note 15, Stockholders' Equity, for further details regarding the July 2025 PIPE Financing.

Under ASC 815, the Company recognizes the June and July 2025 Pre-Funded Warrants, respectively, at fair value as Pre-funded warrant liabilities within its consolidated balance sheet. The change in fair value of the Company's Pre-Funded Warrants is recognized as a Change in fair value of assets and liabilities, net in its consolidated statements of operations. The fair value of these instruments are estimated based on the Company's stock price observable in the market less the exercise price, which represents a Level 1 measurement within the fair value hierarchy. For the year ended December 31, 2025, the Company recognized a $22.9 million loss related to the change in fair value of the Pre-funded June and July Warrants.

The following table provides a roll forward of the aggregate fair values of the Company's financial instruments described above, for which fair value is determined using Level 3 inputs (in thousands):

	Beckley Psytech Additional Warrants	New Convertible Notes Conversion Feature	Contingent Consideration Liability - Related Parties [i]	Contingent Consideration Liabilities [ii]
Balance as of December 31, 2024	$ 2,783	$ 2,611	$ 110	$ 212
Change in fair value	(2,783)	20,249	(6)	(7)
Conversion of convertible notes	—	(22,860)	—	—
Balance as of December 31, 2025	$ —	$ —	$ 104	$ 205

[i] Includes Perception milestone based contingent consideration liability.
[ii] Includes contingent consideration liability related to DemeRx IB Stock Purchase and contingent consideration liability related to the TryptageniX research and development milestone success fee payments and royalties payments.

	IntelGenx Convertible Notes Receivable	IntelGenx Investments Held at Fair Value [i]	IntelGenx Subsequent DIP Loan Commitment	Contingent Consideration Liability - Related Parties [ii]	Contingent Consideration Liabilities [iii]	New Convertible Notes Conversion Feature	Beckley Psytech Additional Warrants
Balance as of December 31, 2023	$ 11,202	$ 6,124	$ —	$ 620	$ 1,637	$ 2,385	$ —
Initial fair value of instrument	8,243	420	680	—	—	3,590	2,645
Change in fair value, including interest	(13,729)	(6,544)	—	(510)	(1,425)	(3,363)	1,676
Additional Warrants received	—	—	—	—	—	—	(1,538)
Reduction in commitment	—	—	(680)	—	—	—	—
Consideration for acquisition	(5,715)	—	—	—	—	—	—
Balance as of December 31, 2024	$ —	$ —	$ —	$ 110	$ 212	$ 2,611	$ 2,783

[i] Includes, Initial Warrants, Additional Unit Awards, 2023 Initial Warrants, 2023 Subsequent Warrants, and Call Option Units.
[ii] Includes Perception's milestone-based contingent consideration liability.
[iii] Includes the contingent consideration liability related to DemeRx IB Stock Purchase and the contingent consideration liability related to the TryptageniX research and development milestone success fee payments and royalties payments.

9. Prepaid Expenses and Other Current Assets

Prepaid expenses consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Tax receivables	$ 13,135	$ 1,348
Prepaid research and development related expenses	3,715	4,900
Other	946	421
Accounts receivable, net	667	354
Short-term notes receivable, net	625	—
Prepaid insurance	556	772
Total	$ 19,644	$ 7,795

10. Property and Equipment

Property and equipment consisted of the following:

	December 31, 2025	December 31, 2024
Manufacturing equipment	$ 1,734	$ 1,572
Furniture and fixtures	8	973
Laboratory and office equipment	236	236
Computer equipment	29	152
Leasehold improvements	564	—
	$ 2,571	$ 2,933
Less: accumulated depreciation and amortization	405	398
Property and equipment, net	$ 2,166	$ 2,535

As of December 31, 2025 and 2024, substantially all of the Company’s in use manufacturing equipment, laboratory and office equipment and computer equipment were located in North America and are comprised of assets acquired with the Company's acquisition of Nualtis. The Company has $1.0 million of manufacturing equipment not in service located in Germany also acquired with the Company's acquisition of Nualtis. As of December 31, 2024, $0.7 million of the Company's remaining property and equipment was located in Germany, respectively.

In conjunction with the Berlin lease termination described in Note 13, Leases, the Company disposed of certain furniture and fixtures, office equipment, and computer equipment as, pursuant to terms stated in the termination agreement, the Company was required to leave certain fixed assets with the property upon vacating. The Company recognized a $0.7 million loss on the disposal of fixed assets recognized as a component of Other income (expense), net within its consolidated statement of operations.

For the years ended December 31, 2025 and 2024, depreciation and amortization expense on property and equipment was $0.6 million and $0.2 million, respectively.

11. Intangible Assets, Goodwill, and Digital Assets

Intangible Assets

Definite-lived Intangible Assets

In connection with the Company's acquisition of IGX (see Note 4, Acquisitions), the Company acquired ownership and intellectual property rights to IGX's Oral Thin Film ("OTF") platform technology. This platform technology serves as the foundation and platform to deliver active pharmaceutical ingredients for both the Company's and other potential customer products. The Company determined there to be legal and competitive factors that limit the useful life of these OTF Technologies and therefore designated them as a definite-lived intangible asset.

In addition, the Company acquired a manufacturing contract with regards to IGX's right to manufacture gBelBuca, a generic version of Belbuca®, an opioid that is used to manage chronic pain severe enough to require daily, around-the-clock, long-term treatment. This manufacturing contract includes potential future royalty and milestone payments, for which the Company is now eligible to receive.

In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the transaction to the underlying assets acquired and liabilities assumed, based upon the estimated fair values of those assets and liabilities at the date of acquisition. The value allocated to the OTF Technology was $2.4 million, which will be amortized over the remaining estimated useful life of approximately 10 years. The value allocated to the gBelBuca contract was $0.2 million, which will be amortized over the estimated remaining useful life of approximately 19 years.

In addition to the definite-lived intangible assets above, the Company's definite-lived intangible assets also includes internal-use software costs, which will be amortized over the estimated remaining useful life of approximately 4.2 years from the date the software was put into service.

Indefinite-lived Intangible Assets

As of December 31, 2025, the Company owned various intellectual property, including clinical trial data from previously consolidated or wholly owned subsidiaries and other intangible assets. The Company has designated each of these intangible assets to be indefinite-lived as there are no characteristics that limit each asset's useful life. For the year ended December 31, 2025, the Company impaired certain intangible assets and recognized an immaterial impairment expense within Research and development expenses in its consolidated statement of operations.

As of December 31, 2024, the Company determined it was no longer pursuing digital therapeutics as an enabling technology for its product compounds. The Company performed an impairment assessment and concluded its in-process digital therapeutics application platforms were fully impaired. The carrying value of these indefinite-lived intangible assets prior to the Company's assessment was $0.9 million and the Company recognized impairment expense of $0.9 million within Research and development expenses in its consolidated statement of operations for the year ended December 31, 2024.

The Company continually evaluates whether events or circumstances have occurred that indicate that the carrying value of the intangible assets may be impaired or that the estimated remaining useful lives of these assets may warrant revision. The Company recognized an immaterial impairment for the year ended December 31, 2025 related to certain in-process research and development intangible assets. Other than the impairment explained above, as of December 31, 2025, the Company determined that no other intangible assets were impaired and that there are no facts or circumstances that would indicate a need for changing the estimated remaining useful lives of these assets.

Intangible assets consisted of the following (in thousands):

		December 31, 2025				December 31, 2024			
	Remaining Useful Lives	Cost	Accumulated Amortization	Impairment	Net Carrying Amount	Cost	Accumulated Amortization	Impairment	Net Carrying Amount
OTF Technology	8.9 years	$ 2,433	$ (289)	$ —	$ 2,144	$ 2,433	$ (57)	$ —	$ 2,376
gBelBuca manufacturing contract	18 years	192	(12)	—	180	192	(2)	—	190
Internal-use software	0.2 years	694	(648)	—	46	647	(466)	—	181
In-process research and development	indefinite-lived	142	—	(33)	109	1,059	—	(917)	142
Other	various	383	(11)	—	372	368	(11)	—	357
Total		$ 3,844	$ (960)	$ (33)	$ 2,851	$ 4,698	$ (536)	$ (917)	$ 3,246

For the years ended December 31, 2025 and 2024, amortization expense related to these intangible assets was $0.4 million and $0.2 million, respectively.

Estimated future amortization expense for intangible assets subsequent to December 31, 2025 is as follows (in thousands):

2026	$ 293
2027	249
2028	249
2029	249
2030	249
Thereafter	1,095
	$ 2,384

The weighted average remaining useful lives of all amortizable assets is approximately 9.4 years.

Goodwill

In connection with the Company's acquisition of Nualtis (see Note 4, Acquisitions), the Company also recognized $0.3 million in goodwill, which was the difference between the amount of consideration associated with the transaction in excess of the fair value of net assets acquired. The goodwill is primarily attributable to the synergies of merging operations, expected future cash flows and the value of the acquired workforce. As of December 31, 2025 and 2024, the balance of goodwill was approximately $0.3 million.

Digital Assets

In 2025, the Company paid approximately $10.0 million in cash in return for approximately 100 Bitcoins. As of December 31, 2025, the Company's holdings in digital assets consisted exclusively of Bitcoin. The Company did not hold any digital assets until 2025.

Under ASC 350-60, the Company’s digital assets are measured at fair value based on quoted prices on active exchanges, and are therefore categorized as Level 1 investments in the fair value hierarchy. The Company recognizes changes in the fair value of its digital assets as gains or losses in Change in fair value of digital assets, net on the Company's consolidated statements of operations during the period in which they occur.

The details of the activity related to the Company’s digital assets as of December 31, 2025 and December 31, 2024, are as follows (fair value in thousands):

	Units	Fair Value
Digital assets at December 31, 2024	—	$ —
Additions	99.8	9,968
Unrealized loss, net	—	(1,233)
Digital assets at December 31, 2025	99.8	$ 8,735

12. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued payrolls	$ 5,651	$ 3,776
Accrued accounting, legal, and other professional fee	4,487	2,867
Accrued external research and development expenses	3,178	2,479
Other liabilities	534	537
Accrued restructuring costs	298	—
Taxes payable	20	188
Total	$ 14,168	$ 9,847

13. Leases

Operating lease Right-of-Use ("ROU") assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. The operating lease ROU asset also includes lease payments made, lease incentives, and initial direct costs incurred, if any.

The Company leases certain office space under long-term operating leases that expire at various dates through February 2031. The Company generally has options to renew lease terms on its facilities, which may be exercised at the Company's sole discretion.

In connection with the Company's acquisition of Nualtis on October 2, 2024, the Company assumed lessee rights to approximately 43,000 square feet of office, lab, and manufacturing spaces in Montréal, Canada with an initial expiration date of February 2026. The lease terms included an option to renew for an additional 5 years, which was able to be exercised at the Company's sole discretion.

In February 2025, the Company amended the lease agreements to exercise the aforementioned renewal option. As a result, the leases will now expire in February 2031. The Company adjusted the Operating lease right-of-use asset, net and lease liability by approximately $1.7 million to reflect the extended lease term. The amendment does not entitle the Company to lease additional space.

In May 2025, the Company sublet approximately 14,800 square feet of this office, lab, and manufacturing space in Montréal, Canada. The sublease term is for three and a half years and commenced in August 2025. The Company has no options to extend the term of the sublease. Under the terms of the head lease, the Company is not relieved of its obligation as lessee and will continue to make monthly rent payments. The Company performed a recoverability test of the sublease agreement upon inception by comparing the rental income under the sublease to the Company's obligations under the head lease and noted no impairment existed on the head lease. The sublease provides for monthly payments of rent during the lease term. The base rent is currently $0.2 million per year, subject to an annual 3.0% increase in each subsequent year thereafter. Payments received under the sublease are recorded as a reduction to rent expense in the consolidated statements of operations and comprehensive loss.

In November 2025, the Company entered into a lease termination agreement with the landlord for its leased office space in Berlin, Germany that was scheduled to end in March 2028. The Company and the Landlord terminated the lease as of December 31, 2025, provided the following: (i) the landlord securing a tenant to lease the space beginning January 1, 2026 (the "Prospective Tenant") (ii) the Company will leave certain fixed assets on the property that will be retained by Prospective Tenant, and (iii) the Company pays a $0.4 million termination fee within 10 business days of communication from the landlord that the Prospective Tenant is starting its lease January 1, 2026. The Company was notified that the landlord secured a Prospective Tenant to lease the space starting January 1, 2026 on December 23, 2025, left all required fixed assets in the space as outlined in the agreement, and made a $0.4 million payment to the landlord on January 5, 2026. As a result of the lease termination, the Company derecognized both the remaining ROU asset and lease liability and calculated a loss from lease termination equal to the difference between the ROU asset and lease liability plus the lease termination fee. The Company no longer has an obligation under its Berlin lease as of December 31, 2025. The lease termination resulted in the Company recognizing a $0.4 million loss recognized as a component of Other income (expense), net within its consolidated statements of operations. As part of the lease termination, the Company is entitled to receive its $0.1 million security deposit, which was received in January 2026.

The weighted-average remaining lease term for the Company's operating leases as of December 31, 2025 was 5.2 years. The weighted-average discount rate for the Company's operating leases as of December 31, 2025 was 9.1%.

ROU assets and lease liabilities related to the Company's operating leases are as follows (in thousands):

	Balance Sheet Classification	December 31, 2025	December 31, 2024
Right-of-use assets	Operating lease right-of-use asset, net	$ 1,846	$ 1,334
Current lease liabilities	Current portion of lease liability	$ 271	$ 477
Non-current lease liabilities	Non-current portion of lease liability	$ 1,801	$ 732

Expenses related to leases are recorded on a straight-line basis over the lease term. The following table summarizes lease costs by component for the year ended December 31, 2025 and 2024 (in thousands):

Lease Cost Components	Statement of Operations Classification	For the Year Ended December 31, 2025	2024
Operating lease cost	Operating expenses: General and administrative	$ 347	$ 387
Operating lease cost	Operating expenses: Research and development	517	125
Sublease income	Operating expenses: General and administrative	(56)	—
Short-term lease cost	Operating expenses: General and administrative	147	137
Total lease cost		$ 955	$ 649

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

Year Ended	Future Lease Commitments
2026	$ 447
2027	495
2028	510
2029	526
2030	541
Thereafter	91
Total lease payments	$ 2,610
Less: Imputed interest	(538)
Present value of lease liabilities	$ 2,072

Supplemental cash flow information related to the Company's operating leases for the year ended December 31, 2025 and 2024 are as follows (in thousands):

	December 31, 2025	December 31, 2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 574	$ 436
Right-of-use assets obtained in exchange for new operating lease liabilities	1,709	—

14. Debt

Convertible Promissory Notes

Convertible Promissory Notes—Related Parties

During November 2018 and October 2020, the ATAI Life Sciences AG (k/n/a ATAI Life Sciences GmbH) executed a terms and conditions agreement (the "Convertible Note Agreement") under which it would issue convertible promissory notes to investors. An investor would become a party to the Convertible Note Agreement and would be issued a convertible promissory note by executing and delivering a subscription form. In November 2018 and October 2020, certain investors subscribed to the Convertible Note Agreement and the Company issued convertible promissory notes in the aggregate principal amount of €1.0 million or $1.2 million (collectively, the "Convertible Notes"). The Convertible Notes are non-interest-bearing, unsecured and are due and payable on September 30, 2025, unless previously redeemed, converted, purchased or cancelled (the "Maturity Date"). Each Convertible Note has a face value of €1 and is convertible into one share of ATAI Life Sciences AG upon the payment of €17.00. Conversion rights may be exercised by a noteholder at any time prior to maturity, except during certain periods subsequent to the consummation of the IPO. As of December 31, 2023, all notes issued in November 2018 have been converted and the only outstanding Convertible Notes are those issued in October 2020.

Exchange of Convertible Promissory Notes

In November 2023 and April 2024, a noteholder and a related party noteholder, respectively, of the Convertible Notes issued in October 2020 and ATAI Life Sciences AG executed exchange agreements (together the "Exchange Agreements") where each noteholder agreed to exchange its existing Convertible Notes into the same principal amount of new convertible notes issued by, at the time, ATAI Life Sciences NV, which subsequently became AtaiBeckley inc. as described in Note 1, Organization and Description of Business, pursuant to the Redomiciliation Transaction ("New Convertible Notes"). The New Convertible Notes were non-interest-bearing and unsecured, and were due and payable on September 30, 2025, unless previously redeemed, converted, purchased or cancelled (the "Maturity Date"). Each New Convertible Note had a face value of €1 and was convertible into sixteen shares of the Company upon the payment of €17.00. Conversion rights could be exercised by a noteholder at any time prior to maturity. The New Convertible Notes could 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 Convertible Notes could no longer be exercised.

In December 2023 and April 2024, the Company entered into subscription agreements with each of the noteholder and related party noteholder, respectively (together the "Subscription Agreements") and exchanged their respective existing Convertible Notes into New Convertible Notes. The Company determined that the note exchanges were modifications of the debt. The Exchange Agreements and Subscription Agreements resulted in the New Convertible Notes conversion option no longer meeting the equity classification criteria. Accordingly, at the time of the Exchange Agreements modification, the Company bifurcated the conversion option and reclassified the conversion option fair value from equity to a liability, which is included in Convertible promissory notes and derivative liability in the consolidated balance sheets. The conversion option was measured at fair value on a quarterly basis and any changes in the fair value was recorded as Change in fair value of assets and liabilities, net, in the consolidated statements of operations.

Conversion of Convertible Promissory Notes

In September 2025, the noteholder and related party noteholder each exercised the conversion feature of the New Convertible Notes and converted all of their respective New Convertible Notes into a total of 6,185,904 common stock of the Company. The conversion of the New Convertible Notes was accounted for as a conversion as the notes converted pursuant to a conversion feature. Accordingly, the Company derecognized the carrying amount of the notes with no gain or loss recognized upon conversion. Upon conversion, the Company received $7.7 million.

For the years ended December 31, 2025 and 2024, the Company recognized a loss of $20.3 million and a gain of $3.4 million, respectively, as a result of the change in fair value of the New Convertible Notes.

As of December 31, 2024, the fair value of the Short-term convertible Notes and derivative liability was $1.8 million and the fair value of the Short-term convertible promissory note and derivative liability - related party was $1.2 million.

Term Loan

Hercules Loan and Security Agreement

In August 2022, the Company and certain subsidiaries, as guarantors, and Hercules Capital, Inc., a Maryland corporation ("Hercules"), entered into a Loan and Security Agreement (as amended, the "Hercules Loan Agreement"). The Hercules Loan Agreement provided for term loans in an aggregate principal amount of up to $175.0 million under multiple tranches (collectively, the "2022 Term Loan Facility").

The 2022 Term Loan Facility was scheduled to mature on August 1, 2026 (the "Maturity Date"), subject to extension under certain conditions. The outstanding principal balance of the 2022 Term Loan Facility bore interest at a floating interest rate per annum equal to the greater of either (i) the prime rate as reported in the Wall Street Journal plus 4.30% and (ii) 9.05%; provided, that if certain conditions were

satisfied, the rate of interest in the foregoing clause (i) would be prime rate as reported in The Wall Street Journal plus 4.05%. Accrued interest was payable monthly following the funding of each term loan advance. The Company was entitled to make interest only payments, without any loan amortization payments, until September 1, 2025, subject to extension under certain conditions.

The Hercules Loan Agreement contained customary closing and commitment fees, prepayment fees and provisions, events of default and representations, warranties and affirmative and negative covenants, including a financial covenant requiring the Company to maintain certain levels of cash in accounts subject to a control agreement in favor of the Agent (the "Qualified Cash") at all times commencing from August 2022, which included 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 Hercules Loan Agreement required, beginning on October 1, 2024, that the Company maintain Qualified Cash in an amount no less than the sum of (1) 50% of the outstanding amount under the 2022 Term Loan Facility, and (2) the amount of the Borrowers' and Subsidiary Guarantors' accounts payable that had not been paid within 180 days from the invoice date of the relevant account payable, subject to certain exceptions; provided, upon the occurrence of certain conditions, the Company was required to at all times maintain Qualified cash in an amount no less than the sum of (1) 70% of the outstanding amount under the 2022 Term Loan Facility, and (2) the amount of the Borrowers' and Subsidiary Guarantors' accounts payable that had not been paid within 180 days from the invoice date of the relevant account payable, subject to certain exceptions; provided, further, that the financial covenant would not apply on any day that the Company's market capitalization is at least $550.0 million measured on a consecutive 10-business day period immediately prior to such date of measurement and tested on a daily basis. Upon the occurrence of an event of default, subject to any specified cure periods, the Lenders could declare all amounts owed by the Borrowers immediately due and payable by the Lenders. As of the Payoff Date (as defined below), the Company was in compliance with all applicable covenants under the Hercules Loan Agreement.

Prior to the Payoff Date, the Company incurred financing expenses related to the Hercules Loan Agreement, which were recorded as an offset to long-term debt on the Company's consolidated balance sheets. These deferred financing costs were amortized over the term of the debt using the effective interest method, and were included in other income, net in the Company's consolidated statements of operations. For the years ended December 31, 2025 and 2024, interest expense included $0.2 million and $0.5 million of amortized deferred financing costs related to the 2022 Term Loan Facility, respectively.

On May 2, 2025, the Company and Hercules entered into a payoff letter for a voluntary prepayment with respect to the Hercules Loan Agreement (the "Payoff Letter"). Pursuant to the Payoff Letter, on May 2, 2025 (the "Payoff Date"), the Borrowers paid off the outstanding loan amount of approximately $21.8 million in full in repayment of the Company's outstanding obligations under the Hercules Loan Agreement, and thereby terminated the 2022 Term Loan Facility. Due to the early prepayment, the Borrowers incurred a prepayment fee equal to 0.50% of the outstanding principal balance for a total of $0.1 million. In addition, the Borrowers paid an end of term charge equal to 6.95% of the outstanding principal balance for a total of $1.4 million. For the year ended December 31, 2025, the Company recognized a $1.3 million loss on extinguishment of debt, which was recognized as a component of Other income (expense), net within its consolidated statements of operations.

There were no outstanding debt obligations as of December 31, 2025. Outstanding debt obligations as of December 31, 2024 were as follows (in thousands):

	December 31, 2024
Principal amount	$ 20,000
End of the term charge	1,390
Less: unamortized issuance discount	(123)
Less: unamortized issuance costs	(51)
Less: unamortized end of term charge	(709)
Net carrying amount	20,507
Less: current maturities	(6,374)
Long-term debt, net of current maturities and unamortized debt discount and issuance costs	$ 14,133

The fair value of the outstanding debt obligations under the 2022 Term Loan Facility was $21.5 million as of December 31, 2024, and the fair value of the debt obligations under the 2022 Term Loan Facility represented Level 3 measurements within the fair value hierarchy.

15. Stockholders' Equity

Redomiciliation

As noted above in Note 1, Organization and Description of Business, on December 30, 2025, the Company completed the Redomiciliation Transaction. Pursuant to the Redomiciliation Transaction, each ordinary share of Atai Beckley N.V. was exchanged for one ordinary share of atai LuxCo. Pursuant to the Delaware Conversion, each ordinary share of atai LuxCo automatically converted by operation of law to one share of common stock of AtaiBeckley Inc.

Terms of the common stock include the following:

- The voting, dividend, liquidation and other rights and powers of common stock are subject to and qualified by the rights, powers, and preferences of any series of preferred stock as designated by the Board of Directors of the Company
- Subject to the rights and preferences of any holders of preferred stock, the holders of common stock are entitled to any payment of dividends on the Common Stock, if declared by the Board of Directors
- Subject to the rights of any holders of preferred stock, the number of authorized shares of common stock may be increased or decreased by the requisite vote of the stockholders.
- Subject to the rights and preferences of any holders of preferred stock, in the event of dissolution, liquidation, or winding up of the Company, the funds and assets of the Company may be legally distributed among the stockholders of common stock pro rata in accordance with the number of shares held by each such holder.

As part of this process, the legal denomination of the Company's common stock changed from Euro to U.S. dollars. All common stock in atai Life Sciences N.V., at par value €0.10, were canceled and exchanged for common stock in AtaiBeckley Inc., at par value $0.01, on a one-for-one basis. AtaiBeckley Inc.'s common stock par value was decreased by $38.1 million for the difference between the total par value of common stock of AtaiBeckley Inc. and the total par value of common stock of atai Life Sciences N.V. at the date of transfer, with an offset to additional paid in capital. This change did not affect the Company's functional currency, which remains the U.S. dollar, nor did it result in any gain or loss in the consolidated financial statements. The redomiciliation was effected solely for legal and administrative purposes and had no impact on the number of shares outstanding, par value in functional currency terms, or stockholders' equity.

Preferred Stock

Following the Redomiciliation Transaction, the Company is authorized to issue up to 37,500,000 shares of stock designated as "preferred stock," with a par value of $0.01 per share. These shares are issuable from time to time in one or more series as designated by the Company's board of directors, which may resolve to determine and fix the number of shares of such series and such voting powers and designations, including dividend rights, conversion rights, redemption privileges and liquidation preferences, and to increase or decrease the number of shares of any series.

As of December 31, 2025, and 2024, respectively, there are no shares of preferred stock outstanding.

Common Stock

Following the Redomiciliation Transaction, the Company is authorized to issue up to 750,000,000 shares of common stock, with a par value of $0.01 per share. All holders of common stock 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. Upon liquidation, holders of common stock will receive a distribution on a pro rata basis. As of December 31, 2025 and December 31, 2024, no cash dividends have been declared or paid.

Open Market Sale Agreement

In November 2022, the Company entered into the Sales Agreement, with Jefferies, pursuant to which the Company may issue and sell its common stock having an aggregate offering price of up to $150.0 million, from time to time through an "at the market" equity offering program under which Jefferies will act as sales agent. There have been no sales under the Sales Agreement for the years ended December 31, 2025 and 2024, and as of the date of this Annual Report on Form 10-K, there is currently no registration statement effective with respect to offers and sales of common stock pursuant to the Sales Agreement.

February 2025 Public Offering

In February 2025, the Company entered into an underwriting agreement (the "February Underwriting Agreement") with Berenberg Capital Markets LLC in connection with the issuance and sale by the Company in a public offering of 26,190,477 of its common stock, at a public offering price of $2.10 per share, less underwriting discounts and commissions. The common stock was offered pursuant to a registration statement on Form S-3 filed with the SEC on July 1, 2022 and declared effective on July 11, 2022 as well as a prospectus supplement

thereto. Under the terms of the February Underwriting Agreement, the Company granted to the underwriter an option exercisable for 30 days to purchase up to an additional 3,928,571 common stock at the public offering price, less underwriting discounts and commissions. Pursuant to the February Underwriting Agreement, the underwriter exercised the option to purchase the full amount of the additional 3,928,571 common stock.

The net proceeds from the offering of the common stock were approximately $59.1 million, after deducting the underwriting discounts and commissions and offering expenses payable by the Company.

June 2025 PIPE Financing

As described in Note 8, Fair Value Measurement, on June 2, 2025, the Company entered into the June 2025 Subscription Agreements relating to the purchase by the investors party thereto of (i) 9,993,341 common stock of the Company with a nominal value of €0.10 per share for a purchase price of $1.84 per share and (ii) the June 2025 Pre-Funded Warrant to purchase 6,311,006 common stock with an exercise price of $0.01, for a purchase price of $1.84 per common share underlying the June 2025 Pre-Funded Warrant less the exercise price for the June 2025 Pre-Funded Warrant of $0.01 per share, resulting in aggregate gross proceeds to the Company from the June 2025 PIPE Financing of approximately $29.9 million. The closing of the June 2025 PIPE Financing was subject to the satisfaction of the customary closing conditions contained in the June 2025 Subscription Agreements and was completed in June 2025. The June 2025 Subscription Agreements contain customary representations, warranties and agreements by the Company and termination provisions.

The securities were issued and sold in a private placement in reliance on Section 4(a)(2) of the Securities Act and were subsequently registered for resale pursuant to a registration statement on Form S-3 filed with the SEC on September 29, 2025, which became automatically effective upon filing with the SEC. The securities may not be offered or sold in the United States, except pursuant to the effective registration statement or an applicable exemption from the registration requirements of the Securities Act.

The aggregate gross proceeds from the offering of the common stock in the June 2025 PIPE Financing were approximately $18.4 million.

The June 2025 Pre-Funded Warrants were immediately exercisable upon issuance, and do not expire until the date the common stock underlying the June 2025 Pre-Funded Warrants have been exercised in full. Under the terms of the June 2025 Pre-Funded Warrant, the Company may not effect the exercise of any June 2025 Pre-Funded Warrant, and the holder will not be entitled to exercise any portion of any June 2025 Pre-Funded Warrant that, upon giving effect to such exercise, would cause an aggregate number of common stock beneficially owned by such holder (together with its affiliates) to exceed 4.99% of the total number of common stock of the Company outstanding immediately after giving effect to the exercise. The June 2025 Pre-Funded Warrant may be exercised by a holder by paying the exercise price in cash or on a cashless basis. No fractional shares will be issued upon any exercise of the June 2025 Pre-Funded Warrant. If, upon exercise of the June 2025 Pre-Funded Warrant, a holder would be entitled to receive a fractional interest in a share, the Company may at its option, upon exercise, pay cash in lieu of any such factional share or round up to the nearest whole share.

The aggregate gross proceeds from the offering of the June 2025 Pre-Funded Warrants were approximately $11.5 million. Under ASC 815 the Company recognizes the June 2025 Pre-Funded Warrants at fair value as Pre-funded warrant liabilities within its consolidated balance sheet.

The Company incurred offering expenses related to the June 2025 PIPE Financing of $1.8 million, which were allocated based on the relative fair values of common stock and pre-funded warrants issued. The Company recognized an expense for the amount allocated to the pre-funded warrants of $0.7 million (included as a component of Other income (expense), net within the consolidated statement of operations) upon the closing of the offering during the three months ended June 30, 2025. The Company recorded the amount allocated to the common stock of $1.1 million as a reduction in additional paid-in capital on its balance sheets as of December 31, 2025.

July 2025 PIPE Financing

As described in Note 8, Fair Value Measurement, on July 1, 2025, the Company entered into the July 2025 Subscription Agreements relating to the purchase by the investors party thereto of (i) 18,264,840 common stock in the capital of the Company with a nominal value of €0.10 per share for a purchase price of $2.19 per share and (ii) the July 2025 Pre-Funded Warrant to purchase 4,566,210 common stock with an exercise price of $0.01 for a purchase price of $2.19 per common share underlying the July 2025 Pre-Funded Warrant less the exercise price for the Pre-Funded Warrant of $0.01 per share, resulting in aggregate gross proceeds to the Company from the PIPE Financing of approximately $50.0 million. The closing of the July 2025 PIPE Financing was subject to the satisfaction of the customary closing conditions contained in the July 2025 Subscription Agreements and was completed in August 2025. The July 2025 Subscription Agreements contain customary representations, warranties and agreements by the Company and termination provisions.

The securities were issued and sold in a private placement in reliance on Section 4(a)(2) of the Securities Act and were subsequently registered for resale pursuant to a registration statement on Form S-3 filed with the SEC on September 29, 2025, which became automatically effective upon filing with the SEC. The securities may not be offered or sold in the United States, except pursuant to the effective registration statement or an applicable exemption from the registration requirements of the Securities Act.

The aggregate gross proceeds from the offering of the common stock in the June 2025 PIPE Financing were approximately $40.0 million.

The July 2025 Pre-Funded Warrants were immediately exercisable upon issuance, and do not expire until the date the common stock

underlying the July 2025 Pre-Funded Warrants have been exercised in full. Under the terms of the July 2025 Pre-Funded Warrant, the Company may not effect the exercise of any July 2025 Pre-Funded Warrant, and the holder will not be entitled to exercise any portion of any July 2025 Pre-Funded Warrant that, upon giving effect to such exercise, would cause an aggregate number of common stock beneficially owned by such holder (together with its affiliates) to exceed 4.99% of the total number of common stock of the Company outstanding immediately after giving effect to the exercise. The July 2025 Pre-Funded Warrant may be exercised by a holder by paying the exercise price in cash or on a cashless basis. No fractional shares will be issued upon any exercise of the Pre-Funded Warrant. If, upon exercise of the July 2025 Pre-Funded Warrant, a holder would be entitled to receive a fractional interest in a share, the Company may at its option, upon exercise, pay cash in lieu of any such factional share or round up to the nearest whole share.

The aggregate gross proceeds from the offering of the July 2025 Pre-Funded Warrants were approximately $10.0 million. Under ASC 815 the Company recognizes the July 2025 Pre-Funded Warrants at fair value as Pre-funded warrant liabilities within its consolidated balance sheet.

The Company incurred offering expenses related to the July 2025 PIPE Financing of $3.3 million, which were allocated based on the relative fair values of common stock and pre-funded warrants issued. The Company recognized an expense for the amount allocated to the pre-funded warrants of $0.7 million (included as a component of Other income (expense), net within the consolidated statement of operations) upon the closing of the offering during the three months ended September 30, 2025. The Company recorded the amount allocated to the common stock of $2.6 million as a reduction in additional paid-in capital on its balance sheets as of December 31, 2025.

October 2025 Public Offering

In October 2025, the Company entered into an underwriting agreement (the "October Underwriting Agreement") with Jefferies, as representative of the underwriters, in connection with the issuance and sale by the Company in a public offering of 23,725,000 of its common stock, at a public offering price of $5.48 per share, less underwriting discounts and commissions. The common stock was offered pursuant to a registration statement on Form S-3 filed with the SEC on September 29, 2025, which became automatically effective upon filing with the SEC, as well as a prospectus supplement thereto. Under the terms of the October Underwriting Agreement, the Company granted to the underwriters an option exercisable for 30 days to purchase up to an additional 3,558,750 common stock at the public offering price, less underwriting discounts and commissions. Pursuant to the October Underwriting Agreement, the underwriters exercised the option to purchase the full amount of the additional 3,558,750 common stock.

The net proceeds from the offering of the common stock were approximately $139.1 million, after deducting the underwriting discounts and commissions and offering expenses payable by the Company.

16. Stock-Based Compensation

atai Equity Incentive Plans

The Company has stock options and RSUs outstanding under various equity incentive plans, including the 2021 Incentive Plan, 2020 Incentive Plan, and HSOP Plan (all as defined below).

AtaiBeckley, Inc. 2021 Incentive Award Plan

Effective April 23, 2021, the Company originally adopted and the atai shareholders approved the 2021 Incentive Award Plan ("2021 Incentive Plan"). The 2021 Incentive Plan was again approved in connection with the Redomiciliation Transaction. The 2021 Incentive Plan is administered by the Company's board. The 2021 Incentive 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 71,734,896 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 8,301,319 and 8,397,987 shares of common stock effective January 1, 2024 and 2025, respectively. Shares that are expired, terminated, surrendered, or canceled without having been fully exercised will be available for future awards. As of December 31, 2025, 31,145,683 shares were available for future grants under the 2021 Incentive Plan.

Atai Life Sciences 2020 Equity Incentive Plan

Prior to the effective date of the 2021 Incentive Plan, the Company granted equity awards to eligible executive officers, directors, employees and consultants of the Company under the 2020 Employee, Director and Consultant Equity Incentive Plan (as amended from time to time, "2020 Incentive Plan"). As of the effective date of the 2021 Incentive Plan, the Company has not granted any further awards under the 2020 Incentive Plan.

As of December 31, 2025, there were no shares available for future grants under the 2020 Incentive Plan and any shares subject to outstanding stock options originally granted under the 2020 Incentive Plan that terminate, expire or lapse for any reason without the delivery of shares to the holder thereof shall become available for issuance pursuant to the 2021 Incentive Plan.

In October 2024, the Company modified all outstanding pre-IPO stock options under the 2020 Incentive Plan to extend the contractual term to be ten years, to align with stock options granted under the 2021 Incentive Plan, which is consistent with prevailing market practices. The Company recognized approximately $3.2 million in non-cash stock-based compensation expense related to this modification, including $2.0 million of research and development expenses and $1.2 million of general and administrative expenses.

Stock Options

The stock options outstanding below consist primarily of both service and performance-based options to purchase common stock of the Company. These stock options have a ten-year contractual term. These awards are subject to the risk of forfeiture until vested by virtue of continued employment or service to the Company.

The following is a summary of stock option activity from December 31, 2024 to December 31, 2025:

	Number of Options		Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (thousands)
Outstanding as of December 31, 2024	40,042,922		$ 3.81	7.29	$ 5,119
Granted	18,471,241	(i)	1.82	-	-
Exercised	(7,923,098)		1.32	-	-
Cancelled or forfeited	(7,057,939)		5.38	-	-
Outstanding as of December 31, 2025	43,533,126	(ii)	$ 3.11	7.40	$ 75,466
Options exercisable as of December 31, 2025	19,002,507		$ 4.77	6.13	$ 23,654

(i) Includes (a) 13,356,500 stock options that will vest according to certain time-based vesting conditions, (b) 3,568,488 stock options that will vest upon the satisfaction of certain performance obligations, and (c) 1,546,258 stock options issued pursuant to the Beckley Psytech Transaction, all of which are fully vested upon issuance.

(ii) Includes 22,984,366 outstanding unvested stock options includes (a) 18,299,784 stock options that will continue to vest over various service periods, (b) 3,568,488 stock options that will vest upon the satisfaction of certain performance obligations, (c) 1,116,094 stock options that will vest upon the satisfaction of specified market-based conditions tied to the price of the Company's publicly traded stock.

As described in Note 4, Acquisitions, the Company issued 1,546,258 vested stock options as replacement awards to certain consultants of Beckley Psytech and certain equity award holders in Beckley Psytech. The shares underlying the options issued as replacement awards are subject to a lock-up period whereby 1/12th of the shares will be released from the lock-up each calendar month beginning in January 2026, resulting in all shares subject to such options being freely transferable in January 2027. The Company did not recognize any expense related to the issuance of such replacement options.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2025 and 2024 was $1.37 and $1.35, respectively.

The Company estimates the fair values of stock options using the Black-Scholes option-pricing model on the date of grant. For the years ended December 31, 2025 and 2024, the assumptions used in the Black-Scholes option pricing model were as follows:

	December 31,	
	2025	2024
Weighted average expected term in years	5.44	5.95
Weighted average expected stock price volatility	91.0%	95.7%
Risk-free interest rate	3.70% - 4.47%	3.53% - 4.40%
Expected dividend yield	0%	0%

For the years ended December 31, 2025 and 2024, the Company recorded stock-based compensation expense related to stock options of $13.7 million and $23.5 million, respectively.

As of December 31, 2025, total unrecognized compensation cost related to the unvested stock options was $22.8 million, which is expected to be recognized over a weighted average period of 2.15 years.

Restricted Stock Units

The Company has granted RSUs to certain of its employees under the 2021 Incentive Plan, as part of its equity compensation program. Pursuant to the terms of the applicable award agreements, each RSU represents the right to receive one share of the Company’s common stock. The restricted stock units noted below consist of service-based awards vesting over a two-year period, subject to the risk of forfeiture until vested by virtue of continued employment or service to the Company. The Company reflects restricted stock units as issued and outstanding common stock when vested and the shares have been delivered to the individual.

The following is a summary of restricted stock unit activity from December 31, 2024 to December 31, 2025:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2024	719,557	$ 1.18
Granted	6,971,912	4.48
Vested	(7,691,469)	4.17
Forfeited	—	—
Unvested at December 31, 2025	—	$ —

As described in Note 4, Acquisitions, the Company issued 6,971,912 fully vested RSUs as replacement awards to certain equity award holders in Beckley Psytech. The number of RSUs issued as replacement awards was determined net of the exercise price of the equivalent Beckley Psytech option awards to which they correspond. The shares underlying the RSUs are subject to a lock-up period whereby 1/12th of the shares will be released from the lock-up each calendar month beginning in January 2026, resulting in all shares being freely transferable in January 2027. As a result of the RSU issuance, the Company recognized an additional $0.3 million of stock-based compensation expense.

For the years ended December 31, 2025 and 2024, the Company recorded stock-based compensation expense related to restricted stock units of $0.5 million and $1.8 million, respectively. The total fair value of restricted stock units vested during the year ended December 31, 2025 was $0.8 million and there was no unrecognized compensation expense related to any unvested restricted stock units.

Atai Life Sciences Hurdle Share Option Plan

On August 21, 2020, the Partnership (as defined below) approved and implemented an employee stock option plan for selected executives, employees, and consultants of the Partnership (the "Hurdle Share Options Program" or the “HSOP Plan”), which became effective on

January 2, 2021, the date the first grants under the HSOP Plan were made ("HSOP Options"). This plan is primarily aimed at German-based executives, employees, and consultants of the Company (collectively as "HSOP Participants"). The purpose of the HSOP Plan is to permit these individuals to indirectly participate in the appreciation in value of the Company through a German law private partnership, ATAI Life Sciences HSOP GbR (the "Partnership"). The HSOP Plan was established under the Partnership Agreement of the Partnership. The HSOP Plan requires the exercise price to be equal to the fair value of the shares on the date of grant.

The Partnership acquired 7,281,376 shares of atai common stock ("HSOP Shares") pursuant to the HSOP Plan. HSOP Options that are canceled or forfeited without having been fully exercised will be available for future awards. As of December 31, 2025, 257,419 HSOP Options were available for future grants under the HSOP Plan.

The HSOP Plan mimics the economics of a typical stock option plan, however, with the HSOP Shares to which the HSOP Options refer already being issued to the Partnership. Each HSOP Option contains both service and performance-based vesting conditions, including a liquidity-based condition, and gives the holder the option to request the distribution of HSOP Shares under its vested HSOP Options. The grantee is required to pay a nominal value (€0.06 per share) for the shares upon grant ("Nominal Upfront Payment"). The nominal amount paid at the grant date is refundable if the HSOP Options do not vest or are forfeited. Otherwise, the nominal amount is refundable until the later of the occurrence of a Liquidity Event (as defined in the "HSOP Plan") or the exercise date.

The HSOP Shares issued under the HSOP Plan to the Partnership are indirectly owned by HSOP Participants (being the holders of HSOP Options) via their interest in the Partnership. However, each HSOP Participant signed a nonrevocable power of attorney ceding virtually all rights and decisions, including their rights as shareholders to the Managing Partner (as defined in the Partnership Agreement) of the Partnership. HSOP Participants have a forfeitable right to distributions until the HSOP Options vest, at which time the right becomes nonforfeitable. Accordingly, the HSOP Shares issued to the Partnership and allocated to the HSOP Options holders are not considered outstanding for accounting purposes. Therefore, the Company accounted for the Nominal Upfront Payment as an in-substance early exercise provision under ASC 718 as the nominal amount is deducted from the exercise price upon exercise. As of December 31, 2025, the $0.5 million Nominal Upfront Payment was recorded as an Other liability on the consolidated balance sheets. The HSOP Options include a provision that requires the HSOP Options holders pay compensation equal to 2% per annum interest on the unpaid exercise price less the €0.06 nominal amount paid upon grant ("Non-recourse Loan") upon qualifying events (as defined in the Partnership Agreement).

The 2% per annum interest rate is fixed and not linked to something other than a service, performance, or market condition, therefore, the Company accounted for the fixed rate interest charge as an in-substance non-recourse loan in a stock compensation arrangement under ASC 718. In such cases, the rights and obligations embodied in a transfer of equity shares to an employee for a note that provides no recourse to other assets or the employee (other than the correlating shares) are substantially the same as those embodied in a grant of share options. The 2% per annum interest was considered in the valuation of the HSOP Options.

HSOP Options

The HSOP Options outstanding noted below consist of service and performance-based options to request the distribution of HSOP Shares. These HSOP Options have a fifteen-year contractual term. These HSOP Options vest over a three to four-year service period, only if and when a "Liquidity Event" (as defined in the Partnership Agreement) occurs within fifteen years of the date of grant. These awards are subject to the risk of forfeiture until vested by virtue of continued employment or service to the Company.

The liquidity-based performance condition contingent upon the achievement of a Liquidity Event was satisfied in June of 2021, therefore, the Company began recognizing expense for all associated options that were previously deemed improbable of vesting.

The following is a summary of stock option activity under the HSOP Plan from December 31, 2024 to December 31, 2025:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (thousands)
Outstanding as of December 31, 2024	6,921,829	$ 6.64	11.01	$ —
Granted	—	—	—	—
Exercised	—	—	—	—
Cancelled or forfeited	—	—	—	—
Outstanding as of December 31, 2025	6,921,829	$ 6.64	10.01	$ —
Options exercisable as of December 31, 2025	6,921,829	$ 6.64	10.01	$ —

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, 2025 or 2024. The Company did not recognize any stock-based compensation expense related to HSOP Options for the year ended December 31, 2025 and recognized expenses of $0.1 million related to HSOP Options for the year ended December 31, 2024.

As of December 31, 2025, there was no unrecognized compensation cost related to any unvested HSOP Options.

Subsidiary Equity Incentive Plans

Certain controlled subsidiaries of the Company adopt their own equity incentive plan ("EIP"). Each EIP is generally structured so that the applicable subsidiary, and its affiliates' employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options and restricted stock unit awards under their respective EIP. Standard option grants have time-based vesting requirements, generally vesting over a period of four years with a contractual term of ten years. Such time-based stock options use the Black-Scholes option pricing model to determine grant date fair value.

For the years ended December 31, 2025 and 2024, the Company recorded $0.1 million and $0.2 million of stock-based compensation, respectively, in relation to subsidiary EIPs. As of December 31, 2025, 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 3.2 years.

Stock-Based Compensation

Stock-based compensation expense is allocated to either Research and development or General and administrative expense on the consolidated statements of operations based on the cost center to which the option holder belongs.

The following table summarizes the total stock-based compensation expense by function for the year ended December 31, 2025 (in thousands):

	Year ended December 31, 2025		
	atai 2020 and 2021 Incentive Plans	Other Subsidiary Equity Plans	Total
Research and development	$ 3,971	$ 33	$ 4,004
General and administrative	10,187	22	10,209
Total stock-based compensation expense	$ 14,158	$ 55	$ 14,213

The following table summarizes the total stock-based compensation expense by function for the year ended December 31, 2024 (in thousands):

	Year ended December 31, 2024			
	atai 2020 and 2021 Incentive Plans	atai HSOP	Other Subsidiaries Equity Plan	Total
Research and development	$ 10,247	$ —	$ 150	$ 10,397
General and administrative	14,963	117	13	15,093
Total stock-based compensation expense	$ 25,210	$ 117	$ 163	$ 25,490

17. Income Taxes

As noted above in Note 1, Organization and Description of Business, on December 30, 2025, the Company completed the Redomiciliation Transaction. Pursuant to the Redomiciliation Transaction, the Company's tax residency changed from Germany to the United States.

Loss Before Income Taxes and Loss from Equity Method Investments

The components of loss from continuing operations before income taxes and loss from equity method investments by tax jurisdiction for the year ended December 31, 2025 is as follows (in thousands):

	Year Ended December 31, 2025
United States	$ (64,645)
Foreign	(595,204)
Total loss before income taxes and loss from equity method investments	$ (659,849)

The components of loss from continuing operations before income taxes and loss from equity method investments by tax jurisdiction for the year ended December 31, 2024 was as follows (in thousands):

	Year Ended December 31, 2024
Germany	$ (95,551)
International	(52,854)
Total loss before income taxes and loss from equity method investments	$ (148,405)

Total Benefit From (Provision For) Income Taxes

The total tax provision for income taxes for the year ended December 31, 2025 consists of the following (in thousands):

	Year Ended December 31, 2025
Current benefit from (provision for) income taxes:	
United States	$ (15)
United States State & Local	(147)
International	(136)
Total current benefit from (provision for) income taxes	$ (298)
Deferred income tax benefit (provision):	
United States	$ —
United States State & Local	—
International	—
Total deferred income tax benefit (provision)	$ —
Total income tax benefit (provision):	
United States	$ (15)
United States State & Local	(147)
International	(136)
Total income tax benefit (provision)	$ (298)

The total tax benefit from income taxes for the year ended December 31, 2024 consists of the following (in thousands):

	Year Ended December 31, 2024
Current benefit from (provision for) income taxes:	
Germany	$ —
International	356
Total current benefit from (provision for) income taxes:	$ 356
Deferred income tax benefit (provision):	
Germany	$ —
International	—
Total deferred income tax benefit (provision)	$ —
Total income tax benefit (provision):	
Germany	$ —
International	356
Total income tax benefit (provision)	$ 356

The total current tax benefit from (provision for) income taxes for December 31, 2025 and 2024 is comprised of corporate income taxes incurred in United States, United Kingdom and Australia.

Statutory Income Tax Rate Reconciliation

A reconciliation of the statutory income tax rate to the Company's effective income tax rate for continuing operations for the year ended December 31, 2025, after the adoption of ASU 2023-09 as described in Note 2, Basis of Presentation, Consolidation and Summary of Significant Accounting Policies, is as follows (in thousands, except percentages):

	Year Ended December 31, 2025	
	Amount	Percent
U.S federal statutory tax rate:	$ (138,572)	21.00%
State and local income tax, net of national income tax effect*	141	(0.02)%
International tax effects:		
Germany:		
Statutory tax rate difference	(1,529)	0.23%
Changes in valuation allowances	(22,485)	3.41%
Effect of change of domicile	27,581	(4.18)%
Other	(1,585)	0.24%
Canada:		
Changes in valuation allowances	(454)	0.07%
Deferred tax adjustments	572	(0.09)%
Other	14	(0.00)%
United Kingdom:		
Statutory tax rate difference	(21,050)	3.19%
Changes in valuation allowances	16,814	(2.55)%
Non-deductible in-process research and development	131,750	(19.97)%
Effect of deferred tax adjustments	(15,869)	2.40%
Other	(1,007)	0.15%
Netherlands:		
Changes in valuation allowances	747	(0.11)%
Other	9,993	(1.51)%
Other international jurisdictions	123	(0.02)%
Changes in valuation allowances	9,981	(1.51)%
Nontaxable or Nondeductible Items:		
Effect of deferred tax adjustments	3,276	(0.50)%
Other	341	(0.05)%
Changes in unrecognized tax benefits	1,517	(0.23)%
Total income tax expense	$ 298	(0.05)%

*California, New York State, and New York City make up the majority (greater than 50%) of the tax effect in this category

A reconciliation of the statutory income tax rate to the Company's effective income tax rate for continuing operations for the year ended December 31, 2024, prior to the adoption of ASU 2023-09 as described in Note 2, Basis of Presentation, Consolidation and Summary of Significant Accounting Policies, is as follows (in thousands, except percentages):

	Year Ended December 31, 2024
Loss before income taxes:	
Germany	$ (96,160)
International	(52,245)
Total loss before income taxes:	(148,405)
German statutory rate	30.18%
Expected income tax expense (benefit)	(44,781)
US state income taxes, net of US federal tax benefit	$ (1,010)
International tax rate differential	4,589
Effect of Australian R&D tax credit incentives	(134)
Effect of consolidation and deconsolidation of subsidiaries	88
Effect of share-based compensation expense	305
Compensation expenses not deductible under IRC Section 162(m)	975
Expenses not deductible for tax purposes	525
Return to provision and deferred tax adjustments	(10,438)
Uncertain Tax Positions	(22)
Change in German and International valuation allowance	49,547
Total income tax expense	$ (356)
Effective income tax rate:	0.25%

As of December 31, 2025 the company is headquartered in New York City, United States and has subsidiaries in Germany, Australia, the United Kingdom, and Canada as well as minority investments in Canada, Germany, and the United Kingdom. The Company incurred tax losses in most jurisdictions, however, generated taxable profits in certain United States subsidiaries and Australian subsidiaries. The weighted-average United States corporate income tax rate for year ended December 31, 2025 and 2024 was 21.00%. The weighted-average combined German corporate income tax rate for the year ended December 31, 2025 and 2024 was 30.18% (inclusive of a corporate income tax rate of 15.00%, solidarity surcharge of 0.83%, and trade tax rate of 14.35%). The weighted-average Australia corporate income tax rate for the year ended December 31, 2025 and 2024 was 25%. In 2025 it was noted that Atai Therapeutics Pty Ltd, Kures Australia Pty Ltd, and Empathbio Australia Pty Ltd. would not qualify for the reduced rate under the base rate entity ("BRE") test as the amount of passive income exceeds 90% of total income. These entities were therefore subject to a 30% tax rate. The weighted-average United Kingdom corporate income tax rate for the year ended December 31, 2025 and 2024 was 25.00%. The combined Canada federal and provincial corporate income tax rate for the year ended December 31, 2025 and 2024 was 26.5%. The weighted-average Netherlands corporate income tax rate for the year ended December 31, 2025 was 16.00%.

Upon adoption of ASU 2023-09 as described in Note 2, Basis of Presentation, Consolidation and Summary of Significant Accounting Policies, cash paid for income taxes, net of refunds, during the year ended December 31, 2025 was as follows:

	Year Ended December 31, 2025
Income taxes paid	
United States	$ 89
United States State & Local	286
Foreign	214
Total income taxes paid	$ 589

Income taxes paid (net of refunds) exceeded 5 percent of total income taxes paid (net of refunds) in the following jurisdictions:

	Year Ended December 31, 2025
United States - States & Local	
New York	$ 120
New York City	107
Foreign	
United Kingdom	$ 214

Deferred Income Taxes

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 for the year ended December 31, 2025 (in thousands):

	Year Ended December 31, 2025
Deferred tax assets:	
U.S tax loss carryforwards	$ 27,740
Foreign tax loss carryforwards	65,756
Share compensation	31,428
Capitalized research and experimentation expenses	39,023
Other deductible timing differences	1,494
Total deferred tax assets, gross	165,441
Valuation allowance	(147,624)
Total deferred tax assets, net	$ 17,817
Deferred tax liabilities:	
Fixed and intangible assets	$ (1,513)
Unrealized foreign exchange	(5,217)
Outside basis differences in equity and other investments	(3,299)
Investments	(7,765)
Other timing differences	(23)
Total deferred tax liabilities	(17,817)
Total deferred tax asset (liability)	$ —

Significant components of deferred tax assets and deferred tax liabilities consisted of the following for the year ended December 31, 2024 (in thousands):

	Year Ended December 31, 2024
Deferred tax assets:	
German tax loss carryforwards	$ 55,507
International tax loss carryforwards	26,869
Share compensation	39,975
Capitalized research and experimentation expenses	31,010
Other deductible timing differences	1,300
Total deferred tax assets, gross	154,661
Valuation allowance	(139,514)
Total deferred tax assets, net	$ 15,147
Deferred tax liabilities:	
Fixed and intangible assets	$ (1,626)
Unrealized foreign exchange	(6,571)
Outside basis differences in equity and other investments	(2)
Investments	(6,948)
Total deferred tax liabilities	(15,147)
Total deferred tax asset (liability)	$ —

The valuation allowance provided against net deferred tax assets as of December 31, 2025 and 2024 was $147.6 million and $139.5 million, respectively. The valuation allowance recorded at both periods was primarily related to United States and foreign tax loss carryforwards, capitalized research and experimental costs, and stock-based compensation timing differences that, in the judgment of management, are not more-likely-than-not, to be realized.

As relevant to certain United States subsidiaries, the Tax Cuts and Jobs Act of 2017 requires taxpayers to capitalize and amortize certain research and experimental (“R&D”) expenditures under Internal Revenue Code ("IRC") Section 174 for tax years beginning after December 31, 2021 resulting in the capitalization of certain R&D costs within the Company's tax provision in 2024. IRC Section 174 costs attributable to R&D performed in the United States and outside of the United States are amortizable over 5 years and 15 years, respectively. The majority of the Company's R&D costs incurred in 2024 were performed outside of the United States and are amortizable over a 15 year period.

On July 4, 2025, the One Big Beautiful Bill Act of 2025 (the “Tax Act”) was signed into law. The Tax Act includes substantial changes to the U.S. federal tax code and broader fiscal policy for tax years 2025 and forward. The Company has recorded any applicable impacts to its tax provision for the year ended December 31, 2025, and determined that the impact is not significant. There are several provisions of the Tax Act that do not go into effect until future tax years but are also not expected to have significant impact on tax positions as currently recorded.

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, the Company's income tax provision would increase or decrease in the period in which the assessment is changed.

The Company has limited prior earnings history and, due to the early stages of its development and research activities, is expected to generate losses for the next several years and cannot accurately estimate future profit projections beyond such time. As such, management believes that it is more likely than not that the Company will not realize the benefits of such tax loss carryforwards and deductible differences.

As of December 31, 2025 and 2024 the Company did not have any significant unremitted earnings in its foreign subsidiaries.

The Company's gross tax loss carryforward for tax return purposes are as follows for the year ended December 31, 2025 (in thousands):

	Year Ended December 31, 2025
U.S. tax losses	$ 99,701
Foreign tax losses	232,357
Total	$ 332,058

The Company's gross tax loss carryforward for tax return purposes are as follows for the year ended December 31, 2024 (in thousands):

	Year Ended December 31, 2024
Germany tax losses	$ 183,952
International tax losses	97,985
Total	$ 281,937

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 2021 through 2024 tax returns are currently open to audit. The 2021 tax return for Perception Neuroscience Holdings, Inc. was under routine audit by the Internal Revenue Service and was settled in 2024. The 2021 atai Life Sciences GmbH, the 2022 atai Life Sciences N.V., and the 2022 Kures Australia Pty Ltd tax returns are currently under audit.

Unrecognized tax benefits arise when the estimated benefit recorded in the financial statements differs from the amounts taken or expected to be taken in a tax return because of the uncertainties described above. As of December 31, 2025 and 2024, the Company notes the following unrecognized tax benefits (in thousands).

	Year Ended December 31,	
	2025	2024
Balance as of December 31, 2024	$ —	$ 369
Increases—prior year tax positions	1,517	—
Decreases—prior year tax positions	—	(369)
Increases—current year tax positions		—
Balance as of December 31, 2025	$ 1,517	$ —

The balances of unrecognized tax benefits as of December 31, 2025 is $1.5 million, which relates to expected loss of tax attributes due to an in process audit examination. The unrecognized tax benefits as of December 31, 2024 were decreased as the company has settled the audit of the 2021 tax return for Perception.

18. Other income (expense), net

For the years ended December 31, 2025 and 2024, the Company recognized certain expenses for various transactions as Other income (expense), net within its consolidated statement of operations. Other income (expense), net is made up of the following expenses (in thousands):

	For the year ended December 31,	
	2025	2024
Benefit from research and development tax credit	$ 714	$ 525
Pre-funded warrant issuance costs	(1,356)	—
Loss on sale of investment held at fair value	—	(2,075)
Loss on disposal of fixed assets	(692)	—
Loss on lease termination	(408)	—
Loss on extinguishment of debt	(1,317)	—
Gain on settlement of pre-existing contract	—	5,567
Gain on dissolution of a variable interest entity, net	—	1,166
Gain on forgiveness accounts payable	—	331
Total other income (expense), net	$ (3,059)	$ 5,514

19. Net Loss Per Share

Basic and diluted net loss per share attributable to atai stockholders were calculated as follows (in thousands, except share and per share data):

	For the year ended December 31,	
	2025	2024
Basic and Diluted EPS		
Numerator:		
Net loss	$ (660,147)	$ (150,049)
Net loss attributable to noncontrolling interests	(100)	(780)
Net loss attributable to AtaiBeckley Inc. shareholders - basic and diluted	$ (660,047)	$ (149,269)
Denominator:		
Weighted average common stock outstanding attributable to AtaiBeckley Inc. Stockholders - basic and diluted	226,532,786	160,159,983
Net loss per share attributable to AtaiBeckley Inc. shareholders - basic and diluted	$ (2.91)	$ (0.93)

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 stock outstanding in the table above because the HSOP Participants have a forfeitable right to distributions until the HSOP Options vest and are exercised, at which time the right becomes nonforfeitable.

The following also represents the maximum amount of outstanding shares of potentially dilutive securities that were excluded from the computation of diluted net loss per share attributable to common shareholders for the periods presented because including them would have been antidilutive:

	As of December 31,	
	2025	2024
Options to purchase common stock	43,533,126	40,042,921
HSOP options to purchase common stock	6,921,829	6,921,829
2018 short-term convertible promissory notes - related parties	—	2,367,200
2018 short-term convertible promissory notes	—	3,818,704
Pre-funded warrants	10,877,216	—
Restricted stock units subject to lock-up	6,971,912	
Unvested restricted stock units	-	719,557
	68,304,083	53,870,211

20. Commitments and Contingencies

Research and Development Agreements

The Company may enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies and with other vendors for preclinical studies, supplies and other services and products for operating purposes.

Indemnification

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to vendors, lessors, business partners, board members, officers and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements, services to be provided by the Company, negligence or willful misconduct of the Company, violations of law by the Company, or intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with directors and certain officers and employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or employees. No demands have been made upon the Company to provide indemnification under such agreements, and thus, there are no claims that the Company is aware of that could have a material effect on the Company's consolidated financial statements.

The Company also maintains director and officer insurance, which may cover certain liabilities arising from its obligation to indemnify the Company's directors. To date, the Company has not incurred any material costs and has not accrued any liabilities in the consolidated financial statements as a result of these provisions.

Contingencies

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company is unable to predict the outcome of these matters or the ultimate legal and financial liability, and at this time cannot reasonably estimate the possible loss or range of loss and accordingly has not accrued a related liability. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company accrues a liability when a loss is considered probable and the amount can be reasonably estimated. When a material loss contingency is reasonably possible but not probable, the Company does not record a liability, but instead discloses the nature and the amount of the claim, and an estimate of the loss or range of loss, if such an estimate can be made. Legal fees are expensed as incurred. Given that such proceedings are subject to uncertainty, there can be no assurance that such legal proceedings, either individually or in the aggregate, will not have a material adverse effect on our business, results of operations, financial condition or cash flows.

21. License Agreements

National University Corporation Chiba University License Agreement

In August 2017, Perception entered into a license agreement (the “CHIBA License”), with the National University Corporation Chiba University (“CHIBA”), relating to Perception’s drug discovery and development initiatives. Under the CHIBA License, Perception has been granted a worldwide exclusive license under certain patents and know-how of CHIBA to research, develop, manufacture, use and commercialize therapeutic products.

During the years ended December 31, 2025 and 2024, the Company did not make any material payments pursuant to the CHIBA License.

Allergan License Agreement

In February 2020, Recognify entered into an amended and restated license agreement (the "Allergan License Agreement"), with Allergan Sales, LLC, or Allergan, under which Allergan granted Recognify an exclusive (non-exclusive as to know-how), sublicensable and worldwide license under certain patent rights and know-how controlled by Allergan to develop, manufacture and commercialize certain products for use in all fields including the treatment of certain diseases and conditions of the central nervous system.

During the years ended December 31, 2025 and 2024, Recognify did not make any material payments pursuant to the Allergan License Agreement.

Dalriada License Agreement

In December 2021, Invyxis, Inc. (“Invyxis”), a wholly owned subsidiary of the Company, entered into an exclusive services and license agreement (the “Invyxis ESLA”) with Dalriada Drug Discovery Inc. (“Dalriada”). Under the Invyxis ESLA, Dalriada is to exclusively collaborate with Invyxis to develop products, services and processes with the specific purpose of generating products consisting of new chemical entities.

For the year ended December 31, 2025, the Company did not make any material payments pursuant to the Dalriada License Agreement. For the year ended December 31, 2024, the Company made $0.4 million in payments as research and development expense for services under the Invyxis ESLA. During the years ended December 31, 2025 and 2024 Invyxis made no other service fee payments to Dalriada.

Rizafilm LLC License and Supply Agreement

As described in Note 3, Revenue, in January 2025, the Company, through its wholly owned subsidiary Nualtis, entered into an APA and a Supply Agreement with Rizafilm. Under the APA, Nualtis sold licensing and intellectual property rights of Nualtis's oral thin film technology and under the Supply Agreement, subject to approval by the FDA, Nualtis will serve as the sole manufacturer of Rizafilm's products over a five year term with an automatic renewal option for an additional five years unless either party provides sufficient written notice.

During the year ended December 31, 2024, the Company did not recognize any license revenue under the license agreement. During the year ended December 31, 2025, the Company recognized $0.2 million of the upfront fee paid by Rizafilm as license revenue.

Psilera Acquisition

In February 2025, the Company entered into an Intellectual Property Assignment & License Agreement with Psilera, Inc. (“Psilera”) under which the Company has acquired Psilera's dimethyltryptamine (“DMT”) patent portfolio, including all granted and pending patents related to DMT and other related psychedelics. In return, the Company paid Psilera an upfront fee of $0.8 million upon execution of the agreement and may also be required to pay Psilera additional consideration upon the achievement of certain regulatory and sales milestones, in addition to certain sales-based royalties over a ten-year period. The Company determined that the transaction was an asset acquisition under ASC 805 and recognized the upfront fee of $0.8 million as acquired IPR&D expenses in the consolidated statement of operations when incurred during the three months ended March 31, 2025.

The Company has determined the regulatory and sales milestones meet the requirements of contingent consideration acquired via an asset acquisition. As described in Note 2, Basis of Presentation and Summary of Significant Accounting Policies, above, the Company has elected the practical expedient under FASB's Statement 141 for the accounting of the regulatory and sales milestones. Under this guidance, the contingent consideration will be recorded once the contingencies are resolved and the consideration is issued or becomes issuable. In August 2025, Psilera achieved a milestone related to the grant of certain patents by the United States Patent Office. Upon completion of the milestone, the Company paid Psilera $2.3 million, which is also recognized as acquired IPR&D expenses in the consolidated statement of operations for the year ended December 31, 2025. The Company may be required to pay Psilera up to an additional $80.0 million upon the completion of certain sales milestones.

During the year ended December 31, 2025, the Company did not make any other payments to Psilera in connection with the Psilera Agreement. Additionally, as of December 31, 2025, the Company did not record any contingent liabilities in connection with the Psilera Agreement.

22. Government Grant

During August 2025, the Company announced that it has been awarded a multi-year, milestone-driven grant worth up to $11.4 million by the National Institute on Drug Abuse (“NIDA”), part of the National Institutes of Health (“NIH”). The grant funds will be utilized for the optimization and early-stage development of the Company’s novel 5-HT2A/2C receptor agonists with non-hallucinogenic potential for opioid use disorder. The funding is intended to support lead optimization, translational proof-of-concept studies, and the toxicology and manufacturing work needed to file an Investigational New Drug application.

The Company determined that, under Accounting Standards Update 2025-10 *Government Grants*, the NIDA grant received is a grant related to income. The Company recognizes the grant systematically through earnings as the Company determined that it is probable the Company will comply with the conditions of the grant and that the government grant will be received. Accordingly, the Company recognizes qualifying research and development expenditures under the NIDA grant as a reduction in Research and development expense in the statement of operations. For the years ended December 31, 2025, the Company recognized $0.3 million in qualifying Research and development expenditures, which has been recorded as a reduction in Research and development expense in the statement of operations. From the inception of the grant award to December 31, 2025, the Company has not received reimbursements from the NIDA and recognized a grant receivable of $0.3 in Prepaid expenses and other current assets in its consolidated balance sheets.

23. Related Party Transactions

atai Formation

In connection with the formation of the Company in 2018, the Company entered into a series of transactions with its shareholders Apeiron Investment Group Ltd. (“Apeiron”), the family office of Christian Angermayer, Co-Founder and Chairman of the Company, among other shareholders, contributed their investments in COMPASS, Innoplexus and Juvenescence Ltd. to the Company in exchange for the Company's common stock of equivalent value. Apeiron is the family office of the Company’s co-founder who owns 15.2% and 20.1% of the outstanding common stock in the Company as of December 31, 2025 and 2024, respectively.

Amended and Restated Consulting Agreement with Mr. Angermayer

In connection with the Redomiciliation Transaction, the Company and Mr. Angermayer entered into an Amended and Restated Consultancy Agreement pursuant to which Mr. Angermayer will continue to provide services to the Company on business and financing matters until January 5, 2028. Mr. Angermayer’s prior consulting agreement with the Company was substantially similar and provided for consideration in the form of options.

In June 2025, the Company granted to Mr. Angermayer in further consideration of his continued service as a consultant and other valuable consideration (i) an option to purchase 337,686 shares of common stock of the Company that will vest with respect to 131,698 shares subject to the option based on the Company’s standard four year vesting schedule and with respect to 205,988 shares subject to the option based on the Company achieving certain asset value goals by December 31, 2026 and continued service with the Company through such date, and (ii) an option to purchase 292,500 shares that will vest based on Company achieving certain asset value goals by December 31, 2026 and continued service with the Company through such date.

For the years ended December 31, 2025 and 2024, the Company recognized $0.9 million and $0.4 million, respectively, of stock-based compensation included in General and administrative expense in its consolidated statements of operations related to Mr. Angermayer’s consulting agreement.

For the years ended December 31, 2025 and 2024, the Company recorded $0.1 million and $0.3 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 board.

Apeiron's Purchase of Common Stock

As mentioned in Note 15, Stockholders’ Equity, the Company entered into the February Underwriting Agreement in connection with the issuance and sale by the Company in a public offering of its common stock. Apeiron participated in the public offering, purchasing 10,835,718 common stock at a price per share of $2.10. Additionally, in August 2025, the Company sold common shares to certain investors pursuant to the July 2025 Subscription Agreements. Apeiron participated in this offering, purchasing 8,675,799 common shares at a price of $2.19 per share.

Conversion of Convertible Promissory Notes

In September 2025, Apeiron, the related party note holder described in Note 14, Debt, exercised the conversion feature of the New Convertible Notes and converted all of its New Convertible Notes into 2,367,200 common stock.

Beckley Psytech Promissory Note

As mentioned in Note 7, Notes Receivable, the Company issued a Promissory Note to Beckley Psytech in the principal amount of $10.0 million, with net proceeds to be used for the achievement of specified product development milestones. The Promissory Note was settled pursuant to the completion of the Beckley Psytech Acquisition as Beckley Psytech became a wholly owned subsidiary and the Promissory Note became an intercompany transaction that is eliminated in consolidation as of the Acquisition Date.

Amandala Neuro Limited Notes Receivable

As noted above in Note 7, Notes Receivable, upon the acquisition and consolidation of Beckley Psytech in November 2025, the Company recognized $1.5 million of notes receivable from Amandala, in which the Company owns approximately 33.7%.

Consulting Agreement with Mr. Feilding Mellen

Subsequent to the acquisition of Beckley Psytech, the Company appointed Cosmo Feilding Mellen as a Director of the Company and entered into a consulting agreement with him. Pursuant to the consulting agreement with Mr. Feilding Mellen, the Company issued 10,000 stock options that fully vest as of December 31, 2025. For the years ended December 31, 2025, the Company recognized an immaterial amount of stock-based compensation included in General and administrative expense in its consolidated statements of operations related to Mr. Feilding Mellen’s consulting agreement. For the years ended December 31, 2025, the Company recognized $0.1 million of stock-based compensation included in General and administrative expense in its consolidated statements of operations related to Mr. Feilding Mellen’s

service as a board Director. The consulting agreement expired on December 31, 2025 and Mr. Feilding Mellen resigned from the Company's board effective January 6, 2026.

24. Defined Contribution Plan

The Company has a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan allows eligible employees to defer a portion of their annual compensation. Employees may make contributions by having the Company withhold a percentage of their salary up to the Internal Revenue Service annual limit. The Company recorded $0.4 million and $0.5 million of related compensation expense for the years ended December 31, 2025 and 2024.

25. Corporate Restructurings

2025 Restructuring

In March 2025 and November 2025, the Company eliminated approximately 25% and 10%, respectively, of its global workforce as part of a restructuring initiative in order to reduce operational costs and extend the Company's cash runway.

Restructuring expense related to the workforce reductions incurred during the year ended December 31, 2025, resulted in $2.9 million of restructuring expense, which consisted of $2.8 million of cash expenditures for severance and other employee separation-related costs and $0.1 million of non-cash stock-based compensation expense. Of the restructuring expense, for the year ended December 31, 2025, $0.9 million and $1.9 million were recorded in research and development expenses and general and administrative expenses, respectively, in the consolidated statements of operations.

As of December 31, 2025, net restructuring liabilities totaled approximately $0.3 million, which are included in accrued expenses on the Company's consolidated balance sheets.

2024 Restructuring

In February 2024, the Company restructured its workforce and eliminated approximately 10% of its global workforce in order to more effectively allocate its research and development and other resources supporting the revised business and program priorities and to reduce operational costs.

Restructuring expense related to the workforce reduction incurred during the year ended December 31, 2024, resulted in $2.0 million of restructuring expense, which consisted of $1.6 million of cash expenditures for severance and other employee separation-related costs and $0.4 million of non-cash stock-based compensation expense. Of the restructuring expense, for the year ended December 31, 2024, $0.3 million and $1.7 million were recorded in research and development expenses and general and administrative expenses, respectively, in the consolidated statements of operations.

As of December 31, 2024, all restructuring liabilities had been paid in full and there were no restructuring liabilities included in accrued expenses on the Company's consolidated balance sheets.

A reconciliation of the restructuring charges and related payments for the years ended December 31, 2025 and 2024 is as follows (in thousands):

	As of December 31,	
	2025	2024
Restructuring costs expensed during the period	$ 2,860	$ 2,029
Non-cash impact of stock-based compensation	(53)	(358)
Cash payments of restructuring liabilities, net	(2,510)	(1,671)
Ending Restructuring liability	$ 298	$ —

26. Segment Reporting

The Company's operations are organized into one operating and reportable segment dedicated to the global discovery, research, development, and commercialization of highly effective mental health treatments to transform patient outcomes. The Company's Chief Executive Officer is the Company's Chief Operating Decision Maker ("CODM") and makes key operating decisions and assesses performance on a consolidated basis. The Company's determination that it operates as a single operating segment is consistent with the financial information regularly reviewed by the CODM.

The Company has not generated any revenues to date from the sale of its product candidates and does not anticipate generating any revenues from the sale of its product candidates unless and until it successfully completes development and obtains regulatory approval to market its product candidates. The Company does recognize revenue through its licenses of intellectual property and development agreements. Refer to Note 21, License Agreements, for more information.

For the Company's single reportable segment, the CODM uses net loss that is reported on the consolidated statements of operations to allocate resources, predominantly during the annual budget and forecasting process. The CODM also uses non-financial inputs and qualitative information to evaluate the Company's performance, establish compensation, monitor budget versus actual results, and decide the level of investment in the Company's various operating activities and other capital allocation activities.

The Company's reportable segment net loss, including significant segment expenses, for the years ended December 31, 2025 and 2024 consisted of the following (in thousands):

	For the year ended December 31,	
	2025	**2024**
License revenue	$ 202	$ 308
Research and development services revenue	3,887	—
Total revenue	$ 4,089	$ 308
Research and Development		
BPL-003	1,283	—
VLS-01	16,297	10,606
EMP-01	7,894	1,527
Discovery (Non-hallucinogenic)	2,323	2,649
Other programs[(i)]	8,574	16,956
Personnel and employee-related expenses[(ii)]	10,775	10,545
Non-cash share-based compensation expense	4,026	10,390
Depreciation and Amortization	662	184
Other Expenses[(iii)]	531,228	2,597
General and Administrative		
Personnel and employee-related expenses[(ii)]	14,109	12,493
Non-cash share-based compensation expense	10,163	14,767
Accounting and Tax Fees	8,118	5,057
Legal & Intellectual Property Fees	19,437	5,895
Insurance	1,538	2,328
Depreciation and Amortization	350	290
Other Expenses, net[(iii)]	11,373	6,715
Interest income	1,478	778
Interest expense	(1,162)	(3,124)
Other segment items[(iv)]	(16,402)	(45,012)
Segment and consolidated net loss	**$ (660,147)**	**$ (150,049)**

[(i)] Includes direct expenses related to RL-007, PCN-101, KUR-101, RLS-01, EGX-121, and enabling technologies programs and external R&D costs incurred by Nualtis. There were no direct expenses incurred in 2025 related to the RLS-01 and KUR-101 programs

[(ii)] Includes labor, benefits, and personnel-based restructuring expenses.

[(iii)] Includes public company fees, professional consulting services, facilities costs, technology and communication costs, and miscellaneous fees.

[(iv)] Includes change in fair value of assets and liabilities, net, gain on other investments, Gain on the consolidation of Beckley Psytech, change in the fair value of digital assets, net, foreign exchange gains (losses), net, other income (expense), net, benefit (provision) for income taxes, and losses from investments in equity method investees, net of tax.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Limitations on Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2025. Based on this evaluation our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2025 at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our management, including our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025, based on the criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

In accordance with guidance issued by the SEC, companies are permitted to exclude acquisitions from their final assessment of internal control over financial reporting for the first fiscal year in which the acquisitions occurred. Our management's evaluation of internal control over financial reporting excluded the internal control activities of Beckley Psytech. The financial results of this acquisition are included in the consolidated financial statements as of and for the year ended December 31, 2025 and represent approximately 5% of our total assets.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

The Company is in the process of integrating Beckley Psytech, and as a result of these integration activities, certain controls will be evaluated and may be changed. Other than with respect to the Beckley Psytech Acquisition, during the quarter ended December 31, 2025, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(d) or 15d-15(d) of the Exchange Act) identified in management's evaluation during the quarter ended December 31, 2025 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) Disclosure in lieu of reporting on a Current Report on Form 8-K.

None.

(b) Insider trading arrangements and policies.

On December 19, 2025, Kevin Craig, the Company's Chief Medical Officer, entered into a Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c) (the "Craig 10b5-1 Plan"). The Craig 10b5-1 Plan provides for the periodic sale of up to 440,316 shares of common stock until December 31, 2026.

Other than the foregoing, during the quarter ended December 31, 2025, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

We have adopted a written code of conduct that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions. A current copy of the code is posted in the "Investors" section of our website under "Corporate Governance," which is located at ir.ataibeckley.com. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our code of conduct, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at the address and location specified in the preceding sentence. The information contained on our website is not incorporated by reference into this Form 10-K. We granted no waivers under our code of conduct in 2025.

Information About Our Directors and Executive Officers

The following table provides information regarding our executive officers and members of our board of directors (ages as of the date of this Annual Report on Form 10-K):

Name	Age	Position at atai	Principal Employment
Srinivas Rao, Ph.D, M.D.	57	Chief Executive Officer	Same
Anne Johnson	57	Chief Financial Officer	Same
Glenn Short, Ph.D	56	Chief Scientific Officer	Same
Kevin Craig, M.D.	53	Chief Medical Officer	Same
Gerd Kochendoerfer, Ph.D.	58	Chief Operating Officer	Same
Ryan Barrett	45	Chief Legal and Business Officer	Same
Christian Angermayer	47	Founder and Chairman	Founder of Apeiron Investment Group, an investment company
Scott Braunstein, M.D.	62	Vice-chairman and Director	Founder, In Situ Healthcare Consulting
Laurent Fischer, M.D.	62	Director	Chief Executive Officer and President of Adverum Biotechnologies, a biopharmaceutical company
Robert Hershberg	62	Director	Chief Executive Officer, President, and Chair of the Board of HilleVax, Inc., a biopharmaceutical company
John Hoffman	42	Director	Chief Operating Officer of Northern Data AG, an AI and High-Performance Computing (HPC) solutions company
Sabrina Martucci Johnson	59	Director	Founder and Chief Executive Officer of Daré Bioscience, Inc., a biopharmaceutical company
Amir Kalali, M.D.	60	Director	Professor of Psychiatry at the University of California San Diego
Andrea Heslin Smiley	58	Director	President and Chief Executive Officer of VMS BioMarketing, a biomarketing company

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report

(a)(1) Financial Statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits

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

Exhibit Number	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
1.1	Open Market Sale Agreement, dated as of November 10, 2022, between ATAI Life Sciences N.V. and Jefferies LLC	8-K	001-40493	1.1	11/10/2022	
2.1+§	Share Purchase Agreement, dated as of June 2, 2025, among the Company, Beckley Psytech Limited and certain other parties thereto.	8-K	001-40493	2.1	6/2/2025	
3.1	Certificate of Incorporation of AtaiBeckley Inc	8-K12B	001-43037	3.1	12/31/2025	
3.2	Bylaws of AtaiBeckley Inc., adopted as of December 30, 2025	8-K12B	001-43037	3.2	12/31/2025	
4.2	Description of Securities					*
10.1#	Second Amended and Restated Employment Agreement, dated January 8, 2025, between atai Life Sciences US, Inc. and Srinivas Rao	8-K	001-40493	10.1	1/10/2025	
10.2#	Amended and Restated Employment Agreement, dated May 10, 2023, by and between atai Life Sciences US Inc. and Anne Johnson	10-K	001-40493	10.4	3/17/2025	
10.3#	Employment Agreement, dated November 11, 2025, by and between Gerd Kochendoerfer and ATAI Life Sciences AG	8-K	001-40493	10.2	1/10/2025	
10.4#	Amended and Restated Consultancy Agreement, dated December 30, 2025, by and between AtaiBeckley Inc. and Christian Angermayer	8-K12B	001-43037	10.7	12/31/2025	
10.5#	Form of Indemnification and Advancement Agreement	8-K12B	001-43037	10.1	12/31/2025	
10.6#	AtaiBeckley Inc. 2021 Incentive Award Plan	8-K12B	001-43037	10.3	12/31/2025	
10.7#	Form of Option Award Agreement under 2021 Incentive Award Plan					*
10.8#	Form of Restricted Stock Unit Agreement under 2021 Incentive Award Plan					*
10.9#	2020 Employee, Director, and Consultant Equity Incentive Plan	S-1/A	333- 255383	10.20	6/11/2021	

10.10#	Form of Stock Option Agreement under 2020 Employee, Director and Consultant Equity Incentive Plan	S-1/A	333- 255383	10.21	6/11/2021
10.11#	Atai Director Compensation Program	8-K12B	001-43037	10.2	12/31/2025
10.12†	License Agreement, dated as of August 14, 2017, between National University Corporation Chiba University and Perception Neurosciences, Inc., as amended by Amendment No. 1, dated as of August 7, 2018, the Second Amendment, dated as of March 17, 2020, and Amendment No. 3, dated as of March 5, 2021.	S-1	333-255383	10.8	4/20/2021
10.13†	Preferred Stock Purchase Agreement, dated as of August 29, 2019, between GABA Therapeutics, Inc. and ATAI Life Sciences AG, as amended by the Omnibus Amendment, dated as of October 30, 2020	S-1	333-255383	10.11	4/20/2021
10.14†	Series A Preferred Stock Purchase Agreement, dated as of December 27, 2019, among DemeRx IB, Inc., ATAI Life Sciences AG and DemeRx, Inc.	S-1	333-255383	10.13	4/20/2021
10.15†	Series A Preferred Stock Purchase Agreement, dated as of November 6, 2020, between FSV7, Inc. and ATAI Life Sciences AG	S-1/A	333-255383	10.13	5/27/2021
10.16†	Amended and Restated License Agreement, dated as of February 21, 2020, between Allergan Sales, LLC and FSV7, LLC	S-1	333-255383	10.14	4/20/2021
10.17	Partnership Agreement of ATAI Life Sciences HSOP GbR, dated August 21, 2020	S-1/A	333-255383	10.22	6/11/2021
10.18	Amendment to Preferred Stock Purchase Agreement, dated as of May 15, 2021, by and among ATAI Life Sciences AG, GABA Therapeutics, LLC and GABA Therapeutics, Inc.	S-1/A	333-255383	10.26	6/4/2021
10.19†	Amendment to Series A Preferred Stock Purchase Agreement, dated as of May 25, 2021, by and among ATAI Life Sciences AG and FSV7, Inc.	10-K	001-40493	10.28	3/4/2023
10.20†	Second Amendment to Series A Preferred Stock Purchase Agreement, dated as of September 17, 2021, by and among ATAI Life Sciences AG and Recognify Life Sciences Inc., f/k/a FSV7, Inc.	10-K	001-40493	10.29	3/4/2023
10.21†	Omnibus Amendment to Series A Preferred Stock Purchase Agreement, dated as of October 5, 2022, by and among ATAI Life Sciences AG and Recognify Life Sciences, Inc., f/k/a FSV7, Inc.	10-K	001-40493	10.30	3/4/2023

10.22#†	Separation Agreement and Release between Sahil Kirpekar and atai Life Sciences US, Inc., dated April 24, 2025	8-K	001-40493	10.1	4/30/2025	
10.23#	Consulting Agreement between Sahil Kirpekar and atai Life Sciences AG, dated April 3, 2025	8-K	001-40493	10.2	4/30/2025	
10.24§	Shareholders Rights Agreement, dated as of June 2, 2025 between the Company and Apeiron Investment Group Ltd.	8-K	001-40493	10.3	6/2/2025	
10.25	Lock-Up Agreement, dated as of June 2, 2025 between the Company and Apeiron Investment Group Ltd	8-K	001-40493	10.4	6/2/2025	
10.26+§	Subscription Agreement, dated as of June 2, 2025, entered into between the Company and Ferring Ventures S.A	8-K	001-40493	10.5	6/2/2025	
10.27+§	Subscription Agreement, dated as of June 2, 2025, entered into between the Company and Adage Capital Partners LP	8-K	001-40493	10.6	6/2/2025	
10.28+§	Form of Pre-Funded Warrant	8-K	001-40493	10.7	6/2/2025	
10.29+	Registration Rights Agreement, dated as of June 2, 2025, among the Company, Apeiron Investment Group Ltd. and certain shareholders named therein	8-K	001-40493	10.8	6/2/2025	
10.30+§	Form of Subscription Agreement	8-K	001-40493	10.1	7/1/2025	
10.31+§	Subscription Agreement, dated as of July 1, 2025, entered into between the Company and Apeiron Investment Group Ltd.	8-K	001-40493	10.2	7/1/2025	
10.32+§	Subscription Agreement, dated as of July 1, 2025, entered into between the Company and Ferring Ventures S.A	8-K	001-40493	10.3	7/1/2025	
10.33§	Form of Pre-Funded Warrant	8-K	001-40493	10.4	7/1/2025	
10.34+	Registration Rights Agreement, dated as of July 1, 2025, among the Company and the July 2025 PIPE Investors	8-K	001-40493	10.5	7/1/2025	
10.35†	Fourth Amendment to Series A Preferred Stock Purchase Agreement by and among atai Life Sciences AG, Recognify Life Sciences, Inc., f/k/a FSV7, Inc., and the Shareholders (as listed on Exhibit A)	10-Q	001-40493	10.2	11/14/2023	
10.36#§	Consultancy Agreement, dated as of November 25, 2025. by and between Atai Beckley N.V. and Beckley Consultancy Services Ltd.					*

10.37#§	Settlement Agreement, dated as of November 25, 2025, by and between Cosmo Feilding Mellen and Beckley Psytech Limited	*
19.1	Insider Trading Compliance Policy	*
21.1	List of Subsidiaries	*
23.1	Consent of Deloitte & Touche LLP, an independent registered public accounting firm	*
31.1	Certification of Principal Executive Officer pursuant to Exchange Act Rule 13a-14(a)	*
31.2	Certification of Principal Financial Officer pursuant to Exchange Act Rule 13a-14(a)	*
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350	**
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350	**
97.1	Policy for Recovery of Erroneously Awarded Compensation	*
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document	*
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents	*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	*

* Filed herewith.
** Furnished herewith.
# Management contract or compensatory plan, contract or arrangement.
+ Certain of the schedules and attachments to this exhibit have been omitted from this exhibit pursuant to Regulation S-K, Item 601(a)(5). The registrant hereby undertakes to provide further information regarding such omitted materials to the SEC upon request.
§ Certain portions of this exhibit have been redacted pursuant to Regulation S-K, Item 601(a)(6).
† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit pursuant to Regulation S-K, Item 601(b)(10)(iv).

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

AtaiBeckley Inc.

Date: March 6, 2026

By: /s/ Srinivas Rao
Srinivas Rao
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	**Title**	**Date**
/s/ Srinivas Rao Srinivas Rao	Chief Executive Officer (Principal Executive Officer)	March 6, 2026
/s/ Anne Johnson Anne Johnson	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 6, 2026
/s/ Christian Angermayer Christian Angermayer	Chairman of the Board	March 6, 2026
/s/ Scott Braunstein Scott Braunstein	Vice-Chairman of the Board	March 6, 2026
/s/ Laurent Fischer Laurent Fischer	Director	March 6, 2026
/s/ Robert Hershberg Robert Hershberg	Director	March 6, 2026
/s/ John Hoffman John Hoffman	Director	March 6, 2026
/s/ Sabrina Martucci Johnson Sabrina Martucci Johnson	Director	March 6, 2026
/s/ Amir Kalali Amir Kalali	Director	March 6, 2026
/s/ Andrea Heslin Smiley Andrea Heslin Smiley	Director	March 6, 2026

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