UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ 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: 001-39522

COMPASS Pathways plc
(Exact name of registrant as specified in its charter)

England and Wales	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

33 Broadwick Street
London W1F 0DQ
United Kingdom
(Address of principal executive offices, zip code)

+1 (716) 676-6461
(Registrant's telephone number, including area code)

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

Title of Each Class	**Trading Symbol**	**Name of each exchange on which registered**
American Depositary Shares, each representing one ordinary share, par value of £0.008 per share	CMPS	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None.
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐
Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of ordinary shares held by non-affiliates of the Registrant as of June 30, 2025, the last business day of the most recently completed second fiscal quarter, was $257.1 million. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

The registrant had 128,923,295 shares of common stock outstanding as of March 17, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the 2026 Annual Meeting of Shareholders are incorporated herein by reference into Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year ending December 31, 2025.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the "Securities Act," and Section 21E of the Securities Exchange Act of 1934, as amended, or the "Exchange Act". Forward-looking statements generally relate to future events or our future financial or operating performance. All statements other than statements of historical fact included in this Annual Report on Form 10-K, including regarding our strategy, future operations, financial position, estimated revenues and losses, projected costs, prospects, plans and objectives of management, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions. The forward-looking statements and opinions contained in this Form 10-K are based upon information available to our management as of the date of this Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the timing, progress and results of our Phase 3 program for treatment-resistant depression, or TRD, and our other clinical trials of investigational COMP360 psilocybin treatment, including statements regarding the preliminary results to date from our two ongoing Phase 3 trials for TRD, the timing of initiation and completion of trials or studies and related preparatory work, our expectations regarding the periods during which the 26-week results of our second Phase 3 trial for TRD will become available, and our expectations regarding discussions with the Food and Drug Administration, or FDA, including discussions regarding plans for rolling submission of a new drug application, or NDA, for COMP360 psilocybin treatment in TRD;
- the timing, progress and results of our Phase2b/3 clinical trial in post-traumatic stress disorder, or PTSD, including statements regarding our trial designs and our expectations regarding discussions with the FDA, including discussions regarding our trial design;
- our estimates regarding our expenses, capital requirements, the sufficiency of our cash resources and our expected cash runway;
- our reliance on the success of our investigational COMP360 psilocybin treatment;
- the timing, scope or likelihood of regulatory filings and approvals, including an NDA for COMP360 psilocybin treatment in TRD;
- our expectations regarding the size of the eligible patient populations for COMP360 psilocybin treatment, if approved for commercial use;
- our ability to identify third-party clinical sites to conduct our trials and our ability to identify and train appropriately qualified healthcare professionals to monitor and safeguard participants receiving COMP360 psilocybin treatment in our clinical trials;
- our ability to implement our business model and our strategic plans for our business and our investigational COMP360 psilocybin treatment;
- our ability to identify new indications for COMP360 beyond our current primary focus on TRD and PTSD;
- our commercialization, marketing and manufacturing capabilities and strategy, including our ability to accelerate our commercial launch planning;
- the pricing, coverage and reimbursement of our investigational COMP360 psilocybin treatment, if approved;
- the scalability and commercial viability of our manufacturing methods and processes, including our ability to add commercial manufacturing capacity in the U.S.;

- the rate and degree of market acceptance and clinical utility of our investigational COMP360 psilocybin treatment, in particular, and psilocybin-based treatments, in general;
- our ability to raise additional capital or secure other financing to fund our operations;
- the potential for outstanding warrants to purchase American Depositary Shares, or ADSs, to be exercised in full for cash and any expected proceeds from the exercise of our outstanding warrants;
- our ability to establish or maintain collaborations or strategic relationships;
- our expectations regarding potential benefits of our investigational COMP360 psilocybin treatment and our treatment approach generally;
- our expectations around feedback from, and discussions with regulators regarding regulatory development paths and Controlled Substances Act designation, each of which may be subject to potential impacts of regulatory agency staffing cuts and policy changes on regulatory feedback and timing thereof;
- the scope of protection we and any current or future licensors or collaboration partners are able to establish and maintain for intellectual property rights covering COMP360;
- our ability to operate our business without infringing, misappropriating, or otherwise violating the intellectual property rights and proprietary technology of third parties;
- our ability to identify, maintain, utilize, acquire or purchase digital technologies to enhance the administration of our investigational COMP360 psilocybin treatment in the conduct of our clinical trials;
- regulatory developments in the United States, or U.S., under the laws and regulations of England and Wales, and other jurisdictions;
- developments and projections relating to our competitors and our industry;
- the effectiveness of our internal control over financial reporting;
- our ability to attract and retain qualified employees and key personnel, including our ability to grow our commercial team;
- our ability to achieve specified regulatory and commercial milestones, and in the case of the final tranche to secure approval from lenders' investment committees, to draw down additional amounts up to $100.0 million in accordance with the terms of our Loan and Security Agreement, as amended by the third amendment dated January 5, 2026, or the Loan Agreement, with Hercules Capital, Inc., or Hercules, and our ability to comply with the operating and financial covenants, including the minimum cash covenant, in our Loan Agreement;
- the effect of global financial and economic conditions and geopolitical events, including fluctuating interest rates and inflation, foreign exchange fluctuations (particularly the Pound Sterling to U.S. Dollar), the risk of an economic slowdown or recession in the U.S., instability in the banking system, overall market volatility in the U.S. or the UK, including as a result of, among other factors, geopolitical conflict (such as, the war between Russia and Ukraine and conflict in the Middle East), international tensions or instability (including from the effects of announced or future tariff increases), significant changes in U.S. policies or regulatory environment or the disruption to U.S. government agencies or similar events, on our business;
- the effect of public health crises, pandemics or epidemics and any future mitigation efforts, and current or future economic effects, on any of the foregoing or other aspects of our business or operations;
- whether we are classified as a controlled foreign corporation, or CFC, or a passive foreign investment company, or PFIC, under the Internal Revenue Code of 1986, as amended, for current and future periods; and
- the future trading price of the ADSs and impact of securities analysts' reports on these prices.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K.

You should not rely upon forward-looking statements as predictions of future events, which speak only as of the date made. We have based the forward-looking statements contained in this Annual Report on Form 10-K primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcomes of the events described in these forward-looking statements are subject to risks, uncertainties and other factors described in the section titled "Risk Factors" in Part I, Item 1A, of this Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission, or the SEC. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report on Form 10-K. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements. Except as otherwise required by law, we disclaim any obligation to subsequently revise any forward-looking statements to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

References to "we," "our," "us" and "the Company" refer to Compass Pathways plc.

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks and uncertainties include, but are not limited to, 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 achieve or maintain profitability;
- Unless and until we generate product revenue and achieve and sustain profitability, we will continue to need additional financing to fund our operations and capital expenditures. Failure to obtain additional funding when needed or on favorable terms may force us to delay, limit or terminate certain or all of our product discovery, therapeutic development, research operations or commercialization efforts or grant rights to develop and market products or therapeutic candidates;
- Raising additional capital through the sale of equity or convertible securities or the cash exercise of outstanding warrants may cause significant dilution to holders of our ordinary shares and ADSs, and raising additional capital through debt financings, strategic partnerships, collaborations, or other means may restrict our operations or require us to relinquish rights to therapeutic candidates intellectual property rights of third parties could adversely affect our ability to develop or commercialize our investigational treatments, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our investigational treatments. Such litigation or licenses could be costly or not available on commercially reasonable terms;
- Our operating activities may be restricted as a result of covenants related to our Loan Agreement, which could have a material adverse effect on our business, financial condition, and results of operations;
- COMP360 psilocybin treatment is, and any future therapeutic candidates we may develop may be, subject to controlled substance laws and regulations in the jurisdictions where our products, if approved, may be marketed, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, or changes in these laws and regulations may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition;
- Adverse publicity or public perception regarding psilocybin or our current or future investigational treatments using psilocybin, or regarding other controlled substances, may negatively influence the success of these treatments;
- We are dependent on the successful development of our investigational COMP360 psilocybin treatment. Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes;
- COMP360 and any future therapeutic candidates we may develop may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval or adversely affect the commercial profile for the treatment;
- Research and development of drugs targeting the central nervous system is particularly difficult, which makes it difficult to predict and understand why the drug has a positive effect on some patients but not others;
- We have never commercialized a therapeutic candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our treatments on our own or with suitable collaborators or on an accelerated timeline;
- The future commercial success of our investigational COMP360 psilocybin treatment will depend on the degree of market access and acceptance of our potential treatments;
- Our business and commercialization strategy for our investigational COMP360 psilocybin treatment depends on our ability to identify, qualify, prepare, and support third-party treatment sites. If we are unable to do so, our commercialization prospects would be limited and our business would be harmed;
- In our clinical trials, we currently rely on specially trained, licensed healthcare professionals working at third-party clinical trial sites and upon regulatory approval we expect to continue to rely on healthcare professionals working at third-party sites, to monitor and safeguard participants during administration of our COMP360 psilocybin treatment.

If third-party sites fail to recruit, retain or effectively manage a sufficient number of qualified healthcare professionals, our clinical trials may be delayed and our business, financial condition and results of operations would be materially harmed;

- Others may claim an ownership interest in our intellectual property and our product candidates, which could expose us to litigation and have a significant adverse effect on our prospects;
- Recently enacted and future legislation or changes in regulatory conditions may increase the difficulty and cost for us to obtain marketing approval of, adequate reimbursement for and commercialize our investigational COMP360 psilocybin treatment;
- We rely on third parties to supply drug substances and manufacture, package and distribute COMP360 for our clinical trials, and, if approved, we will continue to rely on third parties for commercial supply. If any third-party provider fails to meet its obligations to supply drug substance or manufacture COMP360, or fails to maintain or achieve satisfactory regulatory compliance, the development of such substance and the commercialization of any treatments, if approved, could be stopped, delayed or made commercially unviable, or less profitable or may result in enforcement actions against us;
- There are a number of third parties who conduct investigator-initiated studies, or IISs, using COMP360 provided by us. IISs of COMP360 may generate clinical trial data that raises concerns regarding the safety or effectiveness of COMP360;
- We face substantial competition and our competitors may discover, develop or commercialize treatments before or more successfully than us, which may result in the reduction or elimination of our commercial opportunities;
- We may face business interruptions, data loss, unauthorized access to or disclosure of personal health information or other personally identifiable information, failures or significant downtime of our information technology systems, negative publicity or reputational damage resulting from cyber-attacks on our systems or other cybersecurity incidents or data breaches; and
- Unfavorable global economic and geopolitical conditions as well as volatility in the financial markets have in the past and could in the future adversely affect our business, financial condition or results of operations.

PART I

ITEM 1. BUSINESS

Overview

We are a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. We are motivated by the need to find better ways to help and empower people with serious mental health conditions who are not helped by existing treatments. We are pioneering a new paradigm for treating mental health conditions focused on rapid and durable responses through the development of our investigational COMP360 psilocybin treatment, potentially a first in class treatment. COMP360 is our proprietary psilocybin formulation that includes our pharmaceutical-grade polymorphic crystalline psilocybin, optimized for stability and purity.

We believe that our COMP360 psilocybin treatment could offer a new approach to treatment of serious mental health conditions, including treatment-resistant depression, or TRD, which is a subset of major depressive disorder, or MDD, post-traumatic stress disorder, or PTSD, and potentially many other serious mental health conditions.

Our initial focus is on TRD, comprising patients who are inadequately served by current treatment options. In 2018, we received Breakthrough Therapy designation from the U.S. Food and Drug Administration, or the FDA, for COMP360 for the treatment of TRD. In November 2021, we announced positive top-line results from our Phase 2b clinical trial evaluating COMP360 for the treatment of TRD. On November 3, 2022, *The New England Journal of Medicine* published the positive results from our Phase 2b trial. This is the largest, randomized, controlled, double-blind psilocybin treatment clinical trial completed to date. The objective of the Phase 2b study was to evaluate the efficacy and safety of a single dose of investigational COMP360 psilocybin (25mg or 10mg), compared to 1mg, in patients with TRD. The trial achieved its primary endpoint for the 25mg dose, with a 25mg dose of COMP360 demonstrating a statistically significant and clinically relevant treatment difference against the 1mg dose of COMP360 in reducing depressive symptom severity after three weeks.

In 2025, we completed enrollment for each of the two pivotal trials in our Phase 3 program evaluating our COMP360 psilocybin treatment in TRD. Each of the two pivotal trials has a long-term follow-up component. The pivotal program design is as follows:

• Pivotal trial 1 (COMP005) (n=258): a single dose (25mg) monotherapy compared with placebo.

• Pivotal trial 2 (COMP006) (n=581): a fixed repeat dose monotherapy using three dose arms: 25mg, 10mg and 1mg. This trial is designed to investigate whether a second dose can increase therapeutic response.

• The primary endpoint in both pivotal trials is the change from baseline in the Montgomery-Åsberg Depression Rating Scale, or MADRS, total score at week 6.

In June 2025, we reported that the first pivotal trial, the COMP005 trial, achieved its primary endpoint, with a single 25mg dose of COMP360 versus placebo demonstrating a highly statistically significant reduction in symptom severity as measured by MADRS with a p-value of $p<0.001$ and a clinically meaningful difference of -3.6 in change at six weeks. The COMP005 trial is on-going and is comprised of three parts: Part A, which concluded during the second quarter of 2025, and was blinded through 6 weeks; Part B, which remained blinded through week 26; and Part C, which contains an open-label treatment part from week 26 to 52.

In February 2026, we announced the successful achievement of the primary endpoint in our ongoing Phase 3 COMP006 trial and Part B results from our ongoing Phase 3 COMP005 trial. We reported that the COMP006 trial achieved its primary endpoint with two fixed doses, administered 3 weeks apart, of COMP360 25 mg versus 1 mg demonstrating a highly statistically significant reduction in symptom severity with a p-value of <0.001 and a clinically meaningful difference of -3.8 points in change at six weeks.

Following these data read-outs, we submitted a request for a meeting with the FDA to discuss a rolling submission and review and the FDA has accepted our meeting request.

Beyond TRD, we have been exploring other indications, including PTSD. In May 2024, we completed and announced top-line results from our open label Phase 2 study to assess the safety and tolerability of COMP360 psilocybin treatment in participants with PTSD, as a result of trauma experienced as adults. In line with the study design, the study enrolled 22

participants who were monitored for a 12-week period post dosing. The study met its primary safety endpoint and available secondary efficacy endpoints. Study observations included meaningful and sustained symptom improvement from baseline in mean CAPS-5 total score, a measure of disease severity, and in Sheehan Disability Scale, or SDS, score, a measure of functional impairment in daily life. Administration of COMP360 was well-tolerated, with a safety profile consistent with previous studies of COMP360. In September 2025, the results of this study were published in the *Journal of Psychopharmacology*.

Based on the data from this trial, we determined to advance development of COMP360 for PTSD and finalized the design of a Phase 2b/3 clinical trial in PTSD. In January 2026, the FDA accepted our IND application for COMP360 in PTSD, enabling the initiation of a Phase 2b/3 (COMP202) clinical trial in patients living with PTSD.

The phase 2b/3 multicenter, randomized, double-blind, controlled study, with an open label extension, aims to investigate the efficacy, safety, and tolerability of COMP360 in participants with PTSD.

The study is comprised of 2 parts:

Part A (blinded) is a 12-week fixed repeat-dose, double-blinded, controlled part to confirm the efficacy of two administrations of COMP360 25 mg versus two administrations of COMP360 1 mg. The second COMP360 administration session will occur approximately 4 weeks later. The primary efficacy endpoint is the change from baseline in CAPS-5 total severity score at Week 8.

Part B (open-label) is a 40-week open-label follow-up to evaluate the long-term safety and efficacy of treatment in Part A. Eligible participants will receive a single open label retreatment with COMP360 25 mg. In both Part A and Part B, COMP360 may be administered adjunctively to a single permitted oral antidepressant.

The need for innovation in mental health care is significant, given that current treatment options are ineffective for millions of people. Our vision is a world of mental wellbeing – a world in which mental health isn't simply the absence of mental illness, but the ability to flourish. We want to help reduce the stigma surrounding mental health, to acknowledge that "everyone has a story," and to develop paradigm-changing new treatments for those who are not helped by existing treatment options.

Our Strategy

Our mission is to accelerate patient access to evidence-based innovation in mental health. Key elements of our strategy to achieve this include:

- ***Complete our Phase 3 registrational program and submit our NDA for our investigational COMP360 psilocybin treatment for the treatment of TRD.*** In 2021, we completed a randomized, controlled Phase 2b clinical trial in 233 TRD patients, at 22 sites across North America and Europe. We announced positive top-line results from this trial in November 2021, the results of which were published in the *New England Journal of Medicine* in November 2022. Based on the results from the Phase 2b trial, we advanced clinical development in TRD and our Phase 3 registrational program is ongoing. We completed enrollment in both pivotal trials during 2025 and have reported that we successfully achieved the primary endpoint in both pivotal trials. We expect to report 26-week data from our COMP006 study in early third quarter of 2026 and expect to complete our NDA submission in the fourth quarter.

- ***Expand our investigational COMP360 psilocybin treatment into additional indications, with our next focus on advancing a Phase 2b/3 clinical trial in PTSD.*** We believe that our investigational COMP360 psilocybin treatment may offer beneficial effects in other areas of high unmet need in mental health. Based on the positive Phase 2a results in May 2024, we decided to advance COMP360 into late-stage development in PTSD. Following the FDA's acceptance of our IND, we are initiating our Phase 2b/3 clinical trial in PTSD.

- ***Maximize the potential to reach patients and realize the value of our investigational COMP360 psilocybin treatment by creating a new approach to treating mental health conditions.*** We retain global development and commercialization rights for our investigational COMP360 psilocybin treatment. If we obtain FDA approval for COMP360, our first launch market will be the U.S. and we are accelerating our commercial planning readiness activities in the U.S. and plan to be launch ready by the end of 2026. Delivering COMP360 is expected to require the ability to implement COMP360

seamlessly within a provider's operating practice. In order to ensure we understand implementation challenges, we have entered into collaboration agreements with numerous different types of health care delivery systems in the U.S. The purpose of these agreements is to research and investigate models for the delivery of scalable, commercial COMP360 treatment within different types of healthcare delivery systems, assuming FDA approval.

Our Pipeline

We are currently focusing our efforts on progressing our Phase 3 clinical program in TRD and our Phase 2b/3 clinical trial in PTSD.

Investigational COMP360 Psilocybin Treatment

We are developing our investigational COMP360 psilocybin treatment for the treatment of a range of mental health conditions, with an initial focus on TRD. There is a large unmet need for new treatments to improve the response rate, remission rate, and durability of response for patients suffering with TRD. We believe our investigational COMP360 psilocybin treatment, if successfully developed and approved, represents a promising therapeutic option for TRD, as well as potentially for other mental health and neurological conditions, including PTSD.

TRD

TRD is a subset of MDD. MDD is a condition characterized by a persistent feeling of sadness and heightened negative emotions. It is considered a unipolar condition, which is a distinction between MDD and bipolar depression, the latter of which is often associated with an emotional state fluctuating between depression and hypomania or mania. MDD is a chronic recurring and serious mental health condition associated with high mortality rates, morbidity and diminished quality of life. The World Health Organization estimates as of 2025 that approximately 332 million people worldwide are suffering with MDD. Based on our review of claims data, we estimate that MDD affects approximately 23 million adults in the U.S. each year. It is estimated that approximately 12 million adults with MDD in the U.S. are treated with medication and that approximately 1/3 of these medication-treated MDD patients, or approximately 4 million patients, are considered to have TRD.

Due to the limitations of existing treatments, approximately one-third of adults with MDD will not respond to oral antidepressants and are considered to have TRD. TRD is defined as inadequate response to two oral medications. This condition is referred to as TRD. TRD has greater economic and societal cost than non-TRD MDD. TRD patients are often unable to perform daily tasks, are more likely to receive disability or welfare benefits and more frequently have co-occurring conditions compared with non-TRD MDD patients. In several studies, the direct medical costs for patients with TRD were significantly higher than those for non-TRD MDD patients, driven by, among other factors, increased rates of hospitalization and longer average hospital stays. Patients with TRD have a higher all-cause mortality compared with non-TRD MDD patients.

Patients suffering with depression are treated through a variety of approaches, each of which can have significant shortcomings in certain subsets of patients. Most pharmacotherapies for depression target the modulation of the brain's monoamine receptor system, and have exhibited limited efficacy in a significant portion of patients and can result in high relapse rates. There are only two medicines approved by the FDA for TRD in the US: esketamine and the fixed combination of olanzapine and fluoxetine (fluoxetine is a selective serotonergic reuptake inhibitor). Esketamine was approved in 2019 by the FDA. In addition to pharmacotherapies, various forms of somatic intervention are also used, although these treatments tend to be invasive and/or onerous, and there is limited data supporting their long-term benefit. Psychotherapy is another common treatment approach, but it requires a significant time commitment and is subject to large variability in availability and administration. Despite the range of treatments and therapies currently available for depression, patients suffering with TRD continue to be underserved, prolonging a significant health, social and economic burden. We believe patients suffering with TRD need a paradigm-shifting treatment that can deliver rapid and sustained relief of their depression.

Limitations of Existing Therapies for Depression

Because depression has biological, social, psychological, environmental, genetic, and stress-related determinants, many of which co-occur, treatment options are wide-ranging and often combined. Current pharmacological and non-pharmacological treatments, such as antidepressants and psychotherapy, are well-established and efficacious for a subset of MDD patients. However, many patients fail to experience any benefit or have only a partial response and often relapse. Clinicians often rely on a trial-and-error approach, course correcting as patients experience these relapses or difficult side effects. Experts are

beginning to recommend a shift to more multi-modal treatments where different types of therapy are delivered concomitantly (i.e., a mix of pharmacotherapy, psychological/behavioral, and device interventions).

Patients suffering with TRD are currently treated through a variety of approaches, each of which is associated with significant shortcomings. Consequently, there remains a need for a fast-acting, tolerable treatment that provides a durable response in this patient population. Despite the condition's largely heterogeneous nature, most pharmacotherapies for depression use the same mechanism of action, targeting the brain's various monoaminergic neurotransmitters. As evidenced by low response and high relapse rates, currently approved treatments are not effective for a large number of patients. We believe currently available options do not adequately meet the needs of patients suffering with TRD and there is a significant need for a new therapeutic approach.

Pharmacotherapies

There are five main categories of antidepressants available on the market. These are selective serotonergic reuptake inhibitors, or SSRIs, and serotonergic norepinephrine reuptake inhibitors, or SNRIs, atypical antidepressants, monoamine oxidase inhibitors, or MAOIs, and tricyclic antidepressants, or TCAs. These are frequently used in first- and second-line treatment of depression and can also be used after this point. The Star*D trial conducted by the National Institute of Mental Health in 2006 indicates that only approximately 37% of patients achieve remission with their initial antidepressant treatment and once a patient progresses to third and fourth line, their remission rates drop to 14% and 13% respectively.

Currently approved antidepressants have significant limitations, including delayed onset of action, poor therapy adherence rates and substantial side effects. The onset of action for the most commonly used antidepressants is typically between six and eight weeks. Adherence levels are low, with average adherence rates for oral anti-depressant medications over twelve months being approximately 25%.

There is limited evidence to effectively guide clinical decisions following non-response or partial response to first-line antidepressant medications. Recommended treatment approaches include optimizing the current antidepressant dose or switching to an antidepressant in the same or different class. Partial response or lack of response thereafter is recommended to be addressed by combining antidepressants from different pharmacological classes, or augmenting with an alternative medication, primarily with atypical antipsychotics, but also mood stabilizers, anticonvulsants, thyroid hormones and stimulants, and N-methyl-D-asparate, or NMDA, antagonists.

Antipsychotics, such as olanzapine, quetiapine, cariprazine and aripiprazole are routinely used as adjunctive therapies when there is a lack of notable efficacy with an antidepressant. There is an approved combination of olanzapine and fluoxetine (an SSRI) for TRD. However, using antidepressants and antipsychotics together can have serious side effects, such as weight gain, other metabolic complications, sedation, extrapyramidal side effects (movement disorders), and QTc prolongation, which means the ventricles of the heart take longer than usual to recharge between beats.

Esketamine/Ketamine

Ketamine is an NMDA receptor antagonist that has been approved by the FDA for use for several decades in sedation and anesthesia. The S-enantiomer of ketamine, esketamine, is administered intranasally as a spray and has been approved by the FDA to treat TRD in conjunction with an oral antidepressant (2019), to treat depressive symptoms in adults with MDD with acute suicidal ideation or behavior (2020) and as a monotherapy to treat patients with TRD (2025). Ketamine and esketamine require multiple administration sessions. Both are DEA Schedule III products indicating potential for abuse. There are mixed efficacy results associated with the use of esketamine and esketamine treatments require frequent administration in a controlled environment under medical supervision. This frequency makes administration costly for payors and burdensome for patients.

Somatic Therapies

Patients who suffer with severe TRD and have tried several courses of antidepressants are often treated with resource-intensive somatic therapies like electroconvulsive therapy, or ECT, repetitive transcranial magnetic stimulation, or rTMS, vagal nerve stimulation, or VNS, and deep brain stimulation, or DBS. These therapies are generally administered in inpatient settings. Somatic and device-related interventions like ECT and VNS are associated with significant adverse reactions and interventional risks, such as use of general anesthesia and memory loss in the case of ECT, and surgical intervention and infection risk with VNS implantation. Limitations of rTMS include seizures, pain, face twitching and application discomfort. Similarly, DBS has the potential to cause pain and seizures. These treatments are typically reserved for patients who have not been helped by other treatments, and are characterized as high-cost treatment options with reimbursement limited for a subset of these therapies.

Despite the range of treatments and therapies available for MDD, patients suffering with TRD continue to be underserved, prolonging a significant health, social and economic burden. We believe patients suffering with TRD need a paradigm-shifting treatment that can deliver rapid and sustained relief of their depression.

Post Traumatic Stress Disorder

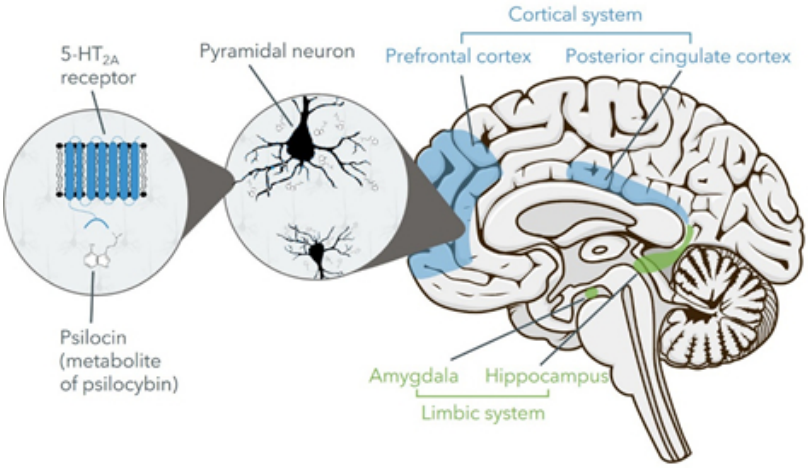
Like TRD, PTSD is a heterogeneous syndrome that can impact quality of life and lead to diminished cognitive and psychosocial functioning, fractured relationships, inability to maintain employment, substance abuse, high healthcare utilization costs, increased depression, and suicide risk. In some people, PTSD can be difficult to distinguish from anxiety and/or depression. PTSD can occur in people who have experienced or witnessed a traumatic event, such as a natural disaster, serious accident, war or rape. People who experience PTSD may relive their traumatic experience(s) through nightmares and flashbacks, have difficulty sleeping, experience intrusive thoughts and feel detached or estranged. Some people with PTSD experience symptoms immediately after the event, while for others symptoms may appear years later. The World Health Organization estimates as of 2025 that approximately 3.9% of the global population, or approximately 320 million people globally, will experience PTSD at some point during their lives. In the U.S., approximately 13 million people suffer from PTSD every year. PTSD disproportionately affects certain demographics including women, people from different racial and ethnic backgrounds and military veterans. The total economic burden for PTSD in the US surpassed $232.2 billion in 2018, or $19,630 per individual with PTSD.

There are limited treatment options for patients with PTSD. Currently only sertraline and paroxetine are approved by the FDA for PTSD. The FDA has not approved any new treatments for PTSD in over 25 years. There remains significant unmet need for PTSD treatments, as only 20-30% of patients treated with currently approved pharmacological interventions for PTSD will reach full remission.

Psilocybin Therapy

Mechanism of Action of Psilocybin

There is an accumulating body of evidence that psilocybin may have beneficial effects on depression and other mental health conditions. We believe that there are multiple mechanisms of action for psilocybin that could provide clinical benefit. As shown in the graphic below, by activating a distinct set of receptors in brain areas critical to mood and cognition, psilocybin acts to induce a range of downstream effects that may have important, sustained effects on brain function. In this way, evidence of the molecular, cellular, and systemic effects of psilocybin in the CNS supports the potential for psilocybin in the treatment of mental health conditions.



1. Stimulation of 5-HT_{2A} receptors results in downstream cascades via G-protein signaling.

2. Simultaneous effects involving multiple neurotransmitters and neuronal activation/signaling.

3. Down-regulation of the default mode network, or DMN, and de-synchronization of cortical activity as well as the emergence of new patterns of functional connectivity across the brain.

4. Sustained cellular changes leading to neuroplasticity and "window of opportunity" for therapy.

Molecular Effects of Psilocybin: Partial Agonism of Serotonin Receptors

At the molecular level, psilocybin is rapidly metabolized to its active metabolite psilocin, which is a partial agonist at several 5-hydroxytryptamine (serotonin) 2A, or 5-HT, receptors, also known as serotonin receptors, including 5-HT_{2A}, $_{2C}$, and $_{1A}$ receptors. This means that psilocin binds to and activates these receptors, all of which are expressed in neurons in different areas of the CNS. In particular, many of the prominent acute effects of psilocybin, such as changes in emotion and cognition, are thought to be mediated by 5-HT_{2A} receptor stimulation, an interpretation that is supported by the fact that blocking the 5-HT_{2A} receptor prevents the psychedelic effects of psilocybin in humans. This mechanism of 5-HT_{2A} receptor stimulation is also implicated as a possible component of the antidepressant action of SSRIs, although these are thought to operate by inhibiting reuptake of serotonin by presynaptic neurons. In contrast, psilocin is believed to initiate an antidepressant effect by directly activating this receptor. The relevance of 5-HT_{2A} receptors in modulating depressive symptoms may is supported by the abundant expression of these receptors in areas of the brain that have important roles in regulating cognitive and emotional processing. Additionally, 5-HT_{2A} receptors are expressed in other key regions of the brain, like the hippocampus and nucleus accumbens, which are associated with functions like memory and reward processing, respectively.

Cellular Effects: Activation of Downstream Signaling Cascades

Activation of 5-HT_{2A} receptors by agonist ligands such as psilocin can modulate a number of downstream signaling cascades to alter the structure and function of neurons, which are important signaling components of the CNS. The 5-HT_{2A}

receptor is a G-protein coupled receptor, which means that it predominantly relays signals through a family of proteins called G-proteins. Specifically, the main signaling cascade downstream of 5-HT_{2A} receptors occurs via the $G\alpha_{q/11}$ protein and leads to increased intracellular calcium release within the cell. In turn, this may promote neuron growth and function. However, non-canonical 5-HT_{2A} receptor signaling cascades specific to certain cell or tissue types may also exist, as there is evidence of certain downstream effects of psychedelic agonists occurring via the $G\alpha_{i/o}$ protein, which typically downregulates signaling pathways related to neurotransmitter release, for example, within neurons. This diverse range of cellular signaling cascades that may be modulated by psilocin likely underlie some of the local circuit-level effects of the drug.

Local Circuit-Level Effects: Neurotransmitter Release and Neuroplasticity

The consequences of 5-HT receptor signaling cascades as modulated by psilocin include (i) changes in activation of neurons in the brain, (ii) neuroplasticity, and (iii) alteration of neurotransmitter release. The activation of neurons, or depolarization, corresponds to positive ions flowing into these cells, which ultimately drives signal transmission and communication between neurons.

Neuroplasticity refers to the ability of the nervous system to reorganize its structure and connections leading to new or adapted functions. This can involve the generation of new neurons, changes in neuron morphology and connectivity, and neurobiochemical changes in receptor and neurotransmitter levels. In particular, the expression of immediate early genes, or IEGs, such as Early Growth Receptor-1, or EGR-1 and Early Growth Receptor-2, or EGR-2, is induced by psilocin. IEGs are genes activated in response to external stimuli and are associated with depolarization. IEGs produce transcription factors that may cause wider changes in gene regulation and, in turn, could enable longer-term neuroplastic changes through structural and connectivity changes at the synapse. The fact that EGR-1 and EGR-2 appear to be induced specifically by psychedelic compounds suggests that these genes could be relevant to the acute and sustained effects of these drugs.

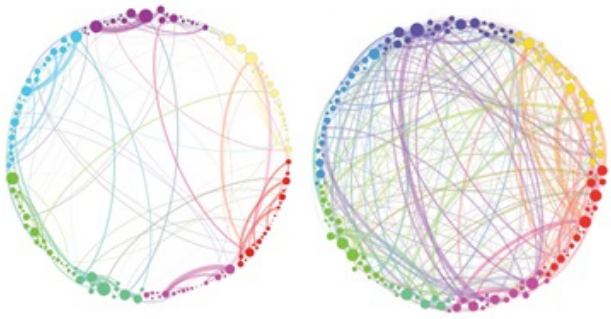
Systemic Effects: Changes in Brain Activity and Functional Connectivity

At the systemic level, psilocybin has been shown to alter the synchronicity of neuronal activation within and between different brain networks, during the psychedelic experience and afterwards. One network that has displayed altered functioning after psilocybin treatment in recent studies is the default mode network, or DMN, a network of brain areas that shows increased activation during self-referential mental activity and recollection of prior experiences and reduced activation during attention-demanding tasks. During the acute experience, psilocybin appears to temporarily reduce synchronicity of areas within the DMN, whereas connectivity between other brain areas and networks is substantially increased.

The below figure is a visualization of the acute changes in brain network connectivity when healthy volunteers were administered with placebo (left) or psilocybin (right). Lines represent connections between or within brain networks (shown as nodes), with the width of those lines representing the weight of each connection. The size of each node corresponds to the sum of its weighted connections. Colors represent communities of networks or regions that are more commonly connected to one another than networks in different communities.

Simplified Visualization of the Acute Changes in Brain Network Connectivity

Placebo **Psilocybin**



Study analyzed fMRI (functional magnetic resonance imaging) data from healthy volunteers to compare resting-state functional brain connectivity after intravenous infusion of placebo and psilocybin. Adapted from Petri et al, 2014.

On the day after these acute effects, individuals administered with psilocybin may exhibit increased synchronicity within the DMN, as well as changes between areas of the DMN and other brain regions. These brain network alterations may indicate the emergence of novel patterns of connectivity upon decoupling of the DMN and could lead to longer-term changes, such as altered emotional processing, that may ultimately affect behavior.

Investigational COMP360 Psilocybin Clinical Development Programs

COMP360 is our proprietary psilocybin formulation that includes our pharmaceutical-grade polymorphic crystalline psilocybin, optimized for stability and purity. We have conducted and/or are conducting clinical development programs in TRD, PTSD and anorexia nervosa.

In our clinical trials, health care professionals, who possess an active license in good professional standing and have the relevant education, experience and training, are engaged and adhere to the below protocols, which are designed to monitor and safeguard clinical trial participants during their psychedelic experience. We have a manualized and standardized process to train healthcare professionals for consistent delivery across all our trial sites. An outline of the support model used in our clinical trials and our training program was published in January 2025 in the peer-reviewed *American Journal of Psychiatry.*

Our trial protocols provide that such support is delivered over three different phases: preparation, the COMP360 administration session, and post-administration follow-up.

- **Preparation:** The objectives of the preparation sessions are to establish a therapeutic alliance between the patient and healthcare professional, and to demonstrate and practice the skills of self-directed inquiry and experiential processing, which we believe are critical for embracing the psychedelic experience in the psilocybin administration session. We have created an online preparation platform and MyPathfinder app for patients where they can learn more about what to expect from the experience and how to prepare for it.

- **COMP360 administration:** A COMP360 administration session lasts approximately six to eight hours and at least one healthcare professional is present throughout the session to monitor and safeguard participants in our clinical trials. The healthcare professional's goal during the session is to establish psychological safety, minimize anxiety and encourage openness to all emerging experiences. The session takes place in a room designed to have a comfortable and calming ambience. Patients wear eye shades to help them focus internally, lie on a bed, and listen to a carefully curated music playlist through a high-quality sound system and earphones. After the acute effects of psilocybin subside, patients are evaluated for safety and discharged.

- **Post-administration follow-up:** The objectives of the follow-up sessions are to help patients process the range of emotional and physical experiences facilitated by the psychedelic experience and to integrate any new insights that can lead to cognitive and behavioral changes. We believe COMP360 psilocybin can give patients a sense of agency, whereby they feel separate from their symptoms and empowered to make changes in their lives.

The methods used in our clinical trials are based on our current understanding of psilocybin's potential to disrupt dysfunctional neural pathways, to allow patients to generate new insights and perspectives leading to reduced negativity or rigidity in thinking. This rapid modification of thought patterns can be uncomfortable or anxiety-provoking. In our clinical trials, healthcare professionals refrain from intervening with the patient's experience, unless required for safety reasons.

Phase 2b Trial of Our COMP360 Psilocybin Treatment in TRD

In 2021, we completed a Phase 2b international multi-site, randomized, controlled, double-blind, dose-finding clinical trial to assess the safety and efficacy of active doses of COMP360 (10mg or 25mg) compared with 1mg COMP360 in 233 patients suffering with TRD, across 22 trial sites in 10 countries in North America and Europe. In November 2022, *The New England Journal of Medicine* published the positive results from our Phase 2b trial of COMP360 psilocybin treatment for TRD.

Trial Design

Participants who were on serotonergic medications were required to taper off their medicine at least two weeks prior to the baseline (Day -1) visit. Prior to administration, participants received at least one, and up to three, preparatory sessions with an assigned healthcare professional, in order to be informed and prepared for the COMP360 psilocybin session. During the COMP360 psilocybin session, a single dose of COMP360 was administered to participants. The objective was to provide a

safe and supportive environment during the session. Participants received two post-administration follow-up sessions with their healthcare professionals in which the psychedelic experience was discussed. Participants were followed for up to 12 weeks, with a visit the day after administration followed by weekly visits for the first three weeks, and visits every three weeks for the remaining nine weeks.

The primary endpoint of this trial was the change in the MADRS total score from baseline to week 3. MADRS, as assessed by independent raters in native language, is a widely accepted assessment of mood disorders. This variable was also being analyzed for change from baseline to Day 2, weeks 1, 6, 9 and 12. This Phase 2b clinical trial was powered to capture a statistically significant reduction in MADRS.

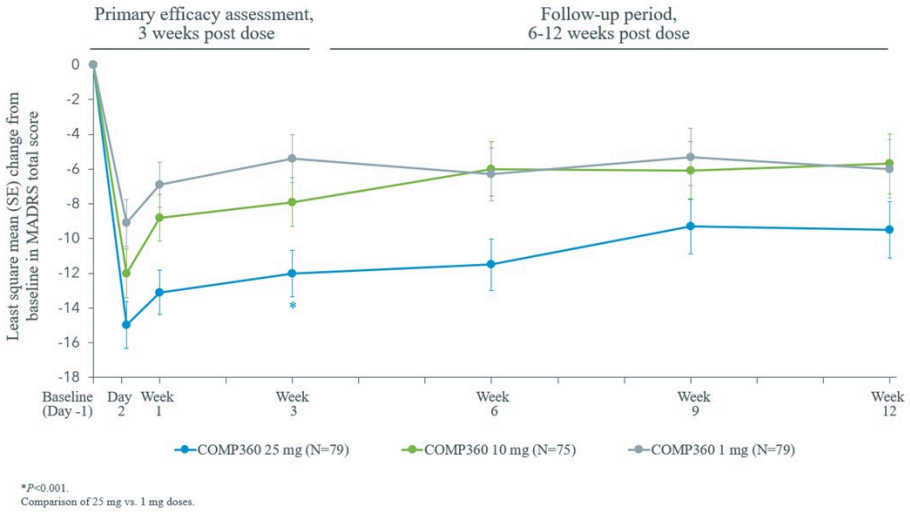
The safety and tolerability of COMP360 in study participants was assessed based on AEs, vital signs, clinical laboratory assessments, ECG findings and suicidal ideation/behavior (measured using the Columbia-Suicide Severity Rating Scale, or C-SSRS score, at all visits).

Enrollment Criteria

We recruited a total of 233 adult patients with TRD into the trial. We define patients with TRD as those who meet Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, or DSM-5, diagnostic criteria for a single or recurrent episode of MDD without psychotic features, who have not responded to an adequate dose and duration of two, three, or four pharmacological treatments for the current episode of depression.

Clinical findings

The Phase 2b study met its primary endpoint. The 25mg group vs the 1mg group showed a -6.6 difference on the MADRS depression scale at week 3 ($p<0.001$). The 25mg group demonstrated statistical significance on the MADRS efficacy endpoint on the day after the COMP360 psilocybin administration, day 2 ($p=0.002$). The 10mg vs 1mg dose did not show a statistically significant difference at week 3. The MADRS was assessed by independent raters who were remote from the trial site, and blind to intervention and study design, effectively creating a triple blind.



MADRS = Montgomery-Åsberg Depression Rating Scale

COMP360 was generally well tolerated, with more than 90% of treatment-emergent adverse events, or TEAEs, being mild or moderate in severity and greater than 77% of TEAEs occurring on the day of administration being resolved on the same day or the next day. 179 patients reported at least one TEAE; the most common TEAEs across treatment groups (>10% overall incidence) were headache, nausea, fatigue, and insomnia. There were 12 patients, 5 patients in the 25 mg group, 6 patients in the 10 mg group and 1 in the 1 mg group, who reported treatment-emergent serious adverse events, or TESAEs. These TESAEs included, among others, suicidal behavior, intentional self-injury, and suicidal ideation, which are regularly observed in a TRD patient population. Two thirds of the patients had previous thoughts of wishing to be dead, as assessed by a suicidality scale completed during patient screening; this included all patients reporting one of these adverse events, meaning that patients who experienced these events during the trial had said in patient screening that they had had suicidal thoughts prior to the trial.

Overall, 209 patients completed the study; there were five withdrawals from the 25mg group, nine from the 10mg, and 10 from the 1mg.

Phase 2 Study of COMP360 Psilocybin Treatment as Adjunct to SSRI Antidepressants

In addition to our completed Phase 2b trial, we also completed a Phase 2 trial of the safety and efficacy of COMP360 in TRD patients when administered as an adjunct to SSRIs. Results of this study were published in *Neuropsychopharmacology* in July 2023.

This open-label study included 19 patients from clinical sites in Ireland and the United States. The primary endpoint was the change in baseline MADRS total score at 3 weeks in patients having 25mg COMP360 psilocybin treatment given in augmentation with their existing SSRI antidepressant regimen.

Clinical Findings

The baseline MADRS score of participants entering the study was 31.7, representing moderate to severe depression. At week 3, 8 of the 19 participants (42.1%) were responders and all 8 were also remitters. The mean reduction from baseline observed in MADRS total score was 14.9 at week 3. There was a rapid response from day 2 to week 3 after COMP360 therapy, which is consistent with the Phase 2b result.

COMP360 psilocybin treatment using a 25mg dose also showed overall signals of improvement in most other measures including improvement in anxiety, clinician and self-rated depressive symptoms, and positive and negative affect.

25mg COMP360 psilocybin treatment was generally well-tolerated when it was administered simultaneously with the patient's existing SSRI treatment. There were no TEAEs classed as serious (life threatening, leading to disabilities, hospitalization or in general medically significant) and no TEAEs related to suicidal ideation or behavior or intentional self-injury.

Long-Term Phase 2 Study

In March 2025, the results from our observational, 52-week follow-up study (COMP004) of 66 participants who took part in our Phase 2b trial were published in the *Journal of Clinical Psychiatry*. Of the 66 participants, 22 participants were in the 25mg group, 19 participants were in the 10mg group, 17 participants were in the 1mg group and 8 participants were in the 25mg plus SSRI group. The primary endpoint of this COMP004 study was the median time to a new depressive event. The pre-specified primary analysis was of the median time for such an event for all participants in our Phase 2b trial, not only those who enrolled in the COMP004 study. The median time to a new depressive event was 92 days for the COMP360 25mg group compared to 86 days for the 10mg group and 62 days for the 1mg group.

A post hoc analysis of the 58 participants who enrolled in the COMP004 from our Phase 2b trial revealed a substantial difference in median time to depressive event for those in the 25 mg group compared to the 10mg and 1mg groups, with median times of 189 days for the 25 mg group, 43 days for the 10 mg group, and 21 days for the 1 mg group.

COMP360 was generally well tolerated. Three participants reported experiencing a treatment emergent serious adverse event post-enrollment to COMP004, occurring more than 6 months after a single dose administration and all deemed unrelated to study drug. With respect to adverse events, twenty-seven or 40.9% of participants had an adverse event that was ongoing as of, or started, after week 12. In addition, a lower proportion of participants started new treatments for depression in the 25mg

and 10mg arm compared to the 1mg arm. Suicidality was recorded as an adverse event across all arms with two in each of the 25mg group and the 10mg group, and one in the 1mg group. The outcomes of the long-term follow-up study informed the design of our Phase 3 registrational program, including investigating whether a second administration of COMP360 may achieve improved durability, response and remission outcomes.

Phase 3 Registrational Program

We are conducting two Phase 3 pivotal trials. The first pivotal trial, COMP005, is a randomized, double-blind, placebo-controlled study, with 258 dosed participants across 40 trial sites in the United States, and is assessing the efficacy and safety of a single dose of 25 mg COMP360 versus placebo for reducing symptom severity in TRD (COMP360 25 mg: n=171; placebo: n=87). The second pivotal trial, COMP006, is a randomized, double-blind study with 581 dosed participants across 116 trial sites in the United States, Canada and Europe and is comparing the efficacy and safety of two fixed doses, taken three weeks apart, of 25 mg COMP360 to 10 mg COMP360 and 1 mg COMP360 (25 mg: n=296; 10 mg: n=142; 1 mg: n=143).

The primary endpoint in both pivotal trials is the change from baseline in the MADRS total score at week 6.

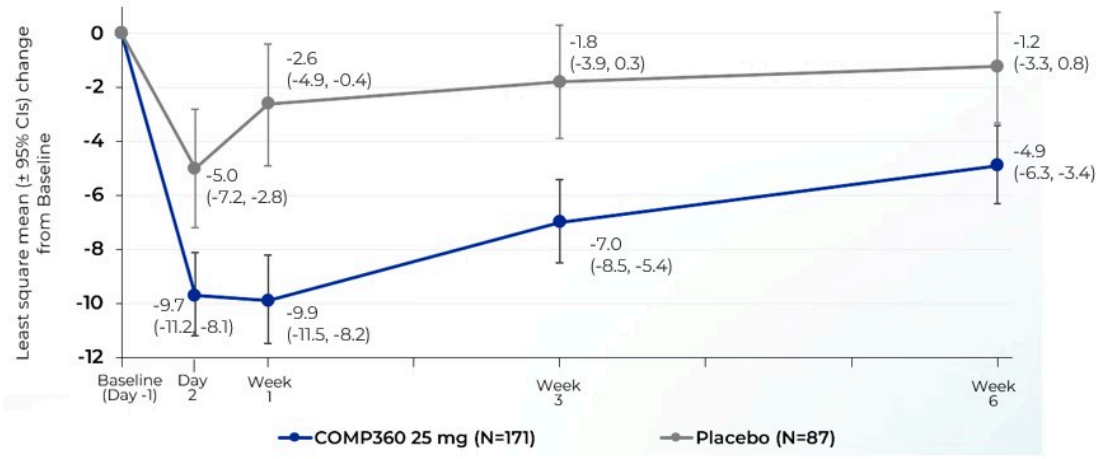
Each of these trials has three parts: Part A is the primary efficacy portion at Week 6, Part B is a blinded 20 week portion and Part C is a 26-week open-label portion. In Part B, participants who complete Part A will be followed for 20 weeks and those who meet criteria for re-treatment will have the option to receive an additional treatment dose according to their assigned dose. Participants who complete part B and go into Part C during which participants who meet criteria for re-treatment may receive a 25mg dose of COMP360 psilocybin. We believe that this design will enable us to appropriately characterize the efficacy, safety and durability of COMP360 administration.

Clinical Findings

COMP005 Trial

We reported that the first pivotal trial, the COMP005 trial, achieved its primary endpoint, with a single 25mg dose of COMP360 versus placebo demonstrating a highly statistically significant reduction in symptom severity as measured by MADRS with a p-value of $p<0.001$ and a clinically meaningful difference of -3.6 in change at six weeks. The COMP005 trial is on-going and is comprised of three parts: Part A, which concluded during the second quarter of 2025, and was blinded through 6 weeks; Part B, which remained blinded through week 26; and Part C, which contains an open-label treatment part from week 26 to 52.

Primary endpoint - Change in MADRS at Week 6

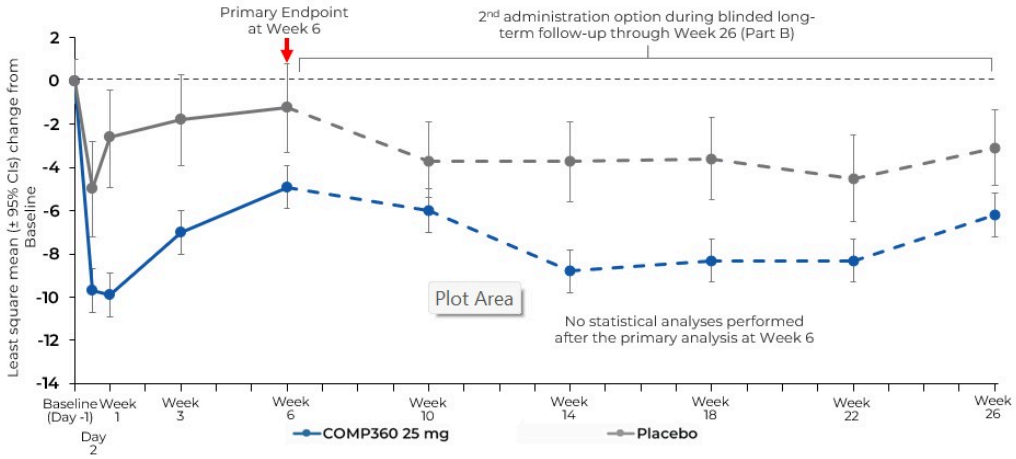


CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery-Åsberg Depression Rating Scale; SD=standard deviation.

Part B - Change in MADRS through Week 26

Through the randomized and blinded Part B up to week 26, the results show that there was a consistent separation between 25 mg of COMP360 and placebo. During Part B, based on pre-specified criteria, participants were eligible either for a second administration of the treatment to which they were randomized or to resume antidepressants. During Part B, 70% of participants in the 25mg arm and 53% of participants in the placebo arm received a second administration.

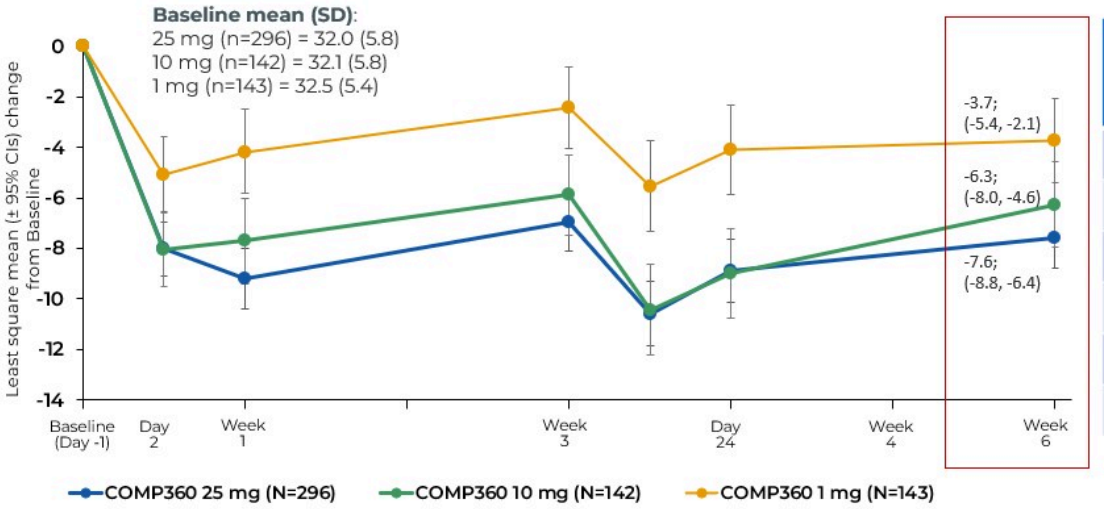
For participants who had a clinically meaningful reduction in MADRS (≥ 25%), a statistically significant rapid onset from the day following administration was maintained at all measured timepoints through Week 6 in the 25 mg arm. Twenty-five percent of participants in the 25 mg arm achieved a clinically meaningful reduction in MADRS (≥ 25%) at Week 6 with durability lasting out through 26 weeks after just one or two doses of 25 mg. Over 40% of those who achieved a clinically meaningful reduction in MADRS but had not remitted by 6 weeks went into remission after the second dose in Part B.



COMP006 Trial

We reported that the second pivotal trial, the COMP006 trial, achieved its primary endpoint with two fixed doses, administered 3 weeks apart, of COMP360 25 mg versus 1 mg demonstrating a highly statistically significant reduction in symptom severity with a p-value of <0.001 and a clinically meaningful difference of -3.8 points in change at six weeks. Thirty-nine percent of participants in the 25 mg arm achieved a clinically meaningful reduction in MADRS (≥ 25%) at Week 6. For participants who achieved a clinically meaningful reduction in MADRS (≥ 25%), a statistically significant rapid onset from the day following administration was maintained at all measured timepoints through Week 6 in the 25 mg arm.

Primary endpoint - Change in MADRS at Week 6



Phase 3 Program - Safety Data

Across Parts A and B of the ongoing COMP005 trial and Part A of the ongoing COMP006 trial, COMP360 is demonstrating a generally well tolerated and safe profile, with most TEAEs being mild or moderate in severity and resolving within a day. In Parts A and B of the ongoing COMP005 trial, 66% of TEAEs occurred on the day of administration and 88% of TEAEs resolved within a day. In Part A of the ongoing COMP006 trial, 73% of TEAEs occurred on the day of administration and 83% of TEAEs resolved within a day. For Parts A and B of the ongoing COMP005 trial, the most common TEAEs across treatment groups (>10% overall incidence) were headache, nausea and visual hallucination. For Part A of the ongoing COMP006 trial, the most common TEAEs across treatment groups (>10% overall incidence) were headache, nausea, anxiety, visual hallucination, illusion, dizziness, fatigue, crying and increased blood pressure. In the ongoing COMP005 trial, through 26 weeks, there were 11 TESAEs reported by 8 participants in the 25 mg arm. In the ongoing COMP006 trial, through Part A, there were 6 TESAEs reported by 6 participants in the 25 mg arm. Across both trials, for the data available as of our February 17, 2026 data announcement, the rate for SAE suicidal ideation was less than 1% and there was only one event of SAE suicidal behavior, which occurred in the 1 mg arm in COMP006.

Phase 2 Study in PTSD

In August 2025, the results from our Phase 2 clinical trial to assess the safety and tolerability of COMP360 psilocybin treatment, as a monotherapy in participants with PTSD, as a result of trauma experienced as adults, were published in the *Journal of Psychopharmacology*.

Trial Design and Demographics

The Phase 2 trial was a multicenter, fixed-dose open label trial. Participants were required to taper off their medicines. Twenty-two participants received a single 25mg dose of investigational COMP360 psilocybin treatment, along with support and monitoring provided by a licensed medical professional, which consisted of preparing participants for the treatment session, observing and being present with participants during the session and supporting them after the session. In line with the study design, participants were monitored for a 12-week period post dosing. Primary endpoint was safety at week 12; available secondary endpoints were change in CAPS-5 from baseline and change in SDS total score from baseline.

The mean baseline severity of symptoms was a baseline of 47.5 (minimum of 25; maximum of 64) CAPS-5 total score, which is considered severe. The CAPS-5 assessment involves a structured interview that provides a PTSD diagnosis and measures symptom severity. The average age of participants at the time of screening was 39 and patients diagnosed with complex PTSD were excluded from study eligibility. The study was conducted at The Institute of Psychiatry, Psychology and Neuroscience at King's College London, Icahn School of Medicine at Mount Sinai in New York and Sunstone Therapies in Rockville, Maryland.

Clinical Findings

The study met its primary safety endpoint and available secondary efficacy endpoints. Study observations included meaningful and sustained symptom improvement from baseline in mean CAPS-5 total score, a measure of disease severity, and in Sheehan Disability Scale or SDS, score, a measure of functional impairment in daily life. Administration of COMP360 was well-tolerated, with a safety profile consistent with previous studies.

The key findings include:

• Administration was generally well tolerated, with no serious adverse events observed. There were no treatment-emergent serious adverse events. Treatment-emergent adverse events included headache (n=11 or 50.0%), nausea (n=8 or 36.4%), crying (n=6 or 27.3%), and fatigue (n=6 or 27.3%). There were two adverse events of suicidal ideation that resolved during the study. The first was a moderate and transient event which resolved on administration day in a patient who went on to be a responder, and it was deemed to be related to study drug. The second event was mild and occurred at week 7 in a non-responder, resolved during the study, and was deemed to be possibly related to study drug. Both participants had previous history of suicidality as measured by the Columbia-Suicide Severity Rating Scale.

• Durable improvement in symptoms from baseline observed following a single administration. Improvement in mean CAPS-5 total score from a baseline of 47.5 was observed (29.9 point reduction at week 4 and 29.5 point reduction at week 12).

• Improvement over time in SDS measure of functional impairment over 12 weeks. From a mean SDS total score of 22.7 at baseline, there was a 11.7 point reduction at week 4 and a 14.4 point reduction at week 12.

• High and sustained rates of response and remission relative to baseline, with early onset of symptom improvement. Response, as defined by patients experiencing a ≥ 15-point improvement on CAPS-5 score, was 81.8% at week 4 and 77.3% at week 12. Remission, as defined by CAPS-5 total score of ≤ 20, was 63.6% at week 4 and 54.5% at week 12.

• No patients withdrew from the study and no patients returned to antidepressant medication treatment during the trial.

The outcomes of this Phase 2 trial informed the design of our Phase 2b/3 trial in PTSD.

Phase 2b/3 Trial in PTSD

The phase 2b/3 multicenter, randomized, double-blind, controlled trial, with an open label extension, aims to investigate the efficacy, safety, and tolerability of COMP360 in participants with PTSD.

The study is comprised of 2 parts:

Part A (blinded) is a 12-week fixed repeat-dose, double-blinded, controlled part to confirm the efficacy of two administrations of COMP360 25 mg versus two administrations of COMP360 1 mg. The second COMP360 administration session will occur approximately 4 weeks later. The primary efficacy endpoint is the change from baseline in CAPS-5 total severity score at Week 8.

Part B (open-label) is a 40-week open-label follow-up to evaluate the long-term safety and efficacy of treatment in Part A. Eligible participants may receive a single open label retreatment with COMP360 25 mg. In both Part A and Part B, COMP360 may be administered adjunctively to a single permitted oral antidepressant.

Phase 2 Trial in Anorexia

In August 2025, we reported data from a double-blind randomized controlled Phase 2 clinical trial investigating the safety and efficacy of COMP360 psilocybin in participants with anorexia nervosa. It was a multicenter study and enrolled 32 patients. This Phase 2 clinical trial evaluated COMP360 dosed at 25mg against a control arm of participants receiving COMP360 1mg. There was an encouraging positive signal of improvement in eating disorder symptom score sustained through 12 weeks in the 25mg arm, but the low overall numbers of participants and high number of dropouts in the control arm (only 6 of the 11 participants in the control arm completed the study) limited the statistical power of the study. The safety profile was aligned with the high-risk patient population of anorexia nervosa and no unexpected safety signals were reported. There was no clinically meaningful imbalance in suicidal ideation across arms.

Other Indications: Investigator-Initiated Studies, or IISs

With respect to clinical studies, we work with leading academic institutions and researchers under IIS clinical trial agreements. These institutions include: Imperial College London, King's College London, Maryland Oncology Hematology, New York State Psychiatric Institute at Columbia University Medical Center, Sheppard Pratt, UC San Diego School of Medicine, University of Copenhagen, and University of Zurich. The indications previously explored or currently being explored in these IIS signal-generating and mechanistic studies include: anorexia nervosa, autism, bipolar type II depression, body dysmorphic disorder, chronic cluster headache, depression in cancer, MDD, severe TRD, and suicidal ideation.

We supply our IIS researchers with COMP360 psilocybin and encourage the open publication of all study findings. If an IIS using COMP360 psilocybin produces results with the potential to improve mental health care, we may seek to advance this research through a clinical development program, with the goal of making it available for patients, although we have no pre-existing contractual right to do so. In addition to providing our IIS researchers with COMP360 psilocybin, we have in the past offered, and may continue to offer, support with regulatory submissions. Through our IIS collaborations, we ultimately hope to bring more innovation to patients, as quickly and safely as possible.

In May 2022, we announced that we would fund an IIS that will use COMP360 psilocybin to explore how COMP360 psilocybin affects specific brain pathways in autistic adults. The double-blind, randomized, placebo-controlled study will investigate whether there is a difference in the function of serotonin brain networks in autistic and non-autistic adults. The researchers will use a range of imaging techniques and behavioral tasks to examine how the serotonin system is modulated by COMP360 psilocybin. This exploratory study is being conducted by a research scientist who is employed by us and is a PhD student at King's College London. The study is being conducted at the Institute of Psychiatry, Psychology & Neuroscience, or IoPPN, at King's College London and is co-sponsored by King's IoPPN and South London and Maudsley NHS Foundation Trust. It will enroll 70 adult participants, including 40 autistic people and 30 non-autistic people.

Data from IISs

In 2020, Imperial College London, London, UK completed an IIS of COMP360 titled "Psilocybin for Major Depressive Disorder: Comparative Mechanisms" (Psilodep-RCT, ClinicalTrials.gov Identifier: NCT03429075). In this randomized, double-blind, exploratory clinical trial, the efficacy and mechanisms of action of COMP360 were compared with those of a six-week course of the SSRI, escitalopram. A total of 59 adult participants with MDD of at least moderate severity were randomized to receive either two 25mg doses of COMP360 three weeks apart or six weeks of daily escitalopram (10mg for three weeks and 20mg for the following three weeks) alongside two 1mg doses COMP360 three weeks apart. In both trial arms, participants received psychological support as part of the trial. The primary efficacy endpoint of the change from baseline on the 16-item Quick Inventory of Depressive Symptomatology-Self-Report (QIDS-SR-16) showed a two-point trend in favor of the COMP360 arm which was apparent from week 1. Adjusted-response rates for QIDS-SR-16 (defined as ≥50% reduction from baseline in the QIDS-SR-16 total score) at week 6 were 70.2% for the COMP360 arm vs. 48.0% for the escitalopram arm and adjusted-remission rates (defined as a QIDS-SR-16 total score ≤5) at week 6 were 57.1% and 29.1%, respectively. For the MADRS – a more widely used and accepted clinician-rated scale which Compass is using as the primary endpoint in their clinical trials – a least square means treatment difference of -7.2 was found. Similar patterns were found on

other secondary endpoints measuring work and social functioning, anxiety, avoidance, anhedonia, and wellbeing. This work has been published in the *New England Journal of Medicine* (Carhart-Harris et al. 2021).

In 2021, Maryland Oncology Hematology at the Aquilino Cancer Center in Rockville, Maryland, U.S. completed an IIS of COMP360 titled "The Safety and Efficacy of Psilocybin in Cancer Patients with Major Depressive Disorder" (ClinicalTrials.gov Identifier: NCT04593563). In this open-label study involving 30 patients with a cancer diagnosis and MDD, patients received a 25mg dose of COMP360 in conjunction with psychological support. Patients began with an average MADRS score of 25.9, representing moderate depression and after COMP360 psilocybin treatment, the average score decreased by 19.1 points. A sustained response (a decrease of ≥50% in the MADRS total score from baseline observed at any visit up to and including week 3, and also fulfilled at week 8) was seen in 24 patients; 15 patients showed remission of depressive symptoms (a MADRS score <10) one week after a single dose of COMP360, which was sustained up to eight weeks. COMP360 psilocybin treatment was found to be generally well-tolerated with no treatment-related serious adverse events. Adverse effects on the day of dosing were transient and as expected in line with other studies included headache, changes in sensory perception, and mood alteration. Top-line results were published in JAMA Oncology in April 2023 and the full results and methodology from this study were published in *Cancer* in December 2023.

In 2022, Sheppard Pratt Health System completed an IIS of COMP360 titled "An Open Label Study of the Safety and Efficacy of COMP360 in Participants With Severe Treatment-Resistant Depression (P-TRD)". The investigator presented data from this study at the Society of Biological Psychiatry Annual Meeting in the second quarter of 2022. In this open-label study involving 12 patients with severe treatment-resistant depression, patients received a 25mg dose of COMP360 with psychological support. All participants had tried at least five antidepressant treatments without success, prior to joining the study. The researchers found that 58.3% (n=7) of the participants had maintained MADRS response criteria at 12 weeks after COMP360 psilocybin administration, and a quarter had maintained remission (n=3). There was no increase in the suicidality score based on the MADRS, and no treatment-related serious adverse events were reported throughout the study.

In 2022, the University of California San Diego School of Medicine completed an IIS of COMP360 titled "Evaluation of Psilocybin in Anorexia Nervosa: Safety and Efficacy." (ClinicalTrials.gov Identifier: NCT04661514). The investigator presented data from this study at the Society of Biological Psychiatry Annual Meeting in the second quarter of 2022. In this open-label study involving 10 patients with anorexia nervosa, patients received a 25mg dose of COMP360 in conjunction with psychological support. The primary aim of this study was to assess the safety and tolerability of a single 25mg dose of psilocybin in participants with anorexia nervosa based on adverse events, changes in vital signs, electrocardiograms and clinical laboratory tests. Forty percent (n=4) experienced clinically meaningful reductions at the 3-month follow-up, based on global score on the Eating Disorder Examination, or EDE. Participants demonstrated nominally statistically significant reductions in shape concerns on the EDE at the 1-month follow-up (mean change from pre-treatment=1.3; p=0.028), and nominally statistically significant reductions in eating concerns on the EDE at the 3-month follow-up (mean change from pre-treatment=1.1; p=0.047). Changes in weight concerns on the EDE were approaching nominal statistical significance at the 3-month follow-up but were not statistically significant (mean change from pre-treatment=1.2). COMP360 psilocybin treatment was well-tolerated with no treatment-related serious adverse events reported. In July 2023, the results of this study showing the potential of investigational COMP360 psilocybin treatment in anorexia nervosa were published in *Nature Medicine*.

In 2022, Sheppard Pratt Health System completed an IIS of COMP360 titled "The Safety and Efficacy of Psilocybin in Participants With Type 2 Bipolar Disorder Depression." (ClinicalTrials.gov Identifier: NCT0443384512). The investigator presented data from this study at the Annual Meeting of the American College of Neuropsychopharmacology in December 2022. In this open-label study involving 14 patients with type 2 bipolar depression, patients received a 25mg dose of COMP360 with psychological support. The study found that 86% (12 out of 14) of the participants met response and remission criteria for the MADRS scale at 12 weeks after COMP360 psilocybin treatment. There was no increase in the suicidality score based on the MADRS, no manic symptoms and no unexpected adverse events or difficulties with the dosing sessions reported throughout the study. No treatment-related serious adverse events were reported. In December 2023, the results of this study demonstrating the potential of investigational COMP360 psilocybin treatment in type 2 bipolar depression were published in *JAMA Psychiatry*.

In 2022, University of Zurich completed an IIS of COMP360 titled "Phase II, Randomized, Double Blind, Placebo Controlled, Parallel Group, Single Center Study of Psilocybin Efficacy in Major Depression." (ClinicalTrials.gov Identifier: NCT03715127). The investigator published data from this study in *The Lancet (Von Rotz et al, Lancet 2023; 56:101809).* In this double-blind, randomized clinical trial, 52 patients with major depressive disorder were randomized 1:1 to receive either a single, moderate dose (0.215 mg/kg body weight) of COMP360 psilocybin or placebo in conjunction with psychological

support. MADRS and Beck's Depression Inventory, or BDI, scores were assessed to estimate depression severity and the primary endpoints were defined as changes from baseline to two weeks after the administration of COMP360. At the two-week endpoint, response rates resulted in 58% for MADRS (COMP360 psilocybin: 15/26 vs. Placebo: 4/26; P = 0.0034) and for BDI in 54% (COMP360 psilocybin: 14/26 vs. Placebo: 3/26; P = 0.0025). At the two-week endpoint, remission rates were reported in 54% of patients for MADRS (COMP360 psilocybin: 14/26 vs. Placebo: 3/26; P = 0.0023) and assessed by BDI in 46% (COMP360 psilocybin: 12/26 vs. Placebo: 3/26; P = 0.013). Adverse events were in line with other studies and included headache, dizziness, nausea and diarrhea. No cases of suicidal behavior occurred during the trial period of approximately one month and no treatment-related serious adverse events were reported.

Preclinical and Drug Discovery Programs

Prior to our strategic reorganization in the fourth quarter of 2024 and decision to stop all non-COMP 360 preclinical activities to allow us to focus entirely on advancing development of our investigational COMP360 psilocybin treatment, we progressed a number of preclinical initiatives during 2024. We retain rights to these preclinical assets and may in the future decide to resume our preclinical activities.

Mechanistic Studies

We continue to work with a small group of academic researchers and CROs to investigate mechanistic characteristics of psilocybin treatment. We currently have a network of studentships predominantly within the United Kingdom (namely at the following universities: University of Oxford, University of Bristol, University of Reading and University of Southampton, University of Cardiff) to research elements of this work. Our mechanistic research utilizes our COMP360 and currently focuses on the following themes:

- Study of the mechanisms by which psilocin, the active moiety of our high-purity polymorphic crystalline formulation of psilocybin, and other psychedelic agents engage receptors in recombinant cell-based assays (collaboration with Professor Trevor Sharp, University of Oxford). The aim here is to understand which systems are optimal to use for discovery research, how different drugs may influence receptor-mediated signal transduction, and how mechanisms of biased agonism may play into mechanistic effects;

- Through collaborations with the University of Bristol (Professor Emma Robinson and Professor Jack Mellor , in particular), we are also investigating the integrated electrophysiological response to psychedelic administration, to determine how changes in neuronal excitatory activity mediate brain-wide changes in resting state network activity and how these influence sustained changes in behavior;

- Preclinical academic collaborations with the University of Bristol, Harvard University, Oxford University and the Southern Denmark University have studied the effects of our high-purity polymorphic crystalline formulation of psilocybin on different aspects of behavior, including affective bias, reward learning and compulsive behavior that may provide insights relevant to information processing alterations frequently observed in mental health conditions. In particular, work at the University of Oxford (collaboration with Professor Mark Walton) is utilizing novel behavioral pharmacological techniques to assess the impact of our high-purity polymorphic crystalline formulation of psilocybin for effects on cognitive flexibility at periods hours to days after administration.

- Collaborations with the University of Reading and the University of Southampton also focus on understanding what the potential role of inflammatory modulating processes might be in the mechanism of action of COMP360, and consider whether COMP360 may have utility in other types of CNS indications. Collaborations with the University of Cardiff (Professor Dominic Dwyer) will also consider effects of COMP360 on measures of affective behavior and anhedonia in transgenic mice carrying disease-relevant genetic mutations, and integrate these findings with cellular and electrophysiological changes;

These studies will further our understanding of the mechanism of action for COMP360 and could inform our future decisions over which other indications, if any, to explore, beyond TRD and PTSD.

Drug Discovery Center

On August 5, 2020, we established a Drug Discovery Center under a sponsored research agreement with the University of the Sciences in Philadelphia, Pennsylvania (which merged into Saint Joseph’s University in 2022), or USciences, to focus on developing optimized psychedelic and related compounds targeting the 5-HT_{2A} receptor, which is believed to mediate the

potential therapeutic effects of psychedelics. Further to the strategic reorganization we announced in the fourth quarter of 2024 and our decision to stop non-COMP360 preclinical and discovery work and focus all our resources on advancing development of our investigational COMP360 treatment, this agreement with USciences was not renewed and will terminate in the second quarter of 2025.

Pursuant to the agreement, USciences performed research services on our behalf, and granted us an exclusive, royalty bearing, worldwide license, including rights to sublicense, all jointly held intellectual property for any and all purposes, and a non-exclusive, fully paid-up, worldwide license to any pre-existing intellectual property utilized over the course of performing the services. As of December 31, 2024, we had identified one compound under this agreement. If in the future we decide to resume development efforts for this compound, we would be obligated to make tiered payments upon completion of certain milestones to USciences for up to an aggregate of $0.9 million per licensed product covered by a valid claim of a patent included in the intellectual property rights licensed to us under the agreement, as well as a low single-digit royalty percentage on annual net sales of licensed products covered by a valid claim of a patent included in the intellectual property rights licensed to us under the agreement, subject to certain reductions. In addition, USciences is entitled to a low double-digit percentage of sublicense revenue for agreements entered into prior to a Phase 2 trial, and a mid-single-digit percentage of sublicense revenue for agreements entered into after the start of a Phase 2 trial.

Ongoing research on prodrug development led to a number of potential candidate leads being identified. We retain rights to these potential candidates and in the future to the extent that we decide to resume non-COMP360 preclinical activities we may continue such potential candidates through further research-based development.

Investment

Delix Therapeutics

We have a strategic investment in Delix Therapeutics, Inc., a clinical-stage neuroscience company developing novel neuroplasticity-promoting therapeutics for psychiatric and neurological disorders. In March 2020, we purchased 1,250,000 shares of series seed preferred stock. In November 2025, we participated in a simple agreement for future equity financing to the extent of our pro-rata ownership of Delix and invested an additional approximately $20,500.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely on contract drug manufacturing organizations, or CDMOs, to synthesize the active pharmaceutical ingredient, or API, that comprises COMP360, and to blend the API excipients and encapsulate. All manufacturing processes are contracted to be compliant with current Good Manufacturing Practice, or cGMP. We expect to continue to rely on third parties for the production of all clinical supply drug substance and drug product that we may use. We use additional contract manufacturers to fill, label, package, store and distribute our drug product. We currently rely on a single supplier for our API but have identified additional manufacturers who have the appropriate experience and expertise to act as back-up suppliers of API and fill-and-finish services. We believe we maintain sufficient supply of API to avoid any material disruptions in the event of any need to replace one or more of our suppliers.

Commercialization

If our COMP360 psilocybin treatment is approved, we plan to use our own sales and marketing capabilities, targeting public and private healthcare providers and clinic networks in the U.S. In select geographies outside the U.S., we may enter into commercialization collaborations with third parties who have complementary commercial capabilities.

We recognize that COMP360 psilocybin treatment, if approved, represents a new approach for many clinical practices and that delivering COMP360 is expected to require the ability to implement COMP360 seamlessly within a provider’s operating practice. In order to ensure we understand implementation challenges, we have entered into a number of collaboration agreements with numerous different types of health care delivery systems in the U.S. We have entered into collaboration agreements with Greenbrook Mental Wellness Centers (acquired by Neuronetics, Inc. in December 2024), a leading provider of interventional psychiatric treatments in the U.S.; Hackensack Meridian Health, a leading not-for-profit health care organization in New Jersey, addressing the full continuum of care for people living with mental health conditions; Reliant Medical Group, an Optum company and integrated primary and specialty care organization; Journey Clinical, a leading psychedelic-assisted psychotherapy platform in the US; Mindful Health Solutions, one of the U.S.’s leading providers of innovative behavioral health care; HealthPort, a multi-site comprehensive community health organization helping people impacted by social determinants of health; and Radial Health, a growing national network of interventional psychiatry

practices leveraging technology and operations expertise to optimize models of care delivery. The goal of these collaborations is to research and investigate models for the delivery of scalable, commercial COMP360 psilocybin treatment within various types of healthcare delivery systems, assuming FDA approval.

We have established Centers of Excellence to serve as research facilities and innovation labs. In strategic collaboration with King's College London and South London and Maudsley NHS Foundation Trust, or SLaM, we opened The Center for Mental Health Research and Innovation with an overarching goal of accelerating patient access to evidence-based innovation in mental health care by driving forward research in psychedelic therapies through, among other things, the development of working model psychedelic treatment clinics, training programs, conducting clinical trials, and data analysis. The Center currently serves as a clinical trial site for our Phase 3 COMP006 trial.

Competition

Our industry is characterized by many newly emerging and innovative technologies, intense competition and a strong emphasis on proprietary product rights. While we believe that our investigational COMP360 psilocybin treatment represents a fundamental shift in the treatment paradigm relative to other TRD treatments, we face potential competition from many different sources, including major pharmaceutical, biopharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and medical research organizations. Any product candidates that we successfully develop and commercialize, including our investigational COMP360 psilocybin treatment, will compete with the standard of care and new therapies, both pharmacological and somatic, that may become available in the future.

Currently, only two pharmacotherapies are approved for TRD in the U.S.: Spravato (esketamine), marketed by Janssen, which is an NMDA receptor antagonist; and olanzapine and fluoxetine hydrochloride capsules, which are available generically. Because TRD, by definition, encompasses patients who have not been helped after two or more MDD therapies, antidepressants indicated for use in MDD are frequently prescribed, combined or augmented with a second agent to treat TRD patients. Several biopharmaceutical companies have therapies in clinical development for TRD. We are aware that Supernus Pharmaceuticals, Neurocrine Biosciences, GH Research and Beckley Psytech, among others, are developing treatments for TRD or inadequate response to treatment in major depressive disorder.

Multiple somatic therapies are also used in TRD, such as ECT and rTMS. Psychotherapeutic approaches, like CBT, are used for MDD and TRD patients.

We also face competition from 501(c)(3) non-profit medical research organizations, including the Usona Institute. In March 2024, Usona Institute announced the launch of its Phase 3 trial evaluating the efficacy and safety of psilocybin 25 mg as a treatment for major depressive disorder, which is expected to enroll approximately 240 adult patients. Usona has 29 clinical trial sites, completed enrollment for its Phase 3 trial and expects to complete the primary endpoint in its Phase 3 trial in April 2026 and the long-term follow-up portion of its Phase 3 trial in December 2026. Such non-profits may be willing to provide psilocybin-based products at cost or for free, undermining our potential market for COMP360. In addition, a number of for-profit biotechnology companies or institutions are specifically pursuing the development of psilocybin to treat mental health illnesses, including Helus Pharma, Inc. (formerly Cybin Inc.), or Helus. In March 2024, Helus announced the design of its Phase 3 program for its deuterated psilocybin analog for the adjunctive treatment of major depressive disorder, which includes two Phase 3 trials and is expected to enroll approximately 550 adult patients. In November 2024, Helus announced the initiation of its Phase 3 program.

We are aware of other organizations or institutions evaluating the use of psilocybin in mental health and neurocognitive conditions. In addition, there are various companies exploring other psychedelic compounds for the treatment of mental health and neurocognitive conditions.

Many of the pharmaceutical, biopharmaceutical and biotechnology companies with whom we may compete have established markets for their therapies and have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market superior products or therapies. In addition, many of these potential competitors have significantly greater experience than we have in undertaking non-clinical studies and human clinical trials of new therapeutic substances and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA, EMA or MHRA approval for alternative or superior products. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. An increasing number of companies are increasing their efforts in discovery of new psychedelic compounds.

Patents and Other Intellectual and Proprietary Rights

Obtaining, maintaining and defending global patents and other intellectual property, or IP, rights, whether independently or in collaboration with our partners, are of key importance in the protection and commercialization of our innovative therapies and technology solutions. We shall continue to seek global patent, trademark, and trade secret protection of our innovations in the U.S., EU, UK, and other key jurisdictions. This includes pursuing patent protection for our novel high-purity polymorphic crystalline psilocybin and related manufacturing processes, pharmaceutical compositions, formulations, and methods of treatment of psychiatric and neurological indications, including TRD, MDD, PTSD, and anorexia.

Upon regulatory approval in a particular jurisdiction, we will also seek to meaningfully protect our innovations by asserting available regulatory exclusivity including regulatory data protection and market exclusivity. For example, upon approval from the FDA, we may be entitled to five years of regulatory exclusivity for New Chemical Entity, or NCE, status and upon approval from the European Medicines Agency, or EMA, we may be entitled to ten years of regulatory exclusivity.

We will defend our patents and other IP and proprietary rights as appropriate if and when we are subjected to third-party challenges (e.g., litigation, post-grant review, inter-partes review, oppositions).

Patents and Patent Applications

Our patent portfolio related to COMP360 includes the following patents and published patent applications:

Territory	Patent Number/Application Number	Subject Matter	Expiration Date	Corresponding Ex-U.S. Patents and Patent Applications or PCT National Stage Applications
US	10,519,175	Methods of treating treatment-resistant depression	ca.2038*	Australia, Brazil, Canada, China, Colombia, Eurasian Patent Organization, European Patent Office, Hong Kong, Indonesia, Israel, India, Japan, Republic of Korea, Mexico, Malaysia, New Zealand, Philippines, Russia, Saudi Arabia, Singapore, Thailand, and South Africa.
US	10,947,257	Oral dosage forms of crystalline psilocybin; Methods of treating major depressive disorder (MDD)	ca.2038*	
US	10,954,259	Crystalline psilocybin; Pharmaceutical formulations; Method of treating MDD	ca.2038*	
US	11,180,517	Method of treating treatment-resistant depression	ca.2038*	
US	11,505,564	Method of manufacturing	ca.2038*	
US	11,629,159	Crystalline psilocybin; Pharmaceutical formulations	ca. 2038*	
US	11,851,451	Crystalline psilocybin; Pharmaceutical formulations	ca. 2038*	
US	11,939,346	Crystalline psilocybin; Pharmaceutical formulations	ca. 2038*	
US	12,459,965	Crystalline psilocybin; Pharmaceutical formulations	ca. 2038*	
US	19/296,350	Crystalline psilocybin; Pharmaceutical formulations	ca. 2038*	
US	19/296,543	Crystalline psilocybin; Pharmaceutical formulations	ca. 2038*	
US	19/296,560	Crystalline psilocybin; Pharmaceutical formulations	ca. 2038*	
US	12,459,965	Crystalline psilocybin; Pharmaceutical formulations	ca. 2038*	
US	12,312,375	Crystalline psilocybin; Pharmaceutical formulations	ca. 2038*	
GB	2571696	Method of manufacturing	ca. 2037*	
GB	2572023	Crystalline psilocybin; Pharmaceutical formulations; Medical uses (including for treatment-resistant depression); Method of manufacturing	ca. 2038*	
GB	2576059	Pharmaceutical formulations	ca. 2038*	
GB	2588505	Method of manufacturing	ca. 2038*	
GB	2588506	Crystalline psilocybin; Pharmaceutical formulations; Method of manufacture	ca. 2038*	
DE	202018006384	Crystalline psilocybin; Pharmaceutical formulations	ca. 2038*	

PCT	WO/2020/212951	Methods of treating anxiety disorders and other conditions	ca. 2040*	Applications filed in Australia, Canada, China, European Patent Office, Hong Kong, Japan and Republic of Korea.
US	11,564,935	Method of treating PTSD	ca. 2040*	
US	11,738,035	Method of treating anorexia	ca. 2040*	
US	11,865,126	Method of treating anxiety	ca. 2040*	
US	12,447,164	Method of treating eating disorders	ca. 2040*	
US	12,433,904	Method of treating migraines	ca. 2040*	
US	19/296,581	Method of treating bipolar disorder	ca. 2040*	
US	19/569,250	Method of treating substance use disorder	ca. 2040	
PCT	WO2020/212948	Methods of treating neurocognitive disorders and other conditions	ca. 2040*	Applications filed in Australia, Canada, China, European Patent Office, Hong Kong, Japan and Republic of Korea.
US	12,377,112	Method of treating attention-deficit hyperactivity disorder, or autism spectrum disorder	ca. 2040*	
US	19/234,582	Method of treating neurocognitive disorders	ca. 2040*	
PCT	WO2020/212952	Methods of treating depression and other disorders	ca. 2040*	Applications filed in Australia, Canada, China, European Patent Office, Hong Kong, Japan, Republic of Korea and Taiwan.
US	19/423,663	Method of treating depression	ca. 2040*	
PCT	WO2022/207746	Pharmaceutical formulations	ca. 2041*	Applications filed in Taiwan, Argentina, Australia, Brazil, Canada, China, Columbia, European Patent office, , Indonesia, Israel, Japan, Hong Kong, and Republic of Korea, Mexico, Malaysia, New Zealand, Philippines, Russia, Saudi Arabia, Singapore, Thailand, Vietnam, and South Africa.
US	18/285,109	Pharmaceutical formulations	ca. 2041*	
PCT	WO 2023/86252	Redosing schedules for subjects with treatment resistant depression	ca. 2042*	Applications filed in Australia, Canada, China, European Patent Office, Japan, Republic of Korea, Mexico, New Zealand, and Singapore.
US	18/703,950	Redosing schedules for subjects with treatment resistant depression	ca. 2042*	
PCT	WO 2023/114097	Method of treating treatment resistant depression with psilocybin and serotonin reuptake inhibitor	ca. 2042*	Applications filed in U.S., Australia, Canada, China, European Patent Office, Japan, Republic of Korea, Mexico, New Zealand, and Singapore.
US	18/718,103	Method of treating treatment resistant depression with psilocybin and serotonin reuptake inhibitor	ca. 2042*	
PCT	WO2025/215243	Scalable Methods of Manufacturing Psilocybin	ca. 2042*	Applicants filed in US and TW.

*In general, a U.S. patent, as well as most foreign patents, will expire after 20 years from the earliest effective filing date. In the U.S., it may be possible to extend the patent term beyond the 20 years by requesting patent term extension, or PTE, of patents that claim a product requiring regulatory approval prior to sale. PTE restores to a patent owner, patent term which was effectively “lost” due to regulatory review. Similar term extensions may be available outside of the U.S. Further, in the U.S., it may also be possible to extend beyond the 20-year patent term as a result of prosecution delays caused by the U.S. Patent and

Trademark Office.

U.S. Patent No 10,519,175, was granted on December 31, 2019, with claims directed to methods of treating treatment-resistant depression with oral dosage formulations of Compass's high-purity crystalline psilocybin (including COMP360). Three Third Party Observations were previously filed during the pendency of the application, each considered by the Examiner and found to not be a barrier to patentability. A Petition for post-grant review of the patent was filed on February 21, 2020 and was dismissed on the merits on August 20, 2020.

On December 15, 2021, Freedom to Operate, Inc., filed a petition for post-grant review of U.S. Patent No. 10,947,257. The patent owner's response was filed on March 29, 2022. On June 22, 2022, the USPTO denied institution of the post-grant review. Freedom to Operate, Inc. filed a request for rehearing on July 22, 2022, and a request for Precedential opinion panel on August 16, 2022. The USPTO Board denied the request for Precedential Opinion Panel review on February 10, 2023. On May 23, 2023, the USPTO Board denied the request for rehearing.

On December 22, 2021, Freedom to Operate, Inc., filed a petition for post-grant review of U.S. Patent No. 10,954,259. The patent owner's response was filed on April 11, 2022. On June 22, 2022, the USPTO denied institution of the post-grant review. Freedom to Operate, Inc. filed a request for rehearing on July 22, 2022, and a request for Precedential opinion panel on August 16, 2022. The USPTO Board denied the request for Precedential Opinion Panel review on February 10, 2023. On May 23, 2023, the USPTO Board denied the request for rehearing.

UK patent, No GB2571696, was granted in May 2020 with claims directed to large scale manufacture of psilocybin, psilocybin made by said process and formulation comprising psilocybin made by said process. The Intention to Grant was sent in December 2019, and Third-Party Observations were filed in late January 2020, shortly before grant was originally scheduled. Grant of the patent was announced in the Patents Journal on May 27, 2020. This patent has an expiry date of October 8, 2037. On June 11, 2020, Kohn & Associates PLLC filed a request at the UK Intellectual Property Office to issue a post-grant opinion on the validity of the patent claims. On April 27, 2021, the agency issued a decision to refuse the request for an opinion finding that it was inappropriate in all the circumstances to issue such an opinion. No appeal to this decision was lodged within the required 28-day period.

UK patent, No GB2572023, was granted in June 2020. This patent includes claims covering our crystalline psilocybin (including the form used in COMP360), pharmaceutical formulations of crystalline psilocybin, medical uses of crystalline psilocybin (including for treatment-resistant depression), and a method of manufacturing crystalline psilocybin. The Intention to Grant was sent in December 2019, and Third-Party Observations were filed in late January 2020. A notification of grant was mailed June 23, 2020, and grant was announced in the Patents Journal on July 22, 2020. This patent has an expiry date of June 28, 2038. On August 27, 2020, Freedom to Operate, Inc. filed a request at the UK Intellectual Property Office to issue a post-grant opinion on the validity of the patent claims. On July 28, 2021 a non-binding opinion was issued by the agency finding that granted claims 1, 3 and 10-20 are not inventive. We submitted an amendment to the patent claims and on November 5, 2021 the agency provided notice that the amended specification would be published for opposition in the Patents Journal on December 1, 2021. On December 17, 2021, the agency then issued a decision to not initiate revocation proceedings against the patent.

On November 22, 2022, Porta Sophia filed a Third-Party Observation against international patent application WO2022/207746. On October 31, 2024, Porta Sophia filed a Third Party Submission against U.S. patent application 18/285,109, which is the U.S. national phase entry of WO2022/207746.

Trademarks

We have pursued protection for our trademarks across Classes 5, 9, 10, 35, 41, 42, 44 or various combinations thereof. Our trademark portfolio includes active filings for the COMPASS, COMPASS PATHWAYS, C Design, MYPATHFINDER, CHANTERELLE, COMPASS PATHWAVES, NUFONDIS, and EMPAQUIST marks in the United States, European Union, and United Kingdom.

We own registrations for the COMPASS, COMPASS PATHWAYS, C Design, and MYPATHFINDER marks in the United States, European Union, and United Kingdom; and for the CHANTERELLE, COMPASS PATHWAVES, NUFONDIS and EMPAQUIST marks in the European Union and United Kingdom. Applications are pending for the CHANTERELLE,

COMPASS PATHWAVES, NUFONDIS, and EMPAQUIST marks in the United States. We also own trademark registrations and pending applications in other countries.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record-keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs. We, along with our vendors, contract research organizations and contract manufacturers, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FDCA, as amended, its implementing regulations and other laws. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other legal requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, suspension or revocation of approved applications, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before our product candidates are approved as drugs for therapeutic indications and may be marketed in the United States generally involves the following:

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- Completion of the manufacture, under current Good Manufacturing Practices, or cGMP, conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- Submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin;
- Approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- Submission to the FDA of a New Drug Application, or NDA;
- Payment of user fees for FDA review of the NDA;
- A determination by the FDA within 60 days of its receipt of an NDA, to accept the filing for review;
- Satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

- Potentially, satisfactory completion of FDA audit of the clinical trial sites that generated the data in support of the NDA; and

- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

Preclinical Studies and Clinical Trials for Drugs

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulation, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a full or partial clinical hold. The FDA must notify the sponsor of the grounds for the hold and any identified deficiencies must be resolved before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A clinical hold can also be imposed once a trial has already begun, thereby halting the trial until the deficiencies articulated by the FDA are corrected.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, who generally are physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, administration procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable compared to the 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. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable safety risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than Phase 1 investigations, must be submitted within specific time-frames for publication on www.ClinicalTrials.gov, a clinical trials database maintained by the National Institutes of Health.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the FDA will nevertheless accept the results of the study in support of an NDA if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- *Phase 1*—Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- *Phase 2*—Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the drug's potential efficacy, to determine the optimal dosages and administration schedule and to identify possible adverse side effects and safety risks.

- *Phase 3*—Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further

test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials or post-marketing 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 and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of NDA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the drug 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 manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. 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.

US Marketing Approval for Drugs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA package requesting approval to market the product for one or more indications. An NDA is a request for approval to market a new drug for one or more specified indications and must contain proof of the drug's safety and efficacy for the requested indications. The marketing application is required to include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use 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 efficacy of the investigational product to the satisfaction of the FDA. The FDA must approve an NDA before a drug may be marketed in the United States.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for the indications sought and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets 10 months, from the filing date, in which to complete its initial review of a new molecular entity NDA and respond to the applicant, and six months from the filing date of a new molecular entity NDA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. In addition, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, if it believes that a REMS is necessary to ensure that the benefits of the drug outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk-minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which 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 typically will 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 requirements and are adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risks to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Expedited Development and Review Programs for Drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs to get them to patients more quickly than standard FDA review timelines typically permit.

A drug is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Rolling review means that the agency may review portions of the marketing application before the sponsor submits the complete application. In addition, a drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review designation, once an NDA or BLA is submitted, if the drug that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review. Products are eligible for Accelerated Approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, which 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.

Accelerated Approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the sponsor fails to conduct such studies in a timely manner and send the necessary updates to the FDA, or if a confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, as a condition for Accelerated Approval, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

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 the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

Orphan Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. If a drug that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the drug is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the drug with orphan exclusivity. Competitors, however, may receive approval of different drugs for the indication for which the orphan drug has exclusivity or obtain approval for the same drug but for a different indication for which the orphan drug has exclusivity. Orphan drug exclusivity also could block the approval of one of our therapeutic candidates for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our therapeutic candidate is determined to be contained within the competitor's drug for the same indication or disease. If a drug designated as an orphan drug receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, benefits.

US Post-Approval Requirements for Drugs

Drugs manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs, and those supplying products, ingredients, and components of them, 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 ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements. In addition, the Drug Supply Chain Security Act, or DSCSA, was enacted in 2013 with the aim of building an electronic system to identify and trace certain prescription drugs and biologics distributed in the United States. The stabilization period for building and validating interoperable electronic tracing systems has ended and trading partners who have not achieved compliance with these requirements must secure an exemption from the FDA. The DSCSA requirements include the quarantine and prompt investigation of a suspect product, to determine if it is illegitimate, notifying trading partners and the FDA of any illegitimate product, and compliance with product tracking and tracing requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Failure to comply with statutory and regulatory requirements may subject a manufacturer to legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

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, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- The issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- Fines, warning letters or holds on post-approval clinical trials;
- Refusal of the FDA to approve 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;
- Injunctions or the imposition of civil or criminal penalties; and
- Consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or mandated modification of promotional materials and labeling and issuance of corrective information.

Controlled Substances

The federal Controlled Substances Act of 1970, or CSA, and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the DEA. The DEA is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV or V — with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or

psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. COMP360, if approved in the United States, will require rescheduling by the DEA before it can be marketed.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s).

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics. In some cases, Schedule III non-narcotic substances may be subject to the import/export permit requirement, if necessary, to ensure that the United States complies with its obligations under international drug control treaties.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year, and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies.

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including boards of pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally follows the same lines as in the United States, although the approval of a medicinal product in the United States is no guarantee of approval of the same product in the EU, either at all or within the same timescale as approval may be granted in the United States. It entails satisfactory completion of pharmaceutical development, non-clinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and subsequently of a marketing authorization application, or MAA, before the product can be marketed and sold in the EU or any of its Member States. If we fail to comply with applicable requirements, we

may be subject to withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Clinical Trial Approval

In the EU, an applicant for authorization of a clinical trial must obtain prior approval from the national competent authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the relevant independent ethics committee has issued a favorable opinion. In April 2014, the EU adopted the Clinical Trials Regulation (EU) No 536/2014, which replaced the previous Clinical Trials Directive 2001/20/EC on January 31, 2022 and overhauls the system of approvals for clinical trials in the EU. Specifically, the Clinical Trials Regulation, which is directly applicable in all EU Member States (meaning that no national implementing legislation in each EU Member State is required), aims at simplifying and streamlining the approval of clinical trials in the EU. For instance, the Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point (instead of submitting applications separately to each national competent authority and ethics committee in the Member States in which the trial will be conducted) and strictly defined deadlines for the assessment of clinical trial applications. The Clinical Trials Regulation also makes it more efficient for EU Member States to evaluate and authorize applications together, via the Clinical Trials Information System. Since January 31, 2025, all new and ongoing clinical trials are regulated by the Clinical Trials Regulation.

Marketing Authorization

To obtain a marketing authorization for a medicinal product in the European Economic Area (comprised of the EU Member States plus Norway, Iceland and Liechtenstein), or EEA, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the EEA.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the EEA and is mandatory for certain products, including products with a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions, and viral diseases. For those products for which the use of the centralized procedure is not mandatory, pursuant to Regulation (EC) No 726/2004, applicants may elect to use the centralized procedure where either the product contains a new active substance indicated for the treatment of diseases other than those on the mandatory list, where the applicant can show that the product constitutes a significant therapeutic, scientific or technical innovation, or for which a centralized authorization would be in the interest of public health. Our investigational COMP360 psilocybin treatment, as a new active substance indicated for the treatment of treatment-resistant depression, will have the option to be filed through the centralized procedure.

Under the centralized procedure, the Committee for Medicinal Products for Human use, or the CHMP, which is the EMA's committee that is responsible for human medicines, is responsible for conducting the assessment of whether a medicine meets the required quality, safety and efficacy requirements, and whether it has a positive risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days from the receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, which makes the final decision to grant a marketing authorization. Within 67 days from the date of the CHMP opinion, the European Commission will adopt its final decision on the MAA. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

Now that the UK (which comprises Great Britain and Northern Ireland) has left the EU, the UK is no longer covered by EU centralized marketing authorizations. On January 1, 2024, the MHRA introduced the International Recognition Procedure, under which the MHRA may have regard to decisions on the approval of marketing authorizations made by the EMA and certain other regulators when considering an application for a UK marketing authorization. The MHRA also has the power to have regard to marketing authorizations approved in EU Member States through decentralized or mutual recognition procedures with a view to more quickly granting a marketing authorization in the United Kingdom.

The decentralized marketing authorization procedure allows an applicant to apply for simultaneous authorization in more than one EU Member State of medicinal products that have not yet been authorized in any EU Member State and that do not fall within the mandatory scope of the centralized procedure.

The mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of another EU Member State. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

PRIME Scheme

In March 2016, the EMA launched a scheme that is intended to reinforce early dialogue with, and regulatory support from, the EMA in order to stimulate innovation, optimize development and enable accelerated assessment of Priority Medicines, or PRIME. It is intended to build upon the scientific advice scheme and accelerated assessment procedure offered by the EMA. The scheme is voluntary and eligibility criteria must be met for a medicine to qualify for PRIME.

The PRIME scheme is open to medicines under development and for which the applicant intends to apply for a MAA through the centralized procedure. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new therapy methods or improving existing ones. Applicants will typically be at the exploratory clinical trial phase of development, and will have preliminary clinical evidence in patients to demonstrate the promising activity of the medicine and its potential to address to a significant extent an unmet medical need. In exceptional cases, applicants from the academic sector or SMEs (small and medium sized enterprises) may submit an eligibility request at an earlier stage of development if compelling non-clinical data in a relevant model provides early evidence of promising activity, and first in man studies indicate adequate exposure for the desired pharmacotherapeutic effects and tolerability.

If a medicine is selected for the PRIME scheme, the EMA:

- appoints a rapporteur from the CHMP or from the Committee for Advanced Therapies to provide continuous support and to build up knowledge of the medicine in advance of the filing of an MAA;
- issues guidance on the applicant's overall development plan and regulatory strategy;
- organizes a kick-off meeting with the rapporteur and experts from relevant EMA committees and working groups;
- provides a dedicated EMA contact person; and
- provides scientific advice at key development milestones, involving additional stakeholders, such as health technology assessment bodies and patients, as needed.

Medicines that are selected for the PRIME scheme are also expected to benefit from the EMA's accelerated assessment procedure at the time of application for marketing authorization. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

Orphan Designation

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (i) such condition affects no more than five in ten thousand persons in the EU when the application is made, or (ii) it is unlikely that the marketing of the product in the EU, without the benefits derived from orphan status, would generate sufficient return to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention, or treatment of such condition authorized for marketing in the EU or, if such method exists, the product would be of significant benefit compared to products available for that condition.

An orphan designation provides a number of benefits in the EU, including fee reductions, regulatory assistance and the ability to apply for a centralized marketing authorization. The application for orphan designation must be submitted before the application for marketing authorization. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The grant of a marketing authorization for an orphan medicinal product leads to a ten-

year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or competent authorities of the Member States can accept an application or grant a marketing authorization for the same therapeutic indication in respect of a "similar medicinal product". A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example because the product is sufficiently profitable not to justify market exclusivity. There are also limited derogations from the ten-year period of market exclusivity pursuant to which marketing authorization may be granted for a similar medicinal product in the same therapeutic indication. These are where: (i) the second applicant can establish that although their product is similar to the orphan medicinal product already authorized, the second product is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized orphan product consents to the second medicinal product application; or (iii) the marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product.

Pediatric Development

In the EU, companies developing a new medicinal product must agree upon a pediatric investigation plan, or PIP, with the EMA's Pediatric Committee, or PDCO, and must conduct pediatric clinical trials in accordance with that PIP unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product for which marketing authorization is being sought. The MAA for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted by the PDCO of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults, in which case the pediatric clinical trials must be completed at a later date. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when this data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate or SPC (provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires), even where the trial results are negative. In the case of orphan medicinal products, a two year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Data and Market Exclusivity

In the EU, innovative medicinal products containing a new active substance and approved on the basis of a complete and independent data package qualify for eight years of data exclusivity upon grant of a marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No. 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity prevents generic and biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a marketing authorization for a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be marketed until the expiration of the market exclusivity period. The overall 10-year period may be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is determined to bring a significant clinical benefit in comparison with existing therapies. There is no guarantee that a product will be considered to contain a new active substance for the purposes of EU data and market exclusivity, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a re-evaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing EU Member State, as applicable. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or

the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the EEA market (in the case of the centralized procedure) or on the market of the authorizing EU Member State (for a national procedure) within three years after authorization ceases to be valid (the so-called sunset clause).

Controlled Drugs Classification

In the UK, psilocybin and psilocin are considered Class A drugs under the Misuse of Drugs Act 1971, as amended, and as Schedule 1 drugs under the Misuse of Drugs Regulations 2001, as amended. Class A drugs are considered to be the most potentially harmful, and have the highest level of control exerted over them under the Misuse of Drugs Act 1971. Similarly, Schedule 1 of the Misuse of Drugs Regulations 2001 lists those drugs to which the most restrictive controls apply: they are considered to have no legitimate or medicinal use, and can only be imported, exported, produced, supplied and the like under a license issued by the UK Government's Home Office. If and when granted a marketing authorization by the MHRA in respect of the UK, psilocybin would still remain a Schedule 1 drug unless and until rescheduled by the UK Government's Home Office. Unless and until psilocybin is rescheduled under the Misuse of Drugs Regulations 2001, and unless a statutory exemption was to be passed for COMP360 following the grant of a UK marketing authorization and before rescheduling, any prescribing doctors in the UK would require a Home Office license to prescribe COMP360, and similarly any patients to whom COMP360 was prescribed would require a Home Office license to possess COMP360. There can be no guarantee that such Home Office licenses would be granted or that rescheduling would be successful.

The position in the Member States of the EU is not harmonized: Member States have implemented the relevant UN Conventions (the Single Convention of Narcotic Drugs 1961 and the Convention on Psychotropic Substances 1971) into their national legislation, which has led to differences in how controlled substances are regulated in different countries of the EU. It is therefore important to determine at a national level whether a substance is controlled and to comply with the applicable legal requirements. If we are successful in obtaining a marketing authorization in key EU Member States, it is likely that rescheduling of psilocybin will also be required to enable prescribing.

Regulatory Requirements After Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product.

These include compliance with the EU's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

In addition, all new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place to document measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. 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. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

Furthermore, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive (EU) 2017/1572, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with EU good manufacturing practice, or GMP, standards which govern the methods, facilities and controls used in manufacturing, processing and packaging of products to assure their quality, safety and identity.

Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products, are strictly regulated in the EU under Directive 2001/83/EC, as amended. The advertising of prescription-only medicines to the general public is not permitted in the EU, or in the UK under the Human Medicines Regulations 2012. Although general requirements for advertising and promotion of medicinal products are established under EU Directive 2001/83/EC as amended, the details are governed by regulations in each EU Member State and can differ from one country to another.

The aforementioned EU rules are generally applicable in the EEA (which consists of the EU Member States plus Norway, Iceland and Liechtenstein).

Reform of the Regulatory Framework in the European Union

The European Commission introduced legislative proposals in April 2023 to replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). In April 2024, the European Parliament adopted its position on the legislative proposals, and in June 2025, the Council of the European Union adopted its position. A common position on the text was agreed upon on December 11, 2025, in the context of subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be adopted, and are not expected to become applicable before 2028.

Brexit and the Regulatory Framework in the United Kingdom

The UK formally left the EU (commonly referred to as "Brexit") on January 31, 2020 and the EU and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations.

At present, the UK has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework with respect to medicines continued to apply in Northern Ireland for a period following Brexit). Except in respect of the EU Clinical Trials Regulation, the regulatory regime in the UK therefore largely aligns with EU regulations, however it is possible that these regimes will diverge more significantly in the future now that the UK's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under a new international recognition procedure mentioned above which was put in place by the MHRA on January 1, 2024, the MHRA may take into account decisions on the approval of a marketing authorization from the EMA (and certain other regulators) when considering an application for a UK marketing authorization.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, and the medicines aspects of the Windsor Framework have applied since January 1, 2025. This new framework fundamentally changes the previous system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. The Windsor Framework removes EU licensing processes and certain EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines. In particular, the MHRA is now responsible for approving medicinal products placed on the UK market (i.e., Great Britain and Northern Ireland), and the EMA no longer has any role in UK marketing authorizations. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. In addition, the new arrangements generally require, for packs placed on the UK market on or after January 1, 2025, a "UK Only" label, indicating they are not for sale in the EU.

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. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis. After an application under the rolling-review procedure has been validated, the final decision should be received within 100 days (subject to clock-stops).

In the UK, the initial duration of a marketing authorization 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 years shall cease to be in force.

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 the Clinical Trials Directive 2001/20/EC, as implemented into UK national law through secondary legislation. In April 2025, the UK introduced the Medicines for Human Use (Clinical Trials) (Amendment) Regulations. These changes, which will take full effect from April 2026, aim to create a streamlined, risk-proportionate system that accelerates approvals while maintaining robust safety standards. In addition, in October 2023, the

MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

We received an Innovation Passport designation from the MHRA for COMP360 for the treatment of treatment-resistant depression. The Innovation Passport is the entry point to the UK's Innovative Licensing and Access Pathway, or ILAP, a scheme intended to accelerate the time to market and facilitate patient access in the UK to certain types of medicinal products in development that target a life-threatening or seriously debilitating condition, or where there is a significant patient or public health need in the UK. Once an Innovation Passport designation is granted, the MHRA and its partner agencies (including the All Wales Therapeutics and Toxicology Centre, the National Institute for Health and Care Excellence, NHS England and the Scottish Medicines Consortium), will work with the Innovation Passport holder to define a Target Development Profile, or TDP. The TDP sets out a unique product-specific roadmap towards patient access in the UK and provides access to tools intended to support stages of the design, development and approvals process, which may include enhanced regulatory and health technology assessment engagement and patient involvement. However, although the goal of the ILAP is to reduce time to market and enable earlier patient access, participation does not accelerate the conduct of clinical trials or mean that the regulatory requirements are less stringent, nor does it ensure that a marketing authorization application will be approved or that any approval will be granted within a particular timeframe or at all.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any psilocybin treatment for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement for our products from third-party payors, such as government health care programs (e.g., Medicare, Medicaid), managed care providers, private health insurers, health maintenance organizations, and other organizations. These third-party payors decide which medications they will pay for and will establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors is essential for most patients to be able to afford treatments such as novel therapies. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, which is a part of the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Our ability to successfully commercialize our product candidates, whether as a single agent or combination therapy, will depend in part on the extent to which coverage and adequate reimbursement for our products and related treatments will be available from third-party payors. Moreover, a payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain price levels sufficient to realize an appropriate return on our investment in product development.

No uniform policy for coverage and reimbursement for products exist among third-party payors in the United States. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. One payor’s determination to provide coverage for a medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

A decision by a third-party payor not to cover or not to separately reimburse for our medical products or therapies using our products could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. If there is coverage for our product candidates, or therapies using our product

candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States will be available for our current or future product candidates, or for any procedures using such product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future. Further, if we or our collaborators develop therapies for use with our product candidates, we, or our collaborators, will be required to obtain coverage and reimbursement for these therapies separate and apart from the coverage and reimbursement we seek for our product candidates, once approved.

Further, third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to secure coverage and reimbursement for any product candidate that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of such product, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product, after approval, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates.

Lastly, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, in the EU, pricing and reimbursement schemes are determined at the level of individual Member States and vary widely from country to country. Some EU Member States provide that products may be marketed only after a reimbursement price has been agreed. Some EU Member States may require the completion of additional studies that compare the cost effectiveness or relative clinical value of a particular product candidate compared to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, EU Member States may restrict the range of products for which their national health insurance systems provide reimbursement and may control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Approaches between EU Member States differ and continue to evolve. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security system. The price of medicines is negotiated with the Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Other EU Member States allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the level of discounts required on pharmaceuticals, and these efforts could continue as countries attempt to manage health care expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel trade (arbitrage between low-priced and high-priced EU Member States) can further reduce prices. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results-based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, even if approved in those countries. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Notwithstanding any of the above, as Schedule I substances under the Controlled Substances Act, psilocybin and psilocin are currently deemed to have no accepted medical use and therapies that use psilocybin or psilocin are currently precluded from reimbursement in the United States.

Other Healthcare Laws and Compliance Requirements

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with

third-party payors, healthcare providers and physicians may expose us to broadly applicable federal and state fraud and abuse laws, as well as other healthcare laws and regulations. These laws may impact, among other things, our business or financial arrangements and relationships through which we research, as well as market, sell and distribute the psilocybin therapies for which we obtain approval. In addition, we may be subject to health information privacy regulation by both the federal government and the states in which we conduct our business. In the United States the laws that may affect our ability to operate include, among others:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare and Medicaid. The term remuneration has been interpreted broadly to include anything of value. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to significant administrative, civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. 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, or FCA, or federal civil money penalties statute. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;

- The federal civil and criminal false claims laws, such as the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented claims for payment or approval from Medicare, Medicaid, or other third-party payors, that are false, fictitious, or fraudulent; from knowingly making, using or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit property to the federal government; or from knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transferring of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of items or services reimbursable by a federal or state healthcare program;

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (i.e., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its respective implementing regulations, which imposes, among other things, certain requirements on

certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions;

- The federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, or ACA, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- Analogous state and foreign equivalents of each of the healthcare laws and regulations described above, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require pharmaceutical companies to comply with the pharmaceutical industry voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government, such as the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals; state laws that require the reporting of information related to drug pricing; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state and local laws that require the licensure and/or registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information that may be more stringent than those in the United States (such as the EU, which adopted GDPR), many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The full scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued to increase their scrutiny on interactions between healthcare companies and healthcare providers, which has led to a number of significant investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including our arrangements with physicians and other healthcare providers and entities, such as our Centers of Excellence or healthcare professionals supporting and monitoring participants in our clinical trials, are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), imprisonment, and additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring

of our operations, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our Centers of Excellence and healthcare professionals supporting and monitoring participants in our clinical trials, are found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions.

Ensuring that our current and future business arrangements with third parties, and our business generally, comply with applicable healthcare laws and regulations, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company's attention from its business.

Healthcare Reform

In the United States and in some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in 2010, the ACA was enacted, which, among other things, increased rebates for drugs sold to Medicaid programs owed by most manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed organizations; imposes mandatory discounts for certain Medicare Part D beneficiaries in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjects drug manufacturers of certain branded prescription drugs to new annual, nondeductible fees and taxes; expanded healthcare fraud and abuse laws (including the FCA and the Anti-Kickback Statute), government investigative powers and enhances penalties for non-compliance; expands eligibility criteria for Medicaid programs thereby potentially increasing manufacturers' Medicaid rebate liability; expands the entities eligible for discounts under the 340B Drug Pricing Program; created new requirements to report financial arrangements with physicians, as defined by such law, and teaching hospitals, commonly referred to as the Physician Payments Sunshine Act; created a new requirement to annually report the identity and quantity of drug samples that manufacturers and authorized distributors of record provide to physicians; created a Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established the Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year. Subsequent legislation extended the 2% payment reduction which remains in effect through 2031.

The American Taxpayer Relief Act reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting on January 1, 2025; however, legislation has been introduced in the U.S. Congress that would, if enacted, reverse these payment reductions. In addition to provider payment cuts under Medicare, the American Rescue Plan Act of 2021 also eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. These laws and regulations may result in additional reductions in Medicare and other healthcare funding available for healthcare providers and may otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; imposes new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare

Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. Under the One Big Beautiful Bill Act of 2025, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan drug designations or indications, are exempt from the Medicare drug price negotiation program. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The overall impact that the IRA will have on our business and the healthcare industry in general is not yet known.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for pharmaceutical products.

On December 19, 2025, CMS released two proposed rules that would incorporate most favored nation, or MFN, pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model, or GLOBE, for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs, or GUARD, model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions fOr U.S. Medicaid, or GENEROUS, Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers. President Trump may issue new executive orders designed to impact drug pricing. Although any proposed measures may require authorization through additional legislation to become effective, and the Trump administration may reverse or otherwise change these measures, both the Trump administration and Congress have indicated that they will continue to seek measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards, or PDABs, and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits, or UPLs, on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company's future revenues.

We expect that additional foreign, federal and state 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 limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

Human Capital Management

As a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health, our team is the key to our success, and we believe it is essential to invest in building an engaged, inclusive, supported, and incentivized workforce who can help us achieve our vision of a world of mental wellbeing. As of December 31, 2025, we had 156 employees, which represented a decrease of 6.0% compared to the prior year, of whom 101 employees are engaged in research and development activities and 55 employees are engaged in general administrative functions. As of December 31, 2024, we had 166 employees, which represented a decrease of 11% compared to the prior year, of whom 125 employees were engaged in research and development activities and 41 employees were engaged in general administrative functions. As of December 31, 2025, 49% of our employees are located in the US, while the remaining 51% are located in the UK.

We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We believe our relations with our employees are good.

Mental Health and Wellbeing

As a biotechnology company focused on mental health, we aspire to be a leader in building a workplace that reduces the stigma of mental illness and fosters employee wellbeing. We take a holistic view of wellbeing support that includes mental and physical health support for all employees at Compass.

We offer various wellbeing resources which include:

- company-paid employee health care coverage, including access and financial support for a private mental health care in the UK;
- a global employee assistance program run by certified counselors, offering up to a specified number of therapy sessions per issue for team members and full access to online resources for their families;
- one-to-one confidential well-being check-ins, onboarding and off boarding with our well-being community lead;
- community circles, providing a forum for employees to discuss any topic with colleagues, providing open communication and support;
- team meetings periodically include well-being segments facilitated by our well-being community lead and we use well-being team surveys and manager-led discussions during team meetings to identify and overcome any wellbeing issues;
- periodic training for managers on how to address well-being issues in their teams and provide support;
- company-wide shutdown over the year-end holiday, to make it easier for team members to disconnect during their time off; and
- company-wide support for dependent childcare, helping both parents remain in the workforce, including pre-tax dependent care benefits in the US and a family allowance in the UK.

In 2023 we signed the StigmaFree pledge organized by the National Alliance on Mental Illness, or NAMI, as part of our commitment to a company culture of openness, acceptance, and understanding about employees' overall mental health and well-being. In 2024, after a thorough and rigorous selection process, we were approved as a Corporate Sponsor of NAMI, enabling an even stronger partnership with them. NAMI is the largest grassroots mental health organization in the United States dedicated to building better lives for the millions of Americans affected by mental illness.

Employee Development and Training

We believe that the individual growth of our employees will fuel the company's growth over time since our talent is uniquely experienced in our pioneering work. We are committed to the continued development of our employees, and to support their growth. To help us identify, foster, and retain high performing employees, we have a range of resources and initiatives, including talent reviews to assess and calibrate talent for the purposes of rewards and development, a process for performance and development goals that is tied to employees receiving feedback throughout the year and assessing individual performance and rewards at the end of the year, and job architecture, providing employees with guidance and clear pathways for developing and progressing their career and twice-yearly promotions cycle. In 2025, we introduced a new leadership development program for senior leaders, to focus on strengthening the leadership pipeline and positively impacting our leadership culture.

Compensation and Benefits

Our compensation and benefits are designed to provide employees with total compensation packages that are competitive with those offered by our peers and other companies with which we compete for talent. We evaluate our offerings on an annual basis to ensure competitiveness of our programs and adjust as needed.

We provide competitive compensation and comprehensive benefits for our employees. Our compensation packages include base salary, annual bonus, annual equity awards, company paid healthcare plans, generous paid time-off and leave policies, travel insurance, life/disability and income protection insurance, and retirement saving plans with company matching contributions. We also have an employee share purchase plan, under which eligible employees have the opportunity to buy our shares through payroll deductions every six months at a discount.

Corporate Information

Compass Pathways plc was originally incorporated as a private limited company under the laws of England and Wales in June 2020 under the name Compass Rx Limited to become a holding company for Compass Pathfinder Holdings Limited. Compass Rx Limited was subsequently re-registered as a public limited company in August 2020 and renamed Compass Pathways plc. Compass Pathfinder Holdings Limited was originally incorporated under the laws of England and Wales in June 2017. Our registered office is located at 3rd Floor, 1 Ashley Road, Altrincham, Cheshire, WA14 2DT, United Kingdom, and our telephone number is +1 (646) 905-3974.

Our website address is www.compasspathways.com. We do not incorporate the information on or accessible through our website into this Annual Report, and you should not consider any information on, or that can be accessed through, our website as part of this Annual Report. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file or furnish such materials to the U.S. Securities and Exchange Commission.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors as well as the other information included in this Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes thereto. Any of the following risks could materially and adversely affect our business, financial condition, or results of operations. The selected risks described below, however, are not the only risks facing us. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial may also materially and adversely affect our business, financial condition, or results of operations. The summary of the material risks associated with our business is included in the "Special Note Regarding Forward-Looking Statements" on page 4 above.

Risks Related to Our Financial Position and Need for Additional Capital

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 achieve or maintain profitability.

We are a clinical-stage biotechnology company and we have not generated any revenue to date. We have incurred significant operating losses since our formation. We incurred total net losses of $287.9 million and $155.1 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $822.6 million. Our historical losses resulted principally from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. During the term of our pre-funded warrants, or the Pre-Funded Warrants, issued in our registered financing in January 2025, or the January 2025 Financing, and in our underwritten offering in February 2026, or the February 2026 Offering, and our ADS warrants, or the 2025 ADS Warrants, issued the January 2025 Financing, which are classified as liabilities, our net loss can change significantly quarter to quarter due to non-cash increases or decreases in the fair value of these warrants. In February 2026, each of these 2025 ADS Warrants were exercised in full and therefore none of the 2025 ADS Warrants are currently outstanding. We intend to continue to conduct research and development, clinical trials, regulatory compliance, market access and commercialization activities that, together with anticipated general and administrative expenses, will result in incurring further significant operating losses for at least the next several years. Our expected operating losses, among other things, may continue to cause our working capital and shareholders' equity to decrease. We anticipate that our expenses will increase substantially if and as we, among other things:

- continue to advance our Phase 3 program for investigational COMP360 psilocybin treatment in TRD and clinical and preclinical supporting studies and accelerate our plans for NDA submission;
- we prepare for commercial launch of COMP360 psilocybin treatment in TRD, if approved, including establishing a sales, marketing and distribution infrastructure and scaling-up manufacturing capabilities;
- advance our commercialization strategy;
- initiate and advance our Phase 2b/3 clinical trial in PTSD;
- continue the training of qualified healthcare professionals to monitor and safeguard participants in our Phase 3 program and other clinical trials;
- service our outstanding indebtedness;

- may in the future resume and pursue research and development programs for our other preclinical stage therapeutic candidates and discovery-stage programs and/or develop and seek regulatory approval for any future therapeutic candidates that successfully complete clinical trials;
- establish and expand the network of public healthcare institutions and private clinics that could administer our investigational COMP360 psilocybin treatment if approved;
- experience heightened regulatory scrutiny;
- pursue necessary scheduling-related decisions by the U.S. Drug Enforcement Administration, or the DEA, and various state governments to enable us to commercialize any therapeutic candidates containing controlled substances for which we may obtain regulatory approval, including COMP360;
- obtain, maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent or other intellectual property infringement claims;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our therapeutic development and potential future commercialization efforts;
- experience any delays or encounter any issues with respect to any of the above, including failed studies, ambiguous trial results, safety issues or other regulatory challenges, including, for example, delays and other impacts as a result of pandemics or other public health crises;
- expand our operations in the U.S. and Europe in the future; and
- incur additional legal, accounting and other expenses associated with operating as an English-domiciled public company listed in the U.S.

We have funded our operations since our initial public offering, or IPO, in 2020, through public equity offerings, private placements of ADSs and warrants and debt financing. To become and remain profitable, we will need to continue developing and eventually commercialize treatments that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing our Phase 3 program of COMP360 in TRD and other clinical trials of COMP360 or any future therapeutic candidates, training a sufficient number of qualified healthcare professionals to monitor and safeguard participants in our clinical trials, discovering and developing any future therapeutic candidates, obtaining regulatory approval for COMP360 psilocybin treatment and any future therapeutic candidates that successfully complete clinical trials, and establishing marketing capabilities. Even if COMP360 psilocybin treatment or any of the future therapeutic candidates that we may develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing COMP360 or any other approved future therapeutic candidate. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with therapeutic development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA, the EMA, the MHRA, or other comparable foreign authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of our investigational COMP360 psilocybin treatment or any future therapeutic candidates, our expenses could increase beyond our current expectations and revenue could be further delayed.

Even if we or any future collaborators do generate sales, we may never achieve, sustain or increase profitability on a quarterly or annual basis. Our failure to sustain profitability would depress the market price of our ADSs and could impair our ability to raise capital, repay our outstanding indebtedness, expand our business, diversify our therapeutic offerings or continue our operations. If we continue to suffer losses, investors may not receive any return on their investment and may lose their entire investment.

Unless and until we generate product revenue and achieve and sustain profitability, we will continue to need additional financing to fund our operations and capital expenditures. Failure to obtain additional funding when needed or on favorable terms may force us to delay, limit or terminate certain or all of our product discovery, therapeutic development, research operations or commercialization efforts or grant rights to develop and market products or therapeutic candidates that we would otherwise prefer to develop and market ourselves.

Unless and until we generate product revenue and achieve and sustain profitability, we will need additional funding in the future to sufficiently finance our operations. If the outstanding warrants issued during the private placement transaction, or the PIPE, and such warrants, the PIPE Warrants, are exercised in full for cash, we would receive an additional $122.4 million in gross proceeds. However, because the holders of the PIPE Warrants are not obligated to exercise such warrants, we have not included any anticipated proceeds from such exercises of PIPE Warrants in our estimate of our cash runway. We expect that our cash and cash equivalents of $149.6 million as of December 31, 2025, together with the net proceeds from our February 2026 Offering and the net proceeds from the exercise of all of our outstanding 2025 ADS Warrants, will enable us to fund our operating expenses and capital expenditure requirements into 2028. We have based our estimated cash runway on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, such as fluctuating inflation and interest rates, 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:

- the progress, timing and completion of our Phase 3 program for our current investigational COMP360 psilocybin treatment program for TRD and clinical and preclinical supporting studies and related preparatory work for our planned NDA submission and potential commercialization activities, a portion of which are subject to further long-term data from our COMP006 trial;

- the progress, timing and completion of our Phase 2b/3 clinical trial in PTSD;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA, the EC, the MHRA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more preclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;
- the outcome and timing of any scheduling-related decisions by the DEA, individual states, and comparable foreign authorities;
- the number of potential future therapeutic candidates we may choose to pursue and identify in the future and decide to develop, either internally through our research and development efforts or externally through acquisitions, licensing or other collaboration agreements;
- the costs involved in growing our organization in the near term to the size needed to prepare for the potential commercialization of our investigational COMP360 psilocybin treatment in TRD and any future therapeutic candidates, including increases to personnel costs;
- the costs of developing sales and marketing capabilities to prepare for potential commercial launch of COMP360 psilocybin treatment in TRD to target public and private healthcare providers and clinic networks in the U.S. and other major markets;
- the costs of training qualified healthcare professionals to monitor and safeguard participants in our clinical trials;
- the costs of maintaining research collaborations, such as the Center for Mental Health Research, which includes conducting clinical trials, including proof of concept studies, to refine our treatment delivery model;
- the time and costs involved in generating and collecting data and advancing and defending our intellectual property portfolio, including the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringements or invalidity raised by third parties;
- the costs of developing, testing and deploying digital technology solutions or paying a third-party to provide such technology solutions to improve the patient experience and therapeutic process via third-party service providers or internally;
- the time and costs involved in obtaining regulatory approval for COMP360 or any future therapeutic candidates, and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to COMP360 or any future therapeutic candidates;

- selling and marketing activities undertaken in connection with the potential commercialization of our investigational COMP360 psilocybin treatment or any future therapeutic candidates, if approved, and costs involved in the creation of an effective sales and marketing organization;
- the amount of revenue, if any, we may derive either directly or in the form of royalty, milestone or other payments from future sales of our investigational COMP360 psilocybin treatment and any future therapeutic candidates, if approved;
- the impact of macroeconomic and geopolitical events, including, among others, fluctuating inflation and interest rates, fluctuations in foreign exchange rates, the risk of economic slowdown or recession in the U.S., international tensions, and changes in legislation and governmental policies and resources, including the effects of announced or future tariff increases; and
- the costs of operating as a public company.

Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, strategic collaborations and alliances, licensing arrangements or monetization transactions.

Our ability to raise additional funds when needed and on acceptable terms or at all will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. For example, volatility in the capital markets, fluctuating inflation and interest rates, concerns about potential recessionary factors, and macroeconomic and geopolitical events and conditions may affect our ability to raise additional funding, including through the exercise for cash of the PIPE Warrants, sales of our securities or issuance of indebtedness, which may harm our liquidity, force us to delay, limit or terminate certain or all of our product discovery, therapeutic development, research operations, preparation efforts for our NDA submission or commercialization planning efforts or cause us to grant rights to develop and market products or therapeutic candidates that we would otherwise prefer to develop and market ourselves. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or our investigational COMP360 psilocybin treatment or any future therapeutic candidate, or we may be unable to take advantage of future business opportunities. Market volatility, geopolitical tensions, such as those resulting from the ongoing war between Ukraine and Russia, conflict in the Middle East, changes in legislation and governmental policies and resources, including the effects of announced or future tariff increases, fluctuating inflation and interest rates, instability in the banking system, and the related impact on U.S. and global economies, the risk of economic slowdown or recession in the U.S., significant changes in U.S. policies or regulatory environment or disruption to U.S. government agencies or other factors could also adversely impact our ability to access capital as and when needed or increase our costs in order to raise capital.

We cannot guarantee that future financing will be available in sufficient amounts, or on commercially reasonable terms, or at all. Recent capital market conditions, including the impact of inflation, have increased borrowing rates compared to rates in the recent past and can be expected to significantly increase our cost of capital as compared to prior periods. Moreover, the terms of any financing may adversely affect the holdings or the rights of holders of our ADSs, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ADSs to decline. Our Loan Agreement with Hercules includes, and any future debt financing, if available, may involve agreements that include affirmative and negative restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. For example, our Loan Agreement with Hercules contains financial covenants requiring us to maintain certain minimum cash balances beginning October 1, 2027 and we will need to raise additional financing or significantly reduce our operating expenses to maintain compliance with this financial covenant. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to COMP360 or any future therapeutics candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Further, any additional fundraising efforts may divert our management from its day-to-day activities, which may adversely affect our ability to develop and commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates.

In addition, heightened regulatory scrutiny, regulatory delays or uncertainty in the regulatory environment could have a negative impact on our ability to raise capital. Our business activities rely on developing laws and regulations in multiple jurisdictions. It is impossible to determine the extent of the impact of any new laws, regulations or initiatives that may be proposed, or whether any proposals will become law. The regulatory uncertainty surrounding our investigational COMP360 psilocybin treatment or any future therapeutic candidates may adversely affect our business and operations, including without limitation, our ability to raise additional capital.

Outstanding warrants for our securities may not be exercised and we may not receive any additional funds upon the exercise of outstanding warrants.

As of December 31, 2025, we had 12,324,700 outstanding PIPE Warrants and 35,059,448 outstanding 2025 ADS Warrants. In February 2026, the 2025 ADS Warrants were exercised in full for cash generating approximately $203 million in net proceeds. The holders of the outstanding PIPE Warrants are not obligated to exercise the PIPE Warrants, so we may not receive any additional proceeds from the PIPE. The PIPE Warrants are exercisable for a three-year period ending in February 2027 and have an exercise price of $9.93, which is higher than the current trading price of our ADSs. We believe the likelihood that these holders will exercise the PIPE Warrants, and therefore any cash proceeds that we may receive in relation to the exercise of such PIPE Warrants, will be dependent on the trading price of our ADSs relative to the exercise price and the trading price of our ADSs may not exceed the exercise price of the PIPE Warrants prior to their expiration.

In addition, the PIPE Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the PIPE Warrants, in which case we would not receive any additional proceeds. If the PIPE Warrants are not exercised for cash, or only a portion of the PIPE Warrants are exercised for cash, we would need to obtain additional funding from other sources and may need to raise funds earlier than expected. Further, changing circumstances, some of which may be beyond our control, such as fluctuating inflation and interest rates, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Adequate additional financing may not be available to us on acceptable terms or at all.

We will not receive any meaningful amount of additional funds upon the exercise of the Pre-funded Warrants; however, any exercise would increase the number of ADSs outstanding and result in dilution to our existing shareholders.

In our January 2025 Financing, we issued and sold 11,044,720 Pre-funded Warrants, of which 8,700,000 remain outstanding as of December 31, 2025. In February 2026, we issued and sold 1,250,000 Pre-funded Warrants to a certain institutional investor and we issued 19,898,829 Pre-funded Warrants to certain institutional investors upon exercise of their 2025 ADS Warrants. Each Pre-funded Warrant will be exercisable until it is fully exercised by means of either a cash payment of the exercise price of $0.0001 per ADS or by way of a cashless exercise, meaning that the holder may not pay a cash purchase price upon exercise, but instead would receive upon such exercise the net number of ADSs representing ordinary shares determined according to the formula set forth in the Pre-funded Warrant. Accordingly, we will not receive any meaningful, or potentially any, additional funds upon the exercise of the Pre-funded Warrants. To the extent such Pre-funded Warrants are exercised, additional ADSs will be issued for nominal or no additional consideration, which will result in dilution to the then existing holders of our ADSs and will increase the number of ADSs and ordinary shares outstanding.

Our history as a clinical stage company, with no approved products to date may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We were formed in 2016 and to date, we have invested most of our resources in developing our investigational COMP360 psilocybin treatment, building our intellectual property portfolio, conducting business planning, raising capital and providing administrative support for these operations. Although we are conducting our first Phase 3 program for our COMP360 psilocybin treatment for TRD, we have not yet demonstrated an ability to successfully complete such 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.

We have in the past encountered, and may in the future encounter, unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. If we receive regulatory approval for our COMP360 psilocybin treatment or any future product candidate, we will need to transition from a company with a clinical development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We 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. In addition, during the term of our 2025 ADS Warrants, which are classified as liabilities, our net loss is expected to fluctuate significantly quarter to quarter due to non-cash increases or decreases in the fair value of these 2025 ADS Warrants. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Raising additional capital through equity financings may cause dilution to holders of our ordinary shares and ADSs and raising additional capital through debt financings, strategic partnerships, collaborations or any other means may restrict our operations or require us to relinquish rights to COMP360 or any future therapeutic candidates.

We may seek additional capital through a combination of equity offerings, debt financings, strategic collaborations and alliances, licensing arrangements or monetization transactions. To the extent that we raise additional capital through the sale of equity, convertible debt securities or other equity-based derivative securities or the exercise of the PIPE Warrants, your ownership interest will be diluted and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. For example, if all of the outstanding PIPE Warrants and the Pre-funded Warrants were exercised, we would issue 42,173,529 ADSs which would result in significant dilution to our shareholders. In addition, we have raised additional funds in the past and may raise additional funds in the future by issuing equity securities under our ATM Facility and, as a result, our stockholders have in the past experienced and may in the future experience dilution. Our Loan Agreement with Hercules includes, and any future debt financing, if available, may involve agreements that include affirmative and negative restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. For example, our Loan Agreement with Hercules contains financial covenants requiring us to maintain certain minimum cash balances beginning October 1, 2027 and we will need to raise additional financing or significantly reduce our operating expenses to maintain compliance with this financial covenant. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ADSs to decline and existing shareholders may not agree with our financing plans or the terms of such financings. If we raise additional funds through strategic collaborations and alliances, licensing arrangements or monetization transactions with third parties, we may have to relinquish valuable rights to our investigational COMP360 psilocybin treatment or any future therapeutic candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds 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 our investigational COMP360 psilocybin treatment or any future therapeutic candidates that we would otherwise prefer to develop and market ourselves. Further, any additional fundraising efforts may divert our management from its day-to-day activities, which may adversely affect our ability to develop and commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates.

Furthermore, certain shareholders and holders of ADSs, including those in the U.S., may, even in the case where preferential subscription rights have not been cancelled or limited, not be entitled to exercise such rights, unless the offering is registered or the ordinary shares are qualified for sale under the relevant regulatory framework. In addition, we have in the past submitted, and may in the future submit, to shareholders a special resolution at our annual meeting to disapply preemptive rights. As a result, there is the risk that investors may suffer dilution of their holdings should they not be permitted to participate in preference right equity or other offerings that we may conduct in the future.

We may not satisfy the conditions set forth in our Loan Agreement with Hercules in order to draw down additional funding on our term loan facility.

We may borrow additional funds of up to $100.0 million in three tranches under the terms of our Loan Agreement. The remaining tranches of term loans under our Loan Agreement with Hercules consist of (i) term loans of up to $30.0 million subject to our achievement of a milestone relating to certain FDA approvals being granted, (ii) term loans of up to $20.0 million subject to our achievement of a specified commercial milestone, and (iii) term loans of up to $20.0 million, plus the $30.0 million that became available to us upon achievement of a specified clinical milestone and any remaining unborrowed amounts from the earlier tranches, subject to the approval of Hercules' investment committee. If these conditions are met, these remaining tranches may be borrowed in drawings of a minimum of $5.0 million each. Without the achievement of the specified regulatory and commercial milestones and the satisfaction of certain customary conditions, we will not be eligible to draw additional funds under the remaining tranches. If we do not receive approval from Hercules' investment committee, which is beyond our control, we will not be eligible to draw funds under the final tranche under our Loan Agreement and will not realize the full benefits of our Loan Agreement. If we are unable to draw down additional funding under the terms of the Loan Agreement, our business, financial condition and results of operation may be harmed and we may be required to seek out alternative financing sources which may have less favorable terms.

Our operating activities may be restricted as a result of covenants related to our Loan Agreement, which could have a material adverse effect on our business, financial condition and results of operation.

On January 5, 2026, we entered into the third amendment to our Loan Agreement with Hercules for an aggregate principal amount of up to $150.0 million, of which the first tranche of $50.0 million was funded at closing and a portion of those proceeds were used to repay the outstanding amounts owed under our existing loan facility with Hercules. Until we have repaid such indebtedness, the Loan Agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance, and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock, to redeem capital stock, to enter into licensing agreements, to engage in transactions with affiliates, or to encumber our intellectual property. These covenants may

adversely affect our ability to raise funds or enter into license agreements or strategic transactions in the future. For example, if we were to seek additional sources of debt financing in the future and indebtedness under the Loan Agreement is outstanding, we would be required to seek the consent of Hercules in order to raise such additional funds. Additionally, there is a financial covenant requiring us to maintain certain minimum cash balances subject to a control agreement in favor of Hercules during the period commencing October 1, 2027 (which commencement date is subject to further adjustments if certain milestones are met) and at all times thereafter, provided that the minimum cash covenant shall not apply on any day that our market capitalization is at least $850.0 million measured on a consecutive 5-trading day period immediately prior to such date of measurement and tested on a daily basis. We need to raise additional financing or significantly reduce our operating expenses to maintain compliance with this financial covenant. Our business may be adversely affected by these restrictions on our ability to operate our business, financial condition and results of operations.

We may not have cash available in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due and our payment obligations may be accelerated upon an event of default.

Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital or other funding on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the state of the capital and lending markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Failure to satisfy our current and future debt obligations under our Loan Agreement could result in an event of default. Additionally, we may be required to repay the outstanding indebtedness under our Loan Agreement if an event of default occurs under the Loan Agreement. Under the Loan Agreement, an event of default will occur if, among other things: we fail to make payments under the Loan Agreement; we breach any of our covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches; the lender determines that a material adverse effect has occurred; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; or we are unable to pay our debts as they become due. As a result of the occurrence of an event of default, Hercules could accelerate all of the amounts due. In the event of an acceleration of amounts due under our Loan Agreement, we may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our investigational COMP360 psilocybin treatment or any future therapeutic candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events. In addition, the Loan Agreement includes customary

affirmative and negative covenants and other defaults or events of default, the occurrence and continuance of which provide Hercules with the right to demand immediate repayment of all principal and unpaid interest under the Loan Agreement, and to exercise remedies against us and the collateral securing the Loan Agreement. These defaults or events of default include, among other things, insolvency, liquidation, bankruptcy or similar events; failure to observe any covenant or secured obligation under the Loan Agreement, which failure, in most cases, is not cured within 10 days; occurrence of an event that could reasonably be expected to have a material adverse effect on our business, operations, properties, assets or financial condition; material misrepresentations; and certain money judgments being entered against us or any portion of our assets are attached or seized.

If an event of default occurs, Hercules could accelerate all of the amounts due under the Loan Agreement. Under such circumstances, we may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time of such acceleration. In that case, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our investigational COMP360 psilocybin treatment or any future therapeutic candidates that we would otherwise prefer to develop and market ourselves. Hercules could also exercise their rights to take possession and dispose of the collateral securing the Loan Agreement, which includes substantially all of our property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

Risks Related to Development, Clinical Testing and Commercialization of Our Investigational COMP360 Psilocybin Treatment and Any Future Therapeutic Candidates

We are dependent on the successful development of our investigational COMP360 psilocybin treatment. We cannot give any assurance that COMP360 will successfully complete clinical trials or receive regulatory approval, which is necessary before it can be commercialized.

We currently have no treatments that are approved for commercial sale and may never be able to develop marketable treatments. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to our investigational COMP360 psilocybin treatment, which is currently our only therapeutic candidate in clinical development, and the potential commercialization of our COMP360 psilocybin treatment, if approved. Accordingly, our business currently depends on the successful regulatory approval of COMP360 and the commercialization of our investigational COMP360 psilocybin treatment. We cannot be certain that COMP360 will receive regulatory approval or that our COMP360 psilocybin treatment will be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of our investigational COMP360 psilocybin treatment, or if COMP360 does not receive regulatory approval or fails to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever.

The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of psilocybin is, and will remain, subject to comprehensive regulation by the FDA, the DEA, the EMA, the MHRA and comparable foreign regulatory authorities. Failure to obtain regulatory approval in the U.S., Europe or other jurisdictions will prevent us from commercializing and marketing our investigational COMP360 psilocybin treatment in such jurisdictions.

Even if we were to obtain approval from the FDA, the EC, the MHRA and foreign regulatory authorities for COMP360, any approval might contain significant limitations related to use, as well as restrictions for specified age groups, warnings, precautions or contraindications, such as a black box warning for increased risk of suicidal thoughts and behaviors. Furthermore, even if we obtain regulatory approval for COMP360, we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize including securing availability of third-party treatment sites for the appropriate administration of our investigational COMP360 psilocybin treatment, secure adequate manufacturing, train and secure access to qualified healthcare professionals to monitor and safeguard patients during administration of COMP360 psilocybin treatment, establish a commercially viable pricing structure, obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs, and achieve the rescheduling of psilocybin and psilocin. If we, or any future collaborators, are unable to successfully commercialize our investigational COMP360 psilocybin treatment, we may not be able to generate sufficient revenue to continue our business.

The success of our investigational COMP360 psilocybin treatment and any future therapeutic candidates will depend on several factors, including the following:

- successful completion of clinical trials, including our Phase 3 program in TRD and related clinical and preclinical studies which will support our first application for approval of our investigational COMP360 psilocybin treatment;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or clearance for conducting our planned clinical trials or future clinical trials;
- successful patient enrollment in and completion of our Phase 2b/3 clinical trial in PTSD and any future clinical trials;
- positive data from our clinical trials that support an acceptable risk-benefit profile of COMP360 and any future therapeutic candidates in the intended populations;
- receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if COMP360 or any future therapeutic candidates are approved;

- recruiting and training qualified healthcare professionals to monitor and safeguard participants receiving our investigational COMP360 psilocybin treatment in our clinical trials;
- entry into collaborations to further the development of our investigational COMP360 psilocybin treatment and any future therapeutic candidates;
- obtaining and maintaining and defending patent and trade secret protection and/or regulatory exclusivity for COMP360 and any future therapeutic candidates;
- successfully launching commercial sales of our investigational COMP360 psilocybin treatment and any future therapeutic candidates, if approved;
- acceptance of COMP360 and any future therapeutic candidates' benefits and uses, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of COMP360 and any future therapeutic candidates;
- effectively competing, including with respect to cost, with companies developing and commercializing other treatments in the indications which our investigational COMP360 psilocybin treatment targets;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- achieving the federal and state-level rescheduling of psilocybin and psilocin;
- maintaining the strength of our reputation; and
- complying with laws and regulations, including laws applicable to controlled substances, data privacy, and pre-commercial activities.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates we develop, which would materially harm our business. If we do not receive marketing approvals for COMP360 and any future therapeutic candidates, we may not be able to continue our operations.

COMP360 psilocybin treatment is, and any future therapeutic candidates we may develop in the future may be, subject to controlled substance laws and regulations in jurisdictions where our products, if approved, may be marketed, such as the U.S., the UK and the rest of Europe, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, or changes in these laws and regulations may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition. In addition, during the review process of COMP360 psilocybin treatment, and prior to any potential approval, the FDA and/or other regulatory bodies

may require additional data, including with respect to whether COMP360 has abuse or misuse potential. This may delay approval and any potential rescheduling process.

In the U.S., psilocybin and its active metabolite, psilocin, are listed 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, or CSA, specifically as a Schedule I substance. The DEA regulates chemical 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 U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. 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 to guard against the theft or diversion of such controlled substances, including with respect to the transportation and distribution of such substances, and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription and may have a black box warning. Further, most state laws in the U.S. classify psilocybin and psilocin as Schedule I controlled substances. For any product containing psilocybin to be available for commercial marketing in the U.S., psilocybin and psilocin must be rescheduled, or the product itself must be scheduled, by the DEA to Schedule II, III, IV or V. Commercial marketing in the U.S. 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. Therefore, while psilocybin and psilocin are Schedule I controlled substances, products approved by the FDA for medical use in the U.S. that contain psilocybin or psilocin should be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. If or when COMP360 receives FDA approval, we anticipate that the DEA will make a scheduling determination and place it in a schedule other than Schedule I in order for it to be prescribed to patients in the U.S. 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 or misuse 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 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 the finished dosage form of COMP360 is listed by the DEA as a Schedule II, III, or IV controlled substance, its manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will continue to be subject to a significant degree of regulation by the DEA. In addition, the scheduling process may take significantly longer than the 90-day deadline set forth in the CSA, thereby delaying the launch of our investigational COMP360 psilocybin treatment in the U.S. 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 investigational COMP360 psilocybin treatment and any future therapeutic candidates containing controlled substances. In addition, therapeutic candidates containing controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, including:

- **DEA registration and inspection of facilities.** Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations may result in delay of the importation, manufacturing or distribution of COMP360. 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 COMP360. 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 partners 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**. Because our investigational COMP360 psilocybin treatment contains psilocybin, to conduct clinical trials with COMP360 in the U.S. prior to approval, each of 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

COMP360 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. The transportation of COMP360 to clinical trial sites is subject to security requirements and other controls under applicable controlled substance laws and regulations. We do not currently conduct any manufacturing or repackaging/relabeling of either COMP360 or its active ingredients (i.e., psilocybin) in the U.S. COMP360 is imported in its fully-finished, packaged and labeled dosage form. Our clinical trials outside the U.S. are subject to similar controlled substance legislation in other countries.

- **Importation.** If COMP360 is approved and classified as a Schedule II, III or IV substance, an importer can import it 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 COMP360 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 COMP360 is approved and classified as a Schedule II controlled substance, federal law may prohibit the import of the substance for commercial purposes. If COMP360 is 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, including psilocybin and psilocin, have never been registered with the DEA for importation for commercial purposes, only for scientific and research needs. Therefore, if neither COMP360 nor its drug substance could be imported, COMP360 would have to be wholly manufactured in the U.S., 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 U.S**. We plan to conduct manufacturing or repackaging/relabeling in the U.S. and our contract manufacturers in the U.S. would be subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of COMP360, the active ingredient in the final dosage form is currently a Schedule I controlled substance and would be subject to such quotas as this substance could remain listed on Schedule I. The annual quota allocated to us or our contract manufacturers for the active ingredient in COMP360 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 U.S**. If COMP360 is scheduled as Schedule II, III or IV, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute COMP360 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 COMP360 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 COMP360 is 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, COMP360 could be determined to have a high potential for abuse and therefore required to be administered at our trial sites, which could limit commercial uptake. 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.

- **Controlled Drug Status in the UK**. Psilocybin and psilocin are "controlled drugs" in the UK, as they are listed under Schedule 1 of the UK's Misuse of Drugs Regulations 2001 and are classified as Class A controlled substances under the Misuse of Drugs Act 1971. Substances listed under Schedule 1 of the Misuse of Drugs Regulations 2001 are considered to have little or no therapeutic benefit and are the most strictly controlled. These substances can therefore only be imported, exported, produced and supplied under a license issued by the UK Government's Home Office. Psilocybin and psilocin may never be rescheduled under the Misuse of Drugs Regulations 2001, or reclassified under the UK's Misuse of Drugs Act 1971.

The potential reclassification of psilocybin and psilocin in the U.S. could create additional regulatory burdens on our operations and negatively affect our results of operations.

If psilocybin and/or psilocin, other than the FDA-approved formulation, is rescheduled under the CSA as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V), the ability to conduct research on psilocybin and psilocin would most likely be improved. However, rescheduling psilocybin and psilocin may materially alter enforcement policies across many federal agencies, primarily the FDA and DEA. The FDA is responsible for ensuring public health and safety through regulation of food, drugs, supplements, and cosmetics, among other products, through its enforcement authority pursuant to the Federal Food, Drug, and Cosmetic Act, or the FDCA. The FDA's responsibilities include regulating the ingredients as well as the marketing and labeling of drugs sold in interstate commerce. Because it is currently illegal under federal law to produce and sell psilocybin and psilocin, and because there are no federally recognized medical uses, the FDA has historically deferred

enforcement related to psilocybin and psilocin to the DEA. If psilocybin and psilocin were to be rescheduled to a federally controlled, yet legal, substance, the FDA would likely play a more active regulatory role. The DEA would continue to be active in regulating manufacturing, distribution and dispensing of such substances. The potential for multi-agency enforcement post-rescheduling could threaten or have a materially adverse effect on our business.

COMP360 contains controlled substances, the use of which may generate public controversy. Adverse publicity or public perception regarding psilocybin or our current or future investigational treatments using psilocybin, or regarding other controlled substances, may negatively influence the success of these treatments.

Treatments containing controlled substances may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, COMP360 and any future therapeutic candidates we may develop. Opponents of these treatments 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 treatments. For example, we may face media-communicated criticism directed at our clinical development program. Adverse publicity from psilocybin misuse or risky behavior associated with recreational use of psilocybin may adversely affect our ability to obtain regulatory approval of our investigational COMP360 psilocybin treatment and, if approved, may adversely affect the commercial success or market penetration achievable by our investigational COMP360 psilocybin treatment. 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 investigational COMP360 psilocybin treatment or any future therapeutic candidates.

If COMP360 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 treatments. We may face limited adoption if third-party treatment sites, prescribing healthcare professionals, qualified healthcare professionals, and patients are unwilling to try such a novel treatment. There has been a history of negative media coverage regarding psychedelic substances, including psilocybin, which may affect the public's perception of our treatments. In addition, psilocybin elicits intense psychological experiences, and this could deter patients from choosing this course of treatment. We could be adversely affected if we were subject to negative publicity or if any of our treatments or any similar treatments 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 our treatments or any similar treatments 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 mental health diseases 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 treatments. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for COMP360 or any future therapeutic candidates.

Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. We have experienced delays in our clinical trials of COMP360 and if we experience delays in the future, we or our future collaborators may be unable to obtain required regulatory approvals, and therefore we will be unable to commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates on a timely basis or at all, which will adversely affect our business.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

We have in the past experienced delays in recruiting and enrolling patients in our Phase 3 programs in TRD and in the future we may experience similar delays in initiating or completing our Phase 2b/3 clinical trial in PTSD or future clinical trials. We may also experience numerous unforeseen events, and in some cases have experienced such events, during our clinical trials that could further delay or prevent our ability to receive marketing approval or commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates, including:

- delays in or failure to obtain regulatory approval to commence or modify a trial, including the imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including after review of an Investigational New Drug Application, or IND, or amendment, clinical trial application, or CTA, or amendment, or equivalent application or amendment, as a result of a finding that the trial presents unreasonable risk to clinical trial participants or a negative finding from an inspection of our clinical trial operations or study sites, or the occurrence of a suspected, unexpected serious adverse reaction, or SUSAR, which we have experienced in the past, or serious adverse reaction, or SAE, during our clinical trials or IISs using COMP360;
- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in or failure to obtain institutional review board, or IRB, or ethics committee approval at each site;
- failure to recruit and enroll a sufficient number of suitable patients to participate in our Phase 2b/3 clinical trial in PTSD or future clinical trials;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- challenges related to conducting adequate and well-controlled clinical trials, including designing an appropriate comparator arm in studies given the potential difficulties related to maintaining the blinding during the trial or placebo or nocebo effects;

- adding new clinical trial sites;
- availability of adequately trained healthcare professionals and appropriate third-party clinical trial sites for the administration of COMP360 psilocybin treatment in our clinical trials, including preparation, the COMP360 administration session, and post-administration follow-up;
- sufficiency of any supporting digital services that may form part of the preparation, post-administration follow-up or long-term follow-up relating to any drug we develop;
- failure to contract for the manufacture of sufficient quantities of the underlying therapeutic substance for use in clinical trials in a timely manner;
- third-party actions claiming infringement by our investigational COMP360 psilocybin treatment or any future therapeutic candidates in clinical trials and obtaining injunctions interfering with our progress;
- safety or tolerability concerns which could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- changes in regulatory requirements, policies and guidelines, including the proposed amendments to the European Union regulations related to pharmaceutical product development and marketing agreed by the Council of the European Union and the European Parliament, which, once formally adopted, will replace the current European Union regulatory framework for medicines;
- changes in regulatory requirements, policies and guidelines, including amendments to the UK clinical trial regulations;
- lower than anticipated retention rates of patients in clinical trials;
- our third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- delays in establishing the appropriate dosage levels in clinical trials;
- delays in our clinical trials due to public health crises due to factors such as a decrease in the willingness or availability of patients to enroll in our clinical trials and challenges in procuring sufficient supplies of the underlying therapeutic substance;
- the quality or stability of the underlying therapeutic substance falling below acceptable standards; and

- business interruptions resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, pandemics, or failures or significant downtime of our information technology systems resulting from cyber-attacks on such systems or those of our third-party providers or otherwise.

We could encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards, or IRBs of the institutions in which such trials are being conducted or ethics committees, by the Data Review Committee, or DRC, or Data Safety Monitoring Board for such trial or by the FDA, the EMA, the MHRA or other regulatory authorities or if the DEA registration of an investigator or site conducting the clinical trial is revoked. Such authorities may impose such a suspension or termination 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, the EMA, the MHRA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including any SUSARs or SAEs which have in the past occurred, or may in the future occur, in our trials or any IISs or other studies using COMP360 and those relating to the class to which COMP360 or any future therapeutic candidates belong, failure to demonstrate a benefit from using a drug, changes in legislation and governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience future additional delays in the completion of, or termination of, any clinical trial of COMP360 or any future therapeutic candidates, the commercial prospects of our investigational COMP360 psilocybin treatment or any future therapeutic candidates will be harmed, and our ability to generate revenue from any such therapeutic candidates will be delayed. In addition, any delays in completing our clinical trials will likely increase our costs, slow down COMP360 or any future therapeutic candidate development and approval process and jeopardize our ability to commence sales and generate revenue. Moreover, if we make changes to COMP360 or any future therapeutic candidates, we may need to conduct additional studies to bridge such modified therapeutic candidates to earlier versions, which could delay our clinical development plan or marketing approval for our investigational COMP360 psilocybin treatment or any future therapeutic candidates. Significant clinical trial delays could also allow our competitors, such as Usona Institute or Helus Pharma (formerly Cybin Inc.), to bring treatments to market before we do or shorten any periods during which we have the exclusive right to commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates and impair our ability to commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates and may harm our business and results of operations.

Any of these occurrences may harm our business, financial condition and prospects significantly. 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 COMP360 or any future therapeutic candidates or result in the development of our investigational COMP360 psilocybin treatment or any future therapeutic candidates being stopped early.

Our clinical trials may fail to demonstrate substantial evidence of the safety and effectiveness of COMP360 or any future product candidates that we may identify and pursue, which would prevent, delay or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our investigational COMP360 psilocybin treatment or future therapeutic candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that the applicable therapeutic candidate is both safe and effective for use in each target indication. A therapeutic candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process, including during our ongoing Phase 3 pivotal trials, and, because our investigational COMP360 psilocybin treatment is our only product in clinical development, there is a high risk of failure and we may never succeed in developing marketable products. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We have limited experience in managing late-stage clinical trials; our Phase 3 pivotal trials for COMP360 in TRD represent our first pivotal trials and we may not be able to successfully complete our Phase 3 pivotal trials.

We cannot be certain that our Phase 3 pivotal trials for COMP360 in TRD, our Phase 2b/3 clinical trial in PTSD or any other future clinical trials will be successful. Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our investigational COMP360 psilocybin treatment. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same therapeutic 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 clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of COMP360, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with COMP360, we may be delayed in obtaining marketing approval, or we may never obtain marketing approval. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of COMP360 in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

Even if our clinical trials are successfully completed, preclinical and clinical data are often susceptible to varying interpretations and analyses and we cannot guarantee that the FDA, the EMA or comparable foreign regulatory authorities will interpret the results as we do, or agree that our clinical trials have been appropriately designed or powered to demonstrate the safety and efficacy of COMP360. Accordingly, more trials could be required before we submit COMP360 for approval. 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, approval of COMP360 may be significantly delayed, or 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 COMP360. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. Due to the inherent risk in the development of therapeutic substances, there is a significant likelihood that COMP360 and any future therapeutic candidates will not

successfully complete development and receive approval. Many other companies that believed their therapeutic candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their product. If we do not receive regulatory approvals for COMP360 or future therapeutic candidates, we may not be able to continue our operations. Even if regulatory approval is secured for COMP360 or any future therapeutic candidate, the terms of such approval may limit the scope and use of a specific therapeutic candidate, which may also limit its commercial potential.

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 becomes available and are subject to audit and verification procedures that could result in material changes in the final data. This data may not be sufficient to support regulatory submissions or approvals.

We have in the past published and, from time to time in the future we may publish, interim, top-line or preliminary data from our clinical trials. We may decide to conduct an interim analysis of the data after a certain number or percentage of subjects have been enrolled, but before completion of the trial. Similarly, we may report top-line or preliminary results of primary and key secondary endpoints before the final trial results are completed. For example, in February 2026, we reported preliminary results from our Phase 3 trials in TRD, and the full results and safety data from our Phase 3 clinical trials in TRD may not be consistent with the preliminary results to date. Interim, top-line and preliminary data from our clinical trials may change as more patient data or analyses become available and are not necessarily predictive of final results. Further interim, top-line and preliminary data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, 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 preliminary data we previously published. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects or cause the price of our stock to decline.

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 therapeutic candidate and our company in general, and regulatory agencies may request further data from us. In addition, you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular therapeutic candidate. If the top-line 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 COMP360 or any future product candidate, our business, operating results, prospects or financial condition may be harmed.

The regulatory approval process of the FDA, the EMA, the MHRA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for COMP360 and any future therapeutic candidates, our business will be substantially harmed.

We have not previously submitted a new drug application, or NDA, to the FDA, or a marketing authorization application, or MAA, to the EMA or the MHRA, and have not obtained regulatory approval for COMP360. Before obtaining regulatory approvals for the commercial sale of COMP360 or any future therapeutic candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that COMP360 and any future therapeutic candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and while COMP360 is in a late stage of development, there continues to be a high risk of failure and we may never succeed in developing marketable products.

The time required to obtain approval by the FDA, the EMA, the MHRA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a therapeutic candidate's clinical development and may vary among jurisdictions and legal or regulatory changes could prevent, limit or delay regulatory approval of a therapeutic candidate. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad. For example, we cannot yet be certain of the impact on our therapeutic candidates of the proposed amendments to the European Union regulations related to pharmaceutical product development and marketing which have been agreed by the Council of the European Union and the European Parliament, which, once formally adopted, will replace the current European Union regulatory framework for medicines. In addition, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes.

We have in the past experienced, and may in the future also experience, delays in the development and approval of COMP360. We are conducting a Phase 3 program for COMP360 in TRD. We have Breakthrough Therapy Designation and have had dialogue with the FDA regarding our Phase 3 trial design, including certain protocol amendments that we implemented in the first half of 2023. We anticipate having on-going dialogue with the FDA throughout the conduct of the Phase 3 trials. Following our data read-outs in February 2026, we submitted a request for a meeting with the FDA to discuss a rolling submission and review and the FDA has accepted our meeting request. . With a rolling review, the FDA may consider for review sections of our NDA on a rolling basis before the complete application is submitted. However, the FDA may ultimately disagree with our proposed approach and may not permit us to utilize the rolling review process. Even if the FDA

grants our request for a rolling review, COMP360 may not experience a faster review or approval compared to conventional FDA procedures. Furthermore, policy changes or political interference by the Trump administration could negatively impact the FDA review process. In June 2023, the FDA published draft guidance regarding the nonclinical, clinical and safety considerations, as well as abuse potential assessment and risk mitigation and public health considerations for conducting trials for psychedelics, such as psilocybin. We believe our Phase 3 program reflects the key principles set forth in the draft guidance. We continued to conduct our Phase 3 program in accordance with our previously announced study design. However, the FDA may disagree with our study design or conduct, which may impact the review process for our new drug application for COMP360. Given these uncertainties in the regulatory review and approval process, it is possible that neither COMP360 nor any future therapeutic candidates we may seek to develop in the future will ever obtain regulatory approval.

COMP360 or any future therapeutic candidates could fail to receive regulatory approval from the FDA, the EMA, the MHRA or comparable foreign regulatory authorities or be precluded from commercial marketing for many reasons, including the following:

- the FDA, the EMA, the MHRA or comparable foreign regulatory authorities may disagree with, question or request changes in the size, design or implementation of our clinical trials;
- the FDA, the EMA, the MHRA or comparable foreign regulatory authorities may determine that COMP360 or any future therapeutic candidates are not safe and effective, only moderately effective, or have undesirable or unintended side effects, toxicities, or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA, the MHRA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our investigational COMP360 psilocybin treatment or any future therapeutic candidate’s clinical and other benefits outweigh its safety risks;
- the FDA, the EMA, the MHRA 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 our investigational COMP360 psilocybin treatment or any future therapeutic candidates may not be sufficient to support the submission of an NDA or other submission, or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA, the EMA, the MHRA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- the approval policies or regulations of the FDA, the EMA, the MHRA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- the potential risk of our novel treatment and delivery method, including the use of third-party clinical trial sites and qualified healthcare professionals to monitor and safeguard patients receiving COMP360 psilocybin treatment.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market any COMP360 or any future therapeutic candidates, which would significantly harm our business, results of operations and prospects. The FDA, the EMA, the MHRA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any of COMP360 or any future therapeutic candidates and may decide that our data are insufficient for approval or require additional preclinical, clinical, or other data. Even if we believe the data collected from clinical trials of COMP360 or any future therapeutic candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA, the MHRA or any other regulatory authority. For example, concerns about functional unblinding, expectancy bias or the impact of our model for supporting and monitoring participants in our clinical trials evaluating COMP360 could hinder interpretability or regulatory acceptability of data from clinical trials of our investigational COMP360 psilocybin treatment. If COMP360 or any future therapeutic candidates fails to obtain approval on the basis of any applicable condensed regulatory approval process, this will prevent such therapeutic candidates from obtaining approval on a shortened time frame, or at all, resulting in increased expenses which would materially harm our business.

In addition, even if we were to obtain approval, regulatory or pricing authorities may approve COMP360 or any future therapeutic candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our treatments, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a therapeutic candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that therapeutic candidate. For example, esketamine, a drug targeting major depressive disorder, or MDD, is only available through a Risk Evaluation and Mitigation Strategy, or REMS, program, under the applicable FDA regulations and, as is required for antidepressants, has a black box warning for increased risk of suicidal thoughts and behaviors in pediatric and young adult patients. Any of the foregoing scenarios may have a negative impact on the commercial prospects for our investigational COMP360 psilocybin treatment or any future therapeutic candidates.

Even if COMP360 or any future therapeutic candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, any such therapeutic candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our investigational COMP360 psilocybin treatment or any future therapeutic candidates.

If the FDA, the EMA, the MHRA or a comparable foreign regulatory authority approves COMP360 or any future therapeutic candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the treatment and underlying drug substance will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMPs, and with good clinical practices, or GCPs, for any clinical trials that we conduct post-approval, as well as applicable product tracking and tracing requirements, all of which may result in significant expense and limit our ability to commercialize such treatments. Additionally, a company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the U.S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Later discovery of previously unknown problems with any approved therapeutic candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the labeling, distribution, marketing or manufacturing of COMP360 or any future therapeutic candidates, withdrawal of the product from the market, or product recalls;
- untitled and warning letters, or holds on clinical trials;
- refusal by the FDA, the EMA, the MHRA or other foreign regulatory body to approve pending applications or supplements to approved applications we filed or suspension or revocation of license approvals;
- requirements to conduct post-marketing studies or clinical trials;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- product seizure or detention, or refusal to permit the import or export of the product; and
- injunctions or the imposition of civil or criminal penalties.

In addition, any regulatory approvals that we receive for COMP360 or any future therapeutic candidates may also be subject to limitations on the approved indicated uses for which our COMP360 psilocybin treatment may be marketed or to the

conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of such therapeutic candidates. For instance, we believe that COMP360, if approved, would be subject to a REMS program, under the applicable FDA regulations. REMS programs are costly and time-consuming for providers to comply with, involving high administrative burden, which could delay or limit our ability to commercialize our investigational COMP360 psilocybin treatment.

If there are changes in the application of legislation, regulations or regulatory policies, or if problems are discovered with our investigational COMP360 psilocybin treatment or our manufacture of an underlying therapeutic substance, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the therapeutic or its manufacture and requiring us to recall or remove the therapeutic from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our therapeutic labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such COMP360 psilocybin treatment may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

COMP360 and any future therapeutic candidates we may develop may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of COMP360 or any future therapeutic candidates or following approval, if any, we may need to abandon our development of such therapeutic candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences.

Undesirable side effects that may be caused by COMP360 or any future therapeutic candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials or result in clinical holds and could result in a more restrictive label, a requirement that we implement a REMS plan to ensure that the benefits of the treatment outweigh its risks, or the delay or denial of regulatory approval by the FDA, the EMA, the MHRA or other comparable foreign authorities. We or regulatory authorities may also learn of and take similar actions based on side effects related to COMP360 or compounds similar to COMP360 or any future therapeutic candidates in studies not conducted by us, including in IISs or studies conducted by other sponsors, from spontaneous reports of use of psilocybin outside of the clinical trial setting or from safety reports in literature.

The results of future clinical studies may show that COMP360 or any future therapeutic candidates cause undesirable or unacceptable side effects or even death. For example, there were a number of serious treatment emergent adverse events reported with the results of our Phase 2b and Phase 3 clinical trials in TRD. In addition, there may be serious adverse events reported in healthy volunteer studies. There can be no assurance that deaths or serious side effects will not occur, even in a clinical setting. In the event serious side effects occur, our trials could be suspended or terminated and the FDA, the EMA, the

MHRA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of COMP360 or any future therapeutic candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Further, because of the high variability in how different individuals react to psilocybin, certain clinical trial participants, including healthy volunteers, may have negative experiences with the treatment that could subject us to liability or, if publicized, reputational harm. Any of these occurrences may harm our business, financial condition and prospects significantly.

Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Even if we receive regulatory approval for COMP360 or any future therapeutic candidates, we will have tested them in only a limited number of patients during our clinical trials. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the treatment used to determine whether, on a potentially statistically significant basis, the target safety and efficacy profile of any such therapeutic candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of COMP360 or any future therapeutic candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to such therapeutic candidate for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur. If our applications for marketing are approved and more patients begin to use our COMP360 psilocybin treatment, new risks and side effects associated with our treatments may be discovered. There have been other products and treatments that have been approved by the regulatory authorities but for which safety concerns have been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of treatments from the market, and our investigational COMP360 psilocybin treatment and any future therapeutic candidates may be subject to similar risks. We might have to withdraw or recall our investigational COMP360 psilocybin treatment and any future therapeutic candidates from the marketplace. We may also experience a significant drop in the potential future sales of our investigational COMP360 psilocybin treatment or any future therapeutic candidates if and when regulatory approvals for such treatment are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved therapeutic candidates, if any, or substantially increase the costs and expenses of commercializing and marketing our investigational COMP360 psilocybin treatment and any future therapeutic candidates.

Additionally, if our investigational COMP360 psilocybin treatment or any future therapeutic candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such therapeutic candidates, a number of potentially significant negative consequences could result, including the following:

- regulatory authorities may withdraw approvals of such treatments and require us to take our approved therapeutic candidates, if any, off the market;

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a REMS plan to ensure that the benefits of the therapeutic candidate outweigh its risks;
- we may be required to change the way the COMP360 psilocybin treatment is administered, conduct additional clinical trials or change the labeling of the therapeutic candidate;
- we may be subject to limitations on how we may promote the therapeutic candidate;
- sales of the COMP360 psilocybin treatment may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the affected therapeutic candidate or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our investigational COMP360 psilocybin treatment or any future therapeutic candidates.

Even if we obtain FDA, EC or MHRA approval for COMP360 or any future therapeutic candidates that we may identify and pursue in the U.S., Europe or the UK, we may never obtain approval to commercialize any such therapeutic candidates outside of those jurisdictions, which would limit our ability to realize their full market potential.

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

Seeking foreign regulatory approval could result in difficulties and costs and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our investigational COMP360 psilocybin treatment and any future therapeutic

candidates in those countries. The foreign regulatory approval process may include all of the risks associated with obtaining FDA, EC or MHRA approval. We do not have any therapeutic candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets for COMP360 or any future therapeutic candidates. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our investigational COMP360 psilocybin treatment and any future therapeutic candidates will be harmed.

The results of preclinical studies and early-stage clinical trials of our investigational COMP360 psilocybin treatment or any future therapeutic candidates may not be predictive of the results of later stage clinical trials. Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of COMP360 or any future therapeutic candidates. There is a high failure rate for drugs proceeding through clinical trials, including in Phase 3 pivotal trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

Additionally, several of our past clinical trials utilized, and in the future we may conduct clinical trials that utilize, an “open-label” trial design. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Research and development of drugs targeting the central nervous system is particularly difficult, which makes it difficult to predict and understand why the drug has a positive effect on some patients but not others.

Discovery and development of new drugs targeting central nervous system, or 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. Any such setbacks in our clinical development could have a material adverse effect on our business and operating results. In addition, our later stage clinical trials may present challenges related to conducting adequate and well-controlled clinical trials, including designing an appropriate comparator arm in trials given the potential difficulties related to maintaining the blinding during the trial or placebo or nocebo effects.

Due to the complexity of the human brain and the central nervous system, it can be difficult to predict and understand why a drug, including COMP360, may have a positive effect on some patients but not others and why some individuals may react to the drug differently from others. For example, the population of those suffering with TRD is large and heterogenous and individuals may have different levels of severity of TRD. These differences may further result in different reactions impacting the effectiveness of our investigational COMP360 psilocybin treatment which may cause the percentage of patients, if any, that go into remission to fluctuate. All of these factors may make it difficult to assess the prior use or the overall efficacy of our investigational COMP360 psilocybin treatment. In addition, certain diseases or conditions that we target or may decide to target have in the past and may in the future present increased or unique challenges in clinical development. For example, drug development for anorexia nervosa is not well understood, and we experienced challenges in recruiting, screening and retaining participants for our Phase 2 study in anorexia nervosa. We have experienced and expect to continue to experience some recruitment challenges based on the patient populations for our clinical trials and the challenges with clinical study conduct. Moreover, these increased or unique challenges could ultimately impact our ability to seek and obtain regulatory approval in these conditions.

We depend on the enrollment and retention of patients in our clinical trials for COMP360 and any future therapeutic candidates. If we are unable to enroll and retain patients in our clinical trials, our research and development efforts and business, our financial condition and results of operations could be materially adversely affected.

Retaining a sufficient number of enrolled patients to complete our Phase 3 clinical trials in TRD and identifying and qualifying patients to participate in our Phase 2b/3 clinical trial in PTSD or future clinical trials for COMP360 in other indications or any future therapeutic candidates is critical to our success. Patient retention and enrollment depends on many factors, including:

- the length of the clinical trial and patient burden in participating in such clinical trials;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- identifying and enrolling eligible patients, including those willing to discontinue use of their existing medications;
- the design of the clinical protocol and the patient eligibility and exclusion criteria for the trial;
- safety profile, to date, of the therapeutic candidate under study;

- the willingness or availability of patients to continue to participate in our Phase 3 trials in TRD and to participate in our Phase 2b/3 clinical trial in PTSD or future clinical trials due to a number of factors, including due to the perceived risks and benefits, stigma or other side effects of use of a controlled substance, any public health crisis or other factors;
- perceived risks and benefits of our approach to treatment of indication;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions of the potential advantages of the drug being studied in relation to other available treatments, including any new treatments that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient informed consents.

In addition, any negative results we may report in clinical trials of COMP360 or any future therapeutic candidates may make it difficult or impossible to retain a sufficient number of enrolled patients to complete our Phase 3 trials in TRD and to recruit and retain patients in other clinical trials of that same therapeutic candidate. Delays in the enrollment for any clinical trial of COMP360 or any future therapeutic candidates have in the past and will in the future likely increase our costs, delay the timeframe in which the results of our clinical trials will become available, slow down the regulatory approval process and delay or potentially jeopardize our ability to commence sales of our investigational COMP 360 psilocybin treatment, if approved, and generate revenue. For example, in our clinical trials for TRD, reviewing and verifying a participant's medical records to confirm such participant meets the inclusion criteria for TRD is time-consuming and administratively burdensome, which can delay the screening process for our clinical trials. In addition, some 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 COMP360 or any future therapeutic candidates.

Further, retention of patients enrolled in our Phase 3 trials and timely enrollment in our Phase 2b/3 clinical trial in PTSD or future clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things, pandemics. For example, our clinical trial sites may be located in regions which may in the future be impacted by pandemics or public health crises. In addition, in the past, enrollment in our trials was adversely affected as a result of the COVID-19 pandemic due to limited availability of participants, the inability of patients, healthcare professionals to participate in our trials, interruptions in supply chains and delays with regulators and other similar bodies. The conduct of

our trials may continue to be adversely affected by future public health crises or pandemics, despite efforts to mitigate this impact.

We have never commercialized a therapeutic candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our treatments on our own or with suitable collaborators or on an accelerated timeline.

While we are currently engaged in commercial preparedness planning and activities, we have limited organizational experience in the sale or marketing of therapeutic candidates. To achieve commercial success for any approved treatment, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into partnerships.

If our investigational COMP360 psilocybin treatment is approved for commercial sale, we plan on establishing our own market access and commercialization capabilities in primary markets in North America. In select geographies, we might also consider relying on the support of a Contract Sales Organization, or CSO, or enter into commercialization arrangements with companies with relevant commercialization capabilities. There are risks involved in establishing our own sales and marketing capabilities, as well as with entering into arrangements with third parties to perform these services. Even if we establish sales and marketing capabilities, we may fail to launch our treatments effectively or to market our treatments effectively since we have limited organizational experience in the sales and marketing of therapeutic substances. In addition, we may not be able to launch our treatments on an accelerated timeline or at all. In addition, recruiting and training a sales force is expensive and time-consuming, and could delay any therapeutic launch. In the event that any such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our treatments on our own include:

- our inability to train an adequate number of healthcare professionals to meet the demand for COMP360 psilocybin treatment;
- the ability of healthcare professionals at third-party treatment sites to perform their roles consistently with our training and our guidelines for the administration of our investigational COMP360 psilocybin treatment;
- our inability to recruit, train and retain effective market access and commercial personnel;
- the inability of commercial personnel to obtain access to or educate adequate numbers of physicians on the benefits of prescribing any future treatments;
- our inability to identify a sufficient number of treatment centers in third-party treatment sites to meet the demands of our treatments;

- the lack of complementary treatments to be offered by our commercial personnel, which may put us at a competitive disadvantage relative to companies with more extensive therapeutic lines;
- unforeseen costs and expenses associated with creating an independent market access and commercial organization; and
- costs of market access and commercialization above those anticipated by us.

If we enter into arrangements with third parties to perform market access and commercial services for any approved treatments, the revenue or the profitability of these revenues to us could be lower than if we were to commercialize any treatments that we develop ourselves. Such collaborative arrangements may place the commercialization of any approved treatments outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our treatments or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy. Our business may be adversely affected by business combinations, restructurings or other corporate transactions, worsening of our collaboration partner's financial position or significant changes in its strategy. We may not be successful in entering into arrangements with third parties to commercialize our treatments or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to commercialize our treatments effectively, to set up a sufficient number of treatment centers in third-party treatment sites, or to recruit, train and retain an adequate number of healthcare professionals to administer our treatments.

If we do not establish commercial capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our treatments, which in turn would have a material adverse effect on our business, prospects, financial condition and results of operations.

The future commercial success of our investigational COMP360 psilocybin treatment or any future therapeutic candidates will depend on the degree of market access and acceptance of our potential treatments among healthcare professionals, patients, healthcare payors, health technology assessment bodies and the medical community at large.

We may never have a product that is commercially successful. To date, we have no product authorized for marketing. We must make substantial additional investments to complete our Phase 3 trials of our investigational COMP360 psilocybin treatment in TRD, prepare and submit our new drug application to the FDA for review, successfully obtain FDA approval, secure federal and state rescheduling for COMP360, and build a sales and marketing organization before we can generate any product revenue. Furthermore, if approved, our COMP360 psilocybin treatment may not achieve an adequate level of acceptance by payors, health technology assessment bodies, healthcare professionals, patients and the medical community at large, and we may not become profitable. The level of acceptance we ultimately achieve may be affected by negative public

perceptions and negative media coverage of psychedelic substances, including psilocybin. As a result, efforts to educate the medical community and third-party payors and health technologies assessment bodies on the benefits of our investigational COMP360 psilocybin treatment may require significant resources and may never be successful, which would prevent us from generating significant revenue or becoming profitable.

Market acceptance of any of our future treatments by healthcare professionals, patients, healthcare payors and health technology assessment bodies will depend on a number of factors, many of which are beyond our control, including, but not limited to, the following:

- acceptance by healthcare professionals, patients and healthcare payors of each treatment as safe, effective and cost-effective;
- changes in the standard of care for the targeted indications for any therapeutic candidate;
- the strength of sales, marketing and distribution support;
- potential product liability claims;
- the therapeutic candidate's relative convenience, ease of use, ease of administration and other perceived advantages over alternative treatments;
- the prevalence and severity of adverse events or publicity;
- limitations, precautions or warnings listed in the summary of therapeutic characteristics, patient information leaflet, package labeling or instructions for use;
- the cost of treatment with COMP360 in relation to alternative treatments;
- the steps that prescribers and dispensers must take, given that COMP360 includes a controlled substance, as well as the perceived risks based upon its controlled substance status;
- the ability to manufacture our product in sufficient quantities and yields;
- the availability and amount of coverage and reimbursement from healthcare payors, and the willingness of patients to pay out of pocket in the absence of healthcare payor coverage or adequate reimbursement;
- the willingness of the target patient population to try, and of healthcare professionals to prescribe, our COMP360 psilocybin treatment;
- any potential unfavorable publicity, including negative publicity associated with recreational, spiritual or medical use or abuse of psilocybin or other psychedelic drugs or with adverse outcomes or side effects from the use of psilocybin

or other psychedelic drugs such as unfavorable publicity related to use of psilocybin at Oregon state-licensed psilocybin service centers under the supervision of a state-licensed facilitator;

- any restrictions on the use, sale or distribution of our investigational COMP360 psilocybin treatment or any future therapeutic candidates, including through a REMS program;
- the extent to which treatments are approved for inclusion and reimbursed on formularies of hospitals and managed care organizations; and
- whether our treatments are designated under physician treatment guidelines or under reimbursement guidelines as a first-line, second-line, third-line or last-line treatment.

If our investigational COMP360 psilocybin treatment or any future therapeutic candidates fail to gain market access and acceptance, this will have a material adverse impact on our ability to generate revenue to provide a satisfactory, or any, return on our investments. Even if some treatments achieve market access and acceptance, the market may prove not to be large enough to allow us to generate significant revenue.

Our business and commercialization strategy for our investigational COMP360 psilocybin treatment depends on our ability to identify, qualify, prepare and support third-party treatment sites which will administer COMP360 psilocybin treatment. If we are unable to do so, our commercialization prospects would be limited and our business, financial condition and results of operations would be harmed.

If we are able to commercialize our investigational COMP360 psilocybin treatment or future treatments, our success will be dependent upon our ability to identify, qualify, prepare, certify and support third-party treatment sites that offer and administer our treatments. Our commercial model of delivering our investigational COMP360 psilocybin treatment will also involve third-party healthcare professionals before, during and after the COMP360 psilocybin administration session, which will be hosted in one of the third-party treatment sites. We intend to commercialize our investigational COMP360 psilocybin treatment and any future therapeutic candidates by building close relationships with qualified third-party treatment sites where these healthcare professionals will administer our investigational COMP360 psilocybin treatment. Because we expect our COMP360 psilocybin treatment to be subject to a REMS program and because we intend to work only with third-party sites and providers who agree to adhere strictly to our treatment protocols, we may face limitations on the number of sites available to administer our investigational COMP360 psilocybin treatment. Any such limitations could make it impracticable or impossible for some potential patients to access our investigational COMP360 psilocybin treatment, if approved, which could limit the overall size of our potential patient population and harm our future results of operations.

If we are unable to establish a sufficient network of third-party treatment sites certified under applicable standards, including regional, national, state or other applicable standards as needed to administer our COMP360 psilocybin treatment if regulatory approval is obtained, including the certifications that such third-party treatment sites may require, it would have a

material adverse effect on our business and ability to grow and would adversely affect our results of operations and commercialization efforts. We expect the healthcare professionals to be employed by the third-party treatment sites where the healthcare professionals administer our treatments. Third-party treatment sites could, for a number of reasons, demand higher payments for our treatments or take other actions to increase their income from selling our treatments, which could result in higher costs for payors and for our patients to get access to our treatments. For example, legal regimes may have higher levels of licensure which force us to contract with third-party treatment sites that demand higher payment rates to administer our COMP360 psilocybin treatment, if regulatory approval is obtained. In addition, third-party treatment sites may have difficulty meeting any applicable regulatory or accreditation requirements.

Given the novel nature of our treatment, third-party treatment sites may face additional financial and administrative burdens in order to deliver any approved treatment, including adhering to a REMS plan in the U.S. or a Risk Management Program, or RMP, in Europe. The process for a third-party treatment site to obtain a certificate under a REMS plan can be very costly and time-consuming, which could delay a third-party treatment site's ability to provide our treatments and materially adversely affect our commercialization trajectory. Furthermore, third-party treatment sites will need to ensure that they have the necessary infrastructure and equipment in order to deliver our investigational COMP360 psilocybin treatment, such as adequate audio-visual equipment, ancillary equipment and sufficient treatment rooms. This may deter third-party treatment sites from providing our therapeutic candidate and reduce our ability to expand our network and generate revenue. Our ability to develop and maintain satisfactory relationships with third-party treatment sites may otherwise be negatively impacted by other factors not associated with our operations and, in some instances, outside of our direct or indirect control, such as negative perceptions regarding the medical use of psilocybin or other psychedelic drugs, changes in Medicare and/or Medicaid or commercial payors reimbursement levels and other pressures on healthcare providers and consolidation activity among hospitals, physician groups and the providers. Reimbursement levels may be inadequate to cover third-party treatment sites' costs of delivering our investigational COMP360 psilocybin treatment. The failure to maintain or to secure new cost-effective contracts with third-party treatment sites may result in a loss of or inability to grow our network of third-party treatment sites, patient base, higher costs to our patients and us, healthcare provider network disruptions and/or difficulty in meeting regulatory or accreditation requirements, any of which could have a material adverse effect on our business, financial condition and results of operations.

We currently rely on specially trained, qualified healthcare professionals working at third-party clinical trial sites to administer our investigational COMP360 psilocybin treatment in our clinical trials and we expect this to continue upon approval, if any, of COMP360 or any future psychedelic-based drug candidates. If third-party sites fail to recruit and retain a sufficient number of healthcare professionals or effectively manage their healthcare professionals, our business, financial condition and results of operations would be materially harmed.

We currently administer our investigational COMP360 psilocybin treatment in our clinical trials with support and monitoring from qualified third-party healthcare professionals working at third-party clinical trial sites. However, there are

currently not enough trained healthcare professionals to support administration of our investigational COMP360 psilocybin treatment at a commercial scale, and our efforts to facilitate training programs may be unsuccessful.

While we currently provide training to healthcare professionals working at third-party clinical trial sites and expect to continue providing training in the future (either directly or indirectly through third-party providers), we do not currently employ the healthcare professionals who deliver our treatments in our clinical trials and do not intend to do so in the future. Such healthcare professionals are typically employed by the third-party treatment sites. If our investigational COMP360 psilocybin treatment or any future therapeutic candidates are approved for commercialization, third-party treatment sites may demand substantial financial resources from us to recruit and retain a team of specially trained, qualified healthcare professionals to administer our investigational COMP360 psilocybin treatment or any future therapeutic candidates. If the third-party treatment sites fail to recruit, train and retain a sufficient number of healthcare professionals or if a competitor develops a similar treatment that is effective without the requirement of engaging healthcare professionals to monitor and safeguard patients receiving such treatments, our ability to offer and administer our treatments will be greatly harmed, which may in turn reduce the market acceptance rate of our treatments or limit our ability to grow our business. If this occurs, our commercialization prospects would be negatively affected and our business, financial condition and results of operations would be harmed.

Although we currently provide training and expect to continue providing training to the healthcare professionals (directly or through third-party providers), we generally rely on qualified and certified third-party treatment sites to manage the healthcare professionals and monitor the administration of our treatments and ensure that the administration process of our treatments comply with our established protocols. However, if not properly managed and supervised, there is a risk that healthcare professionals may deviate from our training protocols, fail to follow the guidelines we have established, or abuse patients during psilocybin administration sessions. The healthcare professionals might also administer unauthorized treatments to patients using illegal psilocybin compounds in "underground" clinics. Such illegal activities would put the patients at risk and subject us to potential liabilities, litigations, 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.

Commercialization of our COMP360 psilocybin treatment or other psychedelic-based drug candidates is dependent on our relationships with affiliated professional entities, which we do not own, to provide physician services, and our business would be adversely affected if those relationships were disrupted.

There is a risk that U.S. state authorities in some jurisdictions may find that our contractual relationships with our affiliated providers and our Centers of Excellence violate laws prohibiting the corporate practice of medicine and certain other health professions. These laws generally prohibit the practice of medicine and certain other health professions by lay persons or entities and are intended to prevent unlicensed persons or entities from interfering with or inappropriately influencing the

professional judgment of clinicians and other health care practitioners. The professions subject to corporate practice restrictions and the extent to which each jurisdiction considers particular actions or contractual relationships to constitute improper influence of professional judgment vary across jurisdictions and are subject to change and evolving interpretations by state boards of medicine and other health professions and enforcement agencies, among others. As such, we must monitor our compliance with laws in every jurisdiction in which we operate on an ongoing basis and we cannot guarantee that subsequent interpretation of the corporate practice laws will not further circumscribe our business operations. State corporate practice restrictions also often impose penalties on health professionals for aiding a corporate practice violation, which could discourage clinicians or other licensed professionals from participating in our network of providers or Centers of Excellence. Any difficulty securing clinicians to participate in our network could impair our ability to provide treatments and could have a material adverse effect on our business.

Corporate practice restrictions exist in some form, whether by statute, regulation, professional board or attorney general guidance, or case law, in at least 42 U.S. states, though the broad variation between jurisdictions with respect to the application and enforcement of the doctrine makes establishing an exact count difficult. Because of the prevalence of corporate practice restrictions on medicine, we contract for provider services and other services provided by the Centers for Excellence through various agreements, such as service agreements, rather than employ providers. We expect that these relationships will continue, but we cannot guarantee that they will. The arrangement in which we have entered to comply with state corporate practice of medicine doctrines could subject us to additional scrutiny by federal and state regulatory bodies regarding federal and state fraud and abuse laws. In addition, a material change in our relationship with providers, whether resulting from a dispute among the entities, a change in government regulation, or the loss of these affiliations, could impair our ability to provide treatments and could have a material adverse effect on our business, financial condition and results of operations.

Changes in methods of therapeutic candidate manufacturing or formulation may result in additional costs or delay.

As therapeutic candidates are developed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, may be altered along the way in an effort to optimize processes and results. Any of these changes could cause our investigational COMP360 drug product or any future drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of COMP360 or any future therapeutic candidates and jeopardize our ability to commence product sales and generate revenue and add commercial manufacturing capacity in the U.S.

Breakthrough Therapy designation by the FDA for COMP360 or any future therapeutic candidates may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our investigational COMP360 psilocybin treatment or any future therapeutic candidates will receive marketing approval.

We have received Breakthrough Therapy designation for COMP360 for the treatment of TRD and may seek it for any future therapeutic candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing treatments on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if in the future we have therapeutic candidates that we believe meet the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for COMP360 and any future therapeutic candidates may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even though COMP360 has been designated as a breakthrough therapy, the FDA may later decide that it, or any future therapeutic candidates that are designated by the FDA as breakthrough therapies, no longer meet the conditions for qualification.

Fast Track designation, if granted by the FDA, may not actually lead to a faster development or regulatory review or approval process.

We may seek Fast Track designation for any of our therapeutic candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular therapeutic candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we receive Fast Track designation for any future therapeutic candidates, we may not experience a faster development process, review or approval compared to non-expedited FDA review procedures. In addition, the FDA may withdraw Fast Track designation for any therapeutic candidate that is granted Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may in the future enter into collaborations for the discovery, development and/or commercialization of additional therapeutic candidates or research programs. Such collaborations may not result in the development of commercially

viable therapeutic candidates or the generation of significant future revenue, or we may fail to enter into profitable relationships.

We may enter into collaborations with pharmaceutical companies or others for the discovery, development and/or commercialization of future therapeutic candidates or research programs. For example, we established a Discovery Center under a sponsored research agreement with University of the Sciences Philadelphia (which merged into Saint Joseph's University in 2022), or USciences. If we fail to enter into or maintain collaborations on reasonable terms, our ability to discover and develop future therapeutic candidates and research programs could be delayed or become more costly. Any future collaborations may subject us to a number of risks, including the following:

- the inability to control the amount and timing of resources that our collaboration partner devotes to our future research programs and therapeutic candidates;
- for collaboration agreements where we may be solely or partially responsible for funding development expenses through a defined milestone event, we may never recoup the costs of these investments if the therapeutic candidate fails to achieve regulatory approval or commercial success;
- we may rely on the information and data received from third parties regarding their research programs and therapeutic candidates without independent verification;
- we may not have control of the process conducted by the third party in gathering and composing data regarding their research programs and therapeutic candidates and we may not have formal or appropriate guarantees with respect to the quality and the completeness of such data;
- we may not have sufficient funds to satisfy any milestone, royalty or other payments we may owe to any third party collaborator;
- our collaboration agreements may contain non-competition provisions which place restrictions on our business operations and the therapeutic candidates and/or indications we may pursue;
- a collaborative partner may develop or commercialize a competing therapeutic candidate either by itself or in collaboration with others, including one or more of our competitors;
- our collaborative partners' willingness or ability to complete their obligations under our collaboration arrangements may be adversely affected by business combinations or significant changes in a collaborative partner's strategy;
- our collaborative partners may experience delays in, or increases in the costs of, the discovery and development of our future therapeutic candidates and research programs and we may be required to pay for any cost increases;

- we may have disagreements with collaborative partners, including disagreements over proprietary rights, selection of lead therapeutic candidates, contract interpretation or the preferred course of development that might cause delays or termination of the research, development or commercialization of therapeutic candidates, might lead to additional responsibilities for us with respect to therapeutic candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- our collaborative partners may not properly obtain, maintain, defend or enforce intellectual property rights; and
- our collaborative partners may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability.

We may face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a collaborative partnership depends, among other things, upon our assessment of a potential collaborator's resources and expertise, the terms and conditions of the proposed partnership and the potential collaborator's evaluation of a number of factors. Proposing, negotiating, and implementing collaborations, licensing arrangements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. We have limited institutional knowledge and experience with respect to such activities and we may also not realize the anticipated benefits of any such transaction or arrangement.

Should any of the foregoing risks materialize, any collaborations we enter into could fail to result in the development of commercially viable therapeutic candidates or the generation of future revenue, which could have a material adverse effect on our business.

Developing Centers of Excellence has in the past and may in the future involve significant costs, time and resources. If our efforts are unsuccessful, our business, prospects and financial condition would be adversely affected.

We have, and may in the future, set up research facilities and innovation labs, which we refer to as Centers of Excellence, in key markets. For example, in March 2022, we announced a strategic collaboration with King's College London and South London and Maudsley NHS Foundation Trust, or SLaM, to establish The Center for Mental Health Research and Innovation with an overarching goal of accelerating patient access to evidence-based innovation in mental health care by driving forward research in psychedelic treatments through, among other things, the development of working model psychedelic treatment clinics, our training programs, conducting clinical trials, and data analysis.

We have in the past used, and may in the future use, Centers of Excellence to gather evidence to optimize our treatment delivery, train qualified healthcare professionals, conduct clinical trials, including proof of concept studies, test digital technology solutions to improve patient experience and outcomes and pursue other activities to refine our approach to delivering our investigational COMP360 psilocybin treatment safely and cost-effectively. Our efforts to design, build and staff Centers of Excellence, or identify suitable third parties with whom we may collaborate to open these centers, will involve significant time, costs, including potential capital expenditures to acquire and develop facilities, and other resources, and may

divert our management team's focus from executing on other key elements of our business strategy. If we fail to enter into or maintain agreements with third parties to develop and operate Centers of Excellence on reasonable terms, or at all, our ability to develop our future research programs and therapeutic candidates could be delayed, the commercial potential of our treatments could change and our costs of development and commercialization could increase. If our efforts to develop these Centers of Excellence are unsuccessful, it will have a materially adverse impact on our business, future prospects and financial position.

We may become exposed to costly and damaging liability claims, either when testing our investigational COMP360 psilocybin treatment or any future therapeutic candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of therapeutic substances. Currently, we have no treatments that have been approved for commercial sale; however, the current and future use of our investigational COMP360 psilocybin treatment or any future therapeutic candidates by us and our corporate collaborators in clinical trials, under regulatory frameworks, such as expanded access programs, that allow for the use of investigational drugs and the potential sale of any approved treatments in the future, may expose us to liability claims. These claims might be made by patients or healthy volunteers who receive our investigational COMP360 psilocybin treatment in clinical trials and if regulatory approval is obtained, by patients who receive it under prescription and by healthcare providers, pharmaceutical companies, our corporate collaborators or other third parties that sell COMP360 psilocybin treatment or any future therapeutic candidates. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our investigational COMP360 psilocybin treatment or any future therapeutic candidates or any prospects for commercialization of our investigational COMP360 psilocybin treatment or any future therapeutic candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If COMP360 or any future therapeutic candidates cause adverse side effects during clinical trials or after regulatory approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with warnings that identify known potential adverse effects and describe which patients should not use COMP360 or any future therapeutic candidates. Regardless of the merits or eventual outcome, liability claims may cause, among other things, the following:

- decreased demand for our treatments due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;

- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue from therapeutic sales; and
- the inability to commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates, if approved.

It is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial treatments if we obtain marketing approval for our investigational COMP360 psilocybin treatment or any future therapeutic candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business, financial condition and results of operations could be materially adversely affected.

Liability claims resulting from any of the events described above could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Regulatory Compliance

Psilocybin and psilocin are listed as Schedule I controlled substances under the CSA in the U.S., and similar controlled substance legislation in other countries and any significant breaches in our compliance with these laws and regulations, or changes in the laws and regulations, may result in interruptions to our development activity or business continuity.

Psilocybin and psilocin are categorized as Schedule I controlled substances under the CSA, Schedule 1 drugs under the UK's Misuse of Drugs Regulations 2001 and are similarly categorized by most states and foreign governments. Even assuming that COMP360 or any future therapeutic candidates containing psilocybin or psilocin are approved and scheduled by regulatory authorities to allow their commercial marketing, the ingredients in such therapeutic candidates would likely continue to be Schedule I, or the state or foreign equivalent. Violations of any federal, state or foreign laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges and penalties, including, but not limited to, disgorgement of profits, cessation of business activities, divestiture, or prison time. This could have a material adverse effect on us, including on our reputation and ability to conduct business, our financial position, operating results, profitability or liquidity or the market price of our publicly traded ADSs. In addition, it is difficult for us to estimate the time or resources that would be needed for the investigation or defense of any such matters or our final resolution because, in part, the time and

resources that may be needed are dependent on the nature and extent of any information requested by the applicable authorities involved, and such time or resources could be substantial. It is also illegal to aid or abet such activities or to conspire or attempt to engage in such activities. An investor's contribution to and involvement in such activities may result in federal civil and/or criminal prosecution, including, but not limited to, forfeiture of his, her or its entire investment, fines and/or imprisonment.

Various federal, state, provincial and local laws govern our business in the jurisdictions in which we operate or currently plan to operate, and to which we export or currently plan to export our products, including laws relating to health and safety, the conduct of our operations, and the production, storage, sale and distribution of our products. Complying with these laws requires that we comply concurrently with complex federal, state, provincial and/or local laws. These laws change frequently and may be difficult to interpret and apply. To ensure our compliance with these laws, we will need to invest significant financial and managerial resources. It is impossible for us to predict the cost of such laws or the effect they may have on our future operations. A failure to comply with these laws could negatively affect our business and harm our reputation. Changes to these laws could negatively affect our competitive position and the markets in which we operate, and there is no assurance that various levels of government in the jurisdictions in which we operate will not pass legislation or regulation that adversely impacts our business.

In addition, even if we or third parties were to conduct activities in compliance with U.S. state or local laws or the laws of other countries and regions in which we conduct activities, potential enforcement proceedings could involve significant restrictions being imposed upon us or third parties, while diverting the attention of key executives. Such proceedings could have a material adverse effect on our business, revenue, operating results and financial condition as well as on our reputation and prospects, even if such proceedings conclude successfully in our favor. In the extreme case, such proceedings could ultimately involve the criminal prosecution of our key executives, the seizure of corporate assets, and consequently, our inability to continue business operations. Strict compliance with state and local laws with respect to psilocybin and psilocin does not absolve us of potential liability under U.S. federal law, EU law or English law, nor provide a defense to any proceeding which may be brought against us. Any such proceedings brought against us may adversely affect our operations and financial performance.

Despite the current status of psilocybin and psilocin as Schedule I controlled substances in the U.S., there may be changes in the status of psilocybin or psilocin under the laws of certain U.S. cities or states. For instance, the city of Denver voted to decriminalize the possession of psilocybin in 2019, and in Oregon, Measure 109 was passed in November 2020 to pave the way for the legal use of "psilocybin products," including naturally-derived psilocybin substances, in licensed facilities with supervision by licensed facilitators. Oregon psilocybin service centers opened and licensed facilitators began offering psilocybin services to adults over the age of 21 in January 2023. In November 2022, voters in Colorado approved a ballot measure legalizing the use of naturally-derived psilocybin and psilocin in state-regulated centers under the supervision of state-licensed facilitators and Colorado began accepting licensing applications on December 31, 2024. In April 2025, New

Mexico's governor signed SB 219, the Medical Psilocybin Act, which provides for a medical program for naturally-derived psilocybin. This bill creates a regulated medical psilocybin program overseen by the New Mexico Department of Health, allowing licensed healthcare providers to prescribe naturally-occurring psilocybin to patients with qualifying conditions, including, among others, TRD and PTSD. The program was originally expected take effect in 2028; however, the state has announced plans to start this program in December 2026. In January 2026, New Jersey's governor signed law Senate Bill No. 2283 (2R), establishing the *Psilocybin Behavioral Health Access and Therapy Pilot Program*. This bill appropriates $6.0 million of funding and authorizes a regulated pilot program designed to evaluate the safety, efficacy and feasibility of psilocybin which will be overseen by the NJ Department of Health. The research funded and completed through this pilot program in New Jersey will comply with FDA and DEA regulations, as New Jersey evaluates whether it can establish a safe, legal, and affordable medical psilocybin care delivery system. Some cities have also passed measures that decriminalizes or minimizes enforcement actions for psilocybin, including, for example, Washington, D.C. (November 2020), Somerville, Massachusetts (January 2021), Cambridge, Massachusetts (February 2021), Northampton, Massachusetts (April 2021), Seattle, Washington (October 2021), San Francisco, California (September 2022), Minneapolis, Minnesota (July 2023) and Portland, Maine (October 2023). The legalization of psilocybin without regulatory oversight or with minimal regulatory oversight may lead to the setup of clinics without proper therapeutic infrastructure or adequate clinical research, which could put patients at risk and bring reputational and regulatory risk to the entire industry, making it harder for us to achieve regulatory approval. Furthermore, the legalization of psilocybin could also impact our commercial sales if we receive regulatory approval as it would reduce the barrier to entry and could increase competition.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from manufacturing COMP360 and developing and selling our investigational COMP360 psilocybin treatment or any future therapeutic candidates outside the U.S. or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the UK Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage.

The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, a financial or other advantage to government officials or other persons to induce them to improperly perform a relevant function or activity (or reward them for such behavior).

Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We, along with those acting on our behalf and our commercial partners, operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, 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.

Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. 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. If we expand our operations, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the UK and the U.S., and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from manufacturing COMP360 and developing and selling our investigational COMP360 psilocybin treatment or any future therapeutic candidates outside of the U.S., which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar

issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by UK, U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

We may become subject to U.S. federal and state forfeiture laws which could negatively impact our business operations.

Violations of any U.S. federal laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges, including, but not limited to, seizure of assets, disgorgement of profits, cessation of business activities or divestiture. As an entity that conducts business involving psilocybin and psilocin, we are potentially subject to federal and state forfeiture laws (criminal and civil) that permit the government to seize the proceeds of criminal activity. Civil forfeiture laws could provide an alternative for the federal government or any state (or local police force) that wants to discourage residents from conducting transactions with psilocybin- and psilocin-related businesses but believes criminal liability is too difficult to prove beyond a reasonable doubt. Also, an individual can be required to forfeit property considered to be the proceeds of a crime even if the individual is not convicted of the crime, and the standard of proof in a civil forfeiture matter is lower than the standard in a criminal matter. Depending on the applicable law, whether federal or state, rather than having to establish liability beyond a reasonable doubt, the federal government or the state, as applicable, may be required to prove that the money or property at issue is proceeds of a crime only by either clear and convincing evidence or a mere preponderance of the evidence.

Investors located in jurisdictions where psilocybin and psilocin remains illegal may be at risk of prosecution under conspiracy, aiding and abetting, and money laundering statutes, and be at further risk of losing their investments or proceeds under forfeiture statutes. Many jurisdictions remain fully able to take action to prevent the proceeds of psilocybin and psilocin businesses from entering their state. Our investors and prospective investors should be aware of these potentially relevant laws in considering whether to invest in us.

We are subject to certain tax risks and treatments that could negatively impact our results of operations.

Section 280E of the Internal Revenue Code of 1986, as amended, or the Code, prohibits businesses from deducting certain expenses associated with trafficking controlled substances (within the meaning of Schedule I and II of the CSA). The U.S. Internal Revenue Service, or IRS, has invoked Section 280E in tax audits against various businesses in the U.S. that are permitted under applicable state laws. Although the IRS issued a clarification allowing the deduction of certain expenses, the scope of such items is interpreted very narrowly and the bulk of operating costs and general administrative costs are not permitted to be deducted. There is no guarantee that any federal court will issue an interpretation of Section 280E favorable to psilocybin and psilocin businesses.

We may be unable to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments or benefit from favorable UK tax legislation.

As a UK incorporated and tax resident entity, we are subject to UK corporation tax on tax-adjusted trading profits. Due to the nature of our business, we have generated losses since inception and therefore have not paid any UK corporation tax. We had accumulated trading losses for carry forward in the UK of $577.9 million and $280.8 million as of December 31, 2025 and December 31, 2024, respectively. Subject to any relevant utilization criteria and restrictions (including, but not limited to, those that limit the percentage of profits that can be reduced by carried forward losses and those that can restrict the use of carried forward losses where there is a change of ownership of more than half of our ordinary shares and a major change in the nature, conduct or scale of the trade), we expect these to be eligible for carry forward and utilization against future operating profits. The use of loss carryforwards in relation to UK profits incurred on or after April 1, 2017 is limited each year to £5.0 million per group plus, broadly, an incremental 50% of the remaining UK taxable profits. In addition, if we were to have a major change in the nature of the conduct of our trade, loss carryforwards may be restricted or extinguished.

As a company that carries out extensive R&D activities, we seek to benefit from the UK R&D tax relief programs, which historically consisted of the Small and Medium-sized Enterprises, or SME, R&D tax relief program, or SME Program, and, to the extent that our projects are grant funded or relate to work subcontracted to us by third parties, the Research and Development Expenditure Credit program, or RDEC Program. For accounting periods starting on or after April 1, 2024, the SME and RDEC regimes have been merged; this change impacted us for the first time beginning January 1, 2025. Under this new merged scheme, for non research intensive companies, the effective net credit will be 16.2% for in-house expenditure and 10.5% for any work that is contracted out. This merged regime will apply to both SME and large companies. For accounting periods starting on or after April 1, 2023 and before April 1, 2024, under the SME Program, trading losses that arise from qualifying R&D activities can be surrendered for a cash rebate of an amount up to an effective rate of 18.6% of such qualifying R&D expenditures or 12.1% for any work that is contracted out. The majority of our research, clinical trials management and clinical manufacturing development activities are eligible for inclusion within these tax credit cash rebate claims.

The SME Program and the new merged scheme incorporates a cap on repayable credits to a multiple of payroll taxes (broadly, to a maximum payable credit equal to £20,000 plus three times the total PAYE and NICs liability of the company) subject to an exception which prevents the cap from applying. That exception requires the company to be creating, taking steps to create or managing intellectual property, as well as having qualifying R&D expenditure in respect of connected parties which does not exceed 15% of the total claimed. If the exception does not apply, this could restrict the amount of payable credit that we claim.

The rates described above relate to non research intensive companies. However, new rules were introduced by the Finance Act 2024 for an enhanced rate of relief for research intensive companies, or ERIS, which are approximately 27.0% for

qualifying expenditure and approximately 17.5% for qualifying subcontracted expenditure (paid to an unconnected subcontractor). To be eligible as a research intensive company, the qualifying R&D expenditure for tax purposes must be at least 40% of the aggregate expenditure across the consolidated group. The threshold has decreased from 40% to 30% from January 1, 2025.

For the years ended December 31, 2023 to 2025, we are currently having discussions with the UK tax authority His Majesty's Revenue and Customs, or HMRC, regarding whether we have met the R&D intensity condition and therefore are eligible for the enhanced effective rate due to uncertainties over whether impairments on intercompany loans and investments in subsidiary companies should be taken into account in determining the R&D intensity threshold. The outcome of this matter under discussion with HMRC is currently unknown.

We believe that the impairments of intercompany loans and investments in subsidiary companies should be disregarded and that we meet the R&D intensity condition in the years ended December 31, 2023 and December 31, 2024. As we believe that we meet the R&D intensity condition for the year ended December 31, 2024, we should automatically meet the expenditure conditions to be eligible for the enhanced rate in the year ended December 31, 2025, as a company remains research intensive unless it fails to meet the eligibility requirements for two consecutive years. Given the uncertainty over the outcome of discussions with HMRC, the enhanced R&D credits have not been reflected in our financial statements. If we reach a successful conclusion with HMRC, additional credits of $4.1 million in the year ended December 31, 2023, $7.0 million in the year ended December 31, 2024 and $7.3 million in the year to December 31, 2025 could be claimed.

Restrictions have also been introduced on relief that may be claimed for expenditure on contracted out R&D activity where the work is undertaken outside the UK, save for certain exceptions. These changes may impact the quantum of R&D relief that we are able to claim in the future and took effect for accounting periods starting from April 1, 2024, which has therefore impacted us for the first time from January 1, 2025. These restrictions and the application of the exceptions have been taken into account in the assessment of qualifying expenditure.

We may benefit in the future from the UK's "patent box" regime, which allows certain profits attributable to revenue from patented products (and other qualifying income) to be taxed at an effective rate of 10% by giving an additional tax deduction. We own two UK patents which cover our investigational COMP360 psilocybin treatment, and accordingly, future upfront fees, milestone fees, product revenue and royalties could be eligible for this deduction. When taken in combination with the enhanced relief available on our R&D expenditures, we expect a long-term rate of corporation tax lower than the statutory rate to apply to us. If, however, there are unexpected adverse changes to the UK R&D tax credit regime or the "patent box" regime, or for any reason we are unable to qualify for such advantageous tax legislation, or we are unable to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments then our business, results of operations and financial condition may be adversely affected. This may impact our ongoing requirement for investment and the timeframes within which additional investment is required.

HMRC has an increased focus on claims for R&D tax reliefs and we may be subject to increased scrutiny in respect of any claims it makes. In addition, the legislation on the UK R&D tax reliefs regime is updated and changed frequently, so there can be no guarantee of our ability to make use of reliefs as it might currently expect to in future.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of, adequate reimbursement for and commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates and could have a material adverse effect on our business.

In the U.S., the EU and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and there may continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. For more information regarding the risks related to these laws and regulations, please see the section entitled "*Business—Healthcare Reform*" in our Annual Report on Form 10-K for the year ended December 31, 2025.

We expect that changes and challenges to the ACA, as well as 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, new payment methodologies, and additional downward pressure on the price that we receive for any future approved product.

New laws and additional health reform measures may result in additional reductions in Medicare and other healthcare funding, which may adversely affect customer demand and affordability for our investigational COMP360 psilocybin treatment and any future therapeutic candidates and, accordingly, the results of our financial operations. These 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 investigational COMP360 psilocybin treatment or any future therapeutic candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and

- the availability of capital.

The growing legislative and enforcement interest in the United States with respect to drug pricing practices; has resulted in several U.S. Congressional inquiries and federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022, or the IRA, for example, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries to $2,000 starting in 2025, eliminating the prescription drug coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of an HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs were previously exempted from the Medicare drug price negotiation program; however, this exemption was restricted to drugs with only one orphan designation and for which the only approved indication is for that disease or condition. If a product received multiple orphan designations or had multiple approved indications, it would not qualify for the orphan drug exemption. Under the One Big Beautiful Bill Act of 2025, or OBBBA, this restriction was eliminated; effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan designations or indications, are exempt from the Medicare drug price negotiation program. The effects of the IRA and the OBBBA on our business and the healthcare industry in general is not yet known.

On April 15, 2025, the Trump Administration published Executive Order 14273, “Lowering Drug Prices by Once Again Putting Americans First,” which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called “pill penalty” under the Inflation Reduction Act that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump Administration published Executive Order 14297, “Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients” which generally, among other things, directs the federal government to establish and communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Trump Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the most-favored-nation lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to “take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries.” Notably, a similar “Most Favored Nation” pricing rule enacted under

the first Trump Administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021. Recent CMS proposals, including the GLOBE, GUARD, and GENEROUS proposals, could materially impact our revenue.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments are likely, and there may be ongoing initiatives in the U.S. to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from one or more of our approved products or other therapeutic 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 therapeutic candidates.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers may be subject, directly or indirectly, to U.S. federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, other healthcare laws and regulations and other foreign privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any treatments on the market, our current and future operations may be directly, or indirectly through our relationships with investigators, health care professionals, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute or the federal Anti-Kickback Statute. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any treatments for which we obtain marketing approval. These laws impact, among other things, our research activities and proposed sales, marketing and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals who participate in our clinical research program, healthcare professionals and others who recommend, purchase, or provide our approved treatments, and other parties through which we market, sell and distribute our treatments for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business, along with foreign regulators (including European data protection authorities). Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. For more information regarding the risks related to these laws and regulations, please see the section entitled "*Business—Other Healthcare Laws and Compliance Requirements*" in our Annual Report on Form 10-K for the year ended December 31, 2025.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including licensing, extensive record-keeping, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

Further, if any of our Centers for Excellence conduct clinical studies, we may face risks relating to operating a clinical trial site. Such risks may include, but are not limited to, research misconduct and patient injury. In addition, we may end up possessing a large amount of individually identifiable health information. Such activities are subject to a wide variety of laws, such as the Health Insurance Portability and Accountability Act, or HIPAA.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Even if precautions are taken, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations 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 these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, 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, reputational harm and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Failure to comply with health and data protection laws and regulations could lead to U.S. federal and state government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to U.S. federal and state data protection laws and regulations, such as laws and regulations that address privacy and data security. In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. At the federal

level, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission, or FTC Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities.

In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, which are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economics and Clinical Health, or HITECH. To the extent that we act as a business associate to a healthcare provider engaging in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of patient-identifiable health information, mandates the adoption of standards relating to the privacy and security of patient-identifiable health information, and requires the reporting of certain security breaches to healthcare provider customers with respect to such information. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Regulators and legislators in the U.S. are also increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Department of Justice's January 8, 2025, rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

In addition, certain state laws govern privacy and security of personal information. For example, in California, the California Consumer Privacy Act, or CCPA, which came into effect on January 1, 2020, established a comprehensive privacy framework for covered businesses by creating an expanded definition of personal information, providing new data privacy rights for consumers and imposing operational requirements for companies. The CCPA required covered companies to provide certain disclosures to consumers about their data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. In particular, the CCPA gave California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and to receive detailed information about how their personal information is used. While clinical trial data and information governed by HIPAA are currently exempt from the CCPA, other personal information may be applicable and possible changes to the CCPA may broaden its scope.

As of January 2026, 20 states now have similarly comprehensive privacy laws in effect, adding complexity, variation in requirements, restrictions and potential legal risk, requiring additional investment of resources in compliance programs. The existence of comprehensive privacy laws in different states make may also increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. These laws may also impact our strategies, the availability of previously useful data and could result in increased compliance costs as well as other changes in our business practices and policies.

Several states are also specifically regulating health information and other specific categories of personal information. For example, Washington's My Health My Data Act, which became effective on March 31, 2024, regulates the collection and sharing of health information and has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. State laws are changing rapidly and there are discussions in the U.S. Congress of new comprehensive federal data privacy laws to which we could become subject to, if enacted. Likewise, a small number of states, including Illinois and Texas, have enacted laws that specifically target the collection and use of biometric information.

Compliance with U.S. and foreign privacy and data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure, or perceived failure, to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Any of the foregoing could have a material effect on our business, financial condition, results of operations and prospects.

European data collection is governed by restrictive privacy and security regulations governing the use, processing and cross-border transfer of personal information.

We are subject to European data protection regulations, where we collect and use personal data relating to Europe, including to conduct and enroll subjects in clinical trials in the UK or the European Economic Area, or EEA. This includes the EU General Data Protection Regulation, or EU GDPR, and the UK equivalent of the same, the UK GDPR (collectively referred to as the GDPR), as well as other national data protection legislation in force in the UK and relevant EEA Member States (including the UK Data Protection Act 2018 in the UK), which govern the collection, use, storage, disclosure, transfer, or other processing of personal data (including health data processed in the context of clinical trials) (i) regarding individuals

in the UK and EEA, and/or (ii) carried out in the context of the activities of our establishment in the UK and any EEA Member State.

The GDPR is wide-ranging in scope and imposes numerous additional requirements on companies that process personal data, including imposing special requirements in respect of the processing of health and other sensitive data, requiring that consent of individuals to whom the personal data relates is obtained in certain circumstances, requiring additional disclosures to individuals regarding data processing activities, requiring that safeguards are implemented to protect the security and confidentiality of personal data, limiting retention periods for personal data, increasing requirements pertaining to health data and pseudonymized (i.e., key-coded) data, creating mandatory data breach notification requirements in certain circumstances, and requiring that certain measures (including contractual requirements) are put in place when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the UK and EEA, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenue, whichever is greater. The GDPR provides individuals with various rights in respect of their personal data, including rights of access, erasure, portability, rectification, restriction and objection. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

The GDPR provides that EEA Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences between EEA Member States, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition.

In addition, we are subject to evolving and strict rules on the transfer of personal data out of the UK and EEA to third countries such as the U.S. in certain circumstances, unless a derogation exists or a valid GDPR transfer mechanism (for example, the European Commission approved Standard Contractual Clauses, or SCCs, and the UK International Data Transfer Agreement/Addendum, or UK IDTA) have been put in place. Where relying on the SCCs or the UK IDTA for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. Any inability to transfer personal data from the UK and EEA to third countries in compliance with data protection laws may adversely affect our operations and our business and financial position. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore

decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition, and results of operations.

The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR. While we have taken steps to comply with the GDPR, and implementing legislation in the UK and applicable EEA Member States, including by seeking to establish appropriate lawful bases for the various processing activities we carry out as a controller or joint controller, reviewing our security procedures and those of our vendors and collaborators, and entering into data processing agreements with relevant vendors and collaborators, we cannot be certain that our efforts to achieve and remain in compliance have been, and/or will continue to be, fully successful.

The UK data protection regime is independent from but currently still aligned with the EEA's data protection regime. However, going forward, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the UK and EEA. Although the UK is regarded as a third country under the EU's GDPR, the European Commission has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. Similarly, the UK Data (Use and Access) Bill 2025 is now in full force and may further differentiate the UK and EEA data protection regimes. Following the entry into force of the Act, the European Commission renewed the EU–UK adequacy decisions for another six years, meaning the UK's data protection framework is still considered to provide "essentially equivalent" safeguards to the EU's GDPR. While this renewal reduces immediate adequacy concerns, future divergence remains a possibility. Such divergence between the EU GDPR and UK GDPR would create additional regulatory uncertainty increasing legal risk, complexity and compliance cost to our handling of personal data. This may require us to adapt our privacy and data security compliance programs to account for legal and regulatory divergence between the UK and the EEA.

The successful commercialization of our investigational COMP360 psilocybin treatment or any future therapeutic candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our investigational COMP360 psilocybin treatment or any future therapeutic candidates, if approved, could limit our ability to market those treatments and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford treatments such as our investigational COMP360 psilocybin treatment or any future therapeutic candidates, if approved. The OBBBA reduced funding to federal healthcare programs and imposed additional requirements, including implementing work requirements for some beneficiaries, to be eligible for healthcare, which may result in decreased access to healthcare, particularly in Medicaid programs. As Schedule I substances under the CSA, psilocybin and psilocin are deemed to have no

accepted medical use and treatments that use psilocybin or psilocin are precluded from reimbursement in the U.S. Our products must be scheduled as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V) before they can be commercially marketed. Our ability to achieve acceptable levels of coverage and reimbursement for treatments by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract additional collaboration partners to invest in the development of our investigational COMP360 psilocybin treatment or any future therapeutic candidates. There is limited clinical data on the long-term efficacy of psilocybin on treating TRD. Certain patients may need repeated treatments over their lifetime to avoid relapse. This may increase treatment costs, making it more difficult for us to secure reimbursement. Even if we obtain coverage for a given treatment by third-party payors, the resulting reimbursement payment rates may not be adequate or may require patient out-of-pocket costs that patients may find unacceptably high. We cannot be sure that coverage and reimbursement in the U.S., Europe or elsewhere will be available for any treatment that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. For more information regarding the risks related to these laws and regulations, please see the section entitled "*Business—Coverage, Pricing and Reimbursement*" in our Annual Report on Form 10-K for the year ended December 31, 2025.

We intend to seek approval to market our investigational COMP360 psilocybin treatment or future therapeutic candidates in both the U.S. and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for COMP360 or our future therapeutic candidates, we will be subject to rules and regulations in those jurisdictions.

In some foreign countries, particularly certain countries in Europe, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our investigational COMP360 psilocybin treatment or our future therapeutic candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a therapeutic candidate. In addition, market acceptance and sales of our investigational COMP360 psilocybin treatment or future therapeutic candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our investigational COMP360 psilocybin treatment or future therapeutic candidates and may be affected by existing and future healthcare reform measures.

Third-party payors are increasingly challenging prices charged for therapeutic substances and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive drug is available. It is possible that a third-party payor may consider our investigational COMP360 psilocybin treatment or any future therapeutic candidates as substitutable and only offer to reimburse patients for the less expensive drug. Even if we show improved efficacy or improved convenience of administration with our investigational COMP360 psilocybin treatment or any future therapeutic candidates, pricing of existing drugs may limit the amount we will be able to charge. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed treatments at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our

investigational COMP360 psilocybin treatment or any future therapeutic candidates, and may not be able to obtain a satisfactory financial return on therapeutic candidates that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved treatments. In the U.S., third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug products before they will reimburse health care providers who use such treatments. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our investigational COMP360 psilocybin treatment or any future therapeutic candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug products exists among third-party payors in the U.S. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our treatments to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

On the state level, local governments have been very aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. 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. This could reduce the ultimate demand for our treatments or put pressure on our therapeutic pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, and other countries has and will continue to put pressure on the pricing and usage of our investigational COMP360 psilocybin treatment or any future therapeutic candidates. In many countries, the prices of medical treatments are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical treatments, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulations could restrict the amount

that we are able to charge for our investigational COMP360 psilocybin treatment or any future therapeutic candidates. Accordingly, in markets outside the U.S., the reimbursement for our treatments may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU-wide, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of treatments in that context. In general, however, the healthcare budgetary constraints in many EU Member States have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with increasing EU and national regulatory burdens on those wishing to develop and market treatments, this could prevent or delay marketing approval of our investigational COMP360 psilocybin treatment or any future therapeutic candidates, restrict or regulate post-approval activities and affect our ability to commercialize any treatments for which we obtain marketing approval.

EU drug marketing regulation may materially affect our ability to market and receive coverage for our treatments in the EU Member States. Much like the federal Anti-Kickback Statute prohibition in the U.S., the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal treatments is also prohibited in most countries within the EU. The provision of benefits or advantages to induce or reward improper performance generally is typically governed by the national anti-bribery laws of EU Member States, and in respect of the UK, the Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Payments made to physicians and other healthcare professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician’s employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in individual EU Member States and the particular requirements can therefore vary widely amongst the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in some foreign countries, including certain EU Member States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from

country to country. For example, individual Member States in the EU have the ability to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced Member States, can further reduce prices. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our investigational COMP360 psilocybin treatment or any of our future therapeutic candidates to other available treatments in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our treatments. Historically, drug products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower. 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 treatments is unavailable or limited in scope or amount, our revenue from sales and the potential profitability of our investigational COMP360 psilocybin treatment or any of our future therapeutic candidates in those countries would be negatively affected.

Moreover, efforts by governmental and third-party payors in the EU, the U.S. and elsewhere to cap or reduce healthcare costs may cause such organizations to limit coverage and the level of reimbursement for newly approved treatments and, as a result, they may not cover or provide adequate payment for our investigational COMP360 psilocybin treatment or any future therapeutic candidates. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific treatments. We expect to experience pricing pressures in connection with the sale of our investigational COMP360 psilocybin treatment or any future therapeutic candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new treatments.

We could experience difficulty enforcing our contracts.

Due to the nature of our business and the fact that some of our contracts involve psychedelics including psilocybin and psilocin, the use of which 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, operating results, financial condition or prospects.

In order to manage our contracts with contractors, we ensure that such contractors are appropriately licensed at the state and federal level in the U.S., and at the appropriate level in other territories. 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 investigational COMP360 psilocybin treatment or any future psychedelic-based drug candidate.

Risks Related to Intellectual Property

We rely on patents and other intellectual property rights to protect our investigational COMP360 psilocybin treatment, the enforcement, defense and maintenance of which may be challenging and costly. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for COMP360, any future therapeutic candidates, any associated support and monitoring provided by licensed healthcare professionals, digital tools, methods used to manufacture the underlying drug substances, and the methods for treating patients using those substances, or on licensing in such rights. Failure to obtain, maintain, protect, enforce or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our investigational COMP360 psilocybin treatment and any future therapeutic candidates. We also rely on trade secrets and know-how to develop and maintain our proprietary and intellectual property position. Any failure to protect our trade secrets and know-how could adversely affect our operations and prospects.

We cannot be certain that patents will be issued or granted with respect to patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid or unenforceable. The patent position of companies like ours is generally uncertain because it involves complex legal and factual considerations. The standards applied by the European Patent Office, the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in pharmaceutical patents. Consequently, patents may not issue from our pending patent applications, and even if they do issue, such patents may not issue in a form that effectively prevents others from developing or commercializing competing treatments. As such, we do not know the degree of future protection that we will have on our proprietary treatments.

The patent prosecution process is expensive, complex and time-consuming, and we and our current or future third party partners, licensors, licensees, or collaboration partners may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaboration partners will fail to identify patentable aspects of inventions made in the course of research, development or commercialization activities before it is too late to pursue patent protection on them. In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, publications

of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not published until and unless granted. Therefore, we cannot be certain that 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. Similarly we cannot be certain that for any licensed patents or pending patent applications, the named applicant(s) were the first to make the inventions claimed in such patents or pending patent applications or that the named applicant(s) were the first to file for patent protection for such inventions.

Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaboration partners' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our treatments, in whole or in part, or that effectively prevent others from commercializing competitive technologies and treatments.

Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors, licensees or collaboration partners. If our current or future licensors, licensees or collaboration partners fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaboration partners are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent examination process may require us or our licensors, licensees or collaboration partners to narrow the scope of the claims of our or our licensors', licensees' or collaboration partners' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application.

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 U.S. and abroad. Even if patents do successfully issue and even if such patents cover COMP360 and any future therapeutic candidates, third parties may initiate an opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation proceedings in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. For example, in December 2021, a third party filed two petitions requesting post grant review of two of our patents (U.S. Patent 10,947,257 and U.S. Patent 10,954,259) before the Patent Trial & Appeal Board of the U.S. Patent and Trademark Office, or the USPTO Board. On June 22, 2022, the USPTO Board issued decisions in both cases denying institution of post grant review on the merits of the arguments presented in each of the challenges. On July 22, 2022, the third-party challenger filed a request with the USPTO Board for rehearing of the USPTO Board's decision, as well as a request for

Precedential Opinion Panel on August 16, 2022 in each of the challenges. On February 10, 2023, the USPTO Board denied the request for Precedential Opinion Panel in each of the challenges. On May 23, 2023, the USPTO Board denied the requests for rehearing in each of the challenges. We cannot provide any assurances that we will successfully defend ourselves against any future patent challenges.

Our and our licensors', licensees' or collaboration partners' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. In addition, patents and other intellectual property rights also will not protect our technology, COMP360 and any future therapeutic candidates if third parties, including our competitors, design around our protected technology and our investigational COMP360 psilocybin treatment and any future therapeutic candidates without infringing, misappropriating or otherwise violating our patents or other intellectual property rights. Moreover, some of our patents and patent applications 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 treatments 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.

Because patent applications are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our current or future licensors, licensees or collaborators were or will be the first to file any patent application related to a therapeutic candidate. Furthermore, if patent applications of third parties have an effective filing date before March 16, 2013, an interference proceeding can be initiated by such third parties at the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If patent applications of third parties have an effective filing date on or after March 16, 2013, a derivation proceeding can be initiated by such third parties at the USPTO to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, we may be subject to third-party challenges regarding our exclusive ownership of our intellectual property. If a third party were successful in challenging our exclusive ownership of any of our intellectual property, we may lose our right to use such intellectual property, such third party may be able to license such intellectual property to other third parties, including our competitors, and our competitors could market competing treatments and technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Issued patents covering one or more of our investigational therapeutics could be found invalid or unenforceable if challenged in court.

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. Enforcement of intellectual property rights is difficult, unpredictable and expensive, and many of our or our licensors' or collaboration partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaboration partners can. Accordingly, despite our or our licensors' or collaboration partners' efforts, we or our licensors or collaboration partners may not prevent third parties from infringing upon, misappropriating or otherwise violating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the UK, EU and the U.S. We may fail in enforcing our rights, in which case our competitors and other third parties may be permitted to use our treatments without payment to us.

In addition, litigation involving our patents carries the risk that one or more of our patents will be held unenforceable, one or more claims narrowed or held invalid (in whole or in part, on a claim-by-claim basis). Such an adverse court ruling could allow third parties to commercialize our treatments, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our investigational treatments, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the U.S. or in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. A claim for a validity challenge may be based on failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. A claim 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. Third parties may also raise challenges to the validity of our patent claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover COMP360 or any future therapeutic candidates. For example, on July 22, 2022, a third-party challenger filed with the USPTO Board requests for rehearing of the USPTO Board's decisions to deny institution of post-grant reviews of U.S. Patent 10,947,257 and U.S. Patent 10,954,259, and on August 16, 2022, the third-party challenger also filed requests for a Precedential Opinion Panel in each of the patents. On February 10, 2023, the USPTO Board denied the request for a Precedential Opinion Panel in each of the challenges. On May 23, 2023, the USPTO Board denied the requests for rehearing in each of the challenges. The outcome following legal assertions of invalidity and unenforceability during patent litigation or other proceedings is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant or third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on COMP360 or one or more of any future therapeutic candidates. Such a loss of patent protection could have a

material adverse impact on our business, financial condition, results of operations, and prospects. Further, litigation could result in substantial costs and diversion of management resources, regardless of the outcome, and this could harm our business and financial results.

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 and annuity fees on any issued patent are due to be paid to the European Patent Office, the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The European Patent Office, the USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our collaboration partners to pay these fees due to the U.S. and comparable foreign patent agencies and take the necessary action to comply with such requirements with respect to our intellectual property. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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 failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaboration partners fail to maintain the patents and patent applications covering our investigational treatments, third parties, including our competitors might be able to enter the market with similar or identical treatments or technologies, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation for extending the term of patents covering each of our investigational treatments, our business may be materially harmed.

In the U.S., if all maintenance fees are paid on time, the natural expiration of a patent is generally 20 years from its earliest non-provisional 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 investigational treatments, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive treatments. Given the amount of time required for the development, testing and regulatory review of new investigational treatments, patents protecting such candidates and concomitant treatments might expire before or shortly after such candidates and concomitant treatments are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing treatments similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of COMP360 and any future therapeutic candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price

Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, and similar legislation in the EU. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term loss during product development, the FDA regulatory review process and the issuance of a final decision controlling the product under the Controlled Substance Act. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method of manufacturing it may be extended. However, we may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will not be lengthened and third parties, including our competitors, may obtain approval to market competing treatments sooner than we expect. As a result, our revenue from applicable treatments could be materially reduced and our business, financial condition, results of operations, and prospects could be materially harmed.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds or develop digital assets that are the same as or similar to our investigational COMP360 psilocybin treatment, any future therapeutic candidates and digital assets but that are not covered by the claims of the patents that we own or control;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or any current or future collaboration partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or control;
- we or our licensors or any current or future collaboration partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our current and future pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by third parties;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive treatments for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our treatments or technologies could unknowingly use the intellectual property of others without obtaining a proper license;
- we may not develop additional technologies that are patentable; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property, or otherwise develop similar know-how.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims by third parties asserting that our current or former employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our current and former consultants, advisors and employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors and potential competitors, or have worked with collaborators while working at the Company or in connection with such previous employment. Some of these individuals executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment or otherwise acquired confidential information or intellectual property owned by another person or entity while working with us or for a former employer. Although we intend that our consultants, advisors and employees do not use proprietary information or know-how owned by another company or person while working for us, we have in the past been, and may in the future be, subject to claims that we or these individuals have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, owned by another person or entity. Litigation has in the past been, and may in the future be, necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our treatments. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract our management from its day-to-day activities.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our

own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Intellectual property rights of third parties could adversely affect our ability to compete or commercialize our investigational treatments, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our investigational treatments. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our commercial success depends upon our ability and the ability of our future collaborators to develop, manufacture, market, and sell any investigational treatments that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In the past, we have been subject to, and in the future we may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to COMP360 or any future therapeutic candidates. If the outcome of any such proceeding or litigation is adverse to us, it may affect our ability to compete effectively.

Additionally, our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our treatments or elements thereof, our manufacture or uses relevant to our development plans, the targets of COMP360 or any future therapeutic candidates, or other attributes of our investigational COMP360 psilocybin treatment or any future therapeutic candidates. In such cases, we may not be in a position to develop or commercialize such therapeutic candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, which may not be available on commercially reasonable terms or at all. In the event that a patent has not expired at the time of approval of such investigational treatments or therapeutic candidate and the patent owner were to bring an infringement action against us, we may have to argue that our investigational treatments or the manufacture or use of the underlying therapeutic substances do not infringe a valid claim of the patent in question. Alternatively, if we were to challenge the validity of any issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would need to present clear and convincing evidence as to the invalidity of the patent's claims. The same applies to other jurisdictions. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. In the event that a third party successfully asserts its patent against us such that such third party's patent is found to be valid and enforceable and infringed by COMP360 or further therapeutic products, unless we obtain a license to such patent, which may not be available on commercially reasonable terms or at all, we could be prevented from continuing to commercialize COMP360 or further therapeutic products. Similarly, the targets for our investigational COMP360 psilocybin treatment have also been the subject

of research by other companies, which have filed patent applications or have patents on aspects of the targets or their uses. There can be no assurance any such patents will not be asserted against us or that we will not need to seek licenses from such third parties. We may not be able to secure such licenses on acceptable terms, or at all, and any such litigation would be costly and time-consuming.

It is possible that we have failed, and in the future may fail, to identify relevant patents or applications that may be asserted against us. For example, certain U.S. applications filed after November 29, 2000 can remain confidential until and unless issued as patents, provided that inventions disclosed in the applications have not and will not be the subject of a corresponding application filed outside the U.S. In general, patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our treatments could have been filed by others without our knowledge. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our treatments or the use of our treatments.

Third-party intellectual property right holders, including our competitors, have in the past brought, and may in the future bring, infringement, misappropriation or violation claims against us based on existing or future intellectual property rights, regardless of their merit. We may not be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our treatments.

If we are unsuccessful defending in any such claim, in addition to being forced to pay damages, we or our licensees may be temporarily or permanently prohibited from commercializing any of our investigational treatments that were held to be infringing. If possible, we might be forced to redesign our investigational COMP360 psilocybin treatment or any future therapeutic candidates so that we no longer infringe the intellectual property rights of third parties, or we may be required to seek a license to any such technology that we are found to infringe, which license may not be available on commercially reasonable terms or at all. Even if we or our licensors or collaboration partners obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaboration partners and it could require us to make significant licensing and royalty payments. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

In addition, if the breadth or strength of protection provided by our or our licensors' or collaboration partners' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future investigational treatments. 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.

Intellectual property litigation could cause us to spend substantial resources, distract our personnel from their normal responsibilities, harming our reputation and our business operations.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development and commercialization activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may not be successful in obtaining or maintaining necessary rights to COMP360 or any future therapeutic candidates through acquisitions and in-licenses.

In the future, our programs may require the use of proprietary rights held by third parties, and the growth of our business will likely depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. In addition, with respect to any patents we co-own with third parties, we may require licenses to such co-owners' interest in such patents. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for COMP360 or any future therapeutic candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of an investigational treatment or program, we may have to abandon development of that

investigational treatment or program, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

For example, we sometimes collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our applicable investigational treatment or program.

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

We are or may become a party to third-party agreements under which we grant or are granted rights to intellectual property that are potentially important to our business and we expect that we may need to enter into additional license or collaboration agreements in the future. Our existing third-party agreements impose, and we expect that future license agreements will impose, various obligations related to, among other things, therapeutic development and payment of royalties and fees based on achieving certain milestones. In addition, under several of our collaboration agreements, we are prohibited from developing and commercializing treatments that would compete with the treatments licensed under such agreements. If we fail to comply with our obligations under these agreements, our licensor or collaboration partner may have the right to terminate the agreement, including any licenses included in such agreement.

The termination of any license or collaboration agreements or failure to adequately protect such license agreements or collaboration could prevent us from commercializing our investigational COMP360 psilocybin treatment or any future therapeutic candidates covered by the agreement or licensed intellectual property. For example, we may rely on license agreements which grant us rights to certain intellectual property and proprietary materials that we use in connection with the development of our treatments. If this agreement were to terminate, we would be unable to timely license similar intellectual property and proprietary materials from an alternate source, on commercially reasonable terms or at all, and may be required to conduct additional bridging studies on our investigational COMP360 psilocybin treatment or any future therapeutic candidates, which could delay or otherwise have a material adverse effect on the development and commercialization of our investigational COMP360 psilocybin treatment or any future therapeutic candidates.

Several of our existing license agreements are sublicenses from third parties which are not the original licensor of the intellectual property at issue. Under these agreements, we must rely on our licensor to comply with its obligations under the primary license agreements under which such third party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If the licensors fail to comply with their obligations under these

upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate the sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property and, in the case of a sublicense, if we were not able to secure our own direct license with the owner of the relevant rights, which it may not be able to do at a reasonable cost or on reasonable terms, it may adversely affect our ability to continue to develop and commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates incorporating the relevant intellectual property.

Disputes may arise regarding intellectual property subject to a license or collaboration agreement, including the following:

- the scope of rights granted under the agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor or collaboration partner that is not subject to the agreement;
- the sublicensing of patent and other rights under any current or future collaboration relationships;
- our diligence obligations under the 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 collaboration partners; and
- the priority of invention of patented technology.

In addition, our third-party agreements are complex, and certain provisions in such 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 therapeutic candidate, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value. However, trade secrets and confidential know-how are difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by third parties and our competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or confidential know-how. Also, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our trade secrets and confidential know-how to our competitors and other third parties or breach such agreements, and we may not be able to obtain an adequate remedy for such breaches. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is difficult, expensive, time-consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Furthermore, if a competitor or other third party lawfully obtained or independently developed any of our trade secrets or confidential know-how, we would have no right to prevent such competitor or other third party from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

Failure to obtain or maintain trade secrets or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets or confidential know-how.

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 registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. 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. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world.

We may not be able to protect our intellectual property rights throughout the world and may face difficulties in certain jurisdictions, which may diminish the value of intellectual property rights in those jurisdictions.

Filing, prosecuting and defending patents on therapeutic candidates in all countries and jurisdictions throughout the world would be prohibitively expensive and our intellectual property rights in some countries outside of the UK and the U.S., could be less extensive than those in the UK and the U.S., assuming that rights are obtained in the UK and the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the UK and the U.S., or from

selling treatments or importing drug substances made using our inventions in and into the UK and the U.S., or other jurisdictions. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same therapeutic candidate or technology.

Competitors may use our and our licensors' or collaboration partners' technologies in jurisdictions where we have not obtained patent protection to develop their own treatments and, further, may export otherwise infringing treatments to territories where we and our licensors or collaboration partners have patent protection, but enforcement is not as strong as that in the UK and the U.S. These treatments may compete with COMP360 or any future therapeutic candidates, and our and our licensors' or collaboration partners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the UK and the U.S., and companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors or collaboration partners is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

Proceedings to enforce our and our licensors' or collaboration partners' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaboration partners' efforts and attention from other aspects of our business, regardless of whether we or our licensors or collaboration partners are successful, and could put our and our licensors' or collaboration partners' patents at risk of being invalidated or interpreted narrowly. In addition, such proceedings could put our and our licensors' or collaboration partners' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaboration partners. We or our licensors or collaboration partners may not prevail in any lawsuits that we or our licensors or collaboration partners initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our future product candidates.

We rely on the protection of our intellectual property in various jurisdictions. Changes in patent laws in the U.S. and other jurisdictions could cause us to lose protection over certain of our patents and therefore impair our ability to protect our future product candidates. For example, in the U.S., recent decisions raise questions regarding the award of patent term adjustment for patents in families where related patents have been issued without a patent term adjustment. Thus, it cannot be said with certainty how a patent term adjustment award will or will not be viewed in future and whether patent expiration dates may be impacted. The complexity and uncertainty of European patent laws have also increased in recent years. For example, in Europe, a 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, or the 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 may decide to opt out of our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Risks Related to Our Dependence on Third Parties

We rely on third parties to supply drug substance and manufacture, package and distribute COMP360 and expect to continue to rely on third parties to supply and manufacture any future therapeutic candidates, and if COMP360 is approved, we will rely on third parties to manufacture these substances for commercial supply. If any third-party provider fails to meet its obligations to supply drug substance or manufacture COMP360 or our future therapeutic candidates, or fails to maintain or achieve satisfactory regulatory compliance, the development of such substance and the commercialization of any treatments, if approved, could be stopped, delayed or made commercially unviable, less profitable or may result in enforcement actions against us.

We do not currently have, nor do we plan to acquire, the infrastructure or capability necessary to manufacture COMP360 or any future therapeutic candidates, including the psilocybin incorporated into such therapeutic candidates. We rely on, and expect to continue to rely on, contract manufacturers, or CMOs, for the development, manufacture and production of the psilocybin used in our investigational treatments administered in our clinical trials and will continue to rely on such CMOs for the development, manufacture and production of any commercial supply, if our investigational treatments are approved.

Currently, we engage with multiple different CMOs in the UK for all activities relating to the development, manufacture and production of all components incorporated in COMP360 and we are in the process of engaging additional CMOs in the U.S. to manufacture and produce commercial supply. Reliance on third-party providers, such as CMOs, exposes us to more risk than if we were to manufacture COMP360, or any future therapeutic candidates. We do not control the manufacturing processes of the CMOs we contract with and are dependent on those third parties for the production of COMP360 or any future therapeutic candidates in accordance with relevant regulations (such as the FDA's good laboratory practices, or GLP, cGMPs or similar regulatory requirements outside the US) for the manufacture of drug substances, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. Some of the suppliers currently engaged in the production process of COMP360, including our current supplier of API, have not in the past been subject to inspection by the FDA and/or EMA, but could be subject to a pre-approval inspection if we submit an application for marketing authorization of COMP360, and there can be no assurance that they are in compliance with all applicable regulations. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of COMP360 or any future therapeutic candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of COMP360 or any future therapeutic candidates and harm our business and results of operations.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our demand for COMP360 or any future therapeutic candidates including as a result of trade tensions, supply chain delays or increasing costs, we could experience delays in our research or planned clinical studies or commercialization. In addition, quality issues may arise during scale-up activities. We could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes and at an acceptable cost. For example, the COVID-19 pandemic created supply constraints generally globally. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, may significantly delay our clinical studies and the commercialization of our treatments, if approved, which would materially adversely affect our business, prospects, financial condition and results of operations.

In complying with the manufacturing regulations of the FDA, the DEA, the EMA, the MHRA and other comparable foreign authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the drug product meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of drug product and shutting down of production, any of which could materially adversely affect our business, prospects, financial condition and results of operations. We and any of these third-party suppliers may also be subject to audits by the FDA, the DEA, competent authorities of the EU Member States, the MHRA or other comparable foreign authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable

manufacturing regulations, our ability to develop and commercialize the treatments could suffer significant interruptions. We face risks inherent in relying on a limited number of CMOs, as any disruption, such as a fire, natural hazards or vandalism at the CMO could significantly interrupt our manufacturing capability. We currently do not have disaster recovery facilities available. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all, and we would likely experience months of manufacturing delays as we build or locate replacement facilities and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis or at all. In addition, operating any new facilities may be more expensive than operating our current facility, and business interruption insurance may not adequately compensate us for any losses that may occur, in which case we would have to bear the additional cost of any disruption. In such a scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

For these reasons, a significant disruptive event of the manufacturing facility could have a material adverse effect on our business, including placing our financial stability at risk.

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, academic collaborators and contract research organizations, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, academic collaborators and third-party contract research organizations, or CROs, to conduct our preclinical studies and clinical trials and

to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the EMA, the MHRA and comparable foreign regulatory authorities for all of our treatments in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our investigators, academic collaborators or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA, the MHRA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure, or the failure of our third-party contractors and CROs, to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Further, these investigators, academic collaborators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our investigational COMP360 psilocybin treatment or any future therapeutic candidates and clinical trials. If independent investigators, academic collaborators or CROs fail to devote sufficient resources to the development of our investigational COMP360 psilocybin treatment or any future therapeutic candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of our investigational COMP360 psilocybin treatment or any future therapeutic candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. In addition, investigators, academic collaborators and CROs may have difficulty staffing, undergo changes in priorities or become financially distressed or form relationships with other entities, some of which may be our competitors, any of which materially adversely affect our business.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

There is a limited number of third-party service providers that specialize in or have the expertise required to achieve our business objectives. If any of our relationships with these third-party CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative CROs, academic collaborators or investigators on commercially reasonable terms or at all. If CROs, academic collaborators or clinical investigators do not successfully carry out their contractual duties

or obligations or meet expected deadlines, or if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates. As a result, our results of operations and the commercial prospects for our investigational COMP360 psilocybin treatment or any future therapeutic candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional CROs (or investigators) involves additional cost and requires management time and focus. In addition, delays occur during the natural transition period when a new CRO commences work, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future, or that these delays or challenges will not have a material adverse impact on our business or financial condition and prospects.

There are a number of third parties that conduct IISs using COMP360 provided by us. Generally, we do not sponsor these IISs, and we encourage the open publication of all IIS findings. Any failure by a third party to meet its obligations with respect to the clinical development of our investigational COMP360 psilocybin treatment or any future therapeutic candidates may delay or impair our ability to obtain regulatory approval for COMP360. IISs of COMP360 or any future therapeutic candidates may generate clinical trial data that raises concerns regarding the safety or effectiveness of COMP360 and any data generated in IISs may not be predictive of the results in populations or indications in which we are conducting, or plan to conduct, clinical trials.

There are a number of academic and private non-academic institutions that conduct and sponsor clinical trials relating to COMP360. We do not control the design or conduct of the IISs sponsored by third-parties, and the FDA or comparable foreign regulatory authorities could determine that these IISs do not provide adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the studies, safety concerns or other study results. Third-party investigators may design IISs that are underpowered, use clinical endpoints that are not widely accepted, questionable, or more difficult to achieve, or in other ways increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. In addition, these IISs may be conducted using different populations or indications than are used in our clinical trials or IISs which we sponsor, including milder or more severe patient populations. We also do not have control over academic or private non-academic institutions' disclosure of information, and these parties may disclose sensitive information or results of studies without our approval or consent.

As a result of these IISs sponsored by third-parties, we will receive certain information rights with respect to the IISs, including access to and the ability to use and reference the resulting data, including for our own regulatory filings. However, we do not have control over the timing and reporting of the data from IISs, nor do we always own or control the data from the IISs. If we are unable to confirm or replicate the results from the IISs or if negative results are obtained, we would likely be

further delayed or prevented from advancing further clinical development of COMP360 or any future therapeutic candidates. Any data generated in IISs may not be predictive of the results in populations or indications in which we are conducting, or plan to conduct, clinical trials. Any data perceived to be negative, however, could harm our ability to advance the clinical development of our investigational COMP360 psilocybin treatment or any future therapeutic candidates, and we may not be able to investigate whether such negatively perceived data reflects issues with the design and/or conduct of the IIS or if it actually reflects characteristics of our therapeutic approach. Moreover, we rely on our investigators and institutions to provide us timely information. We have in the past, and may in the future, experience delays in receiving notice of reportable adverse events or SUSARs from IISs. For example, we were informed in September 2020 of a SUSAR in an IIS at the University of Zurich that had occurred a few weeks earlier, despite an obligation by the site investigator to report such an event to us immediately. Such delays, or any failures to provide contractually required information, could negatively impact us or cause delays in our reporting requirements to applicable regulatory authorities. Further, if investigators or institutions breach their obligations with respect to the clinical development of our investigational COMP360 psilocybin treatment or any future therapeutic candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the IISs been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

Additionally, the FDA or comparable foreign regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these IISs, or our interpretation of preclinical, manufacturing or clinical data from these IISs. If so, the FDA or other comparable foreign regulatory authorities may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate our planned trials and/or may not accept such additional data as adequate to initiate our planned trials.

Risks Related to Our Business Operations, Managing Growth and Employee Matters

Our future growth and ability to compete effectively depends on our ability to manage senior management changes and our ability to retain our key personnel and recruit additional qualified personnel, and on the key personnel employed by our collaborative partners.

Our success depends upon the continued contributions of our key executives, managers, scientific and medical personnel, many of whom have been instrumental for us and have substantial experience with our treatments and related technologies, and our ability to recruit sales and marketing professionals to grow our commercial organization in advance our anticipated commercial launch of COMP360 psilocybin treatment, subject to regulatory approval. These key management individuals include the members of our board of directors and certain executive officers. We do not currently maintain any key person insurance. The loss of key executives, managers and senior scientists or medical personnel could delay our research and development activities. The failure to recruit a sufficient number of qualified sales and marketing professionals could delay or negatively impact our anticipated commercial launch. In addition, we may experience increased employee turnover as a result

of general market conditions and a competitive talent market, as well as company-specific factors, such as a decline in the price of our ADSs, business performance, and leadership changes. If we are not successful in managing any future changes in senior management, it could negatively impact our corporate culture, negatively impact our relationships with employees, investors, suppliers, CROs, principal investigators, key opinion leaders, regulators and other key stakeholders, or otherwise disrupt our business operations, which could have a material adverse effect on our business and prospects. In addition, our ability to compete in the highly competitive pharmaceutical and biotechnology industry depends upon our ability to attract and retain highly qualified management, sales and marketing, scientific and medical personnel. Many other companies and academic institutions that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Therefore, we might not be able to attract or retain these key persons on conditions that are economically acceptable. Moreover, some qualified prospective employees may choose not to work for us due to negative perceptions regarding the therapeutic use of psilocybin or other objections to the therapeutic use of a controlled substance. Furthermore, we will need to recruit new managers and qualified scientific and medical personnel to develop our business if we expand into fields that will require additional skills. Our inability to attract and retain these key persons could prevent us from achieving our objectives and implementing our business strategy, which could have a material adverse effect on our business and prospects.

As part of our commercial preparation efforts, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the area of sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The significant growth and expansion of our operations may lead to significant costs, may divert our management and business development resources and may negatively impact our corporate culture. Any inability to manage growth or raise funds to support our growth could delay the execution of our business plans or disrupt our operations.

In addition, certain key academic and scientific personnel play a pivotal role in our collaborative partners' research and development activities. If any of those key academic and scientific personnel who work on the development of our research programs, our investigational COMP360 psilocybin treatment and any future therapeutic candidates leave our collaborative partners, the development of our research programs, our investigational COMP360 psilocybin treatment and any future therapeutic candidates may be delayed or otherwise adversely affected.

Our employees, independent contractors, principal investigators, institutions and researchers of IISs, CROs, consultants, vendors, third-party treatment sites, healthcare professionals and collaboration partners and third parties may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could have a material adverse effect on our business.

We are exposed to the risk that our employees, independent contractors, principal investigators, institutions and researchers of IISs, CROs, consultants, vendors, third-party treatment sites, healthcare professionals or other qualified professionals and collaboration partners may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless and negligent conduct or unauthorized activities that violate, among other things: (i) the regulations of the FDA, the EMA, the MHRA and other comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and abroad; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

Our commercialization model also entails the risk of malpractice and professional liability claims against both our third-party treatment sites and us as a result of actual or alleged misconduct by healthcare professionals supporting and monitoring patients during the administering our COMP360 psilocybin treatment. Although we, and the third-party treatment sites with which we engage, carry insurance covering malpractice and professional liability claims in amounts that we believe are appropriate in light of the risks attendant to our business, successful malpractice or professional liability claims could result in substantial damage awards that exceed the limits of our insurance coverage and our third-party treatment sites' insurance coverage. In addition, professional liability insurance is expensive and insurance premiums may increase significantly in the future, particularly as we expand our services. As a result, adequate professional liability insurance may not be available to our providers or to us in the future at acceptable costs or at all. Any claims made against us that are not fully covered by insurance could be costly to defend against, result in substantial damage awards against us and divert the attention of our management and our third-party treatment sites from our operations, which could have a material adverse effect on our business, financial condition and results of operations. In addition, any such claims may materially and adversely affect our business or reputation.

It is not always possible to identify and deter misconduct by employees and other third parties, including healthcare professionals who monitor and safeguard participants receiving investigational COMP360 psilocybin treatment in our clinical trials, 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 comply with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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 and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, imprisonment, 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, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We face substantial competition and our competitors may discover, develop or commercialize treatments before or more successfully than us, which may result in the reduction or elimination of our commercial opportunities.

The pharmaceutical and psychedelic industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, universities and other research institutions. We also face competition from 501(c)(3) non-profit medical research organizations, including the Usona Institute, which, in August 2023, published results from its Phase 2, double-blind, placebo-controlled study evaluating a single dose of psilocybin to treat major depressive disorder. In March 2024, Usona Institute announced the launch of its Phase 3 trial evaluating the efficacy and safety of psilocybin 25mg in as a treatment for major depressive disorder, which was expected to enroll approximately 240 adult patients, and Usona announced that it completed enrollment in its Phase 3 trial in November 2025. Such non-profits may be willing to provide psilocybin-based products at cost or for free, undermining our potential market for COMP360. In addition, a number of for-profit biotechnology companies or institutions are specifically pursuing the development of psilocybin, including Helus Pharma, and other psychedelic compounds to treat mental health illnesses, including TRD. Helus Pharma is conducting a Phase 3 program for its proprietary novel serotonergic agonists (a proprietary deuterated psilocin analog) for the adjunctive treatment of major depressive disorder, which includes two Phase 3 trials and is expected to enroll approximately 550 adult patients, with the first Phase 3 trial expected to report top-line data in the fourth quarter of 2026. In addition, an increasing number of companies are stepping up their efforts in discovery of new psychedelic compounds. It is also probable that the number of companies seeking to develop psychedelic products and treatments for mental health illnesses, such as depression, will increase. If any of our competitors is granted an NDA for their psychedelic treatments before us and manages to obtain approval for a broader indication, such as major depressive disorder, and thus access a wider patient population, we may face more intensified competition from such potential psychedelic treatments and increased difficulties in winning market acceptance of our investigational COMP360 psilocybin treatment or any future therapeutic candidates. All of these risks are heightened because psilocybin, which is a naturally occurring substance and therefore not subject to patent protection, may be deemed an appropriate substitute for COMP360.

We also face competition from major pharmaceutical, biopharmaceutical and biotechnology companies who have developed or are developing non-psilocybin or psychedelic based treatments for the treatment of MDD and TRD, and will face future competition for any other indications we may seek to treat with our investigational COMP360 psilocybin treatment.

There are a number of companies that currently market and sell products or treatments, or are pursuing the development of products or treatments, for the treatment of depression, including antidepressants such as SSRIs and serotonergic norepinephrine reuptake inhibitors, or SNRIs, antipsychotics, cognitive behavioral therapy, or CBT, esketamine and ketamine, repeat transcranial magnetic stimulation, or rTMS, electroconvulsive therapy, or ECT, vagus nerve stimulation, or VNS, and deep brain stimulation, or DBS, among others. Many of these pharmaceutical, biopharmaceutical and biotechnology competitors have established markets for their treatments and have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market superior products or treatments. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of new therapeutic substances and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA, European Commission or MHRA approval for alternative or superior products. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

The field in which we operate is characterized by a growing and shifting understanding of disease biology, changing technologies, and strong intellectual property barriers to entry, and many companies are involved in the creation, development and commercialization of novel therapeutics and technology platforms. Our competitors may develop treatments that are more effective, more convenient, more widely used and less costly or have a better safety profile than our treatments and these competitors may also be more successful than we are in manufacturing and marketing their treatments. Additionally, there can be no assurance that our competitors are not currently developing, or will not in the future develop, technologies and treatments that are equally or more economically attractive as our investigational COMP360 psilocybin treatment or any future therapeutic candidates. Competing alternative treatments or technology platforms may gain faster or greater market acceptance than our treatments or technology platforms and medical advances or rapid technological development by competitors may result in our investigational COMP360 psilocybin treatment or any future therapeutic candidates or technology platforms becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we are unable to compete effectively against these companies, then we may not be able to commercialize our investigational COMP360 psilocybin treatment or any future therapeutic candidates or achieve a competitive position in the market. This would materially and adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We anticipate that we will face intense and increasing competition as new treatments enter the market.

Acquisitions and investments could result in operating difficulties, dilution and other harmful consequences that may adversely impact our business, financial condition and results of operations. Additionally, if we are not able to identify and successfully acquire suitable businesses, our operating results and prospects could be harmed.

We may in the future make additional acquisitions or investments to add employees, complementary companies, treatments, products, solutions, technologies, or revenue. These transactions could be material to our business, financial condition and results of operations. We also expect to continue to evaluate and enter into discussions regarding a wide array of potential strategic transactions. The identification of suitable acquisition or investment candidates can be difficult, time-consuming and costly, and we may not be able to complete acquisitions or investment on favorable terms, if at all. The process of integrating an acquired company, business or technology and managing our future investments may create unforeseen operating difficulties and expenditures. The areas where we face risks include:

- loss of key employees of the acquired company and other challenges associated with integrating new employees into our culture, as well as reputational harm if integration is not successful;
- diversion of management time and focus from operating our business to addressing acquisition integration and investment management challenges;
- high uncertainty with respect to any investment in companies engaging in early stage drug discovery and development with limited proof of concept, which might result in significant investment loss;
- challenges in identifying suitable investment opportunities in the digital health market and diversion of management time and resources to integrate such investments into our business due to our lack of experience in such market;
- implementation or remediation of controls, procedures, and policies at any acquired company;
- difficulties in integrating and managing the combined operations, technologies, technology platforms and products of any acquired companies and realizing the anticipated economic, operational and other benefits in a timely manner, which could result in substantial costs and delays or other operational, technical or financial problems;
- integration of the acquired company's accounting, human resource and other administrative systems, and coordination of product, engineering and sales and marketing function;
- assumption of contractual obligations that contain terms that are not beneficial to us, require us to license or waive intellectual property rights, or increase our risk for liabilities;
- failure to successfully further develop the acquired technology or realize our intended business strategy;
- our dependence on unfamiliar affiliates and partners of acquired businesses;
- uncertainty of entry into markets in which we have limited or no prior experience or in which competitors have stronger market positions;
- unanticipated costs associated with pursuing investments or acquisitions;

- failure to find commercial success with the products or services of the acquired company;
- difficulty of transitioning the acquired technology onto our existing platforms and maintaining the security standards for such technology consistent with our other solutions;
- responsibility for the liabilities of acquired businesses, including those that were not disclosed to us or exceed our estimates, as well as, without limitation, liabilities arising out of their failure to maintain effective data protection and privacy controls and comply with applicable regulations;
- inability to maintain our internal standards, controls, procedures, and policies;
- failure to generate the expected financial results related to an acquisition in a timely manner or at all;
- difficulties in complying with antitrust and other government regulations;
- challenges in integrating and auditing the financial statements of acquired companies that have not historically prepared financial statements in accordance with U.S. GAAP;
- potential accounting charges to the extent intangibles recorded in connection with an acquisition, such as goodwill;
- trademarks, client relationships or intellectual property, are later determined to be impaired and written down in value; and
- failure to accurately forecast the impact of an acquisition transaction.

Moreover, we may rely heavily on the representations and warranties provided to us by the sellers of acquired companies or strategic partners, including as they relate to creation of, and ownership and rights in, intellectual property, existence of open source and compliance with laws and contractual requirements. If any of these representations and warranties are inaccurate or breached, such inaccuracy or breach could result in costly litigation and assessment of liability for which there may not be adequate recourse against such sellers, in part due to contractual time limitations and limitations of liability.

Future acquisitions and investments could also result in expenditures of significant cash, dilutive issuances of our equity securities, the incurrence of debt, restrictions on our business, contingent liabilities, amortization expenses or write-offs of goodwill, any of which could harm our financial condition. In addition, any acquisitions or investments we announce could be viewed negatively by collaborative partners, employees, vendors, patients, shareholders, or investors.

Additionally, competition within our industry for acquisitions of business, technologies and assets may become heightened. Even if we are able to identify an acquisition or investment that we would like to consummate, we may not be able to complete the acquisition or investment on commercially reasonable terms or the target may be acquired by another company. We may enter into negotiations for acquisitions or investments that are not ultimately consummated. Those

negotiations could result in diversion of management time and significant out-of-pocket costs. If we fail to evaluate and execute acquisitions or investments successfully, we may not be able to realize the benefits of these acquisitions or investments, and our operating results could be harmed. If we are unable to successfully address any of these risks, our business, financial condition and results of operations could be harmed.

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 third-party treatment sites, healthcare professionals, patients and collaborators, and to our ability to attract clinics to become our third-party treatment sites offering our treatments. The promotion of our brand has required and may continue to require us to make substantial investments and we anticipate that, as our market becomes increasingly competitive, these marketing and other initiatives may become increasingly difficult and expensive. Brand promotion and marketing activities may not be successful or yield increased revenue, to the extent we generate any future revenue, and to the extent that these activities yield increased future 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 failing to meet the expectations of our network of third-party treatment sites, healthcare professionals and patients, could harm our reputation and brand and make it substantially more difficult for us to attract new third-party treatment sites, healthcare professionals and patients. If we do not successfully maintain, protect or enhance our reputation and brand recognition, our business may not grow and we could lose our relationships with third-party treatment sites, healthcare professionals and patients, which would harm our business, financial condition and results of operations.

Our digital technologies may fail, which may adversely affect our business, financial condition and results of operations.

We currently employ digital technologies to collect data, educate patients and healthcare professionals in our clinical trials and collect audio/video recordings. For some of our trials, we also collect digital phenotyping information, and record and transcribe audio data. We use certain internally developed digital technologies in the conduct of certain of our clinical trials and we continuously maintain, evaluate and improve the performance, security and reliability. In addition, we will also rely on third-parties in the future to provide us with digital technology services that will be used in the conduct of certain of our clinical trials. There can be no assurance that these digital technologies do not or will not have inaccuracies or errors. As with any digital technology, poor performance, unreliability or errors or inaccuracies may adversely impact the conduct of our clinical trials, our reputation and our plans to use digital technologies to complement our investigational treatments. Our efforts to maintain and optimize the digital technologies used in the conduct of our clinical trials, either internally or through a third-party service provider, or to develop or acquire alternate technologies if required for the conduct of our clinical trials may involve significant time, costs, and other resources, and may divert our management team's attention and focus from executing

our clinical trials or other key elements of our strategy. If our efforts to maintain or optimize our current digital technologies, either internally or through a third-party service provider, or, if needed, develop or acquire these digital technologies are unsuccessful, it may have a materially adverse impact on the conduct of our trials, future prospects and financial position.

Our digital technology solutions, including those provided by third parties, could be leveraged to compromise sensitive information related to our business, patients, healthcare professionals, third-party treatment sites and collaborators, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

Our digital technology solutions, including those provided by third parties, may involve the collection, storage, usage or disclosure of confidential and sensitive data, including protected health information, or PHI, and other types of personal data or personally identifiable information, or PII. For example, as part of our clinical trials, we may use digital technology solutions to record and analyze therapeutic sessions. We may also process and store, and use additional third parties to process and store, confidential or sensitive information, including intellectual property and other proprietary business information of ours and our third-party collaborators.

We are highly dependent on information technology networks and systems, including the internet and external cloud providers, to securely process, transmit and store this critical information. Security incidents or breaches of this infrastructure, including cybersecurity incidents, physical or electronic break-ins, computer viruses, attacks by hackers, data breaches, and employee or contractor error, negligence or malfeasance, could create system disruptions, shutdowns or unauthorized disclosure or modifications of confidential information, causing patient health information to be accessed, acquired or altered without authorization or to become publicly available. In addition, we use certain systems that rely on machine learning systems, which are complex and may have errors or inadequacies that are not easily detectable. These machine learning systems may inadvertently reduce the efficiency of our systems, or may cause unintentional or unexpected outputs that are incorrect, do not match our business goals, do not comply with our policies, or otherwise are inconsistent with our guiding principles, and mission. Any errors or vulnerabilities discovered in our systems or data could also result in damage to our reputation or liability for damages, any of which could adversely affect our growth prospects and our business.

We utilize third-party service providers for important aspects of the collection, storage and transmission of patient information, and other confidential and sensitive information as well as encryption of data at rest and in transit, along with appropriate system logging and access controls, and therefore rely on third parties to manage functions that have material cybersecurity risks. We and our third party service providers are at constant risk of cyber-attacks or cyber intrusions via viruses, worms, break-ins, malware, ransomware, social engineering (including phishing attacks), hacking, denial-of-service attacks or other attacks and similar disruptions from the unauthorized use of or access to computer systems (including from internal and external sources) that attack or otherwise exploit any vulnerabilities in our systems or those of our third party service providers, or attempt to fraudulently induce our employees, consumers, third party service providers or others to

disclose passwords or other sensitive information or unwittingly provide access to our systems or data. These types of incidents continue to be prevalent and pervasive across industries, including in our industry, and are being facilitated or enhanced by evolving technologies, including artificial intelligence, or AI. While we take certain administrative and technological safeguards designed to address these risks, measures taken to protect our systems, those of our subcontractors, or the PHI, other PII, or other sensitive data we or our subcontractors process or maintain, may not adequately protect us from the risks associated with the collection, storage and transmission of such information. Although we take steps to help protect confidential and other sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses, failures or breaches due to third-party action, employee negligence or error, malfeasance or other disruptions. Like other companies in our industry, we, and our third party vendors, have experienced cybersecurity incidents relating to our information technology systems and infrastructure, and the systems of our third party vendors.

Attempts to disrupt or gain unauthorized access to our and our third-party vendors' information systems from malicious third parties or insider threats may incorporate widely varying and frequently changing tactics, which may be enhanced or facilitated by AI. A cybersecurity incident, data breach or other security or privacy event that leads to disclosure or unauthorized use, loss of, or modification of, or that prevents access to or otherwise impacts the confidentiality, security, or integrity of, patient information, including PHI or other PII, or other sensitive information we or our subcontractors maintain or otherwise process, could harm our reputation, compel us to comply with breach notification laws, require us to verify the accuracy of database contents, and cause us to incur significant costs for remediation, including measures intended to repair or replace systems or technologies or upgrade systems to prevent future occurrences, fines, penalties, and potential increases in insurance premiums. If we are unable to prevent such cybersecurity incidents, data breaches or other security or privacy events or implement satisfactory remedial measures, or if it is perceived that we have been unable to do so, our operations could be disrupted, we may be unable to provide access to our digital technology solutions and tools, and our ability to conduct our clinical trials may be negatively impacted, including patient enrollment in clinical trials and to train healthcare professionals for our clinical trials, and we may suffer loss of reputation, adverse impacts on patients, physicians, clinical trial sites and investor confidence, financial loss, governmental investigations or other actions, regulatory or contractual penalties, and other claims and liability. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. In addition, cybersecurity incidents, data breaches and other inappropriate access to, or acquisition or processing of, information can be difficult to detect, and any delay in identifying such incidents or in providing any notification of such incidents to impacted stakeholders (including investors, regulators and affected individuals), may lead to increased harm.

Any such cybersecurity incident, data breach or other interruption of our systems or any of our third-party information technology partners, could compromise our networks or data security processes and confidential or sensitive information could

be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost, misused, or stolen. Any such interruption of access, improper or unauthorized access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws and regulations that protect the privacy and security of patient information or other personal information, such as HIPAA, and the GDPR, the CCPA, and regulatory penalties.

Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct clinical trials for COMP360 psilocybin treatment or any future therapeutic candidates, obtain regulatory approval of and commercialize COMP360 psilocybin treatment or any future therapeutic candidates, conduct research and development activities, collect, process, and prepare company financial information and provide information about our current and future therapeutic candidates. Any such cybersecurity incident or data breach could also result in the compromise of our trade secrets and other proprietary information or that of third parties whose information we maintain, which could adversely affect our business and competitive position. While we maintain insurance covering certain security and privacy damages and claim expenses, we may not carry insurance or maintain coverage sufficient to compensate for all liability and in any event, insurance coverage may not address the reputational damage that could result from a security incident.

A pandemic, epidemic, or outbreak of an infectious disease or other public health crises may materially and adversely affect our business, including our preclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results.

The future extent of the impact of any public health crisis on our preclinical studies or clinical trial operations, our supply chain and manufacturing and our office-based business operations, will depend on future developments, which remain highly uncertain and cannot be predicted with confidence. Such events could result in disruptions to patient enrollment, clinical site operations, significant and material disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of COMP360 and any future therapeutic candidates due to a public health crisis. Future developments are inherently hard to predict and there can be no guarantee we will not face difficulties or additional costs in retaining a sufficient number of participants in our Phase 3 clincial trials in TRD to complete those studies, enrolling and retaining patients in our Phase 2b/3 clinical trial in PTSD or any future clinical trials, that we will be able to achieve full enrollment of our planned studies within the timeframes we anticipate, or at all, or that supply disruptions would not adversely impact our ability to initiate and complete preclinical studies or clinical trials. Any public health crisis may in the future affect employees of third-party CROs that we rely upon to carry out our clinical trials and may cause disruptions that could severely impact our business and clinical trials, including the diversion of healthcare resources away from our clinical trials, the interruption of key clinical trial activities, delays in receiving authorizations from regulatory authorities, changes in local regulations, supply chain disruptions and continued volatility in the public equity markets and global economic disruptions, among other things.

Any public health crisis in the future may cause significant volatility in public equity markets and disruptions to the U.S. and global economies. Increased volatility and economic dislocation may make it more difficult for us to raise capital on

favorable terms, or at all. To the extent that any future public health crisis adversely affects our business and financial results, it may also heighten many of the other risks described in this ‘‘Risk Factors’’ section, such as those relating to the timing and completion of our clinical trials and our ability to obtain future financing.

Our current operations are headquartered in one location, and we or the third parties upon whom we depend may be adversely affected by natural disasters, as well as occurrences of civil unrest, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters.

Our current business operations are headquartered in our offices in London, UK, with additional offices in New York for operations in the U.S. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, 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 contract 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 investigational COMP360 psilocybin treatment or any future therapeutic candidates or interruption of our business operations. Such natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, 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 may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot ensure that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed.

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 diseases our investigational COMP360 psilocybin treatment or any future therapeutic candidates are being developed to treat, and we may use appropriate social media in connection with our commercialization efforts of our investigational COMP360 psilocybin

treatment following approval of COMP360 or future therapeutic candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve, and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to certain prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrollment may be adversely impacted, we fail to monitor and comply with applicable adverse event reporting obligations, or that 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 investigational COMP360 psilocybin treatment or any future therapeutic 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.

Risks Related to the Ownership of Our ADSs

The market price of our ADSs has been and will likely continue to be volatile and you could lose all or part of your investment.

The market price of our ADSs has been and may continue to be highly volatile and could be subject to large fluctuations in response to the risk factors discussed in this section, and others beyond our control, including the following:

- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- positive or negative developments in the regulatory approval process for psychedelic-based compounds developed by us, strategic partners or competitors;
- timing of completion of our Phase 3 program and the time period during which results of our Phase 3 trials will become available;
- delays in entering into strategic relationships with respect to development or commercialization of our investigational COMP360 psilocybin treatment or any future therapeutic candidates;
- changes in our strategic focus and research and development priorities;
- entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial therapeutic introductions by competitors;
- changes in government regulations and healthcare payment systems;

- developments concerning proprietary rights, including patent and litigation matters;
- public concern relating to the commercial value or safety of our investigational COMP360 psilocybin treatment or any future therapeutic candidates;
- negative publicity or public perception of the use of psilocybin as a treatment for mental health conditions;
- reorganizations, restructurings, financings or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- the trading volume of our ADSs on Nasdaq, including sales of ADSs upon the exercise of the outstanding PIPE Warrants and/or Pre-funded Warrants;
- sales of our ADSs by us (including through our ATM Facility), members of our senior management and directors or our significant shareholders or the anticipation that such sales may occur in the future;
- general market conditions in the pharmaceutical industry or in the economy as a whole;
- general economic, political, geopolitical and market conditions, including the recent fluctuations in inflation in the U.S., UK and Europe, the effects of announced or future tariff increases, and overall market volatility in the U.S. or the UK as a result of, among other factors, macroeconomic conditions and the ongoing war between Russia and Ukraine, conflict in the Middle East, significant changes in U.S. policies or regulatory environment or similar events; and
- other events and factors, many of which are beyond our control.

In recent years, the stock markets, and particularly the stock of pharmaceutical and biotechnology companies, at times have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of affected companies. In addition, if the market for pharmaceutical and biotechnology stocks or the broader stock market continues to experience a loss of investor confidence, the trading price of our ADSs could decline for reasons unrelated to our business, financial condition or results of operations. Since our ADSs were sold in our IPO at a price of $17.00 per ADS, our ADS price has fluctuated significantly, ranging from an intraday low of $2.25 to an intraday high of $61.69 for the period beginning September 18, 2020, our first day of trading on The Nasdaq Global Select Market, through March 19, 2026. If the market price of our ADSs does not exceed the price at which you acquired them, you may not realize any return on your investment in us and may lose some or all of your investment.

Because we have no present intention to pay dividends on our ordinary shares for the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

Under current English law, a company's accumulated realized profits must exceed its accumulated realized losses (on a non-consolidated basis) before dividends can be declared and paid. Therefore, we must have distributable profits before declaring and paying a dividend. We have not paid dividends in the past on our ordinary shares. We intend to retain earnings, if any, for use in our business and do not anticipate paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, on our ADSs will be your sole source of gains for the foreseeable future, and you will suffer a loss on your investment if you are unable to sell your ADSs at or above the price at which you purchased them. Any recommendation by our board of directors to pay dividends will depend on many factors, including our financial condition (including losses carried forward), results of operations, legal requirements and other factors. In addition, our Loan Agreement with Hercules currently prohibits, and any future debt financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our ordinary shares. We are unlikely to pay dividends or other distributions in the foreseeable future. If the price of our ADSs declines before we pay dividends, you will incur a loss on your investment, without the likelihood that this loss will be offset in part or at all by potential future cash dividends.

If securities or industry analysts do not continue to publish research or publish inaccurate research or unfavorable research about our business, the price of our ADSs and trading volume could decline.

The trading market of our ADSs depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have control over these analysts. If one or more of the analysts who covers us downgrades our ADSs or publishes incorrect or unfavorable research about our business, the price of our ADSs would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our ADSs could decrease, which could cause the price of our ADSs or trading volume to decline.

Holders of our ADSs do not have the same voting rights as the holders of our ordinary shares, and may not receive voting materials or any other documents that would need to be provided to our shareholders pursuant to English corporate law, including the UK Companies Act 2006, or Companies Act 2006, in time to be able to exercise their right to vote.

Except as described in the deposit agreement, holders of the ADSs are not able to exercise voting rights attached to the ordinary shares represented by the ADSs. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon our request, the depositary shall distribute to the holders as of the record date (i) the notice of the meeting or solicitation of consent or proxy sent by us and (ii) a statement as to the manner in which instructions may be given by the holders. We cannot guarantee that ADS holders will receive the voting materials in time to ensure that they can instruct the depositary to vote the ordinary shares underlying their ADSs.

Otherwise, ADS holders will not be able to exercise their right to vote, unless they withdraw the ordinary shares underlying the ADSs they hold. However, ADS holders may not know about the meeting far enough in advance to withdraw

those ordinary shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. As a result, ADS holders may not be able to exercise their right to vote, and there may be nothing they can do if the ordinary shares underlying their ADSs are not voted as they requested or if their shares cannot be voted.

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

Certain members of our senior management and certain members of our board of directors are non-residents of the U.S., and all or a substantial portion of our assets and the assets of such persons are located outside the U.S. As a result, it may not be possible – subject to satisfying additional procedural requirements – to serve process on such persons or us in relation to any U.S. court proceeding or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the U.S. federal securities laws.

The U.S. and the UK do not currently have a treaty providing for the mutual recognition and enforcement of judgments (other than arbitration awards, which are subject to the New York Convention) in civil and commercial matters. The Hague Convention of the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters, which provides for the recognition and enforcement of judgments between contracting states, came into force in the UK on July 1, 2025. While the U.S. is also a signatory, it has not yet ratified the convention. Consequently, a final judgment for payment given by a court in the U.S., whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the UK. In addition, uncertainty exists as to whether the courts of England and Wales would entertain original actions brought in the UK against us or our directors or senior management predicated upon securities laws of the U.S. or any state in the U.S. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by the courts of England and Wales as a cause of action in itself and sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that certain requirements are met. Whether these requirements are met in respect of a judgment based upon the civil liability provisions of the U.S. securities laws, including whether the award of monetary damages under such laws would constitute a penalty (which may include punitive damages) is an issue for the court making such decisions. The courts of England and Wales will not recognize or enforce a decision of the U.S. courts if the U.S. courts did not have proper jurisdiction to determine the claim, if the judgment was obtained by fraud, or if to do so would be contrary to public policy.

If the courts of England and Wales give a judgment for the sum payable under a U.S. judgment, the English judgment will be enforceable by methods generally available for this purpose. These methods generally permit the courts of England and Wales discretion to prescribe the manner of enforcement. Any proceedings to enforce a judgment must be commenced within six years of the date on which the judgment is enforceable.

As a result, U.S. investors may not be able to enforce against us or certain of our directors any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

Fluctuations in the exchange rate between the U.S. dollar and the pound sterling may increase the risk of holding our ADSs.

Our ADSs trade on the Nasdaq Global Select Market in U.S. dollars. Fluctuations in the exchange rate between the U.S. dollar and the pound sterling have occurred in the past and may continue in the future. Such fluctuations may result in temporary differences between the value of our ADSs and the value of our ordinary shares, which may result in heavy trading by investors seeking to exploit such differences.

In addition, as a result of fluctuations in the exchange rate between the U.S. dollar and the pound sterling, the U.S. dollar equivalent of the proceeds that a holder of ADSs would receive upon the sale in the UK of any ordinary shares withdrawn from the depositary and the U.S. dollar equivalent of any cash dividends paid in pound sterling on our ordinary shares represented by ADSs could also decline.

Holders of ADSs may be subject to limitations on the transfer of their ADSs and the withdrawal of the underlying ordinary shares.

ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason, subject to the right of ADS holders to cancel their ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders meeting or we are paying a dividend on our ordinary shares. In addition, ADS holders may not be able to cancel their ADSs and withdraw the underlying ordinary shares when they owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing our ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, holders and beneficial owners of ADSs irrevocably waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our ADSs or the deposit agreement.

If this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the U.S. Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and our ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or our ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

Our articles of association, or Articles, provide that the courts of England and Wales are the exclusive forum for the resolution of all shareholder complaints other than complaints asserting a cause of action arising under the Securities Act or the Exchange Act, and that the U.S. District Court for the Southern District of New York is the exclusive forum for the resolution of any shareholder complaint asserting a cause of action arising under the Securities Act or the Exchange Act.

Our Articles provide that, unless we consent by ordinary resolution to the selection of an alternative forum, the courts of England and Wales shall, to the fullest extent permitted by law, be the exclusive forum for: (a) any derivative action or proceeding brought on our behalf; (b) any action or proceeding asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us; (c) any action or proceeding asserting a claim arising out of any provision of the Companies Act 2006 or our Articles (as may be amended from time to time); or (d) any action or proceeding asserting a claim or otherwise related to our affairs, or the England and Wales Forum Provision. The England and Wales Forum Provision

does not apply to any causes of action arising under the Securities Act or the Exchange Act. Our Articles further provide that unless we consent by ordinary resolution to the selection of an alternative forum, the U.S. District Court for the Southern District of New York is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act or the Exchange Act, or the U.S. Federal Forum Provision. In addition, our Articles provide that any person or entity purchasing or otherwise acquiring any interest in our shares is deemed to have notice of and consented to the England and Wales Forum Provision and the U.S. Federal Forum Provision; provided, however, that our shareholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The England and Wales Forum Provision and the U.S. Federal Forum Provision in our Articles may impose additional litigation costs on our shareholders in pursuing any such claims. Additionally, the forum selection clauses in our Articles may limit the ability of our shareholders to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our shareholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts, including the courts of England and Wales and other courts within the U.S., will enforce our U.S. Federal Forum Provision. If the U.S. Federal Forum Provision is found to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our results of operations and financial condition. The U.S. Federal Forum Provision may also impose additional litigation costs on our shareholders who assert that the provision is not enforceable or invalid. The courts of England and Wales and the U.S. District Court for the Southern District of New York may also reach different judgments or results than would other courts, including courts where a shareholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders.

Our classification as a passive foreign investment company in any period would result in adverse U.S. federal income tax consequences to U.S. holders.

Under the Code, we will be a passive foreign investment company, or PFIC, for any taxable year in which (i) 75% or more of our gross income consists of passive income or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as holding and receiving directly its proportionate share of assets and income of such corporation. If we are a PFIC for any taxable year during which a U.S. Holder (as defined below in the section entitled "U.S. Federal Income Tax Considerations for U.S. holders" in Part II, Item 9B. "Other Information") holds our ordinary shares or ADSs, the U.S. Holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC,

including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred and additional reporting requirements. Based on the composition of our income and assets and the value of our assets, we believe that we were not a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2024 and December 31, 2025. However, no assurances regarding the determination of our PFIC status can be provided for the 2024 taxable year, the 2025 taxable year or any future taxable years. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by the spending of the cash we raise in any offering. Each U.S. Holder should consult its own tax advisors with respect to the potential adverse U.S. tax consequences to it if we are or were to become a PFIC.

If we are a controlled foreign corporation, there could be adverse U.S. federal income tax consequences to certain U.S. Holders.

Each "Ten Percent Shareholder" (as defined below) in a non-U.S. corporation that is classified as a "controlled foreign corporation," or a CFC, for U.S. federal income tax purposes generally is required to include in income for U.S. federal tax purposes such Ten Percent Shareholder's pro rata share of the CFC's "Subpart F income," "global intangible low-taxed income" (for tax years beginning prior to January 1, 2026), "net CFC tested income" (for tax years beginning after December 31, 2025) and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. In addition, if a non-U.S. corporation owns at least one U.S. subsidiary, under current law, any current non-U.S. subsidiaries and any future newly formed or acquired non-U.S. subsidiaries of the non-U.S. corporation will generally be treated as CFCs of such U.S. subsidiary, regardless of whether the non-U.S. corporation is treated as a CFC (although United States Treasury regulations limit the application of these rules in certain regards for tax years beginning before January 1, 2026, and the OBBBA limits the application of these rules in certain regards for tax years beginning after December 31, 2025). Subpart F income generally includes dividends, interest, rents, royalties, gains from the sale of securities and income from certain transactions with related parties. In addition, a Ten Percent Shareholder that realizes gain from the sale or exchange of shares in a CFC may be required to classify a portion of such gain as dividend income rather than capital gain. A non-U.S. corporation generally will be classified as a CFC for U.S. federal income tax purposes if Ten Percent Shareholders own, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A "Ten Percent Shareholder" is a United States person (as defined by the Code) who owns or is considered to own 10% or more of the value or total combined voting power of all classes of stock entitled to vote of such corporation.

Based on our review of beneficial ownership reports filed with the SEC, we do not believe that we were classified as a CFC for the 2025 taxable year. However, no assurances regarding the determination of our CFC status can be provided for

the 2025 taxable year or any future taxable years. Moreover, the determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. An individual that is a Ten Percent Shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a Ten Percent Shareholder that is a U.S. corporation. Failure to comply with CFC reporting obligations may subject a United States shareholder to significant monetary penalties. We cannot provide any assurances that we will furnish to any Ten Percent Shareholder information that may be necessary to comply with the reporting and tax paying obligations applicable under the CFC rules of the Code.

Each U.S. Holder should consult its own tax advisors with respect to the potential adverse U.S. tax consequences of becoming a Ten Percent Shareholder in a CFC.

We have incurred and will continue to incur increased costs as a result of operating as an English-domiciled public company listed in the U.S., and our board of directors will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As an English domiciled public company listed in the U.S., we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, 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 foreign reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our board of directors, management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, each year in our annual reports on Form 10-K, we are required to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. However, we will not require an attestation report on internal control over financial reporting issued by our independent registered public accounting firm for so long as we do not qualify as an accelerated filer or large accelerated filer. In order to achieve and maintain compliance with Section 404, we have documented and evaluated our internal control over financial reporting, which is both costly and challenging. In this regard, we continue to dedicate internal resources, have

engaged outside consultants and adopted a detailed work plan to continually assess and document the adequacy of internal control over financial reporting, taken steps to improve control processes as appropriate, validated through testing that controls are functioning as documented and have implemented a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk in any given year that we will not be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. Moreover, if in future years an attestation report on internal control over financial reporting issued by our independent registered public accounting firm may be required and if our independent registered public accounting firm were to be unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our ADSs could be negatively affected, and we could become subject to investigations by the SEC or other regulatory authorities or to stockholder litigation, which could have an adverse impact on the market price or our ADSs and cause us to incur additional expenses.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our securities less attractive to investors.

We are a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. As a result, we may take advantage of certain of the scaled disclosures available to smaller reporting companies. These include, but are not limited to, reduced disclosure obligations regarding executive compensation and an exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures. As a smaller reporting company with annual revenues of less than $100.0 million and a non-accelerated filer, we are also not required to provide an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We will be able to take advantage of these scaled disclosures and exemptions for so long as (i) our voting and non-voting shares held by non-affiliates is less than $250.0 million measured on the last business day of our most recent second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting shares held by non-affiliates is less than $700.0 million measured on the last business day of our most recent second fiscal quarter. We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ADSs.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. The Sarbanes-Oxley Act requires, among

other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures and that we furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations.

In addition, testing required to be conducted by us in connection with Section 404, and subsequent testing by our independent registered public accounting firm, may identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. If material weaknesses or other deficiencies are identified in the future, we may be required to undertake remedial measures, which could be costly and time-consuming, and we may be unable to conclude that our internal control over financial reporting is effective.

Our internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud. Even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. If we are unable to maintain effective internal controls or produce timely and accurate financial statements, we could be subject to regulatory scrutiny or investigations by Nasdaq, the SEC or other regulatory authorities, and our business, results of operations, and the trading price of our ADSs could be adversely affected. See "*Risks Related to the Ownership of Our ADSs—We have incurred and will continue to incur increased costs as a result of operating as an English public company listed in the U.S., and our board of directors will be required to devote substantial time to new compliance initiatives and corporate governance practices.*"

You may face difficulties in protecting your interests, and your ability to protect your rights through the U.S. federal courts may be limited, because we are incorporated under the laws of England and Wales, conduct most of our operations outside the U.S. and many members of our senior management and certain members of our board of directors reside outside the U.S.

We are incorporated and have our registered office in, and are currently existing under the laws of, England and Wales. In addition, most of our tangible assets are located, and many members of our senior management and certain of our directors reside, outside of the U.S. As a result, it may not be possible to serve process within the U.S. on certain directors or us or to enforce judgments obtained in U.S. courts against such directors or us based on civil liability provisions of the securities laws of the U.S. As a result, it may not be possible for investors to effect service of process within the U.S. upon such persons or to enforce judgments obtained in U.S. courts against them or us, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws. In order to effect service on such persons, it is likely that investors would need to rely on the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters,

or Hague Service Convention, to which the U.S. and the UK are both signatories. While there are a number of methods of service available, generally service of U.S. proceedings in the UK is effected through the Central Authority for the U.K. (the Senior Master of the King's Bench Division of the High Courts of Justice in London) which specifies certain procedural requirements.

As set out in detail above, the U.S. and the UK do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a court in the U.S., whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the UK. In addition, uncertainty exists as to whether courts of England and Wales would have the jurisdiction to determine actions brought in England and Wales against us or our directors or senior management predicated upon the securities laws of the U.S. or any state in the U.S. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by the courts of England and Wales as a cause of action in itself and sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that certain requirements are met.

As a result, U.S. investors may not be able to enforce against us or certain of our directors any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

As an English domiciled public limited company, certain capital structure decisions will require shareholder approval, which may limit our flexibility to manage our capital structure.

English law provides that a board of directors may only allot shares (or grant rights to subscribe for or to convert any security into shares) with the prior authorization of shareholders, such authorization stating the aggregate nominal amount of shares that it covers and being valid for a maximum period of five years, each as specified in the articles of association or relevant ordinary resolution passed by shareholders at a general meeting. Such authorities from our shareholders to allot additional shares for a period of five years from May 9, 2024 and June 12, 2025, respectively, were included in the ordinary resolutions passed by our shareholders on May 9, 2024 and June 12, 2025, respectively, for which authorizations will need to be renewed upon expiration (i.e., at least every five years) but may be sought more frequently for additional five-year terms (or any shorter period).

English law also generally provides shareholders with preemptive rights when new shares are issued for cash. However, it is possible for the articles of association, or for shareholders to pass a special resolution at a general meeting, being a resolution passed by at least 75% of the votes cast, to disapply preemptive rights. Such a disapplication of preemptive rights may be for a maximum period of up to five years from the date of adoption of the articles of association, if the disapplication is contained in the articles of association, but not longer than the duration of the authority to allot shares to which this disapplication relates or from the date of the shareholder special resolution, if the disapplication is by shareholder special resolution. In either case, this disapplication would need to be renewed by our shareholders upon its expiration (i.e., at least

every five years). Such authorities from our shareholders to disapply preemptive rights for a period of five years was included in the special resolutions passed by our shareholders on May 9, 2024 and June 12, 2025, respectively, for which disapplication will need to be renewed upon expiration (i.e., at least every five years) to remain effective, but may be sought more frequently for additional five-year terms (or any shorter period).

English law also generally prohibits a public company from repurchasing its own shares without the prior approval of shareholders by ordinary resolution, being a resolution passed by a simple majority of votes cast, and other formalities. Such approval may be for a maximum period of up to five years.

Shareholder protections found in provisions under the UK City Code on Takeovers and Mergers, or the Takeover Code, do not apply to us while our place of central management and control is outside of the UK and our securities are not quoted on a UK regulated market.

As our securities are not quoted on a UK regulated market (or UK multilateral trading facility or certain exchanges in the Channel Islands or the Isle of Man) and our place of central management and control is outside of the UK, the Takeover Code does not apply to us. As a result, our shareholders are not currently entitled to the benefit of certain takeover offer protections provided under the Takeover Code, including the rules regarding mandatory takeover bids (a summary of which is set out below).

The Takeover Panel has confirmed that, from February 3, 2027, the location of our place of central management and control will no longer be relevant in determining whether the Takeover Code applies to us. From February 3, 2027, the Takeover Code will only apply to us in the event that our securities are quoted on a UK regulated market (or UK multilateral trading facility or certain exchanges in the Channel Islands or the Isle of Man).

In the event that this changes, or if the interpretation and application of the Takeover Code by the Panel on Takeovers and Mergers, or Takeover Panel, changes (including changes to the way in which the Takeover Panel assesses the application of the Takeover Code to English companies whose shares are listed outside of the UK), the Takeover Code may apply to us in the future.

The Takeover Code provides a framework within which takeovers of companies which are subject to the Takeover Code are regulated and conducted. The following is a brief summary of some of the most important rules of the Takeover Code:

- When any person acquires, whether by a series of transactions over a period of time or not, an interest in shares which (taken together with shares already held by that person and an interest in shares held or acquired by persons acting in concert with him or her) carry 30% or more of the voting rights of a company that is subject to the Takeover Code, that person is generally required to make a mandatory offer to all the holders of any class of equity share capital or other class of transferable securities carrying voting rights in that company to acquire the balance of their interests in the company.

- When any person who, together with persons acting in concert with him or her, is interested in shares representing not less than 30% but does not hold more than 50% of the voting rights of a company that is subject to the Takeover Code, and such person, or any person acting in concert with him or her, acquires an additional interest in shares which increases the percentage of shares carrying voting rights in which he or she is interested, then such person is generally required to make a mandatory offer to all the holders of any class of equity share capital or other class of transferable securities carrying voting rights of that company to acquire the balance of their interests in the company.

- A mandatory offer triggered in the circumstances described in the two paragraphs above must be in cash (or be accompanied by a cash alternative) and at not less than the highest price paid within the preceding 12 months to acquire any interest in shares in the company by the person required to make the offer or any person acting in concert with him or her.

- In relation to a voluntary offer (i.e., any offer which is not a mandatory offer), when interests in shares representing 10% or more of the shares of a class have been acquired for cash by an offeror (i.e., a bidder) and any person acting in concert with it in the offer period and the previous 12 months, the offer must be in cash or include a cash alternative for all shareholders of that class at not less than the highest price paid for any interest in shares of that class by the offeror and by any person acting in concert with it in that period. Further, if an offeror acquires for cash any interest in shares during the offer period, a cash alternative must be made available at not less than the highest price paid for any interest in the shares of that class.

- If, after making an offer for a company, the offeror or any person acting in concert with them acquires an interest in shares in an offeree company (i.e., a target) at a price higher than the value of the offer, the offer must be increased to not less than the highest price paid for the interest in shares so acquired.

- An offeree company must appoint a competent independent adviser whose advice on the financial terms of the offer must be made known to all the shareholders, together with the opinion of the board of directors of the offeree company.

- Special or favorable deals for selected shareholders are not permitted, except in certain circumstances where independent shareholder approval is given and the arrangements are regarded as fair and reasonable in the opinion of the financial adviser to the offeree.

- All shareholders must be given the same information.

- Each document published in connection with an offer by or on behalf of the offeror or offeree must state that the directors of the offeror or the offeree, as the case may be, accept responsibility for the information contained therein.

- Profit forecasts, quantified financial benefits statements and asset valuations must be made to specified standards and must be reported on by professional advisers.
- Misleading, inaccurate or unsubstantiated statements made in documents or to the media must be publicly corrected immediately.
- Actions during the course of an offer by the offeree company, which might frustrate the offer are generally prohibited unless shareholders approve these plans. Frustrating actions would include, for example, lengthening the notice period for directors under their service contract or agreeing to sell off material parts of the target group.
- Stringent requirements are laid down for the disclosure of dealings in relevant securities during an offer, including the prompt disclosure of positions and dealing in relevant securities by the parties to an offer and any person who is interested (directly or indirectly) in 1% or more of any class of relevant securities.
- Employees of both the offeror and the offeree company and the trustees of the offeree company's pension scheme must be informed about an offer. In addition, the offeree company's employee representatives and pension scheme trustees have the right to have a separate opinion on the effects of the offer on employment appended to the offeree board of directors' circular or published on a website.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

We are incorporated under the laws of England and Wales. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by the laws of England and Wales, including the provisions of the Companies Act 2006, and by our Articles. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations. See the information under the heading "Description of Share Capital and Articles of Association—Differences in Corporate Law" in our prospectus dated October 17, 2024, filed with the SEC pursuant to Rule 424(b), which information is incorporated herein by reference, for a description of the principal differences between the provisions of the Companies Act 2006 applicable to us and, for example, the Delaware General Corporation Law relating to shareholders' rights and protections.

The principal differences include the following:

- Under English law and our Articles, each shareholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U.S. law, each shareholder typically is entitled to one vote per share at all meetings.
- Under English law, it is only on a poll that the number of shares determines the number of votes a holder may cast. You should be aware, however, that the voting rights of ADSs are also governed by the provisions of a deposit agreement with our depositary bank.

- Under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares for cash. Under U.S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise.

- Under English law and our Articles, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution (or on a poll of shareholders representing 75% of the ordinary shares voting (in person or by proxy)), including amendments to the Articles. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U.S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions.

- In the UK, takeovers may be structured as takeover offers or as schemes of arrangement. Under English law, a bidder seeking to acquire us by means of a takeover offer would need to make an offer for all of our outstanding ordinary shares/ADSs. If acceptances are not received for 90% or more of the ordinary shares/ADSs under the offer, under English law, the bidder cannot complete a "squeeze out" to obtain 100% control of us. Accordingly, acceptances of 90% of our outstanding ordinary shares (including those represented by ADSs) will likely be a condition in any takeover offer to acquire us, not 50% as is more common in tender offers for corporations organized under Delaware law. By contrast, a scheme of arrangement, the successful completion of which would result in a bidder obtaining 100% control of us, requires the approval of a majority of shareholders voting at the meeting and representing 75% of the ordinary shares (including those represented by ADSs) voting at the meeting for approval.

- Under English law and our Articles, shareholders and other persons whom we know or have reasonable cause to believe are, or have been, interested in our shares may be required to disclose information regarding their interests in our shares upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on certain transfers of the shares, withholding of dividends and loss of voting rights. Comparable provisions generally do not exist under U.S. law.

- The quorum requirement for a shareholders' meeting is one or more qualifying persons present at a meeting and between them holding (or being the proxy or corporate representative of the holders of) at least thirty-three and one-third percent (33 ⅓%) in number of the issued shares (excluding any shares held as treasury shares) entitled to attend and vote on the business to be transacted. Under U.S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders' meeting in order to constitute a quorum. The minimum number of shares required for a quorum can be reduced pursuant to a provision in a company's certificate of incorporation or bylaws, but typically not below one-third of the shares entitled to vote at the meeting.

General Risk Factors

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

Due to the international scope of our operations, our assets, earnings, expenses and cash flows are influenced by movements in exchange rates of several currencies, particularly the U.S. dollar, the Pound Sterling and the Euro. Our reporting currency is denominated in U.S. dollars and our functional currency is the U.S. dollar (except that the functional currency of our UK subsidiary is the Pound Sterling) and the majority of our operating expenses are paid in both Pound Sterling and U.S. dollars. We also regularly acquire services, consumables and materials in U.S. dollars, Pound Sterling and the Euro. Further potential future revenue may be derived from abroad, particularly from the U.S. As a result, our business and the price of our ADSs has been affected, and may in the future be affected, by fluctuations in foreign exchange rates between the Pound Sterling and these other currencies, 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. See Note 2 in the notes to our annual consolidated financial statements for a description of foreign exchange risks.

In addition, the possible abandonment of the Euro by one or more members of the European Union, or the EU, could materially affect our business in the future. Despite measures taken by the EU to provide funding to certain EU member states in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the Euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the re-introduction of individual currencies in one or more EU member states, or in more extreme circumstances, the dissolution of the EU. The effects on our business of a potential dissolution of the EU, the exit of one or more EU member states from the EU or the abandonment of the Euro as a currency, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

Unfavorable global economic and geopolitical conditions have in the past and could in the future adversely affect our business, financial condition or results of operations.

Our results of operations have in the past been, and could in the future be, adversely affected by general conditions in the global economy, geopolitics and the global financial markets. Key national economies, including the U.S. and UK, have been affected from time to time by economic downturns or recessions, government shutdowns, supply chain constraints, fluctuating inflation and interest rates, international tariffs, changes in international trade relationships, restricted credit, poor liquidity, reduced corporate profitability, volatility in credit, equity and foreign exchange markets, bankruptcies and overall uncertainty with respect to the economy. For example, while we do not have activities in Russia and Ukraine or the Middle East, the ongoing conflicts and any further escalation of geopolitical tensions related to these conflicts, including the imposition of sanctions by the U.S. and other countries, has and could result in, among other things, supply disruptions, fluctuations in foreign exchange rates, increased probability of a recession and increased volatility in financial markets. In addition, in the past, U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the U.S. Although U.S. lawmakers passed legislation to raise the federal debt ceiling

on multiple occasions, ratings agencies have lowered or threatened to lower the long-term sovereign credit rating on the U.S. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. Furthermore, the global markets have experienced volatility from the effects of announced or future tariff increases by the U.S. and such tariffs or increasing international tension have in the past, and may in the future, lead to increased economic uncertainty, raise the possibility of an economic slowdown, impact supply chains or have other adverse consequences on our business. In addition, additional tariffs may specifically be placed on pharmaceuticals and pharmaceutical ingredients in the future. Any of these disruptions could adversely affect our businesses, results of operations and financial condition.

A deterioration in the global economy and financial markets could result in a variety of risks to our business. In addition, due to the international scope of our operations, our financial condition is and will continue to be influenced by movements in exchange rates of several currencies because our functional currency for our wholly-owned UK operating subsidiary is the Pound Sterling, and we report our financial results in U.S. dollars. For example, inflation rates, particularly in the U.S., have seen increased levels for the last few years compared to recent history. Elevated inflation has in the past resulted in, and may in the future result in, further currency fluctuations, increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. Although the U.S. Federal Reserve lowered interest rates in 2024, the U.S. Federal Reserve had previously raised, and may again raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets and geopolitics, may have the effect of further increasing economic uncertainty and heightening these risks. In addition, fluctuating interest rates or a general economic downturn or recession could reduce our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy, supply disruptions or international trade disputes could also strain our third-party 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 and future economic climate and financial market conditions could adversely impact our business. Moreover, instability in the banking system, international trade disputes, including the imposition of tariffs by the U.S. and other countries has in the past increased, and may in the future increase, market volatility. Due to these and other macroeconomic factors, there is a risk of a recession occurring in the U.S., and perhaps in other major global economies. These developments may adversely affect our business, financial condition and results of operations.

The U.S. Congress and the Trump administration have in the past made, and the Trump administration or any future administration may in the future make, substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

Since the start of the Trump administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new

administration have impacted, and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation, the operation of governmental agencies that regulate our business and other areas. For example, increasing international trade tensions has resulted in increased volatility in the financial markets and increased economic uncertainty. In addition, the OBBBA was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and our financial condition. For example, under Section 174 of the IRC, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31 2024. The OBBBA contains a variety of provisions that could impact our business and results of operations, including certain changes to Medicaid and the ACA, among other provisions, and we will continue to evaluate the potential impact as further information becomes available. Additional federal and state guidance is expected to be issued in the future in order to implement these OBBBA provisions and may adversely impact our business and results of operations. Although we cannot predict the impact, if any, of these changes to our business, they have resulted in increased market volatility in the past and could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Disruptions at the FDA, the SEC, the DEA, the U.S. Patent and Trademark Office and other government agencies, including any disruption caused by changes in policy of the Trump administration and decisions to reduce the number of federal employees, and any funding shortages or potential funding shortages could hinder their ability to hire and retain key leadership and other personnel, prevent new drugs from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business and our timelines.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including changes in government budget and funding levels, the ability to hire and retain key personnel, shifting policy priorities as a result of changes in the presidential administration and political appointees tasked to oversee the agency, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years and recently other companies

have reported delays in the FDA providing guidance and reviewing product applications, and additional delays in review by the FDA may in the future increase as a result. In addition, government funding of the SEC, the DEA, the U.S. Patent and Trademark Office and other government agencies on which our operations may rely is subject to the impacts of political events, which are inherently fluid and unpredictable. Furthermore, the current administration is focused on reducing costs of the federal government generally, including significantly reducing the number of government employees, which could result in reduced resources, including personnel at the agencies that regulate us and delays in reviewing our submissions.

Disruptions at the FDA, DEA and other agencies may slow conduct of our clinical trials, including without limitation due to delays in obtaining DEA licenses required for conduct of our clinical trials, and the time necessary for review and approval of COMP360 and related rescheduling decisions, which could adversely affect our business. For example, if the FDA or DEA experiences significant decreases in funding or personnel, it could significantly impact the ability of the FDA and DEA to issue licenses needed for the conduct of our clinical trials and timely review and process our applications or submissions, which could have a material adverse effect on our business and our timelines.

There continues to be substantial uncertainty as to the extent to which the Trump administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval, and the extent to which the FDA's review processes or decisions may be impacted by input from the administration. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidate. Additionally, the Trump administration could issue or promulgate additional executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates.

Changes and uncertainties in the tax system in the countries in which we have operations could materially adversely affect our financial condition and results of operations, and reduce net returns to our shareholders.

We conduct business globally and file tax returns in multiple jurisdictions. Our consolidated effective corporate income tax rate could be materially adversely affected by several factors, including: changing tax laws, regulations and treaties, or the interpretation thereof; tax policy initiatives and reforms being implemented or under consideration (such as, without limitation, those related to the Organization for Economic Co-Operation and Development's, or OECD, Base Erosion and Profit Shifting, or BEPS, Project, the European Commission's state aid investigations and other anti-tax avoidance legislative efforts and other initiatives); the practices (published or otherwise) of tax authorities in jurisdictions in which we operate; the resolution of issues arising from tax audits or examinations and any related interest or penalties. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid.

We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes (which may have retroactive effect), to the extent they are brought into tax legislation,

regulations, policies or practices in jurisdictions in which we operate, could increase the estimated tax liability that we have expensed to date and paid or accrued on our balance sheets, and otherwise affect our financial position, future results of operations, cash flows in a particular period and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders and increase the complexity, burden and cost of tax compliance.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, or may apply existing rules in an unforeseen manner, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, HMRC, the IRS or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a ‘‘permanent establishment’’ under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. If we are assessed with additional taxes, this may result in a material adverse effect on our results of operations and/or financial condition.

A tax authority may take the position that material tax liabilities, interest and penalties are payable by us, for example where there has been a technical violation of contradictory laws and regulations that are relatively new and have not been subject to extensive review or interpretation, in which case we expect that we might contest such assessment. High-profile companies can be particularly vulnerable to aggressive application of unclear requirements. Many companies must negotiate their tax bills with tax inspectors who may demand higher taxes than applicable law appears to provide. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable, or result in other liabilities (including, without limitation, in relation to penalties and interest), which in turn could affect our results and the returns available to investors.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new treatments from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new treatments can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. 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 may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, including a 43-day shutdown in the fourth quarter of 2025, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities during such shutdowns.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

There continues to be substantial uncertainty as to the extent and manner in which the Trump administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our therapeutic candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our therapeutic candidates. Additionally, the new administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates.

Because we are subject to environmental, health and safety laws and regulations, we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities which may adversely affect our business and financial condition.

Our operations, including our research, development, testing and manufacturing activities, are subject to numerous foreign, federal, state and local environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, manufacture, handling, release and disposal of and the maintenance of a registry for, hazardous materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens.

We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. Furthermore, if we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous materials and, as a result, may incur material liability as a result of such release or exposure. Environmental, health and safety laws and regulations are becoming more stringent. We may incur substantial expenses in connection with any current or future environmental

compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be materially adversely affected. In the event of an accident involving such hazardous materials, an injured party may seek to hold us liable for damages that result.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general or prevent us from obtaining patents and thereby impair our ability to protect our investigational treatments.

As is the case with other companies in our industry, our success is heavily dependent on our intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve technological and legal complexity. Therefore, obtaining and enforcing patents for therapeutics is costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the U.S. or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, the America Invents Act, or the AIA, enacted in the U.S. in 2012 and 2013, has resulted in significant changes to the U.S. patent system.

Prior to the enactment of the AIA, assuming that other requirements for patentability are met, the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 16, 2013, under the AIA, the U.S. transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention regardless of whether a third party was the first to invent the claimed invention. On or after that date, a third party that files a patent application in the USPTO before us could be awarded a patent covering an invention of ours even if we made the invention before the third party. The AIA will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide additional opportunities for third parties to challenge any pending patent application or issued patent in the USPTO. Such opportunities 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 proceeding. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. 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 in our patents 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. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Our business is subject to risks associated with conducting business internationally. Accordingly, our future results could be harmed by a variety of factors, including the following:

- economic weakness, including fluctuating inflation and interest rates, political instability, including foreign conflicts, and the emergence of any future public health crisis or any future mitigation efforts and current or future economic effects;
- differing regulatory requirements for drug approvals;
- differing jurisdictions potentially presenting different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- 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;
- changes in regulations and customs, tariffs and trade barriers;
- changes in currency exchange rates of the Euro, U.S. dollar, Pound Sterling and currency controls;
- changes in a specific country’s or region’s political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain international markets;
- negative consequences from changes in tax laws or practice;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the U.S., UK and European Union;

- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war, terrorism, pandemics, or natural disasters including earthquakes, typhoons, floods and fires.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cybersecurity or cybersecurity of our collaborators, vendors and other partners.

Given our reliance on technological infrastructure, we continue to evaluate internal security measures and policies. Our internal computer systems, which are managed partially by a third party, and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, pandemics and telecommunications and electrical failure. Any system failure, accident or cybersecurity incident, compromise or data breach that causes interruptions in our own or in third-party service vendors' operations could result in a material disruption of our therapeutic development programs. In addition, our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. Cybersecurity incidents and data breaches have been increasing in sophistication and frequency and can include third parties gaining access to employee or clinical trial data using stolen or inferred credentials, computer malware, viruses, spamming, social engineering (including phishing attacks), ransomware, card skimming code, inadvertent or wrongful conduct by our employees or vendors, and other deliberate attacks and attempts to gain unauthorized access. While we conduct periodic penetration testing and perform security monitoring, as the techniques used by adversaries who may attempt to penetrate and sabotage our network security or our website change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques, and the costs to protect our network and systems may increase.

Additionally, it is also possible that unauthorized access to employee or clinical trial data may be obtained through inadequate use or circumvention of security controls by customers, suppliers or other vendors. While we continue to expend time and resources on the mitigation of such risks, there is the possibility of an adverse impact from such an attack in the future.

If a cybersecurity event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of COMP360 or any future therapeutic candidates

and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or cybersecurity incident, compromise or data breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our investigational COMP360 psilocybin treatment or any future therapeutic candidates could be hindered or delayed. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security compromises or breaches, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants. Although we maintain cyber liability insurance, we cannot be certain that our coverage will be adequate for liabilities actually incurred or that insurance will continue to be available to us on economically reasonable terms, or at all.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We are a clinical-stage biotechnology company and continue to mature as a public company since our initial public offering in 2020. We have developed cybersecurity policies, procedures and practices and an enterprise risk management program designed to align to the nature, size and scale of our business operations and cybersecurity threat profile.

Cybersecurity Governance

Our board of directors has delegated oversight responsibility for risk management, including cybersecurity risks, to our audit and risk committee, and such responsibilities are set forth in the audit and risk committee's charter. At routine board meetings, the chair of the audit and risk committee regularly provides a report to the full board on the committee's oversight activities.

As part of our enterprise risk management program, which is overseen by the audit and risk committee, we identify and review risks related to cybersecurity on a regular basis, including risks related to third-party access to our information technology systems. We conduct periodic enterprise risk assessments and report the results to the executive team and the audit and risk committee.

Our vice-president of information technology has primary operational responsibility for managing the overall cybersecurity posture and strategy, managing internal and external cybersecurity resources and organizing and leading efforts to prevent, detect and respond to cybersecurity incidents and threats. Our vice-president of information technology has 25 years of experience in information technology and most recently served as senior director of information technology operations and infrastructure at another biotechnology company. As part of our quarterly disclosure committee process, any significant cybersecurity issues, including any potential risks related to cybersecurity incidents, are discussed with our chief executive officer, chief financial officer and other members of the disclosure committee.

Cybersecurity Risk Management Strategy

Our cybersecurity risk management program is integrated into our overall enterprise risk management system. We have developed and implemented policies, procedures, practices and technology platforms designed to protect the information and systems that support our operations and assets. In developing our policies and procedures, we were informed by certain industry standards and guidelines. We routinely train our employees on cybersecurity awareness and our information security and data protection policies.

We have policies and procedures designed to prevent, detect and respond to cybersecurity incidents or threats. We use industry standard security and monitoring systems that are managed by our internal information technology team with support from third-party IT services firms. We also periodically conduct security testing or hire third-parties to conduct security testing, such as phishing testing and penetration testing. The results of our security testing are reported to our vice president of information technology and, when relevant, with the wider executive team.

When engaging third-parties, we have procedures and protocols designed to protect our information technology systems and our confidential information. For example, before we grant third-parties access to our information technology systems, we typically require agreements with such third-parties, we ordinarily require such third parties to complete cybersecurity training and we typically require specific contract terms in our agreements with such third-parties.

To date, we have not identified any risks from cybersecurity threats, including those resulting from any previous cybersecurity incidents experienced by us or, to our knowledge, by any of our third-party service providers, that have materially affected, or are reasonably likely to materially affect, our business strategy, results of operations, or financial condition. Refer to the risk factor captioned "***Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber security or cyber security of our collaborators, vendors and other partners.***" in Part I, Item 1A. "Risk Factors" for additional description of cybersecurity risks.

ITEM 2. PROPERTIES

Facilities

We lease office space, located at Fora - Soho, 33 Broadwick Street, London, W1F 0DQ, United Kingdom, which is the Company's corporate headquarters. The lease expires in 2027.

In 2023, we entered into a lease for office space at 44 W. 37th Street, New York, NY. The lease expires in 2026.

We believe our facilities are adequate for our current needs and that suitable additional or substitute space would be available as needed to accommodate our anticipated needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that we believe are likely to have a material adverse effect on our business, financial condition, results of operations or prospects. Regardless of the outcome, litigation can have an adverse impact on our business, financial condition, results of operations or prospects because of defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON STOCK

Market Information and Holders of Ordinary Shares and ADSs

Our American Depositary Shares, or ADSs, each represent one ordinary share, nominal value £0.008 per share, of COMPASS Pathways plc. An ADS may be evidenced by an American Depositary Receipt issued by Citibank, N.A. as depositary bank. Our ADSs have been listed and traded on The Nasdaq Global Select Market under the symbol "CMPS" since September 18, 2020. As of March 19, 2026, there were approximately three holders of record of our ordinary shares, nominal value £0.008 per share, and fifteen holders of record of our ADSs. The closing sale price per ADS on The Nasdaq Global Select Market on March 19, 2026 was $5.73.

Dividends

We have never declared or paid any cash dividend, and we do not anticipate declaring or paying any cash dividends in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business.

Under English law, among other things, we may only pay dividends if we have sufficient distributable reserves (on a non-consolidated basis), which are our accumulated realized profits that have not been previously distributed or capitalized less our accumulated realized losses, so far as such losses have not been previously written off in a reduction or reorganization of capital.

Our Equity Compensation Plans Information

Information required by Item 5 of Form 10-K regarding our equity compensation plans is incorporated herein by reference in Item 12 of Part III of this Annual Report.

Unregistered sale of equity securities

Not applicable.

Issuer Purchases of Equity Securities

None.

Defaults upon senior securities

Not applicable.

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 in conjunction with the consolidated financial statements and the related notes to those statements included earlier in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, beliefs and expectations that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements. Important factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in Part I, Item 1A. "Risk Factors" and the section titled "Special Note Regarding Forward-Looking Statements."

References to "we," "our," "us" and "the Company" refer to Compass Pathways plc.

Operating Results

Overview

We are a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. We are motivated by the need to find better ways to help and empower people with serious mental health conditions who are not helped by existing treatments. We are pioneering a new paradigm for treating mental health conditions focused on rapid and durable responses through the development of our investigational COMP360 psilocybin treatment, potentially a first in class treatment. COMP360 is our proprietary psilocybin formulation that includes our pharmaceutical-grade polymorphic crystalline psilocybin, optimized for stability and purity.

We believe that our COMP360 psilocybin treatment could offer a new approach to treatment of serious mental health conditions, including treatment-resistant depression, or TRD, which is a subset of major depressive disorder, or MDD, post-traumatic stress disorder, or PTSD, and potentially many other serious mental health conditions.

Our initial focus is on TRD, comprising patients who are inadequately served by current treatment options. In 2018, we received Breakthrough Therapy designation from the U.S. Food and Drug Administration, or the FDA for COMP360 for the treatment of TRD. In November 2021, we announced positive top-line results from our Phase 2b clinical trial evaluating COMP360 for the treatment of TRD. On November 3, 2022, *The New England Journal of Medicine* published the positive results from our Phase 2b trial. This is the largest, randomized, controlled, double-blind psilocybin treatment clinical trial completed to date. The objective of the Phase 2b study was to evaluate the efficacy and safety of a single dose of investigational COMP360 psilocybin (25mg or 10mg), compared to 1mg, in patients with TRD. The trial achieved its primary endpoint for the 25mg dose, with a 25mg dose of COMP360 demonstrating a statistically significant and clinically relevant treatment difference against the 1mg dose of COMP360 in reducing depressive symptom severity after three weeks.

In 2025, we completed enrollment for each of the two pivotal trials in our Phase 3 program evaluating our COMP360 psilocybin treatment in TRD,. Each of the two pivotal trials has a long-term follow-up component. The pivotal program design is as follows:

• Pivotal trial 1 (COMP005) (n=258): a single dose (25mg) monotherapy compared with placebo.

• Pivotal trial 2 (COMP006) (n= 581): a fixed repeat dose monotherapy using three dose arms: 25mg, 10mg and 1mg. This trial is designed to investigate whether a second dose can increase therapeutic response.

• The primary endpoint in both pivotal trials is the change from baseline in the Montgomery-Åsberg Depression Rating Scale, or MADRS, total score at week 6.

In June 2025, we reported that the first pivotal trial, the COMP005 trial, achieved its primary endpoint, with a single 25mg dose of COMP360 versus placebo demonstrating a highly statistically significant reduction in symptom severity as measured by MADRS with a p-value of $p<0.001$ and a clinically meaningful difference of -3.6 in change at six weeks. The COMP005 trial is on-going and is comprised of three parts: Part A, which concluded during the second quarter of 2025, and was blinded through 6 weeks; Part B, which remained blinded through week 26; and Part C, which contains an open-label treatment part from week 26 to 52.

In February 2026, we announced the successful achievement of the primary endpoint in our ongoing Phase 3 COMP006 trial and Part B results from our ongoing Phase 3 COMP005 trial. We reported that the COMP006 trial achieved its primary endpoint with two fixed doses, administered 3 weeks apart, of COMP360 25 mg versus 1 mg demonstrating a highly statistically significant reduction in symptom severity with a p-value of <0.001 and a clinically meaningful difference of -3.8 points in change at six weeks.

Following these data read-outs, we submitted a request for a meeting with the FDA to discuss a rolling submission and review and the FDA has accepted our meeting request.

Beyond TRD, we have been exploring other indications, including PTSD. In May 2024, we completed and announced top-line results from our open label Phase 2 study to assess the safety and tolerability of COMP360 psilocybin treatment in participants with PTSD, as a result of trauma experienced as adults. In line with the study design, the study enrolled 22 participants who were monitored for a 12-week period post dosing. The study met its primary safety endpoint and available secondary efficacy endpoints. Study observations included meaningful and sustained symptom improvement from baseline in mean CAPS-5 total score, a measure of disease severity, and in Sheehan Disability Scale, or SDS, score, a measure of functional impairment in daily life. Administration of COMP360 was well-tolerated, with a safety profile consistent with previous studies of COMP360. In September 2025, the results of this study were published in the *Journal of Psychopharmacology*.

Based on the data from this trial, we determined to advance development of COMP360 for PTSD and finalized the design of a Phase 2b/3 clinical trial in PTSD. In January 2026, the FDA accepted our IND application for COMP360 in PTSD, enabling the initiation of a Phase 2b/3 (COMP202) clinical trial in patients living with PTSD.

Since our formation, we have devoted substantially all of our resources to conducting preclinical studies and clinical trials, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio. We do not have any therapeutic candidates approved for sale and have not generated any revenue. We have funded our operations primarily with proceeds from the sale of our ordinary shares, ADSs, including in our offerings pursuant to our at-the-market, or ATM, offering program, proceeds from a loan agreement with Hercules, or the Hercules Loan Agreement, and proceeds from a private placement transaction, or the PIPE. We were party to a Sales Agreement for our ATM offering program, dated October 8, 2021, with TD Securities (USA) LLC, or TD Cowen, under which we were able to issue and sell from time to time up to $150.0 million of our ADSs, each representing one ordinary share, through TD Cowen, as the sales agent. Pursuant to the Sales Agreement dated October 8, 2021, through February 27, 2025, we sold 5,491,836 ADSs under our ATM offering program, resulting in $54.8 million in net proceeds. On February 27, 2025, we entered into a new Sales Agreement under which we may issue and sell from time to time up to $150.0 million of our ADSs, subject to the terms of the Sales Agreement. Sales of our ADSs, if any, will generally be made at market prices. To date, we have not sold any ADSs under this Sales Agreement.

On June 30, 2023, we entered into the Hercules Loan Agreement, which provided for aggregate maximum borrowings of up to $50.0 million, including a term loan of $30.0 million, which was funded on June 30, 2023. On August 16, 2023, we entered into a Securities Purchase Agreement, pursuant to which we agreed to sell and issue in a private placement transaction (i) 16,076,750 ADSs and (ii) PIPE Warrants to purchase up to 16,076,750 ADSs, at a purchase price of approximately $7.78 per ADS and accompanying PIPE Warrant to purchase one ADS. Each PIPE Warrant has an exercise price of $9.93 per ADS and is exercisable for a three year period beginning in February 2024. The PIPE Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the PIPE Warrants. During the year ended December 31, 2024, PIPE Warrants were exercised for 3,752,050 ADS, resulting in $37.3 million in exercise proceeds. During the year ended December 31, 2025, no PIPE warrants were exercised. We will receive up to an additional approximately $122.4 million in gross proceeds if the PIPE Warrants are fully exercised.

In January 2025, we issued and sold (i) 24,014,728 ADSs and accompanying warrants to purchase up to 24,014,728 ADSs, and (ii) in lieu of ADSs, to certain investors, Pre-funded Warrants to purchase up to 11,044,720 ADSs and accompanying 2025 ADS Warrants to purchase up to 11,044,720 ADSs. The offering price was $4.2750 per ADS and accompanying 2025 ADS Warrant, and $4.2649 per Pre-funded Warrant and accompanying 2025 ADS Warrant. The Pre-funded Warrants have an exercise price of $0.0001 per ADS and are exercisable immediately. The Pre-funded Warrants expire when exercised in full. The 2025 ADS Warrants have an exercise price of $5.7960 per ADS and are exercisable following a specified data milestone. The 2025 ADS Warrants will expire three years after such warrants become exercisable. Once the

2025 ADS Warrants become exercisable, we may force the exercise of the 2025 ADS Warrants (by way of cash or cashless exercise, at our option), in whole or in part, by delivering a notice of forced exercise to the holders, provided that the closing price for our ADSs on Nasdaq exceeded the warrant exercise price of $5.7960 for the three consecutive trading days prior to the date on which the notice of forced exercise is delivered. During the year ended December 31, 2025, 2,344,720 Pre-funded Warrants were exercised on a cashless basis.

We have incurred recurring losses since our inception, including net losses of $287.86 million and $155.1 million for the year ended December 31, 2025 and 2024, respectively. In addition, as of December 31, 2025, we had an accumulated deficit of $822.6 million. Our historical losses resulted principally from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials, regulatory compliance, market access and commercialization 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 investigational COMP360 psilocybin treatment for TRD, and we expect they will continue to increase as we complete our Phase 3 program in TRD for our investigational COMP360 psilocybin treatment candidate and accelerate plans for our NDA submission and commercial launch, although a majority of the planned commercialization activities will be subject to further Phase 3 data. In addition, our spending in the future may increase as we initiate our planned Phase2b/3 clinical trial in PTSD, or if we choose to expand into additional indications, or to initiate the development for different therapeutic candidates. Furthermore, since the completion of our IPO, we have incurred, and expect to continue to incur, significant costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses. As a result, we will need additional funding in the longer term to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from sales of therapeutic candidates, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

As of December 31, 2025, we had cash and cash equivalents of $149.6 million. In February 2026, we issued and sold in an underwritten offering, or the February 2026 Offering, 17,500,000 ADSs at a public offering price of $8.00 per ADS, each representing one ordinary share, and in lieu of ADSs, to certain institutional investors, Pre-funded Warrants to purchase up to 1,250,000 ADSs at a public offering price of $7.9999 per Pre-funded Warrant. We received net proceeds of approximately $140.5 million, after deducting underwriting discounts and commissions and estimated offering costs. In February 2026, subsequent to the February 2026 Offering, we received net proceeds of $203.2 million following the exercise of 35,059,448 ADS warrants, which were issued on January 13, 2025. We believe that our existing cash and cash equivalents as of December 31, 2025, together with the net proceeds from the February 2026 Offering and the net proceeds from the exercise of all of our outstanding 2025 ADS Warrants, will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2028. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources—Funding Requirements" below.

Macroeconomic Conditions and Changes in Regulatory Landscape

We continue to monitor current macroeconomic and geopolitical events, including, among others, financial and economic conditions (such as fluctuating inflation and interest rates, instability in the banking system, and fluctuations in foreign exchange rates) and the risk of an economic slowdown or recession in the U.S., significant changes in U.S. policies or regulatory environment or disruption to U.S. government agencies, and significant changes in geopolitics and international tensions (such as from the effects from announced or future tariff increases, the war between Ukraine and Russia and conflict in the Middle East), for any potential impact that these or other events or conditions may have on our business.

Changes in policy or resources of governmental agencies, including, but not limited to, changes at the FDA, DEA, SEC, IRS and U.S. Patent and Trademark Office, could impact our business and results of operations. The Trump administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of our current product or future products. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. In addition, the ability of the DEA to inspect clinical trial sites and issue controlled substance licenses to our clinical trial sites in a timely manner and the ability of the FDA to review and clear or approve new products has in the past and may in the future be affected by changes in government budget and funding levels,

the ability of the government to hire and retain key personnel, and shifting policy priorities. If we become negatively impacted by future governmental orders, regulations, policies or guidance or a prolonged government shutdown, there could be a material adverse effect on us and our business.

Our ability to raise additional funds may be adversely impacted by macroeconomic conditions and geopolitical events, changing regulatory conditions, including potential impacts of regulatory agency staffing cuts and policy changes on regulatory feedback and timing thereof, and disruptions to and volatility in the credit and financial markets in the U.S. and worldwide. Failure to raise capital or secure other funding as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. There can be no assurances, however, that our current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue and do not expect to generate any revenue from the sale of therapeutic candidates in the near future. If our development efforts for our investigational COMP360 psilocybin treatment are successful and result in regulatory approval of COMP360, we may generate revenue in the future.

Operating Expenses

Research and Development

Research and development activities are central to our business model. Product or therapeutic 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 and related product manufacturing expenses. As a result, we expect that our research and development expenses will continue to increase as we seek to complete the clinical development for our investigational COMP360 psilocybin treatment for TRD and prepare for regulatory filings related to our COMP360 psilocybin treatment in TRD and initiate a new Phase 2b/3 clinical trial for our COMP360 psilocybin treatment in PTSD.

The successful development and commercialization of our investigational COMP360 psilocybin treatment is highly uncertain. This is due to the numerous risks and uncertainties associated with development and commercialization, including the following:

- successful completion of our Phase 3 trials in TRD and successful enrollment in and completion of our Phase 2b/3 trial in PTSD and future clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials, including our Phase 3 clinical trials in TRD, and our ability to raise capital on favorable terms or at all;
- receiving regulatory approvals or clearance for conducting our planned clinical trials or future clinical trials;
- receiving positive data from our clinical trials that support an acceptable risk-benefit profile of COMP360 psilocybin treatment and any future therapeutic candidates in the intended patient populations;
- receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- establishing and scaling up, through third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any therapeutic candidates are approved;
- entry into collaborations to further the development of our investigational COMP360 psilocybin treatment and our future therapeutic candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for COMP360 and any future therapeutic candidates;
- successfully launching commercial sales of our investigational COMP360 psilocybin treatment and any future therapeutic candidates, if approved;
- acceptance of our current and future therapeutic candidates' benefits and uses, if approved, by patients, the medical community and third-party payors; and
- maintaining a continued acceptable safety profile of our investigational COMP360 psilocybin treatment and our future therapeutic candidates following approval.

A change in the outcome of any of these variables, amongst others, with respect to the development of our investigational COMP360 psilocybin treatment in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of our investigational COMP360 psilocybin treatment. For example, if the FDA, the European Medicines Agency, or EMA, the European Commission, or the EC, the Medicines and Healthcare products Regulatory Agency, or MHRA, or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience additional significant delays in enrollment in any of our planned clinical trials, we could be required to commit significant additional financial resources and time on the completion of clinical development of that therapeutic candidate.

General and Administrative

We anticipate we will continue to incur significant accounting, audit, legal, regulatory and compliance costs, as well as investor and public relations expenses associated with being a public company. Subject to further Phase 3 data in 2026, we anticipate increases in both personnel and other expenses as we prepare for potential commercial operations, particularly as it relates to the planned sales and marketing activities of our therapeutic candidate.

Other Income, Net

Benefit from Research and Development Tax Credit

Benefit from R&D tax credit consists of the R&D tax credit received in the UK, which is recorded within other income, net. As a company that carries out extensive research and development activities, we have historically benefited from the Small and Medium sized Enterprise, or SME, Program and from January 1, 2025, the new merged regime. Qualifying expenditures largely comprise employment costs for research staff, consumables, a proportion of relevant, permitted sub-contract costs and certain internal overhead costs.

Based on criteria established by His Majesty's Revenue and Customs, or HMRC, a portion of expenditures being recognized in relation to our pipeline research and development, clinical trial management and third-party manufacturing development activities were eligible under the SME regime for the year ended December 31, 2024, and the new merged regime for the year ended December 31, 2025. For the year ended December 31, 2025, restrictions have also been introduced on relief that may be claimed for expenditure on contracted out R&D activity where the work is undertaken outside the UK, save for certain exceptions. These restrictions and the application of the exceptions have been taken into account in the assessment of qualifying expenditure. We expect such elements to be eligible for R&D incentives in the future although there may be some limitations on expenditure on activities undertaken outside the UK.

The UK R&D tax credit is fully refundable to us and is not dependent on current or future taxable income. As a result, we have recorded the entire benefit from the UK R&D tax credit as a benefit which is included in our net loss before income tax and, accordingly, not reflected as part of the income tax provision. If, in the future, any UK R&D tax credits generated are needed to offset a corporation tax liability in the UK, that portion would be recorded as a benefit within the income tax provision and any refundable portion not dependent on taxable income would continue to be recorded within other income, net.

Interest Income

Interest income relates to interest earned on cash deposits.

Interest Expense

Interest expense relates to interest paid on debt.

Fair value changes of warrant liabilities

The fair value changes in warrant liabilities are attributable to the warrant liabilities which are subject to re-measurement at each balance sheet date until the warrants are exercised or expire, and any change in fair value will be recognized in the consolidated statements of operations and comprehensive loss.

Foreign exchange gains (losses)

Foreign exchange gains (losses) consist of foreign exchange impacts arising from foreign currency transactions, primarily related to the translation of intercompany balances as a result of a change in our functional currency, as well as bank balances held in a foreign currency.

Corporate Income Tax Expense

We are subject to corporate taxation in the U.S. and the UK (known as corporation tax in the UK). Due to the nature of our business, we have generated losses since inception and have therefore not been required to pay UK corporation tax. Our corporate income tax expense represents only income taxes in the U.S.

UK losses not surrendered may be carried forward indefinitely and may be offset against future taxable profits, subject to numerous utilization criteria and restrictions. The amount that can be offset each year is limited to £5.0 million plus an incremental 50% of UK taxable profits. After accounting for tax credits receivable, we had accumulated trading losses for carry forward in the UK of $577.9 million and $280.8 million as of December 31, 2025 and 2024, respectively, which is offset by a full valuation allowance.

During the years ended December 31, 2025 and 2024, we recorded a tax benefit of $2.5 million and income tax provision of $1.6 million, respectively, related to the corporate income tax obligations of our operating company in the U.S., which generates a profit for tax purposes.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Year ended December 31,	
	2025	2024
OPERATING EXPENSES:		
Research and development	$ 118,436	$ 119,039
General and administrative	60,601	59,166
Total operating expenses	179,037	178,205
LOSS FROM OPERATIONS	(179,037)	(178,205)
OTHER (EXPENSE) INCOME, NET:		
Fair value change of warrant liabilities	(122,561)	—
Benefit from R&D tax credit	3,747	21,097
Interest income	7,182	8,268
Foreign exchange gains (losses)	3,471	(1,032)
Interest expense	(4,517)	(4,479)
Other income	1,380	823
Total other (expense) income, net	(111,298)	24,677
Loss before income taxes	(290,335)	(153,528)
Income tax benefit (expense)	2,473	(1,594)
Net loss	$ (287,862)	$ (155,122)

Comparison For The Years Ended December 31, 2025 and 2024

Research and Development

Research and development expenses consist of the following (in thousands):

	Year ended December 31,		
	2025	2024	Change
Development expenses	$ 82,372	$ 76,993	$ 5,379
Personnel expenses	24,420	26,707	(2,287)
Facilities and other expenses	6,556	5,030	1,526
Non-cash share-based compensation expense	5,088	10,309	(5,221)
Total research and development expenses	$ 118,436	$ 119,039	$ (603)

For the year ended December 31, 2025, the decrease in research and development expenses, as compared to the same period in 2024, was primarily attributable to the following:

- a decrease in non-cash share-based compensation expense and personnel expenses as a result of decreased staffing levels associated with the reorganization that took place in the fourth quarter of 2024.

Offset by:

- an increase in development expenses associated with advancing our late-stage COMP360 clinical trials; and
- an increase in facilities and other expenses primarily due to an increase in external consulting fees.

We expect to continue to incur significant research and development costs at least through completion of our Phase 3 program for COMP360 psilocybin therapy in TRD and our late-stage development program in PTSD.

General and Administrative

General and administrative expenses consist of the following (in thousands):

	Year ended December 31,		
	2025	2024	Change
Legal and professional fees	$ 23,521	$ 14,535	$ 8,986
Personnel expenses	19,716	23,422	(3,706)
Facilities and other expenses	8,862	12,001	(3,139)
Non-cash share-based compensation expense	8,502	9,208	(706)
Total general and administrative expenses	$ 60,601	$ 59,166	$ 1,435

For the year ended December 31, 2025, the increase in general and administrative expenses, as compared to the same period in 2024, was primarily attributable to the following:

- an increase in legal and professional fees, primarily related to issuance costs related to the January 2025 Financing as well as expenses associated with consulting, accounting and legal advice.

Offset by:

- a decrease in personnel expenses and non-cash share-based compensation expense as a result of decreased staffing levels associated with the reorganization that took place in the fourth quarter of 2024.
- a decrease in facilities and other expenses as a result of lower insurance premiums, lower banking fees, and the reduction of spend from vendors that were associated with the reorganization that took place in the fourth quarter of 2024.

We expect to continue to incur significant general and administrative expenses as a result of ongoing requirements as a public company, in addition to ongoing general and administrative support for research and development activities, as well as commercial preparedness activities.

Other Income, Net

Other income, net consists of the following (in thousands):

	Year ended December 31,		
	2025	2024	Change
Fair value change of warrant liabilities	$ (122,561)	$ —	$ (122,561)
Benefit from R&D tax credit	3,747	21,097	(17,350)
Interest income	7,182	8,268	(1,086)
Interest expense	(4,517)	(4,479)	(38)
Foreign exchange gains (losses)	3,471	(1,032)	4,503
Other income	1,380	823	557
Total other (expense) income, net	$ (111,298)	$ 24,677	$ (135,975)

For the year ended December 31, 2025, the decrease in other (expense) income, net, as compared to the same period in 2024, was primarily attributable to the following:

- a decrease due to the change in fair value of the warrant liabilities during the period, related to the warrants issued in the January 2025 Financing; and
- a decrease in the benefit from R&D tax credit due to the uncertainty of meeting the R&D intensity condition and therefore eligibility for the enhanced effective rates, which is currently under discussion with the HMRC; and
- a decrease in interest income primarily due to interest earned on lower cash deposit levels.

Partially offset by:

- an increase due to foreign exchange gains following remeasurement of foreign currency denominated assets and liabilities; and

Comparison For The Years Ended December 31, 2024 and 2023

Please refer to the Annual Report on Form 10-K filed for December 31, 2024 for details on the comparisons for the years ended December 31, 2024 and 2023.

Liquidity and Capital Resources

We are a clinical-stage biotechnology company and we have not yet generated any revenue to date. We have incurred significant operating losses since our formation. We have not yet commercialized any therapeutic candidates. We currently expect that, if we receive marketing approval from the FDA for our first product candidate and are able to successfully launch and commercialize such product, we could begin generating revenue from product sales as early as next year. However, there can be no assurance as to the timing of any such approval, the success of any commercial launch, the level of market acceptance, or whether we will generate revenue on that timeline, if at all. We have primarily funded our operations with proceeds from the sale of our ordinary shares, ADSs, including our ATM offering program, proceeds from the Hercules Loan Agreement, and proceeds from the PIPE. The ATM offering program allows us to issue and sell from time to time up to $150.0 million of our ADSs. Pursuant to the Sales Agreement dated October 8, 2021, through February 27, 2025, we sold 5,491,836 ADSs under our ATM offering program, resulting in $54.8 million in net proceeds. On February 27, 2025, we entered into a new Sales Agreement under which we may issue and sell from time to time up to $150.0 million of our ADSs, subject to the terms of the Sales Agreement. Sales of our ADSs, if any, will generally be made at market prices. To date, we have not sold any ADSs under this Sales Agreement. The Hercules Loan Agreement provided for aggregate maximum borrowings of up to $50.0 million, of which we have funded $30.0 million. Within the PIPE agreement, we agreed to sell and issue PIPE Warrants to purchase up to 16,076,750 ADSs. Each PIPE Warrant has an exercise price of $9.93 per ADS and is exercisable for a three-year period beginning in February 2024. During the year ended December 31, 2024, PIPE Warrants were exercised for 3,752,050 ADS, resulting in $37.3 million in exercise proceeds. During the year ended December 31, 2025, no PIPE warrants were exercised. We will receive up to an additional approximately $122.4 million in gross proceeds if the PIPE Warrants are fully exercised for cash. In January 2025, we completed the January 2025 Financing in which we issued and sold ADSs and, in lieu of ADSs, Pre-funded Warrants to certain investors along with accompanying 2025 ADS Warrants to purchase ADSs. Through December 31, 2025, 2,344,720 Pre-funded Warrants were exercised. In February 2026, we issued and sold in an underwritten offering, or the February 2026 Offering, 17,500,000 ADSs at a public offering price of $8.00 per ADS, each representing one ordinary share, and in lieu of ADSs, to certain institutional investors, Pre-funded Warrants to purchase up to 1,250,000 ADSs at a public offering price of $7.9999 per Pre-funded Warrant.

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than our operating leases, and debt obligations under our Loan Agreement with Hercules described in the notes to our consolidated financial statements.

Cash Flows

The following table summarizes our cash flows for each of the periods (in thousands):

to f

	Year Ended December 31,		Change
	2025	2024	
Net cash used in operating activities	$ (157,240)	$ (119,186)	$ (38,054)
Net cash provided by financing activities	$ 140,712	$ 63,824	$ 76,888
Effect of exchange rate changes on cash, cash equivalents and restricted cash	$ 1,045	$ 194	$ 851
Net (decrease)/increase in cash, cash equivalents and restricted cash	$ (15,483)	$ (55,168)	$ 39,685

Net Cash Used in Operating Activities

Net cash used in operating activities increased during the year ended December 31, 2025, compared to the same period in 2024, primarily due to unfavorable working capital related activities of $26.0 million, as well as an increase of $120.7 million of non-cash adjustments, including the change in fair value of warrant liabilities of $122.6 million, which was offset by a $132.8 million increase in our net loss.

Net Cash Provided by Financing Activities

Net cash provided by financing activities increased during the year ended December 31, 2025, compared to the same period in 2024, primarily as a result of proceeds from the January 2025 Financing for the issuance of ADSs and the Pre-funded Warrants of $140.4 million, compared to the proceeds from the issuance of ordinary shares through our ATM facility of $26.2 million and the proceeds from the exercise of warrants of $37.3 million in 2024.

Funding Requirements

We expect our expenses to continue to increase substantially in connection with our ongoing activities, particularly as we continue to advance our Phase 3 program of COMP360 in TRD and supporting clinical and preclinical studies and related preparatory work for an NDA submission, including a potential rolling NDA submission, as well as manufacturing activities and commercial preparedness activities, the majority of which will be subject to further Phase 3 data, and as we initiate our planned Phase 2b/3 clinical trial in PTSD. In addition, we expect to continue to incur significant costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses. Our expenses will increase as we:

- continue to advance our Phase 3 program for investigational COMP360 psilocybin treatment in TRD and clinical and preclinical supporting studies and accelerate our plans for NDA submission;
- we prepare for commercial launch of COMP360 psilocybin treatment in TRD, if approved, including establishing a sales, marketing and distribution infrastructure and scaling-up manufacturing capabilities;
- advance our commercialization strategy;
- initiate and advance our Phase 2b/3 clinical trial in PTSD;
- continue the training of qualified healthcare professionals to monitor and safeguard participants in our Phase 3 program and other clinical trials;
- service our outstanding indebtedness;

- may in the future resume and pursue research and development programs for our other preclinical stage therapeutic candidates and discovery-stage programs and/or develop and seek regulatory approval for any future therapeutic candidates that successfully complete clinical trials;
- establish and expand the network of public healthcare institutions and private clinics that could administer our investigational COMP360 psilocybin treatment if approved;
- experience heightened regulatory scrutiny;
- pursue necessary scheduling-related decisions by the U.S. Drug Enforcement Administration, or the DEA, and various state governments to enable us to commercialize any therapeutic candidates containing controlled substances for which we may obtain regulatory approval, including COMP360;
- obtain, maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent or other intellectual property infringement claims;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our therapeutic development and potential future commercialization efforts;
- experience any delays or encounter any issues with respect to any of the above, including failed studies, ambiguous trial results, safety issues or other regulatory challenges, including, for example, delays and other impacts as a result of pandemics or other public health crises;
- expand our operations in the U.S. and Europe in the future; and
- incur additional legal, accounting and other expenses associated with operating as an English-domiciled public company listed in the U.S.

As of December 31, 2025, we had cash and cash equivalents of $149.6 million. In February 2026, we issued and sold in an underwritten offering, or the February 2026 Offering, 17,500,000 ADSs at a public offering price of $8.00 per ADS, each representing one ordinary share, and in lieu of ADSs, to certain institutional investors, Pre-funded Warrants to purchase up to 1,250,000 ADSs at a public offering price of $7.9999 per Pre-funded Warrant. We received net proceeds of approximately $140.5 million, after deducting underwriting discounts and commissions and estimated offering costs. In February 2026, subsequent to the February 2026 Offering, we received proceeds of approximately $203.2 million following the exercise of 35,059,448 2025 ADS Warrants. Upon exercise of these outstanding warrants, we issued 15,160,619 ADSs and in lieu of ADSs, to certain institutional investors, Pre-funded Warrants to purchase up to 19,898,829 ADSs.

We believe that our existing cash and cash equivalents, together with the net proceeds from the February 2026 Offering and the net proceeds from the exercise of all of our outstanding 2025 ADS Warrants, will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2028. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. As we progress with our development programs and the regulatory review process, we expect to incur significant commercialization expenses related to product manufacturing, pre-commercial activities and commercialization.

Because of the numerous risks and uncertainties associated with research, development and commercialization of therapeutic candidates and programs, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the progress, timing and completion of our Phase 3 program for our current investigational COMP360 psilocybin treatment program for TRD, and clinical and preclinical supporting studies and related preparatory work for our planned NDA submission and potential commercialization activities;
- the progress, timing and completion of our Phase 2b/3 clinical trial in PTSD;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA, the EC, the MHRA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more

preclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;

- the outcome and timing of any scheduling-related decisions by the DEA, individual states, and comparable foreign authorities;
- the number of potential future therapeutic candidates we may choose to pursue and identify in the future and decide to develop, either internally through our research and development efforts or externally through acquisitions, licensing or other collaboration agreements;
- the costs involved in growing our organization in the near term to the size needed to prepare for the potential commercialization of our investigational COMP360 psilocybin treatment in TRD and any future therapeutic candidates, including increases to personnel costs;
- the costs of developing sales and marketing capabilities to prepare for potential commercial launch of COMP360 psilocybin treatment in TRD to target public and private healthcare providers and clinic networks in the U.S. and other major markets;
- the costs of training qualified healthcare professionals to monitor and safeguard participants in our clinical trials;
- the costs of maintaining research collaborations, such as the Center for Mental Health Research, which includes conducting clinical trials, including proof of concept studies, to refine our treatment delivery model;
- the time and costs involved in generating and collecting data and advancing and defending our intellectual property portfolio, including the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringements or invalidity raised by third parties;
- the costs of developing, testing and deploying technology solutions or paying a third-party to provide such digital technology solutions to improve the patient experience and therapeutic process via third-party service providers or internally;
- the time and costs involved in obtaining regulatory approval for COMP360 or any future therapeutic candidates, and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to COMP360 or any future therapeutic candidates;
- selling and marketing activities undertaken in connection with the potential commercialization of our investigational COMP360 psilocybin treatment or any future therapeutic candidates, if approved, and costs involved in the creation of an effective sales and marketing organization;
- the amount of revenue, if any, we may derive either directly or in the form of royalty, milestone or other payments from future sales of our investigational COMP360 psilocybin treatment and any future therapeutic candidates, if approved;
- the impact of macroeconomic and geopolitical events, including, among others, fluctuating inflation and interest rates, fluctuations in foreign exchange rates, the risk of economic slowdown or recession in the U.S., international tensions and changes in legislation and governmental policies and resources, including the effects of announced or future tariff increases; and
- the costs of operating as a public company.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additional financing may not be available at all or on acceptable terms. To the extent that we raise additional capital through the sale of equity or exercise of outstanding warrants, current ownership interests will be diluted. If we raise additional funds through government or third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish future revenue streams, research programs or therapeutic candidates or grant licenses

on terms that may not be favorable to us. Debt financing, if available, may involve high interest rates or agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise additional funds 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 products or therapeutic candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, income and expenses, and the disclosure of contingent assets and 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. We do not have any significant judgments or estimates.

Critical Accounting Policies

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements, we believe that the following accounting policies are those most critical to the preparation of our consolidated financial statements.

Research and Development Incentives and Receivables

We are subject to corporate taxation in the UK. Due to the nature of our business, we have generated losses since our inception. The benefit from research and development, or R&D, tax credit is recognized in our consolidated statements of operations and comprehensive loss as a component of other income (expense), net, and represents the sum of our R&D tax credits recoverable in the UK. Each reporting period, we evaluate which UK R&D tax credit programs we expect to be eligible for, that we plan to submit a claim for, and we have reasonable assurance that the amount will ultimately be realized.

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

As a Company, we currently meet the conditions of the SME regime. A large portion of costs relating to R&D, clinical trials and clinical manufacturing activities are eligible for inclusion within these tax credit cash rebate claims. We carry out extensive R&D activities and, therefore, have historically benefited from the UK R&D tax credit regime under the scheme for small or medium-sized enterprises, ("SME's"). For accounting periods starting on or after April 1, 2024, the UK R&D regimes have changed, such that the effective cash credit will be 16.2% for in-house expenditure and 10.5% for any work that is contracted out.

However, new rules were introduced by the Finance Act 2024 for an enhanced rate of relief for research intensive companies ("ERIS"), which are approximately 27.0% for qualifying expenditure and approximately 17.5% for qualifying subcontracted expenditure (paid to an unconnected subcontractor). Beginning January 1, 2025, to be eligible as a research intensive company, the qualifying R&D expenditure for tax purposes must be at least 30% of the aggregate expenditure across the consolidated group. During the year ended December 31, 2024 the threshold was 40%.

For the years ended December 31, 2023 to 2025, we are currently having discussions with HMRC regarding whether we have met the R&D intensity condition and therefore are eligible for the enhanced effective rate due to uncertainties over whether impairments on intercompany loans and investments in subsidiary companies should be taken into account in determining the R&D intensity threshold. The outcome of this matter under discussion with HMRC is currently unknown. As a result of these discussions the Company recorded a change in estimate for the 2023 claim, which was initially recorded during the first quarter of 2025, of $4.1 million to reduce its receivable for amounts claimed at the enhanced rate. The

Company recorded a change in estimate for the 2024 claim, which was initially recorded during the year ended December 31, 2025, of $7.0 million to reduce its receivable for amounts previously claimed at the enhanced rate.

The Company believes that the impairments of intercompany loans and investments in subsidiary companies should be disregarded and that it meets the R&D intensity condition in the year ended December 31, 2023 and December 31, 2024. As the Company believes that it meets the R&D intensity condition for the year ended December 31, 2024, it should automatically fulfil the expenditure conditions to be eligible for the enhanced rate in the year ended December 31, 2025 as a company remains research intensive unless it fails to meet the eligibility requirement for two consecutive years. However, given the uncertainty over the outcome of the discussions with HMRC the enhanced R&D credits have not been reflected in the financial statements. If the Company reached a successful conclusion with HMRC additional credits of $4.1 million in the year ended December 31, 2023, $7.0 million in the year ended December 31, 2024 and $7.3 million in the year to December 31, 2025 could be claimed.

Qualifying expenditures largely comprise employment costs for research staff for which an estimate of time spent directly or indirectly supporting the pursuit of R&D activities is made, consumables, outsourced contract research organization costs, which are considered to be subcontracted costs, and utilities costs incurred as part of our research projects. A large portion of costs relating to R&D, clinical trials and manufacturing activities are eligible for inclusion within our tax credit cash rebate claims. For the year ended December 31, 2025, restrictions have also been introduced on relief that may be claimed for expenditure on contracted out R&D activity where the work is undertaken outside the UK, save for certain exceptions. These restrictions and the application of the exceptions have been taken into account in the assessment of qualifying expenditure.

Included in the total employment costs are estimates relating to the allocation of time spent on R&D activities by individuals. These estimates are based on real time data such as time spent by various team members, considerations given for non-R&D related events and general day to day activities. The estimates are based on the most accurate representation of the total time spent on qualifying R&D activities.

The classification of consumables, outsourced contract research organization costs and utilities costs are based on analysis undertaken by management relating to the direct nature of such costs. The costs incurred relate directly to our pursuit of R&D activities.

We have recorded a benefit from the R&D tax credit in other income of $3.7 million and $21.1 million for the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025 and 2024, our tax incentive receivable from the UK government was $26.3 million and $20.7 million, respectively. During the year ended December 31, 2025, we did not receive any cash proceeds from the UK government in respect of prior year R&D tax credit claims.

Warrant Liabilities

We account for our warrants in accordance with the guidance contained in ASC Topic 815-40-15-7D, or Derivatives and Hedging, under which the warrants that do not meet the criteria for equity treatment must be recorded as liabilities. Accordingly, we classify the warrants as liabilities at their fair value and adjust the warrants to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until the warrants are exercised or expire, and any change in fair value will be recognized in our consolidated statements of operations and comprehensive loss. The fair values of these warrants are determined using the Black-Scholes pricing model.

The warrant liabilities are classified as current on the consolidated balance sheets due to the likelihood of exercise and it is reasonably expected that we would be required to use existing resources classified as current assets, or create other current liabilities, to settle the warrant liabilities at this time. Management reviews the classification of warrant liabilities at each reporting period to determine whether any change in classification is warranted based on changes in facts or circumstances, including the proximity to expiration or likelihood of exercise.

Smaller Reporting Company Status

We are a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. As a result, we may take advantage of certain of the scaled disclosures available to smaller reporting companies. These include, but are not limited to, reduced disclosure obligations regarding executive compensation and an exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures. As a

smaller reporting company with annual revenues of less than $100.0 million and a non-accelerated filer, we are also not required to provide an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We will be able to take advantage of these scaled disclosures and exemptions for so long as (i) our voting and non-voting shares held by non-affiliates is less than $250.0 million measured on the last business day of our most recent second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting shares held by non-affiliates is less than $700.0 million measured on the last business day of our most recent second fiscal quarter.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business, which are principally limited to interest rate fluctuations and foreign currency exchange rate fluctuations. We maintain significant amounts of cash and cash equivalents that are in excess of federally insured limits in various currencies, placed with one or more financial institutions for varying periods according to expected liquidity requirements.

Interest Rate Risk

As of December 31, 2025, we held cash and cash equivalents of $149.6 million. Our exposure to interest rate sensitivity is impacted by changes in the underlying United States and United Kingdom bank interest rates. Our surplus cash has been invested in interest-bearing savings and short-term deposits from time to time. We have not entered into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, which is predicated on capital preservation of investments with short-term maturities, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our portfolio, and therefore we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

We have borrowed $30.0 million under our debt facility. Amounts outstanding under the debt facility bear interest at an annual rate equal to the greater of either (i) the prime rate as reported in The Wall Street Journal plus 1.50% or (ii) 9.75%. As of December 31, 2025, the carrying value of the term loan under the debt facility was $31.6 million.

Foreign Currency Exchange Risk

The functional currency of Compass Pathways plc and its wholly owned subsidiary Compass Pathfinder Holdings Limited is the U.S. Dollar, or USD. The functional currency of Compass Pathfinder Holdings Limited's wholly owned non-U.S. subsidiary, Compass Pathfinder Limited, is British Pound Sterling and the functional currency of its U.S. subsidiary, Compass Pathways Inc. is USD. The functional currency of these subsidiaries is the same as the local currency.

The translated balances of monetary and non-monetary assets and liabilities recorded in the reporting entity's consolidated financial statements as of the end of the prior reporting period become the new accounting basis for those assets and liabilities in the period of the change. To the extent that the distinct and separable operation has monetary assets and liabilities denominated in the old functional currency, such balances will create transaction gains and losses subsequent to the change in functional currency. The balance recorded in the cumulative translation adjustment account for prior periods is not reversed upon the change in functional currency.

We translate the assets and liabilities of Compass Pathfinder Limited into USD at the exchange rate in effect on the balance sheet date. Income and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of shareholders' equity as a component of accumulated other comprehensive income. For the year ended December 31, 2025, $3.5 million of unrealized gain on foreign currency translation was included in other comprehensive loss compared to an unrealized loss of $1.0 million for the year ended December 31, 2024.

We do not currently engage in synthetic currency hedging activities in order to reduce our currency exposure, but we maintain a spread of deposits in U.S. dollars, pounds sterling and euros to broadly reflect our expected expenditures in those currencies over time, to provide a natural hedge against the impact of foreign exchange rate movements, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements are appended at the end of this Annual Report, starting at page F-1, and incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of December 31, 2025. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosures.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013 framework). Based on our evaluation under that framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm because we are not an accelerated filer or large accelerated filer.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

ITEM 9B. OTHER INFORMATION

(a)

The following summary contains a description of material U.S. federal income tax and UK tax consequences of the acquisition, ownership and disposition of our ordinary shares or ADSs. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to beneficial owners of ADSs.

U.S. Federal Income Tax Considerations for U.S. holders

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of our ordinary shares or ADSs. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire securities. This discussion applies only to a U.S. Holder who holds our ordinary shares or ADSs as a capital asset for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including state and local tax consequences, estate tax consequences, alternative minimum tax consequences, the special tax accounting rules under Section 451(b) of the Code, the potential application of the Medicare contribution tax, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ordinary shares or ADSs as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to ordinary shares or ADSs;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt entities or government organizations;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes;
- regulated investment companies or real estate investment trusts;
- persons that own or are deemed to own 10% or more of the voting power or value of our ordinary shares or ADSs;
- persons who acquired our ordinary shares or ADSs pursuant to the exercise of any employee share option or otherwise as compensation;
- persons holding our ordinary shares or ADSs in connection with a trade or business, permanent establishment, or fixed base outside the United States; and
- persons who own (directly or through attribution) 10% or more (by vote or value) of our outstanding ordinary shares.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ordinary shares or ADSs, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ordinary shares or ADSs and partners in such partnerships are encouraged to consult their tax advisers as to the particular U.S. federal income tax consequences of holding and disposing of ordinary shares or ADSs.

The discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the income tax treaty between the UK and the United States, all as of the date of this Annual Report, changes to any of which may affect the tax consequences described herein-possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares or ADSs and is:

- an individual who is a citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

Generally, a U.S. Holder of an ADS should be treated for U.S. federal income tax purposes as holding the ordinary shares represented by our ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares. The U.S. Treasury has expressed concerns that intermediaries in the chain of ownership between the holder of an ADS and the issuer of the security underlying our ADS may be taking actions that are inconsistent with the beneficial ownership of the underlying security. Accordingly the creditability of foreign taxes, if any, as described below, could be affected by actions taken by intermediaries in the chain of ownership between the holders of ADSs and our company if as a result of such actions the holders of ADSs are not properly treated as beneficial owners of the underlying ordinary shares. These actions would also be inconsistent with the claiming of the reduced tax rate, described below, applicable to dividends received by certain non-corporate holders.

PERSONS CONSIDERING AN INVESTMENT IN ORDINARY SHARES OR ADSs SHOULD CONSULT THEIR TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEM RELATING TO THE ACQUISITION, OWNERSHIP AND DISPOSITION OF THE ORDINARY SHARES OR ADSs, INCLUDING THE APPLICABILITY OF U.S. FEDERAL, STATE AND LOCAL TAX LAWS.

Passive Foreign Investment Company Rules

If we are classified as a passive foreign investment company, or PFIC, in any taxable year, a U.S. Holder will be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income is passive income (such as interest income); or
- at least 50% of its gross assets (determined on the basis of a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income.

We will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other corporation, the equity of which we own, directly or indirectly, 25% or more (by value).

Based on the composition of our income and assets and the value of our assets, we believe that we were not a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2024 and our taxable year ended December 31, 2025. However, no assurances regarding our PFIC status can be provided for any past, the current, or any future taxable years. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. If we are treated as a non-publicly traded CFC for the year being tested for purposes of the PFIC rules, the value of our assets will be measured by the adjusted tax basis of our assets. If we are a publicly traded CFC or not a CFC for such year, the value of our assets generally will be determined by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by the spending of the cash we raise in any offering.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns the ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the tests described above unless (i) we cease to be a PFIC and the U.S. Holder has made a "deemed sale" election under the PFIC rules, or (ii) the U.S. Holder makes a Qualified Electing Fund Election, or QEF Election, with respect to all taxable years during such U.S. Holders holding period in which we are a PFIC. If the "deemed sale" election is made, a U.S. Holder will be deemed to have sold the ordinary shares or ADSs the U.S. Holder holds at their fair market value and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. Holder's ordinary shares or ADSs with respect to which such election was made will not be treated as shares in a PFIC and the U.S. Holder will not be subject to the rules described below with respect to any "excess distribution" the U.S. Holder receives from us or any gain from an actual sale or other disposition of the ordinary shares or ADSs. U.S. Holders should consult their tax advisors as to the possibility and consequences of making a deemed sale election if we cease to be a PFIC and such election becomes available.

For each taxable year we are treated as a PFIC with respect to U.S. Holders, U.S. Holders will be subject to special tax rules with respect to any "excess distribution" such U.S. Holder receives and any gain such U.S. Holder recognizes from a sale or other disposition (including, under certain circumstances, a pledge) of ordinary shares or ADSs, unless (i) such U.S. Holder makes a QEF Election or (ii) our ordinary shares or ADSs constitute "marketable" securities, and such U.S. Holder makes a mark-to-market election as discussed below. Distributions a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions a U.S. Holder received during the shorter of the three preceding taxable years or the U.S. Holder's holding period for the ordinary shares or ADSs will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over a U.S. Holder's holding period for the ordinary shares or ADSs;
- the amount allocated to the taxable year of disposition or distribution, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year for individuals or corporations, as appropriate, and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ordinary shares or ADSs cannot be treated as capital, even if a U.S. Holder holds the ordinary shares or ADSs as capital assets.

If we are a PFIC, a U.S. Holder will generally be subject to similar rules with respect to distributions we receive from, and our dispositions of the stock of, any of our direct or indirect subsidiaries that also are PFICs, as if such distributions were indirectly received by, and/or dispositions were indirectly carried out by, such U.S. Holder. U.S. Holders should consult their tax advisors regarding the application of the PFIC rules to our subsidiaries.

U.S. Holders can avoid the interest charge on excess distributions or gain relating to the ordinary shares or ADSs by making a mark-to-market election with respect to the ordinary shares or ADSs, provided that the ordinary shares or ADSs are "marketable." Ordinary shares or ADSs will be marketable if they are "regularly traded" on certain U.S. stock exchanges or on a foreign stock exchange that meets certain conditions. For these purposes, the ordinary shares or ADSs will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs have been listed on Nasdaq, which is a qualified exchange for these purposes. Consequently, if our ADSs remain listed on Nasdaq and are regularly traded, and you are a holder of ADSs, we expect the mark-to-market election would be available to you if we are a PFIC. Each U.S. Holder should consult its tax advisor as to the whether a mark-to-market election is available or advisable with respect to the ordinary shares or ADSs.

A U.S. Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of the ordinary shares or ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in the ordinary shares or ADSs. An electing holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted basis in the ordinary shares or ADSs over the fair market value of the ordinary shares or ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of the ordinary shares or ADSs will be treated as ordinary income,

and any losses incurred on a sale or other disposition of the shares will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the Internal Revenue Service, or the IRS, unless the ordinary shares or ADSs cease to be marketable.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves "marketable." As a result, even if a U.S. Holder validly makes a mark-to-market election with respect to our ordinary shares or ADSs, the U.S. Holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

We do not intend to provide information necessary for U.S. holders to make QEF elections which, if available, would result in tax treatment different from the general tax treatment for PFICs described above .

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

WE STRONGLY URGE YOU TO CONSULT YOUR TAX ADVISOR REGARDING THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs.

Taxation of Distributions

Subject to the discussion above under "Passive Foreign Investment Company Rules," distributions paid on ordinary shares or ADSs, other than certain pro rata distributions of ordinary shares or ADSs, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we may not calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations and the discussions above regarding concerns expressed by the U.S. Treasury, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to "qualified dividend income" if we are a "qualified foreign corporation" and certain other requirements are met. However, the qualified dividend income treatment will not apply if we are treated as a PFIC with respect to the U.S. Holder. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss. The amount of any distribution of property other than cash (and other than certain pro rata distributions of ordinary shares or ADSs or rights to acquire ordinary shares or ADSs) will be the fair market value of such property on the date of distribution.

For foreign tax credit limitation purposes, our dividends will generally be treated as passive category income. Because no UK taxes will be withheld from dividends on ordinary shares or ADSs, there will be no creditable foreign taxes associated with any dividends that a U.S. Holder will receive. The rules governing foreign tax credits are complex and U.S. Holders should therefore consult their tax advisers regarding the effect of the receipt of dividends for foreign tax credit limitation purposes.

Sale or Other Taxable Disposition of Ordinary Shares and ADSs

Subject to the discussion above under "Passive Foreign Investment Company Rules," gain or loss realized on the sale or other taxable disposition of ordinary shares or ADSs will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the ordinary shares or ADSs for more than one year at the time of sale or other taxable disposition. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ordinary shares or ADSs

disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. Subject to the PFIC rules described above, long-term capital gains recognized by certain non-corporate U.S. Holders (including individuals) will be, under current law, subject to reduced rates of U.S. federal income tax. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the ordinary shares or ADSs are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding on a duly executed IRS Form W-9 or otherwise establishes an exemption.

The amount of any backup withholding from a payment to a U.S. Holder may be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle the U.S. Holder to a refund, provided that the required information is timely furnished to the IRS.

Information with Respect to Foreign Financial Assets

Certain U.S. Holders who are individuals (and, under regulations, certain entities) may be required to report information relating to the ordinary shares or ADSs, subject to certain exceptions (including an exception for ordinary shares or ADSs held in accounts maintained by certain U.S. financial institutions), by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. Such U.S. Holders who fail to timely furnish the required information may be subject to a penalty. Additionally, if a U.S. Holder does not file the required information, the statute of limitations with respect to tax returns of the U.S. Holder to which the information relates may not close until three years after such information is filed. U.S. Holders should consult their tax advisers regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares or ADSs.

UK Taxation

The following is intended as a general guide to current UK tax law and HM Revenue & Customs, or HMRC, published guidance (which is not binding) applying as at the date of this Annual Report (both of which are subject to change at any time, possibly with retrospective effect) relating to the holding of ordinary shares or ADSs. It does not constitute legal or tax advice and does not purport to be a complete analysis of all UK tax considerations relating to the holding of ordinary shares or ADSs, or all of the circumstances in which holders of ordinary shares or ADSs may benefit from an exemption or relief from UK taxation. It is written on the basis that we do not (and will not) directly or indirectly derive 75% or more of its qualifying asset value from UK land, and that we are and will remain solely resident in the UK for tax purposes and will therefore be subject to the UK tax regime and not the U.S. tax regime save as set out above under "U.S. Federal Income Tax Considerations for U.S. Holders."

Except to the extent that the position of non-UK resident persons is expressly referred to, this guide relates only to persons who are resident for tax purposes solely in the UK and do not have a permanent establishment, branch or agency (or equivalent) in any other jurisdiction with which the holding of our ordinary shares or ADSs is connected, or UK Holders, who are absolute beneficial owners of our ordinary shares or ADSs (and do not hold our ordinary shares or ADSs through an Individual Savings Account or a Self-Invested Personal Pension or any other wrapper or similar product).

This guide may not relate to certain classes of UK Holders, such as (but not limited to):

- persons who are connected with us;
- financial institutions;
- insurance companies;
- charities or tax-exempt organizations;
- collective investment schemes;
- pension schemes;
- market makers, intermediaries, brokers or dealers in securities or persons who hold ordinary shares or ADSs otherwise than as an investment; and
- persons who have (or are deemed to have) acquired their ordinary shares or ADSs by virtue of an office or employment or who are or have been our officers or employees or any of our affiliates.

The decision of the First-tier Tribunal (Tax Chamber) in HSBC Holdings PLC and The Bank of New York Mellon Corporation v HMRC (2012) cast some doubt on whether a holder of a depositary receipt is the beneficial owner of the underlying shares. However, based on published HMRC guidance we would expect that HMRC will regard a holder of ADSs as holding the beneficial interest in the underlying shares and therefore these paragraphs assume that a holder of ADSs is the beneficial owner of the underlying ordinary shares and any dividends paid in respect of the underlying ordinary shares (where the dividends are regarded for UK purposes as that person's own income) for UK direct tax purposes.

THESE PARAGRAPHS ARE A SUMMARY OF CERTAIN UK TAX CONSIDERATIONS AND ARE INTENDED AS A GENERAL GUIDE ONLY. IT IS RECOMMENDED THAT ALL HOLDERS OF ORDINARY SHARES OR ADSs OBTAIN ADVICE AS TO THE CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSAL OF OUR ORDINARY SHARES OR ADSs (AS APPLICABLE) IN THEIR OWN PARTICULAR CIRCUMSTANCES FROM THEIR OWN TAX ADVISORS. IN PARTICULAR, NON-UK RESIDENT OR PERSONS SUBJECT TO TAXATION IN ANY JURISDICTION OTHER THAN THE UK ARE ADVISED TO CONSIDER THE POTENTIAL IMPACT OF ANY RELEVANT DOUBLE TAXATION AGREEMENTS.

Dividends

Withholding Tax

Dividends that we pay will not be subject to any withholding or deduction for or on account of UK tax.

Income Tax

An individual UK Holder may, depending on his or her particular circumstances, be subject to UK tax on dividends received from us. An individual holder of ordinary shares or ADSs who is not resident for tax purposes in the UK should not be chargeable to UK income tax on dividends received from us unless he or she carries on (whether solely or in partnership) a trade, profession or vocation in the UK through a permanent establishment, branch or agency to which our ordinary shares or ADSs (as applicable) are attributable. There are certain exceptions for trading in the UK through independent agents, such as some brokers and investment managers.

Dividend income is treated as the top slice of the total income chargeable to UK income tax for an individual UK Holder. An individual UK Holder who receives a dividend in the 2025/2026 tax year will be entitled to a tax-free allowance of £500. Income within the dividend allowance counts towards an individual's basic, higher or additional rate limits and may, therefore, affect the level of personal allowance to which they are entitled. Dividend income received during the 2025/2026 tax year in excess of the relevant tax-free allowance will (subject to the availability of any income tax personal allowance) be taxed at 8.75% for the tax year 2025/2026 (rising to 10.75% for the tax year 2026/2027) to the extent the excess amount falls within the basic rate band, 33.75% for the tax year 2025/2026 (rising to 35.75% for the tax year 2026/2027) to the extent the excess amount falls within the higher rate band, and 39.35% (for the tax years 2025/2026 and 2026/2027) to the extent the excess amount falls within the additional rate band.

Corporation Tax

A corporate holder of ordinary shares or ADSs who is not resident for tax purposes in the UK should not be chargeable to UK corporation tax on dividends received from us unless it carries on (whether solely or in partnership) a trade in the UK through a permanent establishment to which our ordinary shares or ADSs (as applicable) are attributable.

Corporate UK Holders should not be subject to UK corporation tax on any dividend received from us so long as the dividends qualify for exemption, which should be the case, although certain conditions must be met. It should be noted that the exemptions, while of wide application, are not comprehensive and are subject to anti-avoidance rules in relation to a dividend. If the conditions for the exemption are not satisfied, or such anti-avoidance provisions apply or such UK Holder elects for an otherwise exempt dividend to be taxable, UK corporation tax will be chargeable on the amount of any dividends (at the current rate of 25% for companies with profits of more than £250,000 or 19% for companies with profits not exceeding £50,000 with a marginal relief applying to profits between £50,000 and £250,000, in each case for the 2025/2026 tax year).

Chargeable Gains

A disposal or deemed disposal of ordinary shares or ADSs by a UK Holder may, depending on the UK Holder's circumstances and subject to any available exemptions or reliefs (such as the annual exemption), give rise to a chargeable gain or an allowable loss for the purposes of UK capital gains tax (for individual UK Holders) and corporation tax on chargeable gains (for corporate UK Holders).

If an individual UK Holder who is subject to UK income tax at either the higher or the additional rate is liable to UK capital gains tax on the disposal of ordinary shares or ADSs, the capital gains tax rate is 24% (for the 2025/2026 tax year). For an individual UK Holder who is subject to UK income tax at the basic rate and liable to UK capital gains tax on such disposal, the current applicable rate would be 18% (for the 2025/2026 tax year), save to the extent that any capital gains when aggregated with the UK Holder's other taxable income and gains in the relevant tax year exceed the unused basic rate tax band. In that case, the capital gains tax rate currently applicable to the excess would be 24% (for the 2025/2026 tax year).

If a corporate UK Holder becomes liable to UK corporation tax on the disposal (or deemed disposal) of ordinary shares or ADSs, the main rate of UK corporation tax would apply (currently at 25% for companies with profits of more than £250,000 or 19% for companies with profits not exceeding £50,000 with a marginal relief applying to profits between £50,000 and £250,000, in each case for the 2025/2026 tax year).

A holder of ordinary shares or ADSs that is not resident for tax purposes in the UK should not normally be liable to UK capital gains tax or corporation tax on chargeable gains on a disposal (or deemed disposal) of ordinary shares or ADSs, unless the person is carrying on (whether solely or in partnership) a trade, profession or vocation in the UK through a branch or agency (or, in the case of a corporate holder of ordinary shares or ADSs, through a permanent establishment) to which our ordinary shares or ADSs (as applicable) are attributable. However, an individual holder of ordinary shares or ADSs who has ceased to be resident for tax purposes in the UK or is treated as resident outside the UK for the purposes of a double taxation treaty for a period of five years or less and who disposes of ordinary shares or ADSs during that period of temporary non-residence may be liable on his or her return to the UK (or upon ceasing to be regarded as resident outside the UK for the purposes of any relevant double taxation treaty) to UK tax on any capital gain realized (subject to any available exemption or relief), despite the fact that the individual may not be resident in the UK at the time of the disposal.

Stamp Duty and Stamp Duty Reserve Tax

The discussion below relates to the holders of our ordinary shares or ADSs wherever resident, however it should be noted that special rules may apply to certain persons such as market makers, brokers, dealers or intermediaries.

Issue of Ordinary Shares

As a general rule (and except in relation to depositary receipt systems and clearance services (as to which see below)), no UK stamp duty or stamp duty reserve tax, or SDRT, is generally payable on the issue of the ordinary shares (including ordinary shares underlying our ADSs).

Transfer of Ordinary Shares

An unconditional agreement to transfer ordinary shares will normally give rise to a charge to SDRT at the rate of 0.5% of the amount or value of the consideration payable for the transfer. The purchaser of the ordinary shares is liable for the SDRT. Transfers of ordinary shares by way of a written instrument of transfer are generally also subject to stamp duty at the rate of 0.5% of the amount or value of the consideration given for the transfer (rounded up to the nearest £5.00). Stamp duty is

normally paid by the purchaser. The charge to SDRT will be cancelled or, if already paid, repaid (generally with interest), where a transfer instrument has been duly stamped within six years of the charge arising, (either by paying the stamp duty or by claiming an appropriate relief) or if the instrument is otherwise exempt from stamp duty.

Clearance Services and Depositary Receipts

Under current UK tax law (as set out in section 20 and Schedule 11 of the Finance Act of 2024), with effect from 1 January 2024, a higher rate of 1.5% UK stamp duty or UK SDRT (which we refer to as the 1.5% Charge) should not arise in respect of an issue of ordinary shares, or an unconditional agreement to issue ordinary shares, to a clearance service or a depositary receipt system. Further, subject to the below, no 1.5% Charge should arise in respect of a transfer of ordinary shares, or an unconditional agreement to transfer ordinary shares, to a clearance service or depositary receipt system, where the transfer is carried out in the course of "capital-raising arrangements", being arrangements pursuant to which the relevant ordinary shares are issued by the company for the purpose of raising new capital. Where any ordinary shares are subject to restriction that has the effect of preventing the transfer of such ordinary shares into a clearance service or depositary receipt system in the course of capital-raising arrangements, such ordinary shares must be transferred as soon as reasonably practicable after the time at which the restriction ceases to have effect in order to prevent the 1.5% Charge from applying.

Where a clearance service has made and maintained an election under section 97A of the UK Finance Act 1986, or a section 97A election, no 1.5% Charge will apply on any transfer of ordinary shares, or an unconditional agreement to transfer ordinary shares, to that clearance service. It is understood that HMRC regards the facilities of DTC as a clearance service for these purposes, and we are not aware of any section 97A election having been made by the DTC.

If arising, any UK stamp duty or UK SDRT payable on a transfer of ordinary shares to a depositary receipt system or clearance service will in practice generally be paid by the transferors or participants in the clearance service or depositary receipt system.

Issue of ADSs

No UK stamp duty or UK SDRT should be payable on the issue of ADSs in the Company.

If arising, any stamp duty or SDRT payable on a transfer of ordinary shares to a depositary receipt system or clearance service will in practice generally be paid by the transferors or participants in the clearance service or depositary receipt system.

Transfer of ADSs within a clearance system

No UK SDRT should be required to be paid in respect of a paperless transfer of ADSs through the facilities of DTC, provided that no section 97A election has been made and maintained by DTC, and such ADSs are held through DTC at the time of any agreement for their transfer. We are not aware of any section 97A election having been made by the DTC.

Issue or Transfers of ADRs

On the basis of current published HMRC guidance, an ADR is not regarded as stock or a marketable security for the purposes of UK stamp duty or a chargeable security for the purposes of UK SDRT and, as such, no UK stamp duty or SDRT should be required to be paid on the issue or transfer of (including an agreement to transfer) ADRs in the Company.

Chargeable Gains Tax – Warrants

For UK corporate holders of warrants, the precise UK corporation tax treatment of warrants is dependent on whether or not the warrants are considered to constitute derivative contracts for UK tax purposes.

Warrants treated as derivative contracts for UK tax purposes

Where a warrant constitutes a derivative contracts for UK tax purposes, the amounts that are required to be brought into account for UK corporation tax purposes by a UK corporate holder of warrants are, broadly, those amounts which are recognized under relevant generally accepted accounting principles in determining the relevant UK corporation's profits and losses (including those of a capital nature) arising from the warrants, as well as certain related expenses.

UK corporate holders of warrants who consider that any of the warrants may constitute derivative contracts for UK tax purposes should consult with their tax advisors as to the tax implications of such treatment.

UK non-corporate holders, and warrants not treated as derivative contracts for UK tax purposes

Where (for UK corporate holders of warrants) a warrant does not constitute a derivative contract for UK tax purposes, or for UK non-corporate holders of warrants, then (depending on the circumstances) neither the grant nor the exercise of a warrant should generally give rise to a UK chargeable gains / capital gains tax charge, and the relevant UK holder's base cost in the warrant, or (following exercise) the asset which was the subject of the warrant should broadly comprise, in the case of the warrant, any amounts paid by the relevant UK holder for the acquisition of the warrant, and in the case of the asset which was the subject of the warrant, any such amounts, together with any amounts paid for the exercise of the relevant warrant.

A disposal or deemed disposal of a warrant or (following the exercise of a warrant) the asset underlying the warrant by a UK Holder (may, depending on the UK Holder's circumstances and subject to any available exemptions or reliefs (such as the annual exemption), give rise to a chargeable gain or an allowable loss for the purposes of UK corporation tax on chargeable gains and capital gains tax.

If an individual UK Holder who is subject to UK income tax at either the higher or the additional rate is liable to UK capital gains tax on the disposal of our warrants or (following exercise of a warrant) the underlying assets, the current applicable rate will be 24% (for the 2025/2026 tax year). For an individual UK Holder who is subject to UK income tax at the basic rate and liable to UK capital gains tax on such disposal, the current applicable rate would be 18% (for the 2025/2026 tax year), save to the extent that any capital gains when aggregated with the UK Holder's other taxable income and gains in the relevant tax year exceed the unused basic rate tax band. In that case, the rate currently applicable to the excess would be 24% (for the 2025/2026 tax year).

If a corporate UK Holder becomes liable to UK corporation tax on the disposal (or deemed disposal) of a warrant or (following the exercise of a warrant) the asset underlying the warrant, the main rate of UK corporation tax would apply (at 25% for companies with profits of more than £250,000 or 19% for companies with profits not exceeding £50,000, with a marginal relief applied to profits between £50,000 and £250,000, in each case for the 2025/2026 tax year).

A holder of warrants (or the underlying asset thereof) that is not resident for tax purposes in the UK should not normally be liable to UK capital gains tax or corporation tax on chargeable gains on a disposal (or deemed disposal) of a warrant or (following exercise) the asset underlying the warrant, unless the person is carrying on (whether solely or in partnership) a trade, profession or vocation in the UK through a branch or agency (or, in the case of a corporate holder of warrants or (following exercise) the underlying assets, through a permanent establishment) to which our warrants (or, following an exercise, the underlying assets) are attributable. However, an individual holder of warrants who has ceased to be resident for tax purposes in the UK or is treated as resident outside the UK for the purposes of a double taxation treaty for a period of five years or less and who disposes of warrants (or, following exercise, the underlying asset) during that period of temporary non-residence may be liable on his or her return to the UK (or upon ceasing to be regarded as resident outside the UK for the purposes of double taxation treaty) to UK tax on any capital gain realized (subject to any available exemption or relief) despite the fact that the individual may not be resident in the UK at the time of the disposal.

Stamp Duty and Stamp Duty Reserve Tax - Warrants

The UK stamp duty and UK stamp duty reserve tax implications of both the issue, the exercise and the transfer of warrants is complex. Specific professional advice should be sought before incurring or reimbursing the costs of a UK stamp duty or UK SDRT charge in any circumstances relating to a warranty (including the issuance, exercise or transfer of any warrant).

(b) **Rule 10b5-1 Plans**

During the three months ended December 31, 2025, none of our directors or executive officers adopted, terminated or modified the amount, pricing or timing provisions in any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement."

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior officers. The full text of our code of business conduct and ethics is posted on the Investor Relations section of our website at ir.compasspathways.com under "Corporate governance documents." Our website is not incorporated by reference in this filing. We will disclose any amendments to our code of business conduct and ethics, or waivers of its requirements granted to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, on our website or in filings under the Exchange Act as required by applicable law or the listing standards of the Nasdaq Stock Market.

The remaining information called for by this item, including information about our Directors, Executive Officers and Audit Committee and our insider trading policy (a copy of our insider trading policy is filed as Exhibit 19.1 to this report), will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information called for by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information called for by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information called for by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Listing of Documents

1. Financial Statements

The following financial statements are submitted in a separate section beginning on page F-1 of this Annual Report, as follows:

2. Financial Statement Schedules

All other schedules have been omitted because they are not required, not applicable, or the required information is otherwise included.

3. Exhibits

The documents listed in the Exhibit Index of this Annual Report are incorporated by reference or are filed with this Annual Report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

INDEX

Exhibit Number	Description	Incorporation by reference			
		Schedule/Form	File Number	Exhibit	File Date
3.2	Articles of Association of COMPASS Pathways plc.	Form F-1/A	333-248484	3.2	9/14/2020
4.1	Deposit Agreement	Form F-6/A	333-248514	99.(A)	9/17/2020
4.2	Form of American Depositary Receipt (included in exhibit 4.1).				
4.3	Description of Securities	Form 10-K	001-39522	4.3	02/28/2023
4.4	Form of Lender Warrant	Form 8-K	001-39522	4.1	07/05/2023
4.5	Form of PIPE Investor Warrant	Form 8-K	001-39522	4.1	08/16/2023
4.6	Form of Pre-Funded Warrant	Form 8-K	001-39522	4.1	01/10/2025
4.7	Form of ADS Warrant	Form 8-K	001-39522	4.2	01/10/2025
10.1	Investment and shareholders' agreement by and between COMPASS Rx Limited and the shareholders named therein, dated April 17, 2020 and amended and restated on August 7, 2020.	Form F-1	333-248484	10.1	8/28/2020
10.2#	2020 Employee Share Option and Incentive Plan with Non-Employee Sub-Plan and U.S. Sub-Plan, as amended.	Form F-1/A	333-248484	10.2	9/14/2020
10.3#	2020 Employee Share Purchase Plan	Form F-1/A	333-248484	10.3	9/14/2020

10.4	Form of Deed of Indemnity between COMPASS Pathways plc and each of its Directors and Officers.	Form F-1/A	333-248484	10.6	9/14/2020
10.5#	Form of Non-Qualified Share Option Agreement for Company Employees under the 2020 Share Option and Incentive Plan.	Form 8-K	001-39522	10.2	02/04/2022
10.6#	Restricted share unit award agreement for company employees under the COMPASS Pathways plc 2020 Share Option and Incentive Plan	Form 10-K	001-39522	10.12	02/28/2023
10.7#	Employment Agreement with Matthew Owens	10-K	001-39522	10.20	02/24/2022
10.8	Service Agreement by and between Movassate Family Trust and COMPASS Pathways Inc dated August 3, 2021	10-K	001-39522	10.22	02/24/2022
10.9	Master Research Collaboration Agreement by and among COMPASS Pathfinder Limited, King's College London and South London and Maudsley NHS Foundation Trust, dated March 22, 2022	10-Q	001-39522	10.1	05/10/2022
10.10#	Form of Inducement Award Non-Qualified Share Option Agreement.	10-Q	001-39522	10.3	8/04/2022
10.11	License Agreement between Fora Space Limited and COMPASS Pathfinder Limited dated April 4, 2023.	10-Q	001-39522	10.1	05/11/2023
10.12	Securities Purchase Agreement, dated August 16, 2023, by and among the Company and the Purchasers.	8-K	001-39522	10.1	08/16/2023
10.13	Lease Agreement between Azul NYC LLC and COMPASS Pathways, Inc. dated September 28, 2023.	10-Q	001-39522	10.2	11/2/2023
10.14#	Employment Agreement dated May 7, 2020 by and between Compass Pathways and Mary-Rose Hughes, as amended	10-K	001-39522	10.24	02/29/2024
10.15#	Employment Agreement dated December 6, 2023, by and between Compass Pathways and Teri Loxam.	8-K	001-39522	10.1	12/07/2023
10.16#	Amendment to Employment Agreement dated August 1, 2023 by and between Kabir Nath and Compass Pathways, Inc. dated August 1, 2023	10-K	001-39522	10.26	02/29/2024
10.17#	Employment Agreement with Matthew Owens, as amended effective March 6, 2024	10-Q	001-39522	10.1	05/08/2024
10.18#	Amended and Restated Employment Agreement dated May 7, 2025 between Compass Pathfinder Limited and Kabir Nath	10-Q	001-39522	10.1	05/08/2025
10.19#	Settlement Agreement with Matthew Owens dated December 19, 2024	10-K	001-39522	10.22	02/27/2025
10.20#	Amendment dated May 7, 2025 to Employment Agreement dated December 6, 2023 between Compass Pathways, Inc. and Teri Loxam	10-Q	001-39522	10.2	05/08/2025
10.21#	Amended and Restated Employment Agreement dated May 7, 2025 between Compass Pathfinder Limited and Guy Goodwin	10-Q	001-39522	10.3	05/08/2025
10.22†	Amendment No. 1 dated April 30, 2025 to Master Research Collaboration Agreement by and among COMPASS Pathfinder Limited, King's College London and South London and Maudsley NHS Foundation Trust, dated March 22, 2022	10-Q	001-39522	10.4	05/08/2025
10.23	License Agreement and Addendum between Fora Space Limited and COMPASS Pathfinder Limited dated June 6, 2025.	10-Q	001-39522	10.1	07/31/2025
10.23	Second Amendment to Loan and Security Agreement, dated as of June 30, 2023, by and among COMPASS Pathways plc, and its subsidiaries, the lenders party thereto and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent.	10-Q	001-39522	10.2	7/31/2025

10.24†	Third Amendment to Loan and Security Agreement, dated as of June 30, 2023, by and among COMPASS Pathways plc and its subsidiaries, the lenders party thereto and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent.	8-K	001-39522	10.1	01/07/2026
16.1	Letter from PwC UK to the Securities and Exchange Commission, dated April 16, 2025.	8-K	001-39522	16.1	04/16/2025
19.1	Compass Pathways plc Insider Trading Policy	10-K	001-39522	19.1	02/27/2025
21.1	Subsidiaries of COMPASS Pathways plc.	Form F-1	333-248484	21.1	8/28/2020
23.1*	Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm				
23.2*	Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm				
31.1*	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a), by Principal Executive Officer				
31.2*	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a), by Principal Finance Officer				
32.1**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Principal Executive Officer and Principle Financial Officer				
97.1	Compass Pathways plc Compensation Recovery Policy	10-K	001-39522	97.1	2/29/2024
101.INS*	XBRL Instance Document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101).				

# Indicates a management contract or any compensatory plan, contract or arrangement.

† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit pursuant to Item 601(b)(10)(iv). The Company undertakes to furnish supplementally an unredacted copy of the exhibit to the Securities and Exchange Commission upon its request.

* Filed herewith

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

INDEX TO THE FINANCIAL STATEMENTS

Consolidated Financial Statements of Compass Pathways Plc

INDEX TO ANNUAL CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Compass Pathways plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Compass Pathways plc and its subsidiaries (the "Company") as of December 31, 2025, and the related consolidated statements of operations and comprehensive loss, of shareholders' (deficit) equity and of cash flows for the year then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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 audit of these consolidated financial statements 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

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

Benefit from Research and Development Tax Credit

As described in Note 2 to the consolidated financial statements, the Company carries out extensive research and development ("R&D") activities and benefits from the UK R&D tax credit regime. Under the UK R&D tax credit regime, the Company is able to claim a cash rebate based on a portion of such qualifying R&D expenditure. The Company assesses its research and development activities and expenditures to determine whether the nature of the activities and expenditures will qualify for credit under the UK R&D tax credit regime and whether the claims will ultimately be realized based on the allowable reimbursable expense criteria established by the U.K. government, which are subject to interpretation. For the portion of the expense that the Company expects to qualify under the programs and plans to submit a claim for, the Company records a benefit within other (expense) income, net which is included in the loss before income tax. For the year ended December 31, 2025, the Company's benefit from UK R&D tax credit was $3.7 million.

The principal consideration for our determination that performing procedures relating to the benefit from research and development tax credit is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's benefit from the UK R&D tax credit.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others (i) evaluating management's determination that the nature of the activities performed by the Company qualify for the UK R&D tax credit regime; (ii) for a sample of R&D expenditures, testing accuracy and existence by obtaining and inspecting source documents, such as the underlying contracts or agreements, purchase orders, invoices, payroll records, and information received from certain third party service providers, where applicable, and testing the eligibility and classification of expense type based on the relevant tax laws; (iii) testing management's calculation of qualifying expenses based on the rates in the relevant tax laws; and (iv) testing management's calculation of the UK R&D tax credit in accordance with relevant tax laws.

/s/PricewaterhouseCoopers LLP
Boston, Massachusetts
March 24, 2026

We have served as the Company's auditor since 2025.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Compass Pathways plc

Opinion on the Financial Statements

We have audited the consolidated balance sheet of Compass Pathways plc and its subsidiaries (the "Company") as of December 31, 2024, and the related consolidated statements of operations and comprehensive loss, of shareholders' (deficit) equity, and of cash flows for the year then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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 audit of these consolidated financial statements 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 consolidated financial statements are free of material misstatement, whether due to error or fraud.

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

/s/PricewaterhouseCoopers LLP
Reading, United Kingdom
February 27, 2025

We served as the Company's auditor from 2018 to 2025.

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

	December 31,	
	2025	2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 149,608	$ 165,081
Restricted cash	379	389
Prepaid expenses and other current assets	41,503	35,821
Total current assets	191,490	201,291
NON-CURRENT ASSETS:		
Operating lease right-of-use assets	3,424	2,006
Deferred tax assets	3,751	3,774
Long-term prepaid expenses and other assets	11,684	6,595
Total assets	$ 210,349	$ 213,666
LIABILITIES AND SHAREHOLDERS' (DEFICIT)/EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 15,222	$ 12,283
Accrued expenses and other liabilities	9,214	14,495
Debt, current portion	17,523	5,513
Operating lease liabilities - current	2,110	1,725
Warrant liabilities	203,726	—
Total current liabilities	247,795	34,016
NON-CURRENT LIABILITIES:		
Debt, non-current portion	14,110	24,652
Operating lease liabilities - non-current	1,292	303
Total liabilities	263,197	58,971
Commitments and contingencies (Note 14)		
SHAREHOLDERS' (DEFICIT)/EQUITY:		
Ordinary shares, £0.008 par value; 96,085,785 and 68,552,215 shares authorized, issued and outstanding at December 31, 2025 and 2024, respectively	973	702
Additional paid-in capital	783,562	704,919
Accumulated other comprehensive loss	(14,789)	(16,194)
Accumulated deficit	(822,594)	(534,732)
Total shareholders' (deficit)/equity	(52,848)	154,695
Total liabilities and shareholders' (deficit)/equity	$ 210,349	$ 213,666

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

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

	Year Ended December 31,	
	2025	**2024**
OPERATING EXPENSES:		
Research and development	$ 118,436	$ 119,039
General and administrative	60,601	59,166
Total operating expenses	179,037	178,205
LOSS FROM OPERATIONS:	(179,037)	(178,205)
OTHER (EXPENSE) INCOME, NET:		
Fair value change of warrant liabilities	(122,561)	—
Benefit from R&D tax credit	3,747	21,097
Interest income	7,182	8,268
Interest expense	(4,517)	(4,479)
Foreign exchange gains (losses)	3,471	(1,032)
Other income	1,380	823
Total other (expense) income, net	(111,298)	24,677
Loss before income taxes	(290,335)	(153,528)
Income tax benefit (expense)	2,473	(1,594)
Net loss	$ (287,862)	$ (155,122)
Net loss per share attributable to ordinary shareholders—basic and diluted	$ (3.08)	$ (2.30)
Weighted average ordinary shares outstanding—basic and diluted	93,504,836	67,482,902
Net loss	$ (287,862)	$ (155,122)
Other comprehensive loss:		
Foreign exchange translation adjustment	1,405	732
Comprehensive loss	$ (286,457)	$ (154,390)

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

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

	ORDINARY SHARES £0.008 PAR VALUE		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE (LOSS)/INCOME	ACCUMULATED DEFICIT	TOTAL SHAREHOLDERS' (DEFICIT)/EQUITY
	SHARES	AMOUNT	AMOUNT	AMOUNT	AMOUNT	AMOUNT
Balance at December 31, 2023	**61,943,471**	**$ 635**	**621,645**	**$ (16,926)**	**$ (379,610)**	**$ 225,744**
Issuance of ordinary shares under ATM facility, net of issuance costs	2,509,798	25	26,194	—	—	26,219
Issuance of warrants to purchase ordinary shares	3,752,050	38	37,220	—	—	37,258
Exercise of share options	189,214	2	219	—	—	221
Issuance of ordinary shares to settle vested restricted stock units	83,527	1	(1)	—	—	—
Issuance of ordinary shares under employee share purchase plan	74,155	1	364	—	—	365
Shares tendered for withholding taxes	—	—	(239)	—	—	(239)
Share-based compensation expense	—	—	19,517	—	—	19,517
Unrealized gain on foreign currency translation	—	—	—	732	—	732
Net loss	—	—	—	—	(155,122)	(155,122)
Balance at December 31, 2024	**68,552,215**	**$ 702**	**704,919**	**$ (16,194)**	**$ (534,732)**	**$ 154,695**
Issuance of ordinary shares, net of issuance costs	24,014,728	233	54,584			54,817
Exercise of share options	925,179	10	25 —	— —	— —	35
Issuance of ordinary shares to settle vested restricted stock units	156,245	2	(1)	—	—	1
Issuance of ordinary shares under employee share purchase plan	92,752	1	318			319
Issuance of ordinary shares to settle warrant exercised	2,344,666	25	10,127	—	—	10,152
Share-based compensation expense	—	—	13,590	—	—	13,590
Unrealized gain on foreign currency translation	—	—	—	1,405	—	1,405
Net loss	—	—	—	—	(287,862)	(287,862)
Balance at December 31, 2025	**96,085,785**	**$ 973**	**783,562**	**$ (14,789)**	**$ (822,594)**	**$ (52,848)**

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

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

	Year Ended December 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (287,862)	$ (155,122)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	216	233
Non-cash interest	1,468	1,408
Non-cash gain (loss) on foreign currency remeasurement	(1,152)	755
Non-cash share-based compensation	13,590	19,517
Non-cash lease expenses	2,410	2,300
Transaction costs allocated to warrants	5,778	—
Fair value change of warrant liabilities	122,561	—
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(3,238)	3,220
Deferred and prepaid tax assets	23	686
Other assets	(4,711)	135
Operating lease liabilities	(2,452)	(2,265)
Accounts payable	2,034	6,590
Accrued expenses and other liabilities	(5,905)	3,357
Net cash used in operating activities	(157,240)	(119,186)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares and Pre-funded Warrants, net of issuance costs	140,357	26,219
Proceeds from the exercise of warrants	—	37,258
Proceeds from the vesting of restricted share units	1	—
Payments of withholding tax on stock award	—	(239)
Proceeds from the issuance of shares under the employee share purchase plan	319	365
Proceeds from exercise of options	35	221
Net cash provided by financing activities	140,712	63,824
Effect of exchange rate changes on cash, cash equivalents and restricted cash	1,045	194
Net (decrease)/increase in cash, cash equivalents and restricted cash	(15,483)	(55,168)
Cash, cash equivalents and restricted cash, beginning of the period	165,470	220,638
Cash, cash equivalents and restricted cash, end of the period	$ 149,987	$ 165,470
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 3,050	$ 3,070
Cash paid for taxes	$ 755	$ 1,121

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

	Year Ended December 31,	
	2025	**2024**
Cash and cash equivalents	$ 149,608	$ 165,081
Short-term restricted cash	379	389
Total cash, cash equivalents and restricted cash	$ 149,987	$ 165,470

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

COMPASS PATHWAYS PLC
Notes to Consolidated Financial Statements

1. Nature of Business

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

The Company has funded its operations with proceeds from the sale of its ordinary shares, American Depository Shares, or ADSs, including in its offerings pursuant to its at-the-market, or ATM, offering program, proceeds from a loan agreement with Hercules Capital, Inc., and proceeds from a private placement transaction, or the PIPE. The Company was party to a Sales Agreement for its ATM offering program, dated October 8, 2021, with TD Securities (USA) LLC, or TD Cowen, under which the Company was able to issue and sell from time to time up to $150.0 million of its ADSs, each representing one ordinary share, through TD Cowen as the sales agent. Pursuant to the Sales Agreement dated October 8, 2021, through February 27, 2025, the Company sold 5,491,836 ADSs under the Company's ATM offering program, resulting in $54.8 million in net proceeds. On February 27, 2025, the Company entered into a new Sales Agreement to govern the Company's ATM offering program with TD Cowen, or the Sales Agreement, under which the Company may issue and sell from time to time up to $150.0 million of our ADSs, subject to the terms of the Sales Agreement. Sales of its ADSs, if any, will generally be made at market prices. To date, the Company has not sold any ADSs under this Sales Agreement.

On June 30, 2023, the Company entered into a Loan Agreement with Hercules, which provided for aggregate maximum borrowings of up to $50.0 million, including a term loan of $30.0 million, which was funded on June 30, 2023. On August 16, 2023, the Company entered into a Securities Purchase Agreement, pursuant to which the Company agreed to sell and issue in a private placement transaction (i) 16,076,750 ADSs and (ii) PIPE Warrants to purchase up to 16,076,750 ADSs, at a purchase price of approximately $7.78 per ADS and accompanying PIPE Warrant to purchase one ADS. Each PIPE Warrant has an exercise price of $9.93 per ADS and is exercisable for a three year period beginning in February 2024. The PIPE Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the PIPE Warrants. During December 31, 2024, PIPE Warrants were exercised for 3,752,050 ADS, resulting in $37.3 million in exercise proceeds. During the year ended December 31, 2025 no PIPE warrants were exercised. The Company will receive up to an additional approximately $122.4 million in gross proceeds if the PIPE Warrants are fully exercised for cash.

In January 2025, the Company issued and sold (i) 24,014,728 American Depositary Shares, each representing one ordinary share, nominal value £0.008 each, of the Company and accompanying warrants to purchase up to 24,014,728 ADSs, and (ii) in lieu of ADSs, to certain investors, pre-funded warrants, or Pre-funded Warrants, to purchase up to 11,044,720 ADSs and accompanying ADS warrants, or 2025 ADS Warrants, to purchase up to 11,044,720 ADSs. The offering price was $4.2750 per ADS and accompanying 2025 ADS Warrant, and $4.2649 per Pre-funded Warrant and accompanying 2025 ADS Warrant. The Pre-funded Warrants have an exercise price of $0.0001 per ADS and are exercisable immediately. The Pre-funded Warrants expire when exercised in full. The 2025 ADS Warrants have an exercise price of $5.7960 per ADS and are exercisable following a specified data milestone. The 2025 ADS Warrants will expire three years after such warrants become exercisable. Once the ADS Warrants become exercisable, the Company may force the exercise of the 2025 ADS Warrants (by way of cash or cashless exercise, at the Company's option), in whole or in part, by delivering a notice of forced exercise to the holders, provided that the closing price for the Company's ADSs on Nasdaq exceeded the warrant exercise price of $5.7960 for the three consecutive trading days prior to the date on which the notice of forced exercise is delivered. During the year ended December 31, 2025, 2,344,720 Pre-funded Warrants were exercised.

The Company has incurred recurring losses since its inception, including net losses of $287.9 million and $155.1 million for the years ended December 31, 2025 and 2024, respectively. In addition, as of December 31, 2025, the Company had an

accumulated deficit of $822.6 million. The Company expects to continue to generate operating losses for the foreseeable future. The Company believes the cash and cash equivalents on hand as of December 31, 2025 of $149.6 million, together with the $140.5 million net proceeds from the February 2026 Offering and the $203.2 million net proceeds from the exercise of all of our outstanding 2025 ADS Warrants, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next twelve months from the date of issuance of these consolidated financial statements. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all. The Company may raise additional capital through a combination of equity offerings, debt financings, collaborations, and other strategic transactions, including marketing, distribution or licensing arrangements. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial conditions.

Market volatility, geopolitical tensions or instability (including from the effects of announced or future tariff increases), geopolitical conflict (such as the war between Ukraine and Russia and conflict in the Middle East), fluctuating inflation and interest rates and the related impact on U.S., UK and global economies, instability in the banking system, the risk of an economic slowdown or recession in the U.S., significant changes in U.S. policies or regulatory environment or the disruption to U.S. government agencies or other factors could adversely impact the Company's operations, financial results and ability to raise additional funding.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Principles of Consolidation

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

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents.

Restricted Cash

Restricted cash represents a collateral deposit for employee credit cards.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the inputs for the first two are considered observable

and the inputs for the last are considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques

The carrying amounts reflected in the consolidated balance sheets for the Company's cash and cash equivalents, restricted cash, other current assets, accounts payable and accrued expenses approximate fair value because of the short-term nature of these instruments. The carrying value of the Company's outstanding debt approximates fair value, reflecting interest rates currently available to the Company.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk consist primarily of cash and cash equivalents. The Company places cash and cash equivalents in diversified and established financial institutions. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. The Company has cash and cash equivalents in excess of the FDIC insured limit. The Company has no significant off-balance-sheet risk or concentration of credit risk, such as foreign exchange contracts, options contracts, or other foreign hedging arrangements.

Impairment of Long-Lived Assets

The Company evaluates assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. The Company has not recognized any impairment losses or had triggering events related to its underlying assets for the years ended December 31, 2025 and 2024.

Segment Information

In November 2023, the FASB issued ASU 2023-07 - Segment Reporting (Topic 280) - Improvements to Reportable Segment Disclosures, which improved segment disclosure requirements, primarily through enhanced disclosure requirements for significant segment expenses. The improved disclosure requirements apply to all public entities that are required to report segment information, including those with only one reportable segment.

Operating segments are identified as components of an entity that meet all of the following criteria: i) engage in business activities from which it may incur expenses; ii) operating results are regularly reviewed by the chief operating decision maker, to allocate resources and assess performance; iii) discrete financial information is available. The Company's chief operating decision maker ("CODM"), is the Chief Executive Officer. The Company views its operations and manages its business as one operating segment. The CODM uses 'total operating expenses,' research and development and general and administrative 'expenses by category,' 'loss before income taxes' and 'total assets' to assess performance and decide how to allocate resources. The CODM also uses 'total operating expenses' 'expenses by category' and 'loss before income taxes' to monitor budget versus actual results to assess performance. Loss before income taxes is reported on the consolidated statements of operations and comprehensive loss. The measure of assets is reported on the consolidated balance sheets as total assets. As the Company operates in one operating segment, all required financial segment information can be found in these consolidated financial statements. All additional disclosures can be found in Note 15 below.

Research and Development Costs

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

Research Contract Costs, Prepayments and Accruals

The Company has entered into various research and development-related contracts with research institutions and other companies. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. The Company records prepayments and accruals for estimated ongoing research costs and receives updated estimates of costs and amounts owed on a monthly basis from its third-party service providers. When evaluating the adequacy of the prepayments and accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted cost estimates from third-party service providers. Estimates are made in determining the prepaid and accrued balances at the end of any reporting period. The Company considers any prepayment that is more than 12 months in advance of the associated expense to be long-term. Actual results could differ from the Company's estimates. The Company's historical prepayments and accrual estimates have not been materially different from the actual costs.

Share-Based Compensation

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

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

There have been no performance or market conditions attached to the share options granted by the Company to date. The fair value of each share option grant is estimated on the date of grant using the Black-Scholes option pricing model. See Note 10 for the Company's assumptions used in connection with option grants made during the periods covered by these consolidated financial statements. Assumptions used in the option pricing model include the following:

Expected volatility. The Company lacks sufficient company-specific historical and implied volatility information for its ordinary shares. Therefore, it estimates its expected share volatility using a blended rate of: (1) historical volatility of publicly traded peer companies and (2) the Company's historical volatility since being publicly traded since September 2020. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price.

Expected term. The expected term of the Company's share options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The Company utilizes this method due to the lack of historical exercise data and the plain nature of its share-based awards.

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

Expected dividend. Expected dividend yield of zero is based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future. In addition, the Loan Agreement with Hercules currently prohibits dividends that may be declared or paid on our ordinary shares.

Fair value of ordinary shares. The fair value of ordinary shares is determined by reference to the closing price of ADSs on the Nasdaq Global Select Market on the day prior to or day of the grant.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheets as right-of-use assets and current and non-current lease liabilities, as applicable. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and to allocate all the contract consideration to the lease component only. All the Company's leases are classified as operating leases.

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

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

Foreign Currency Translation

The functional currency is the currency of the primary economic environment in which an entity's operations are conducted. The functional currency of Compass Pathways plc and its wholly owned subsidiary Compass Pathfinder Holdings Limited is the U.S. Dollar ("USD"). The functional currency of Compass Pathfinder Holdings Limited's wholly owned non-U.S. subsidiary, Compass Pathfinder Limited, is British Pound Sterling and the functional currency of its U.S. subsidiary, Compass Pathways Inc. is USD. The functional currency of these subsidiaries is the same as the local currency.

The translated balances of monetary and non-monetary assets and liabilities recorded in the reporting entity's consolidated financial statements as of the end of the prior reporting period become the new accounting basis for those assets and liabilities in the period of the change. To the extent that the distinct and separable operation has monetary assets and liabilities denominated in the old functional currency, such balances will create transaction gains and losses subsequent to the change in functional currency. The balance recorded in the cumulative translation reserve, included within accumulated other comprehensive loss, in the consolidated balance sheets for prior periods is not reversed upon the change in functional currency.

The Company translates the assets and liabilities of Compass Pathfinder Limited into USD at the exchange rate in effect on the balance sheet date. Income and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of shareholders' equity as a component of accumulated other comprehensive loss.

Corporate Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in its tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences

are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that deferred tax assets will be recovered in the future to the extent management believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed as the amount of benefit to recognize in the consolidated financial statements. The amount of benefit that may be used is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate, as well as the related net interest and penalties. As of December 31, 2025 and 2024, the Company has not identified any material uncertain tax positions.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2025 and 2024 no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheets.

Benefit from Research and Development Tax Credit

The Company carries out extensive research and development ("R&D") activities and benefits from the UK R&D tax credit regime. Under the UK R&D tax credit regime, the Company is able to claim a cash rebate based on a portion of such qualifying R&D expenditure. The Company assesses its research and development activities and expenditures to determine whether the nature of the activities and expenditures will qualify for credit under the UK R&D tax credit regime and whether the claims will ultimately be realized based on the allowable reimbursable expense criteria established by the U.K. government, which are subject to interpretation. For the portion of the expense that the Company expects to qualify under the programs and plans to submit a claim for, the Company records a benefit within other (expense) income, net which is included in the loss before income tax.

As a Company, we currently meet the conditions of the SME regime. A large portion of costs relating to R&D, clinical trials and clinical manufacturing activities are eligible for inclusion within these tax credit cash rebate claims. We carry out extensive R&D activities and, therefore, have historically benefited from the UK R&D tax credit regime under the scheme for small or medium-sized enterprises, ("SME's"). For accounting periods starting on or after April 1, 2024, the UK R&D regimes have changed, such that the effective cash credit will be 16.2% for in-house expenditure and 10.5% for any work that is contracted out.

However, new rules were introduced by the Finance Act 2024 for an enhanced rate of relief for research intensive companies ("ERIS"), which are approximately 27.0% for qualifying expenditure and approximately 17.5% for qualifying subcontracted expenditure (paid to an unconnected subcontractor). Beginning January 1, 2025, to be eligible as a research intensive company, the qualifying R&D expenditure for tax purposes must be at least 30% of the aggregate expenditure across the consolidated group. During the year ended December 31, 2024 the threshold was 40%.

For the years ended December 31, 2023 to 2025, the Company is currently having discussions with HMRC regarding whether it has met the R&D intensity condition and therefore are eligible for the enhanced effective rate due to uncertainties over whether impairments on intercompany loans and investments in subsidiary companies should be taken into account in determining the R&D intensity threshold. The outcome of this matter under discussion with HMRC is currently unknown. As a result of these discussions the Company recorded a change in estimate for the 2023 claim, which was initially recorded during the first quarter of 2025, of $4.1 million to reduce its receivable for amounts claimed at the enhanced rate. The Company recorded a change in estimate for the 2024 claim, which was initially recorded during the year ended December 31, 2025, of $7.0 million to reduce its receivable for amounts previously claimed at the enhanced rate.

The Company believes that the impairments of intercompany loans and investments in subsidiary companies should be disregarded and that it meets the R&D intensity condition in the year ended December 31, 2023 and December 31, 2024. As the Company believes that it meets the R&D intensity condition for the year ended December 31, 2024, it should automatically fulfil the expenditure conditions to be eligible for the enhanced rate in the year ended December 31, 2025 as a

company remains research intensive unless it fails to meet the eligibility requirement for two consecutive years. However, given the uncertainty over the outcome of the discussions with HMRC the enhanced R&D credits have not been reflected in the financial statements. If the Company reached a successful conclusion with HMRC additional credits of $4.1 million in the year ended December 31, 2023, $7.0 million in the year ended December 31, 2024 and $7.3 million in the year to December 31, 2025 could be claimed.

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

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

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

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in shareholders' equity that result from transactions and economic events other than those with shareholders. For the years ended December 31, 2025 and 2024, the only component of accumulated other comprehensive loss is foreign currency translation adjustment.

Net Loss per Share

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

Long-term Debt

On June 30, 2023, the Company entered into the Loan Agreement with Hercules. The Company assessed all terms and features of the Loan Agreement in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the debt. The Company determined that all features of the Loan Agreement are clearly and closely associated with a debt host and, as such, do not require separate accounting as a derivative liability.

Debt issuance costs consist of costs incurred in obtaining long-term financing. These costs are classified on the consolidated balance sheets as a direct deduction from the carrying amount of the related debt liability. These expenses are deferred and amortized as part of interest expense in the consolidated statements of operations and comprehensive loss using the effective interest rate method over the term of the debt agreement.

Warrants

On June 30, 2023, the Company entered into a warrant agreement with Hercules. The Company assessed all terms and features of the Warrant Agreement in order to determine accounting classification of the warrants as equity or liability. As part

of this analysis, the Company determined it appropriate to account for the warrants issued under the Loan Agreement as equity.

On August 18, 2023, in connection with the PIPE, the Company issued and sold PIPE Warrants to purchase up to 16,076,750 ADSs, each representing one ordinary share, at an exercise price of $9.93 per ADS. The PIPE Warrants are exercisable for a three year period beginning in February 2024. The Company assessed all terms and features of the PIPE Warrant Agreement in order to determine accounting classification of the warrants as equity or liability. As part of this analysis, the Company determined it appropriate to account for the PIPE Warrants as equity.

On January 13, 2025, in connection with the 2025 Financing, the Company issued and sold (i) 24,014,728 ADSs, each representing one ordinary share, (ii) in lieu of ADSs, Pre-funded Warrants to purchase up to 11,044,720 ADSs, and (iii) accompanying 2025 ADS Warrants to purchase up to 11,044,720 ADSs, each representing one ordinary share. The Pre-funded Warrants have an exercise price of $0.0001 per ADS and are exercisable immediately. The Pre-funded Warrants expire when exercised in full. The 2025 ADS Warrants have an exercise price of $5.7960 per ADS and are exercisable following a specified data milestone. The 2025 ADS Warrants will expire three years after such warrants become exercisable. Once the 2025 ADS Warrants become exercisable, the Company may force the exercise of the 2025 ADS Warrants (by way of cash or cashless exercise, at the Company's option), in whole or in part, by delivering a notice of forced exercise to the holders, provided that the closing price for the Company's ADSs on Nasdaq exceeded the warrant exercise price of $5.7960 for the three consecutive trading days prior to the date on which the notice of forced exercise is delivered. The Company assessed all terms and features of the Pre-funded Warrants and the 2025 ADS Warrants in order to determine accounting classification of the warrants as equity or liability. As part of this analysis, the Company determined it appropriate to account for the Pre-funded Warrants and 2025 ADS Warrants as liabilities.

We account for the warrants in accordance with the guidance contained in ASC Topic 815-40-15-7D, ("Derivatives and Hedging"), under which the warrants that do not meet the criteria for equity treatment must be recorded as liabilities. Accordingly, we classify the warrants as liabilities at their fair value and adjust the warrants to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until the warrants are exercised or expire, and any change in fair value will be recognized in our consolidated statements of operations and comprehensive loss. The fair values of these warrants are determined using the Black-Scholes pricing model.

The warrant liabilities are classified as current on the consolidated balance sheets due to the likelihood of exercise and it is reasonably expected that the Company would be required to use existing resources classified as current assets, or create other current liabilities, to settle the warrant liabilities at this time. Management reviews the classification of warrant liabilities at each reporting period to determine whether any change in classification is warranted based on changes in facts or circumstances, including the proximity to expiration or likelihood of exercise.

The Company measured warrants at inception at fair value using the Black-Scholes valuation model. Assumptions used in the warrant pricing model include the following:

Expected volatility. The Company calculates expected volatility based on the historical volatility of the Company's common stock over a period consistent with the expected term of the awards. The Company believes that its historical volatility is representative of future stock price volatility. In some situations the Company may lack sufficient company-specific historical data, in which the Company will estimate its expected volatility using a blended rate of: (1) historical volatility of publicly traded peer companies and (2) the Company's historical volatility since being publicly traded since September 2020.

Expected term. The expected term of the Hercules warrants is 7.5 years. The expected term of the PIPE Warrants is 1.1 year. The expected term of the Pre-funded Warrants and the 2025 ADS Warrant is 3 years.

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

Expected dividend. Expected dividend yield of zero is based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future. In addition, the Loan Agreement with Hercules currently prohibits, and any future debt financing arrangements may contain terms prohibiting or limiting the number of dividends that may be declared or paid on our ordinary shares.

Fair value of ordinary shares. The fair value of the warrants is determined by reference to the closing price of ADSs on the Nasdaq Global Select Market on the day of issuance.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which focuses on the rate reconciliation and income taxes paid. ASU No. 2023-09 requires a public business entity (PBE) to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. For PBEs, the new standard is effective for annual periods beginning after December 15, 2024, with early adoption permitted. For entities other than PBEs, the requirements will be effective for annual periods beginning after December 15, 2025. An entity may apply the amendments in this ASU prospectively by providing the revised disclosures for the period ending December 31, 2025 and continuing to provide the pre-ASU disclosures for the prior periods, or may apply the amendments retrospectively by providing the revised disclosures for all period presented. As of December 31, 2025, the Company adopted this new ASU prospectively and it only impacts the Company's income tax disclosures with no impact to its operations, cash flows, or financial condition.

In November 2024, the FASB issued ASU 2024-03 - Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, designed to improve disclosures, primarily through increased expense disaggregation. Additionally, in January 2025, the FASB issued ASU 2025-01 to clarify the effective date of ASU 2024-03. The guidance is effective for all fiscal years beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. The new standard can be adopted on a prospective basis with an option to be adopted retrospectively and early adoption is permitted. The Company is not early adopting the standard. We are currently evaluating this guidance to determine its impact on the Company’s consolidated financial statement disclosures.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company’s financial instruments measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Fair Value Measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	43,053	—	—	43,053
	$ 43,053	$ —	$ —	$ 43,053

	Fair Value Measurements as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	41,355	—	—	41,355
	$ 41,355	$ —	$ —	$ 41,355

During the years ended December 31, 2025 and 2024, there were no transfers between Level 1, Level 2 and Level 3. Excluded from the table above, is $60.8 million and $73.7 million, as of December 31, 2025 and 2024, respectively, of cash held in notice accounts of less than 90 days, for which the carrying value approximates fair value due to the short-term nature.

4. Prepaid Expenses and Other Current Assets

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

	December 31,	
	2025	2024
UK R&D tax credit	$ 15,387	$ 20,712
Prepaid research and development	17,102	11,332
Prepaid income tax	3,434	197
Other current assets	5,580	3,580
	$ 41,503	$ 35,821

For the years ended December 31, 2023 to 2025, the Company is uncertain whether it met the R&D intensity condition and is eligible for the enhanced effective rate due to uncertainties over whether impairments on intercompany loans and investments in subsidiary companies should be taken into account in determining the R&D intensity threshold. This matter is currently under discussion with HMRC and the outcome is unknown. Given the uncertainty over the outcome of the discussions with HMRC, the enhanced R&D credits as a research intensive company have not been reflected in the financial statements. As a result of these discussions the Company recorded a change in estimate for the 2023 claim, which was initially recorded during the first quarter of 2025, of $4.1 million to reduce its receivable for amounts claimed at the enhanced rate. The Company recorded a change in estimate for the 2024 claim, which was initially recorded during the year ended December 31, 2025, of $7.0 million to reduce its receivable for amounts previously claimed at the enhanced rate. If the Company reaches a successful conclusion with HMRC, additional credits of $4.1 million in the year ended December 31, 2023, $7.0 million in the year ended December 31, 2024 and $7.3 million in the year to December 31, 2025 could be claimed.

5. Long-term Prepaid Expenses and Other Assets

Long-term prepaid expenses and other assets consisted of the following (in thousands):

	December 31,	
	2025	2024
UK R&D tax credit	$ 10,950	$ —
Prepaid research and development - long-term	—	5,737
Other assets	734	858
	$ 11,684	$ 6,595

6. Accrued Expenses and Other Liabilities

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

	December 31,	
	2025	2024
Accrued compensation and benefit costs	$ 5,445	$ 7,914
Accrued research and development expense	1,868	3,724
Accrued professional expenses	1,342	1,532
Other liabilities	559	1,325
	$ 9,214	$ 14,495

7. Debt

On June 30, 2023, or the Effective Date, the Company entered into the Loan Agreement with Hercules, which was subsequently amended on October 31, 2024, and July 30, 2025 (the “Loan Agreement”). The Company evaluated the amendments in accordance with applicable accounting guidance and concluded that they did not result in a debt modification or extinguishment. The Loan Agreement provides for aggregate maximum borrowings of up to $50.0 million, consisting of (i)

a term loan of $30.0 million, which was funded on the Effective Date, and (ii) subject to the approval of Hercules' investment committee in its sole discretion, and available during the interest-only period, an additional term loan of $20.0 million.

The term loan will mature on July 1, 2027. The outstanding principal balance of the term loan bears interest at an annual rate equal to the greater of either (i) the prime rate as reported in The Wall Street Journal plus 1.50% or (ii) 9.75%. Accrued interest is payable monthly following the funding of each term loan. In addition to accrued interest, payment-in-kind (PIK) interest of 1.40% will be added to the balance of the loan. Payments under the Loan Agreement are interest only until the first principal payment is due on January 2, 2026 (subject to extension if a certain performance milestone is met), followed by equal monthly payments of principal and interest through the scheduled maturity date, July 1, 2027. The carrying value of the Company's outstanding debt approximates fair value, reflecting interest rates currently available to the Company.

The Company incurred fees and transaction costs totaling $3.3 million associated with the initial term loan, which are recorded as a reduction to the carrying value of the long-term debt in the consolidated balance sheets. These fees included $0.4 million of facility fees, $0.8 million of company fees, $0.7 million in warrants, and $1.4 million of end of term charges. The fees, transaction costs, and the end of term charges are amortized to interest expense through the maturity date using the effective interest method. The effective interest rate of the Loan Agreement was 14.8% as of December 31, 2025.

The Company issued warrants to Hercules to purchase the Company's Ordinary Shares equal to the quotient derived by dividing (i) the amount equal to (a) 2.5% times (b) the aggregate principal amount of term loan advances made and funded under the Loan Agreement by (ii) the exercise price of the warrants. Upon receipt of the first term loan in June 2023, 94,222 shares became exercisable to Hercules with a fair market value of $0.7 million.

The Loan Agreement includes a financial covenant requiring us to maintain a minimum level of $22.5 million of cash during the period commencing on July 1, 2024 (subject to adjustment if certain performance milestones are met). If the Company meets the performance milestones, the minimum cash covenant will not apply if its market capitalization is at least $750.0 million. The Company was in compliance with all covenants of the Loan Agreement as of December 31, 2025 and 2024.

Long-term debt consisted of the following (in thousands):

	December 31,	
	2025	2024
Term loan payable	$ 30,000	$ 30,000
End of term charge	1,425	1,425
Future principal payments and end of term charge	$ 31,425	$ 31,425
PIK interest payable	1,088	649
Unamortized debt issuance costs	(880)	(1,909)
Carrying value of long-term debt	$ 31,633	$ 30,165
Less: current portion	(17,523)	(5,513)
Non-current portion	$ 14,110	$ 24,652

Future principal payments, including End of Term Charge, are as follows (in thousands):

Year ending December 31, 2026	18,252
Year ending December 31, 2027	13,173
Total	$ 31,425

Interest expense associated with the Loan Agreement for the years ended December 31, 2025 and 2024 was $4.5 million and $4.5 million, respectively.

8. Fair Value Measurements

The following table presents, as of December 31, 2025, information about the Company's warrant liabilities that are measured at fair value on a recurring basis, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

	January 13, 2025		December 31, 2025	
	Level	Amount	Level	Amount
Warrant Liabilities:				
Pre-funded Warrants	2	$ 37,220	2	$ 60,029
2025 ADS Warrants	3	55,726	3	143,697
Total Warrant Liabilities		$ 92,946		$ 203,726

The Pre-funded Warrants and 2025 ADS Warrants are accounted for as liabilities in accordance with ASC 815-40, *Derivatives and Hedging, Contracts in Entity's Own Equity* ("ASC 815-40"), as both warrants contain contingent exercise provisions that do not meet the requirements of the indexation guidance under ASC 815-40 and could require the Company to pay cash to settle the warrants. The warrants are presented within warrant liabilities in the accompanying consolidated balance sheets. The warrant liabilities were measured at fair value at inception and on a recurring basis, with changes in fair value presented within the consolidated statements of operations and comprehensive loss.

The Pre-funded Warrants are considered to be Level 2 in the fair value hierarchy as the inputs used to determine fair market value are observable against the Company's stock price. The 2025 ADS Warrant are considered to be Level 3 in the fair value hierarchy as they have been recorded at fair value using the Black-Scholes model, using unobservable assumptions that have been probability-weighted for specified data milestones. As of December 31, 2025, the assumptions are as follows:

	January 13, 2025	December 31, 2025
Exercise price	$5.7960	$5.7960
Market price	$3.37	$6.90
Volatility	146.1% to 158.7%	143.4% to 144.8%
Risk-free rate	4.6%	3.6%
Dividend yield	—%	—%
Term (in years)	4.0 to 4.4 years	3.1 to 3.2 years

The following table reflects the fair value of the Company's warrant liabilities for the year ended December 31, 2025:

	Pre-Funded Warrants	ADS Warrants
Fair value as of December 31, 2024	$ —	$ —
Initial fair value as of January 13, 2025	37,220	55,726
Exercise of warrant liabilities	(10,153)	—
Fair value change of warrant liabilities	32,962	87,971
Fair value as of December 31, 2025	**$ 60,029**	**$ 143,697**

The fair value change of warrant liabilities at December 31, 2025 was $122.6 million, which included a $1.6 million loss upon issuance of the Pre-funded warrants and a $120.9 million loss in fair value between the initial fair value and the fair value as of the balance sheet date. During the year ended December 31, 2025, there were no transfers between Level 1, Level 2 and Level 3.

9. Shareholders' Equity

Ordinary Shares

Each ordinary share entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Ordinary shareholders are entitled to receive dividends, if any, as may be declared by the board of directors. Through December 31, 2025, no cash dividends had been declared or paid by the Company.

During the years ended December 31, 2025 and 2024, the Company issued ordinary shares in the amount of 925,179 and 189,214, respectively, to settle share options exercised by employees and non-employees.

During the year ended December 31, 2025, a total of 189,174 restricted share units vested, of which 156,245 shares were issued and 32,929 shares were settled.

During the year ended December 31, 2024, a total of 107,644 restricted share units vested, of which 83,527 shares were issued and 24,117 shares were settled.

During the years ended December 31, 2025 and 2024, the Company issued in total 92,752 and 74,155 shares, respectively, under the employee share purchase plan.

At-the-Market Facility

On October 8, 2021, the Company entered into a Sales Agreement with Cowen and Company, LLC, or Cowen, under which the Company was permitted to issue and sell from time to time up to $150.0 million of its ADSs, each representing one ordinary share, through Cowen as the sales agent. Pursuant to the Sales Agreement dated October 8, 2021, through February 27, 2025, we sold 5,491,836 ADSs under our ATM offering program, resulting in $54.8 million in net proceeds. On February 27, 2025, the Company entered into a new Sales Agreement under which the Company may issue and sell from time to time up to $150.0 million of our ADSs, subject to the terms of the Sales Agreement. Sales of the Company's ADSs, if any, will generally be made at market prices. To date, the Company has not sold any ADSs under this Sales Agreement.

Warrants

Equity-classified

On June 30, 2023, the Company entered into a Warrant Agreement with Hercules, which provides Hercules with the right to purchase a number of the Company's Ordinary Shares, equal to the quotient derived by dividing (i) the amount equal to (a) 2.5% times (b) the aggregate principal amount of term loan advances made and funded under the Loan Agreement by (ii) the exercise price. Upon receipt of each term loan, the Warrant will automatically become exercisable and will expire in 10 years (on June 30, 2033). On June 30, 2023, with the receipt of the first term loan, 94,222 shares became exercisable to Hercules with a fair market value of $0.7 million.

On August 18, 2023, in connection with the PIPE, the Company issued and sold warrants to purchase up to 16,076,750 ADSs, each representing one ordinary share, at a purchase price of $9.93 per ADS. The PIPE Warrants became exercisable for a three year period beginning in February 2024. During December 31, 2024, PIPE Warrants were exercised for 3,752,050 ADSs, resulting in $37.3 million in exercise proceeds. During the year ended December 31, 2025, no PIPE warrants were exercised.

Liability-classified

On January 13, 2025, in connection with the 2025 Financing, the Company issued and sold (i) 24,014,728 ADSs, each representing one ordinary share, (ii) in lieu of ADSs, Pre-funded Warrants to purchase up to 11,044,720 ADSs, and (iii) accompanying 2025 ADS Warrants to purchase up to 11,044,720 ADSs, each representing one ordinary share. The Pre-funded Warrants have an exercise price of $0.0001 per ADS and are exercisable immediately. The Pre-funded Warrants expire when exercised in full. The 2025 ADS Warrants have an exercise price of $5.7960 per ADS and are exercisable following a specified data milestone. The 2025 ADS Warrants will expire three years after such warrants become exercisable. Once the 2025 ADS Warrants become exercisable, the Company may force the exercise of the 2025 ADS Warrants (by way of cash or

cashless exercise, at the Company's option), in whole or in part, by delivering a notice of forced exercise to the holders, provided that the closing price for the Company's ADSs on Nasdaq exceeded the warrant exercise price of $5.7960 for the three consecutive trading days prior to the date on which the notice of forced exercise is delivered. During the year ended December 31, 2025, 2,344,720 Pre-funded Warrants were exercised, resulting in a $10.2 million reduction in warrant liabilities.

The 2025 Financing comprised of ADSs, Pre-funded Warrants and 2025 ADS Warrants, resulted in aggregate proceeds of $149.8 million, with issuance costs of $9.4 million. Since the Pre-funded Warrants and 2025 ADS Warrants have been classified as a liability and recorded at fair value with changes in fair value recorded in the consolidated income statement, the aggregate proceeds have been allocated first to these warrants at their respective fair values at the issuance date. The residual has been allocated to the ADSs issued as part of the 2025 Financing and recognized within equity.

10. Share-Based Compensation

2017 Equity Incentive Plan

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

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

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

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

As of December 31, 2025, the Company was authorized to issue a total of 417,254 ordinary shares underlying outstanding options granted under the 2017 Plan prior to our initial public offering, or IPO.

2020 Employee Share Purchase Plan

The Company's 2020 Employee Share Purchase Plan, or the ESPP, provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022 and each January 1 thereafter through termination of the 2020 Plan, by the lesser of (i) 1% of the outstanding number of ordinary shares on the immediately preceding December 31, (ii) 510,080 ordinary shares or (iii) such lesser number of ordinary shares as determined by the plan administrator. The number of shares reserved under the ESPP is subject to change in the event of a share split, share dividend or other change in our capitalization.

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

2020 Share Option Plan

The Company's 2020 Share Option and Incentive Plan, or the 2020 Plan, allows the compensation and leadership development committee to make equity-based, including options and restricted share units, and cash-based incentive awards to the Company's officers, employees, directors and other key persons (including consultants).

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

The Company initially reserved 2,074,325 of its ordinary shares for the issuance of awards under the 2020 Plan. The 2020 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by up to 4% of the outstanding number of ordinary shares on the immediately preceding December 31, or such lesser number of shares as determined by the Company's compensation and leadership development committee. The total number of ordinary shares that were authorized for issuance under the 2020 Plan is 10,680,217 shares as of December 31, 2025, of which 3,184,218 shares remained available for future grant.

The options granted in 2025 under the 2020 Plan to employees generally expire 10 years from the date of grant. There are three potential vesting terms for the 2025 grants including: (i) 25% per year over four year service period, (ii) four year service period with 25% of the vesting on the first anniversary of the commencement date and the balance vesting monthly over the remaining years; and (iii) monthly vesting over four year service period.

2022 Inducement Option Award

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

Restricted Share Units

A summary of the changes in the Company's unvested restricted share units during the year ended December 31, 2025 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested and Outstanding as of December 31, 2024	658,553	$ 10.96
Granted	531,110	3.76
Vested	(189,174)	11.21
Forfeited	(226,062)	8.12
Unvested and Outstanding as of December 31, 2025	774,427	$ 6.79

As of December 31, 2025 and 2024, there was $3.8 million and $5.5 million of unrecognized compensation cost related to unvested restricted share units, respectively, which is expected to be recognized over a weighted-average period of 2.5 years and 2.8 years, respectively. The exercise price of restricted share units is at a nominal value less than £0.01 per share.

Share Options

The following table summarizes the Company's share options activity for the year ended December 31, 2025:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	8,235,619	$ 12.01	6.95	$ 6,009
Granted	2,581,977	$ 6.19		
Exercised	(925,179)	$ 0.08		
Cancelled or forfeited	(2,289,124)	$ 15.13		
Outstanding as of December 31, 2025	7,603,293	$ 10.52	6.87	$ 10,972
Exercisable as of December 31, 2025	4,492,506	$ 13.58	5.67	$ 3,950
Unvested as of December 31, 2025	3,110,787	$ 6.11	8.62	$ 7,022

The aggregate intrinsic value of options exercised during the years ended December 31, 2025, and 2024 was $3.5 million and $1.2 million, respectively.

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

The weighted average grant-date fair value of share options granted was $2.48 and $7.00 per share during the years ended December 31, 2025 and 2024.

As of December 31, 2025 and 2024, there was $15.0 million and $25.5 million of unrecognized compensation cost related to unvested share options, which is expected to be recognized over a weighted-average period of 2.2 years and 2.4 years, respectively.

Share Option Valuation

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the share options granted to employees and directors during the years ended December 31, 2025 and 2024 were as follows:

	Year Ended December 31,	
	2025	2024
Expected option life (years)	5.0 years	5.1 years
Expected volatility	89.42 %	86.05 %
Risk-free interest rate	4.06 %	4.12 %
Expected dividend yield	— %	— %

Share-based Compensation Expense

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

	Year Ended December 31,	
	2025	2024
Research and development	5,088	10,309
General and administrative	8,502	9,208
Total share-based compensation expense	$ 13,590	$ 19,517

11. Income Taxes

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

	Year Ended December 31,	
	2025	2024
United Kingdom	(293,932)	(156,711)
Foreign	3,597	3,183
Loss before provision for income taxes	(290,335)	(153,528)

The provision for income taxes for the years ended December 31, 2025 and 2024 was computed at the UK statutory income tax rate. The income tax provision for the years then ended comprised (in thousands):

	Year Ended December 31,	
	2025	2024
Current income tax provision		
United Kingdom	$ —	$ —
Foreign	(2,495)	2,031
Total current (benefit) expense:	$ (2,495)	$ 2,031
Deferred income tax (benefit) expense:		
United Kingdom	—	—
Foreign	22	(437)
Total deferred income tax (benefit) expense:	$ 22	$ (437)
Total provision for income taxes	$ (2,473)	$ 1,594

A reconciliation of income tax expense computed at the statutory UK corporation tax rate to income taxes as reflected in the consolidated financial statements, in accordance with the guidance in ASU 2023-09, is as follows (in thousands):

	Year Ended December 31, 2025	
	Amount	Rate
Pretax loss	$ (290,335)	
UK Federal Statutory Tax Rate	(72,584)	25.0%
Foreign tax effects:		
United States:		
Foreign rate differential	(144)	—%
Foreign-derived intangible income (FDII) deduction	(2,772)	1.0%
Tax credits - federal research and development credit	(1,478)	0.5%
State and local income taxes, net of federal benefit	19	—%
Other	1,005	(0.3)%
Change in valuation allowance	21,860	(7.5)%
Nontaxable or nondeductible items		
R&D deduction	(64)	—%
R&D deductions surrendered	138	—%
R&D credit included in profit before tax	3,305	(1.1)%
Change in fair value warrant liabilities	42,572	(14.7)%
Group relief	1,705	(0.6)%
Other	3,965	(1.4)%
Income tax benefit	$ (2,473)	0.9%

A reconciliation of income tax expense computed at the statutory UK corporation tax rate to income taxes as reflected in the consolidated financial statements, in accordance with the guidance prior to the adoption of ASU 2023-09, is as follows (in thousands):

	Year Ended December 31, 2024
Corporation tax at UK statutory rate	$ (38,382)
Permanent differences	27
UK R&D tax credit	14,375
Change in valuation allowance	25,410
State income taxes	57
Deferred tax asset true-up	676
Return to provision	(1,214)
Share-based compensation	774
Change in UK tax rate	—
Other	(129)
	$ 1,594

The Company's effective tax rate includes the effects of state and local income taxes, net of the federal income tax benefit, which are primarily attributable to New York and New York City, where the Company has significant business activities. These states have higher tax rates compared to other jurisdictions where the Company operates, and together, they account for more than half of the Company's total state tax expense.

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2025 and 2024 consist of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Net operating loss carryforward	$ 110,742	$ 84,927
Reserves and accruals	2,954	647
Share-based compensation	18,662	18,205
Charitable contributions	44	126
Total deferred tax assets	132,402	103,905
Valuation allowance	(128,651)	(100,090)
Depreciation	—	(41)
Total deferred tax liabilities	—	(41)
Net deferred tax assets	$ 3,751	$ 3,774

As of December 31, 2025 and 2024, the Company had UK net operating loss carryforwards of approximately $577.9 million, and $280.8 million, respectively, that can be carried forward indefinitely.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2025 and 2024 related primarily to the increases in net operating loss and were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Valuation allowance at beginning of year	$ 100,090	$ 76,072
Increases recorded to income tax provision	21,860	25,411
Increases recorded to CTA	6,701	(1,393)
Valuation allowance at end of year	$ 128,651	$ 100,090

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2025 and 2024, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all of the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance against its net UK deferred tax assets as of December 31, 2025 and 2024. The deferred tax asset recognized relates entirely to the US entity.

The Company applies the authoritative guidance on accounting for and disclosure of uncertainty in tax positions, which requires the Company to determine whether a tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals of litigation processes, based on the technical merits of the position. For tax positions meeting the more likely than not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than fifty percent likelihood of being realized upon the ultimate settlement with the relevant taxing authority. There were no material uncertain tax positions as of December 31, 2025 and 2024.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2025 and 2024, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations and comprehensive loss.

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

The following summarizes the Company's income taxes paid, net of refunds received for the year presented below, in accordance with the guidance in ASU 2023-09 (in thousands):

	Year Ended December 31, 2025
United Kingdom	$ —
United States	755
Total	$ 755

One Big Beautiful Bill Act

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law. The OBBBA introduced multiple U.S. federal income tax changes such as deductibility of domestic research and development expenses, deductibility on certain property additions and limitations on interest expense deduction. The OBBBA did not have a material impact on the Company's financial position, results of operations and cash flows for the year ended December 31, 2025. The Company will continue to evaluate the impact of the OBBBA as further information becomes available.

12. Net Loss Per Share

The Company computes basic net loss per share by dividing net loss by the weighted-average number of shares outstanding. The Company computes diluted net loss per share by dividing net loss by the weighted-average number of shares and dilutive potential share equivalents then outstanding during the period. The Company's potentially dilutive securities, which include unvested ordinary shares, unvested restricted share units, options granted and warrants, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of ordinary shares outstanding used to calculate both basic and diluted net loss per share attributable to ordinary shareholders is the same.

The Company excluded the following potential ordinary shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to ordinary shareholders for the years ended December 31, 2025 and 2024 because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2025	2024
Employee share purchase plan	29,943	37,755
Unvested restricted share units	774,427	658,553
Share options	7,603,293	8,235,619
Warrants - equity-classified	12,418,922	12,418,922
Warrants - liability-classified	43,759,448	—
	64,586,033	21,350,849

13. Right of use assets

New York, USA

In September 2023, the Company entered into a lease agreement for office space located in New York, NY, that was undergoing construction to get the space ready for use. The required improvements were subsequently completed in October 2023 and the space was made available for use, resulting in the lease commencing on October 9, 2023. The stated lease term is three years. Lease payments will be made on a monthly basis and increase approximately 3.5% each year over the lease term. The total commitment for lease payments over the stated term is $0.7 million.

Soho, London, UK

In September 2025, the Company entered into a two-year operating lease with Fora Space Limited commencing on September 1, 2025 to remain in its current premises. The recurring residency fee per month is £113,420, and the Company has paid a refundable deposit of £156,000 at the execution of its initial agreement.

Denmark Hill, London, UK

In March 2022, the Company entered into an agreement for a lease with South London and Maudsley NHS Foundation Trust for land and buildings at 5 Windsor Walk, Maudsley Hospital, Denmark Hill, London, UK. The lease commenced on June 21, 2022 and has a contractual term of five years. The rent is £180,000 per year, with no deposit payable.

The following table summarizes our costs included in our consolidated statements of operations and comprehensive loss related to right of use lease assets we have entered for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Lease cost		
Operating lease cost	$ 2,408	$ 2,570
	$ 2,408	$ 2,570
Other information:		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating leases	$ 2,452	$ 2,533
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 3,572	$ 17
Weighted average remaining lease term (in years)	1.6	1.1
Weighted average discount rate	7.8%	8.5%

The following table summarizes the future minimum lease payments due under operating leases as of December 31, 2025, (in thousands):

December 31, 2026	2,285
December 31, 2027	1,320
Total future minimum lease payments	$ 3,605
Less: imputed interest	203
Total	$ 3,402

14. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may be a party to litigation or subject to claims incident to the ordinary course of business. The Company was not a party to any material litigation and did not have material contingency reserves established for any liabilities as of December 31, 2025 or 2024.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into deeds of indemnity with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers in accordance with the indemnification obligations under its Articles of Association. The Company currently has directors' and officers' insurance.

15. Segment Reporting

The Company has one operating segment. The table below is a summary of the segment loss, including significant segment expenses (in thousands):

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and Development:		
Development expenses	$ 82,372	$ 76,993
Personnel expenses	24,420	26,707
Non-cash share-based compensation expense	5,088	10,309
Facilities and other expenses[1]	6,556	5,030
General and Administrative:		
Personnel expenses	19,716	23,422
Legal and professional fees	23,521	14,535
Facilities and other expenses[1]	8,862	12,001
Non-cash share-based compensation expense	8,502	9,208
Total operating expenses	**179,037**	**178,205**
Operating loss	**(179,037)**	**(178,205)**
Fair value change of warrant liabilities	(122,561)	—
Benefit from R&D tax credit	3,747	21,097
Interest income	7,182	8,268
Interest expense	(4,517)	(4,479)
Foreign exchange gains (losses)	3,471	(1,032)
Other income	1,380	823
Income tax benefit (expense)	2,473	(1,594)
Net loss	**$ (287,862)**	**$ (155,122)**

[1]Other expenses include subscriptions and memberships, consulting fees and company insurance.

16. Subsequent Events

On January 5, 2026, or the "Effective Date", the Company entered into a third amendment to the Loan Agreement with Hercules. The Loan Agreement provides for five tranches of term loans in an aggregate principal amount of up to $150.0 million, consisting of (i) a term loan of $50.0 million, which was funded on the Effective Date, (ii) term loans of up to $30.0 million subject to achievement of a clinical milestone (which was achieved in February 2026), (iii) term loans of up to $30.0 million subject to achievement of a milestone relating to certain FDA approvals being granted, (iv) term loans of up to $20.0 million subject to achievement of a specified commercial milestone, and (v) term loans of up to $20.0 million, plus any remaining unborrowed amounts from the earlier tranches, subject to the approval of Hercules' investment committee. If the conditions of each term loan are met, these tranches may be borrowed in drawings of a minimum of $5.0 million each. The Loan Agreement further provides that a portion of the proceeds from the Tranche 1 Advance shall be used to repay the outstanding principal amounts and PIK due under the second amendment to the Loan Agreement, which is approximately $31.1 million.

Borrowings under the Loan Agreement bear interest at an annual rate equal to the greater of (i) 9.75% or (ii) 2.75% plus the Wall Street Journal prime rate. Payments under the Loan Agreement are interest only until the first principal payment is

due in the first quarter of 2029, as may be deferred if the Borrowers achieve certain milestones until the scheduled maturity date on January 5, 2031.

In February 2026, the Company issued and sold in an underwritten offering, or the February 2026 Offering, 17,500,000 ADSs at a public offering price of $8.00 per ADS, each representing one ordinary share, and in lieu of ADSs, to certain institutional investors, Pre-funded Warrants to purchase up to 1,250,000 ADSs at a public offering price of $7.9999 per Pre-funded Warrant. The Company received net proceeds of approximately $140.5 million, after deducting underwriting discounts and commissions and estimated offering costs.

In February 2026, subsequent to the February 2026 Offering, the Company received net proceeds of $203.2 million following the exercise of 35,059,448 2025 ADS Warrants, which were issued on January 13, 2025 as part of the 2025 Financing. Upon exercise of these outstanding warrants, the Company issued 15,160,619 ADSs and in lieu of ADSs, to certain institutional investors, Pre-funded Warrants to purchase up to 19,898,829 ADSs.

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.

COMPASS PATHWAYS PLC

Date: March 24, 2026

By: /s/ Kabir Nath
Kabir Nath
Chief Executive Officer
(Principal 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 and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Kabir Nath Kabir Nath	Chief Executive Officer (Principal Executive Officer)	March 24, 2026
/s/ Teri Loxam Teri Loxam	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 24, 2026
/s/ Gino Santini Gino Santini	Chair of Board of Directors	March 24, 2026
/s/ Justin Gover Justin Gover	Director	March 24, 2026
/s/ Annalisa Jenkins Annalisa Jenkins, MBBS	Director	March 24, 2026
/s/ Jeffrey Jonas Jeffrey Jonas	Director	March 24, 2026
/s/ Daphne Karydas Daphne Karydas	Director	March 24, 2026
/s/ Robert McQuade Robert McQuade	Director	March 24, 2026
/s/ David Norton David Norton	Director	March 24, 2026
/s/ Wayne Riley Wayne Riley, M.D., MPH, M.B.A.	Director	March 24, 2026

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-285297, 333-282522, and 333-274436) and Form S-8 (Nos. 333-285298, 333-276410, 333-269329, 333-266506, and 333-265954) of Compass Pathways plc of our report dated March 24, 2026 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 24, 2026

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-276410, 333-269329, 333-265954, 333-249403, 333-266506 and 333-285298) and Form S-3 (No. 333-274436, 333-282522 and 333-285297) of Compass Pathways plc of our report dated February 27, 2025 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Reading, United Kingdom
March 24, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kabir Nath, certify that:

1. I have reviewed this Annual Report on Form 10-K of COMPASS Pathways plc (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 24, 2026

/s/ Kabir Nath

Kabir Nath

Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Teri Loxam, certify that:

1. I have reviewed this Annual Report on Form 10-K of COMPASS Pathways plc (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 24, 2026

/s/ Teri Loxam

Teri Loxam
Chief Financial Officer

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Kabir Nath, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Annual Report on Form 10-K of COMPASS Pathways plc for the period ended December 31, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of COMPASS Pathways plc.

Date: March 24, 2026

By: /s/ Kabir Nath

Kabir Nath

Chief Executive Officer

The foregoing certification is not deemed filed with the Securities and Exchange Commission for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not to be incorporated by reference into any filing of COMPASS Pathways plc under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

I, Teri Loxam, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Annual Report on Form 10-K of COMPASS Pathways plc for the period ended December 31, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of COMPASS Pathways plc.

Date: March 24, 2026

By: /s/ Teri Loxam

Teri Loxam

Chief Financial Officer

The foregoing certification is not deemed filed with the Securities and Exchange Commission for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and it is not to be incorporated by reference into any filing of COMPASS Pathways plc under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.