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

Form 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The registrant had 96,017,044 shares of common stock outstanding as of October 30, 2025.

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PART II - OTHER INFORMATION

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, 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-Q are based upon information available to our management as of the date of this Form 10-Q, 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 Quarterly Report on Form 10-Q 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 top-line primary endpoint data from the first of our two 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 results of our Phase 3 trials 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;
- our plans for a late-stage program in post-traumatic stress disorder, or PTSD, including statements regarding our proposed trial designs and our expectations regarding discussions with 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 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, including with respect to those outstanding warrants to purchase ADSs, or the 2025 ADS Warrants, issued in our registered financing in January 2025, or the 2025 Financing, our ability to achieve the specified data milestone and to achieve sufficient appreciation in the trading price of our ADSs, such that the closing price of our ADSs is above the exercise price for the 2025 ADS Warrants, for three consecutive trading days to allow us to force the cash exercise of the 2025 ADS Warrants;
- 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 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, regulatory development paths and with respect to Controlled Substances Act designation, including 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 secure approval from lenders' investment committees to draw down additional amounts in accordance with the terms of our Loan and Security Agreement, as amended, 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 (whether from the continued government shutdown or reduced resources) 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 Quarterly Report on Form 10-Q.

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 Quarterly Report on Form 10-Q 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 II, Item 1A, of this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q. 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.

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;
- We will need substantial additional funding to complete the development and commercialization of our investigational COMP360 psilocybin treatment. 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 convertible securities 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;
- COMP360 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 COMP360, in particular, and psilocybin-based treatments, in general, or our future investigational treatments using psilocybin 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 psilocybin treatment 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;

- 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;
- 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;
- Our failure to comply with the financial and other covenants, including the minimum cash covenant, or payment obligations under our existing Loan Agreement with Hercules could result in a default or an event of default, which may result in increased interest charges, acceleration of our repayment obligations or other actions by Hercules, any of which could negatively impact our business, financial condition and results of operations;
- Enacted and future legislation or changes in regulatory conditions may increase the difficulty and cost for us to obtain marketing approval of 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;
- Unfavorable global economic conditions and geopolitical events as well as volatility in the financial markets could adversely affect our business, financial condition or 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; and
- 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.

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 185,937	$ 165,081
Restricted cash	379	389
Prepaid expenses and other current assets	56,072	35,821
Total current assets	242,388	201,291
NON-CURRENT ASSETS:		
Operating lease right-of-use assets	3,931	2,006
Deferred tax assets	4,527	3,774
Long-term prepaid expenses and other assets	4,761	6,595
Total assets	$ 255,607	$ 213,666
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,246	$ 12,283
Accrued expenses and other liabilities	12,023	14,495
Debt, current portion	12,669	5,513
Operating lease liabilities - current	1,949	1,725
Warrant liabilities	165,563	—
Total current liabilities	197,450	34,016
NON-CURRENT LIABILITIES:		
Debt, non-current portion	18,600	24,652
Operating lease liabilities - non-current	1,966	303
Total liabilities	$ 218,016	$ 58,971
Commitments and contingencies (Note 9)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, £0.008 par value; 96,002,044 and 68,552,215 shares authorized, issued and outstanding at September 30, 2025 and December 31, 2024, respectively	973	702
Additional paid-in capital	780,521	704,919
Accumulated other comprehensive loss	(15,187)	(16,194)
Accumulated deficit	(728,716)	(534,732)
Total shareholders' equity	37,591	154,695
Total liabilities and shareholders' equity	$ 255,607	$ 213,666

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

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

	Three Months ended September 30,		Nine Months ended September 30,	
	2025	2024	2025	2024
OPERATING EXPENSES:				
Research and development	$ 27,325	$ 32,928	$ 88,530	$ 86,898
General and administrative	13,211	14,968	44,555	42,893
Total operating expenses	40,536	47,896	133,085	129,791
Loss from operations:	(40,536)	(47,896)	(133,085)	(129,791)
OTHER INCOME (EXPENSE), NET:				
Fair value change of warrant liabilities	(101,318)	—	(84,398)	—
Benefit from R&D tax credit	3,924	4,084	16,659	10,894
Interest income	1,588	1,977	5,872	6,645
Foreign exchange (losses) gains	(883)	4,452	3,599	3,894
Interest expense	(1,105)	(1,137)	(3,380)	(3,347)
Other income	383	191	1,010	486
Total other income, net	(97,411)	9,567	(60,638)	18,572
Loss before income taxes	(137,947)	(38,329)	(193,723)	(111,219)
Income tax benefit (expense)	230	(173)	(261)	(571)
Net loss	$ (137,717)	$ (38,502)	$ (193,984)	$ (111,790)
Net loss per share attributable to ordinary shareholders: basic and diluted	$ (1.44)	$ (0.56)	$ (2.09)	$ (1.67)
Weighted average ordinary shares outstanding: basic and diluted	95,337,993	68,395,343	92,646,458	67,001,326
Net loss	$ (137,717)	$ (38,502)	$ (193,984)	$ (111,790)
Other comprehensive loss:				
Foreign exchange translation adjustment	(605)	339	1,007	384
Comprehensive loss	$ (138,322)	$ (38,163)	$ (192,977)	$ (111,406)

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

COMPASS PATHWAYS PLC
Condensed Consolidated Statements of Shareholders' Equity
(unaudited)
(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' EQUITY
	SHARES	AMOUNT	AMOUNT	AMOUNT	AMOUNT	AMOUNT
Balance at December 31, 2023	**61,943,471**	**$ 635**	**$ 621,645**	**$ (16,926)**	**$ (379,610)**	**$ 225,744**
Exercise of share options	86,510	1	219	—	—	220
Issuance of ordinary shares, net of issuance costs	2,509,798	25	26,194	—	—	26,219
Issuance of ordinary shares to settle vested restricted stock units	50,705	—	—	—	—	—
Issuance of ordinary shares to settle warrants exercised	3,752,050	38	37,220	—	—	37,258
Shares tendered for withholding taxes	—	—	(185)	—	—	(185)
Share-based compensation expense	—	—	5,129	—	—	5,129
Unrealized loss on foreign currency translation	—	—	—	(36)	—	(36)
Net loss	—	—	—	—	(35,187)	(35,187)
Balance at March 31, 2024	**68,342,534**	**$ 699**	**$ 690,222**	**$ (16,962)**	**$ (414,797)**	**$ 259,162**
Exercise of share options	3,845	—	—	—	—	—
Issuance of ordinary shares to settle vested restricted stock units	4,438	—	—	—	—	—
Vesting of equity awards under the employee purchase plan	36,652	—	210	—	—	210
Share-based compensation expense	—	—	4,921	—	—	4,921
Unrealized gain on foreign currency translation	—	—	—	81	—	81
Net loss	—	—	—	—	(38,101)	(38,101)
Balance at June 30, 2024	**68,387,469**	**$ 699**	**$ 695,353**	**$ (16,881)**	**$ (452,898)**	**$ 226,273**
Exercise of share options	13,083	—	—	—	—	—
Issuance of ordinary shares to settle vested restricted stock units	8,516	—	—	—	—	—
Shares tendered for withholding taxes	—	—	(53)	—	—	(53)
Share-based compensation expense	—	—	4,973	—	—	4,973
Unrealized gain on foreign currency translation	—	—	—	339	—	339
Net loss	—	—	—	—	(38,502)	(38,502)
Balance at September 30, 2024	**68,409,068**	**$ 699**	**$ 700,273**	**$ (16,542)**	**$ (491,400)**	**$ 193,030**

	ORDINARY SHARES £0.008 PAR VALUE		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE (LOSS)/INCOME	ACCUMULATED DEFICIT	TOTAL SHAREHOLDERS' EQUITY
	SHARES	AMOUNT	AMOUNT	AMOUNT	AMOUNT	AMOUNT
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	54,583	—	—	54,816
Exercise of share options	164,422	2	—	—	—	2
Issuance of ordinary shares to settle vested restricted stock units	116,961	1	(1)	—	—	—
Share-based compensation expense	—	—	3,935	—	—	3,935
Unrealized loss on foreign currency translation	—	—	—	(117)	—	(117)
Net loss	—	—	—	—	(17,864)	(17,864)
Balance at March 31, 2025	**92,848,326**	**$ 938**	**$ 763,436**	**$ (16,311)**	**$ (552,596)**	**$ 195,467**
Exercise of share options	682,682	7	2	—	—	9
Issuance of ordinary shares to settle vested restricted stock units	9,375	—	—	—	—	—
Issuance of ordinary shares under the employee share purchase plan	45,965	1	156	—	—	157
Share-based compensation expense	—	—	3,596	—	—	3,596
Unrealized gain on foreign currency translation	—	—	—	1,729	—	1,729
Net loss	—	—	—	—	(38,403)	(38,403)
Balance at June 30, 2025	**93,586,348**	**$ 946**	**$ 767,190**	**$ (14,582)**	**$ (590,999)**	**$ 162,555**
Exercise of share options	**44,121**	—	—	—	—	—
Issuance of ordinary shares to settle vested restricted stock units	**26,909**	—	—	—	—	—
Issuance of ordinary shares to settle warrant exercised	**2,344,666**	27	10,124	—	—	10,151
Share-based compensation expense	**—**	—	3,207	—	—	3,207
Unrealized loss on foreign currency translation	**—**	—	—	(605)	—	(605)
Net loss	**—**	—		—	(137,717)	(137,717)
Balance at September 30, 2025	**96,002,044**	**$ 973**	**$ 780,521**	**$ (15,187)**	**$ (728,716)**	**$ 37,591**

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

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

	Nine months ended September 30,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (193,984)	$ (111,790)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	210	183
Non-cash interest	1,104	1,037
Non-cash loss on foreign currency remeasurement	(682)	(802)
Non-cash share-based compensation	10,738	15,023
Non-cash lease expenses	1,114	1,687
Transaction costs allocated to warrants	5,778	—
Fair value change of warrant liabilities	84,398	—
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(17,364)	14,479
Deferred and prepaid tax assets	(753)	46
Other assets	2,035	643
Operating lease liabilities	(1,150)	(1,659)
Accounts payable	(7,719)	1,947
Accrued expenses and other liabilities	(3,177)	1,777
Net cash used in operating activities	(119,452)	(77,429)
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
Payments of withholding tax on stock award	—	(238)
Proceeds from issuance of shares under the employee share purchase plan	157	210
Proceeds from exercise of options	11	220
Net cash provided by financing activities	140,525	63,669
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(227)	464
Net increase in cash, cash equivalents and restricted cash	20,846	(13,296)
Cash, cash equivalents and restricted cash, beginning of the period	165,470	220,638
Cash, cash equivalents and restricted cash, end of the period	$ 186,316	$ 207,342

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

	Nine months ended September 30,	
	2025	**2024**
Cash and cash equivalents	$ 185,937	$ 206,953
Restricted cash	$ 379	$ 389
Total cash, cash equivalents and restricted cash	$ 186,316	$ 207,342

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

COMPASS PATHWAYS PLC
Notes to Condensed Consolidated Financial Statements
(unaudited)

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. Through September 30, 2025, PIPE Warrants were exercised for 3,752,050 ADS, resulting in $37.3 million in exercise proceeds. The Company will receive up to an additional approximately $122.4 million in gross proceeds if the PIPE Warrants are fully exercised for cash. During the three months ended September 30, 2025, no PIPE warrants were exercised.

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 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 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 three months ended September 30, 2025, 2,344,720 Pre-funded warrants were exercised.

The Company has incurred recurring losses since its inception, including net losses of $194.0 million and $111.8 million for the nine months ended September 30, 2025 and 2024, respectively. In addition, as of September 30, 2025, the Company had an accumulated deficit of $728.7 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 September 30, 2025 of $185.9 million 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 condensed 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 (whether from the continued government shutdown or reduced resources) 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 unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or U.S. GAAP. The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements as of and for the year ended December 31, 2024, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair statement of the Company's financial position for the reported periods.

The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full fiscal year. These interim financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2024, and the notes thereto, which are included in the Company's Annual Report on Form 10-K that was filed with the SEC, on February 27, 2025. The condensed consolidated balance sheet at December 31, 2024, was derived from audited annual consolidated financial statements but does not contain all of the footnote disclosures from the annual financial statements.

Principles of Consolidation

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

Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 of the Notes to Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024.

Use of Estimates

The preparation of the condensed 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 condensed consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, warrant liabilities. 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.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09 - Income Taxes (Topic 740): Improvements to Income Tax Disclosures, designed to improve income tax disclosure requirements, primarily through increased disaggregation disclosures within the effective tax rate reconciliation as well as enhanced disclosures on income taxes paid. The guidance is effective for all fiscal years beginning after December 15, 2024. The new standard can be adopted on a prospective basis with an option to be adopted retrospectively and early adoption is permitted. We are currently evaluating this guidance to determine its impact on the Company's year-end consolidated financial statement disclosures.

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.

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 Company has assessed the legislation, and believes the impact of these provisions on our consolidated financial statements will not be material.

3. Prepaid Expenses and Other Current Assets

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

	September 30, 2025	December 31, 2024
UK R&D tax credit	$ 39,309	$ 20,712
Prepaid research and development	13,011	11,332
VAT recoverable	998	1,109
Other current assets	2,754	2,668
	$ 56,072	$ 35,821

The Company was uncertain whether it would meet the R&D intensity condition and be eligible for the enhanced effective rate for its tax submission relating to the year ended December 31, 2023. The Company sought clarity from HMRC in the form of a non-statutory clearance and received a positive response in April 2025. The Company filed a resubmission claim relating to the year ended December 31, 2023 at the enhanced rate, which resulted in an increase in its R&D tax relief claim of $4.1 million.

4. 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") and 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 condensed 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 September 30, 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 September 30, 2025 and December 31, 2024.

Long-term debt consisted of the following (in thousands):

	September 30, 2025	December 31, 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	977	649
Unamortized debt issuance costs	(1,133)	(1,909)
Carrying value of long-term debt	$ 31,269	$ 30,165
Less: current portion	$ (12,669)	$ (5,513)
Non-current portion	$ 18,600	$ 24,652

Future principal payments, including End of Term Charge, are as follows (in thousands):

December 31, 2025	—
December 31, 2026	18,252
December 31, 2027	13,173
Total	$ 31,425

Interest expense associated with the Loan Agreement for the nine months ended September 30, 2025 and 2024 was $3.4 million and $3.3 million, respectively.

5. Fair Value Measurements

The following table presents, as of September 30, 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		September 30, 2025	
	Level	Amount	Level	Amount
Warrant Liabilities:				
Pre-funded Warrants	2	$ 37,220	2	$ 49,850
2025 ADS Warrants	3	55,726	3	115,713
Total Warrant Liabilities		$ 92,946		$ 165,563

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 condensed 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 condensed 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 September 30, 2025, the assumptions are as follows:

	January 13, 2025	September 30, 2025
Exercise price	$5.7960	$5.7960
Market price	$3.37	$5.73
Volatility	146.1% to 158.7%	150.0% to 153.6%
Risk-free rate	4.6%	3.7%
Dividend yield	—%	—%
Term (in years)	4.0 to 4.4 years	3.36 to 3.42 years

The following table reflects the fair value of the Company's warrant liabilities for the nine months ended September 30, 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)	0
Fair value change of warrant liabilities	22,783	59,987
Fair value as of September 30, 2025	**$ 49,850**	**$ 115,713**

The fair value change of warrant liabilities at September 30, 2025 was $84.4 million, which included a $1.6 million loss upon issuance of the Pre-funded warrants and a $82.8 million loss in fair value between the initial fair value and the fair value as of the balance sheet date. During the nine months ended September 30, 2025, there were no transfers between Level 1, Level 2 and Level 3.

6. 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 September 30, 2025, no cash dividends had been declared or paid by the Company.

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. Through September 30, 2025, PIPE Warrants were exercised for 3,752,050 ADSs, resulting in $37.3 million in exercise proceeds. During the three months ended September 30, 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 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 $5.796 for the three consecutive trading days prior to the date on which the notice of forced exercise is delivered. During the three months ended September 30, 2025, 2,344,720 Pre-funded Warrants were exercised, resulting in a $10.2 million reduction in warrant liabilities.

The 2025 Financing comprising 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 condensed 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.

7. 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.

As of September 30, 2025, the Company was authorized to issue a total of 440,101 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.

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).

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 September 30, 2025, of which 2,697,219 shares remained available for future grant.

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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	1,224	2,661	4,037	7,921
General and administrative	1,983	2,312	6,701	7,102
Total share-based compensation expense	$ 3,207	$ 4,973	$ 10,738	$ 15,023

8. 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 periods presented because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2025	2024
Employee share purchase plan	40,342	27,615
Unvested restricted share units	770,652	702,183
Share options	7,991,809	8,718,938
Warrants - equity-classified	12,418,922	12,418,922
Warrants - liability-classified	43,759,448	—
	64,981,173	21,867,658

9. 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 September 30, 2025 or December 31, 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.

10. Segment Reporting

The Company has one operating segment. The table below is a summary of the segment loss, including significant segment expenses (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and Development:				
Development expenses	$ 17,862	$ 22,647	$ 61,000	$ 54,628
Personnel expenses	6,416	6,409	18,598	19,893
Non-cash share-based compensation expense	1,224	2,661	4,037	7,921
Other expenses[1]	1,823	1,211	4,895	4,456
General and Administrative:				
Personnel expenses	4,780	5,169	14,459	16,325
Legal and professional fees	4,440	4,393	17,171	10,143
Facilities and other expenses[1]	2,007	3,093	6,223	9,322
Non-cash share-based compensation expense	1,984	2,313	6,702	7,103
Total operating expenses	**40,536**	**47,896**	**133,085**	**129,791**
Operating loss	**(40,536)**	**(47,896)**	**(133,085)**	**(129,791)**
Fair value change of warrant liabilities	(101,318)	—	(84,398)	—
Benefit from R&D tax credit	3,924	4,084	16,659	10,894
Interest income	1,588	1,977	5,872	6,645
Interest expense	(1,105)	(1,137)	(3,380)	(3,347)
Foreign exchange (losses) gains	(883)	4,452	3,599	3,894
Other income	383	191	1,010	486
Income tax expense	230	(173)	(261)	(571)
Net loss	**$ (137,717)**	**$ (38,502)**	**$ (193,984)**	**$ (111,790)**

[1]Other expenses include subscriptions and memberships, consulting fees and company insurance.

ITEM 2. 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 condensed consolidated financial statements and the related notes to those statements included earlier in this Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q, particularly in Part II, 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 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.

At the beginning of 2023, we commenced our Phase 3 program evaluating our COMP360 psilocybin treatment in TRD. The Phase 3 program is composed of two pivotal trials, each with a long-term follow-up component. The pivotal program design is as follows:

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

• Pivotal trial 2 (COMP006) (n= 585): 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 MADRS (Montgomery-Åsberg Depression Rating Scale) 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 remains blinded through week 26; and Part C, which contains an open-label treatment part from week 26 to 52.

In September 2025, we met with the U.S. Food and Drug Administration, or the FDA, and as part of that meeting discussed our NDA submission strategy. Based on such discussions, we plan to submit a proposal for rolling submission and formal request for rolling review of our NDA to the FDA.

We have completed enrollment for the second pivotal trial, the COMP006 trial, and enrolled 585 participants. The COMP006 trial is comprised of three parts: Part A, which is blinded through 9 weeks, Part B which remains blinded through week 26, and Part C, which contains an open-label treatment part from weeks 26 to 52. To facilitate our plans to submit a proposal for a rolling submission and formal request for rolling review to the FDA, the Company has decided to unblind and disclose primary endpoint and safety data from Part A (9 weeks) of COMP006.

We plan to disclose primary endpoint and safety data from Part A (9 weeks) of the COMP006 trial at the same time that we disclose the 6-week and 26-week MADRS data and safety data from the COMP005 trial in the first quarter of 2026. In addition, we expect to disclose the 26-week data from the COMP006 trial in early third quarter of 2026.

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 (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. Based on the data from this trial, we are in the process of finalizing the design of a late-stage PTSD program.

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. Through September 30, 2025, PIPE Warrants were exercised for 3,752,050 ADS, resulting in $37.3 million in exercise proceeds. We will receive up to an additional approximately $122.4 million in gross proceeds if the PIPE Warrants are fully exercised. During the three months ended September 30, 2025, no PIPE warrants were 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 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 three months ended September 30, 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 $194.0 million and $111.8 million for the nine months ended September 30, 2025 and 2024, respectively. In addition, as of September 30, 2025, we had an accumulated deficit of $728.7 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 late-stage 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 substantial 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 September 30, 2025, we had cash and cash equivalents of $185.9 million. We believe that our existing cash and cash equivalents will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2027. 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 (whether from the continued government shutdown or reduced resources), 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 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. Currently, federal agencies in the United States are operating under a federal government shutdown due to expiration of the continuing resolution that expired on September 30, 2025 and certain federal agencies, such as the FDA, have had to furlough critical employees and stop critical activities, which may which may impact the timeliness of our interactions with the FDA. 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 or potential future therapeutic candidates.

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 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. For 2025, we expect reduced personnel expenses compared to 2024 as a result of the reorganization that we undertook in the fourth quarter of 2024. However, subject to further Phase 3 data next year, we anticipate future increases in both personnel and other expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing 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 seek to benefit 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 for the SME regime for the nine months ended September 30, 2025 and 2024. We expect such elements to be eligible for R&D incentives under the new merged regime in the year ended December 31, 2025 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 research and development 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 condensed 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 $339.7 million and $252.3 million as of December 31, 2024 and 2023, respectively, which is offset by a full valuation allowance.

During the nine months ended September 30, 2025 and 2024, we recorded a tax provision of $0.3 million and $0.6 million, respectively, related to the corporate income tax obligations of our operating company in the U.S., which generates a profit for tax purposes. During the three months ended September 30, 2025 and 2024, the Company recorded a tax benefit of $0.2 million and income tax provision of $0.2 million, respectively, related to the corporate income tax obligations of our operating company in the U.S., which generates a profit for tax purposes. The tax benefit of $0.2 million for the three months ended September 30, 2025, includes the Foreign Derived Intangible Income, or FDII, deduction arising during the period.

Results of Operations

Comparison for the Three and Nine months ended September 30, 2025 and ***2024***

The following table summarizes our results of operations (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2025	2024	Change	2025	2024	Change
OPERATING EXPENSES:						
Research and development	$ 27,325	$ 32,928	$ (5,603)	$ 88,530	$ 86,898	$ 1,632
General and administrative	13,211	14,968	(1,757)	44,555	42,893	1,662
Total operating expenses	40,536	47,896	(7,360)	133,085	129,791	3,294
Loss from operations	(40,536)	(47,896)	7,360	(133,085)	(129,791)	(3,294)
OTHER INCOME, NET:						
Fair value change of warrant liabilities	(101,318)	—	(101,318)	(84,398)	—	(84,398)
Benefit from R&D tax credit	3,924	4,084	(160)	16,659	10,894	5,765
Interest income	1,588	1,977	(389)	5,872	6,645	(773)
Foreign exchange (losses) gains	(883)	4,452	(5,335)	3,599	3,894	(295)
Interest expense	(1,105)	(1,137)	32	(3,380)	(3,347)	(33)
Other income	383	191	192	1,010	486	524
Total other income, net	(97,411)	9,567	(106,978)	(60,638)	18,572	(79,210)
Loss before income taxes	(137,947)	(38,329)	(99,618)	(193,723)	(111,219)	(82,504)
Income tax benefit (expense)	230	(173)	403	(261)	(571)	310
Net loss	$ (137,717)	$ (38,502)	$ (99,215)	$ (193,984)	$ (111,790)	$ (82,194)

Research and Development

Research and development expenses consist of the following (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2025	2024	Change	2025	2024	Change
Development expenses	$ 17,862	$ 22,647	$ (4,785)	$ 61,000	$ 54,628	$ 6,372
Personnel expenses	6,416	6,409	7	18,598	19,893	(1,295)
Non-cash share-based compensation expense	1,224	2,661	(1,437)	4,037	7,921	(3,884)
Facilities and other expenses	1,823	1,211	612	4,895	4,456	439
Total research and development expenses	$ 27,325	$ 32,928	$ (5,603)	$ 88,530	$ 86,898	$ 1,632

For the three months ended September 30, 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 development expenses primarily due to the termination of our discovery programs associated with the reorganization that took place in the fourth quarter of 2024; and
- a decrease in 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.

For the nine months ended September 30, 2025, the increase in research and development expenses, as compared to the same period in 2024, was primarily attributable to the following:

- an increase in development expenses associated with advancing our late-stage COMP360 clinical trials.

Partially 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.

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):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2025	2024	Change	2025	2024	Change
Legal and professional fees	$ 4,440	$ 4,393	$ 47	$ 17,171	$ 10,143	$ 7,028
Personnel expenses	4,780	5,169	(389)	14,459	16,325	(1,866)
Non-cash share-based compensation expense	1,984	2,313	(329)	6,702	7,103	(401)
Facilities and other expenses	2,007	3,093	(1,086)	6,223	9,322	(3,099)
Total general and administrative expenses	$ 13,211	$ 14,968	$ (1,757)	$ 44,555	$ 42,893	$ 1,662

For the three months ended September 30, 2025, the decrease in general and administrative expenses, as compared to the same period in 2024, was primarily attributable to the following:

- a decrease in facilities and other expenses as a result of lower insurance premiums and banking fees; and
- a decrease in personnel 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.

For the nine months ended September 30, 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 2025 Financing as well as expenses associated with consulting, accounting and legal advice.

Partially offset by:

- a decrease in personnel 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; and
- 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):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2025	2024	Change	2025	2024	Change
Fair value change of warrant liabilities	$ (101,318)	$ —	$ (101,318)	$ (84,398)	$ —	$ (84,398)
Benefit from R&D tax credit	3,924	4,084	(160)	16,659	10,894	5,765
Interest income	1,588	1,977	(389)	5,872	6,645	(773)
Foreign exchange (losses) gains	(883)	4,452	(5,335)	3,599	3,894	(295)
Interest expense	(1,105)	(1,137)	32	(3,380)	(3,347)	(33)
Other income	383	191	192	1010	486	524
Total other income, net	$ (97,411)	$ 9,567	$ (106,978)	$ (60,638)	$ 18,572	$ (79,210)

For the three months ended September 30, 2025, the decrease in other income, net as compared to the same periods 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 2025 Financing, including the exercise of 2,344,720 Pre-funded Warrants; and
- a decrease due to foreign exchange losses following remeasurement of foreign currency denominated assets and liabilities.

For the nine months ended September 30, 2025, the decrease in other income, net, as compared to the same periods 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 2025 Financing.
- a decrease in interest income primarily due to interest earned on lower cash deposit levels.

Partially offset by:

- an increase in the benefit from R&D tax credit due to higher R&D expenditures claimed at the enhanced research intensive rate in the current year as well as a resubmission of the Company's 2023 claim at the enhanced rate given clarity provided by HMRC in April 2025.

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 and we do not expect to generate revenue from sales of any therapeutic candidates in the near future, 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. Through September 30, 2025, PIPE Warrants were exercised for 3,752,050 ADS, resulting in $37.3 million in exercise proceeds. 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 2025 Financing in which it issued and sold ADSs and, in lieu of ADSs, Pre-funded Warrants to certain investors

along with accompanying 2025 ADS Warrants to purchase ADSs. 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. Through September 30, 2025, 2,344,720 Pre-funded Warrants were exercised.

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 footnotes to our condensed consolidated financial statements.

Cash Flows

The following table summarizes our cash flows for each of the periods (in thousands):

	Nine Months Ended September 30,		
	2025	2024	Change
Net cash used in operating activities	$ (119,452)	$ (77,429)	$ (42,023)
Net cash provided by financing activities	140,525	63,669	76,856
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(227)	464	(691)
Net increase in cash, cash equivalents and restricted cash	$ 20,846	$ (13,296)	$ 34,142

Net Cash Used in Operating Activities

Net cash used in operating activities increased during the nine months ended September 30, 2025, compared to the same period in 2024, primarily due to unfavorable working capital related activities of $45.36 million, as well as an increase of $85.5 million of non-cash adjustments, including the change in fair value of warrant liabilities of $84.4 million, which was offset by a $82.2 million increase in our net loss.

Net Cash Provided by Financing Activities

Net cash provided by financing activities increased during the nine months ended September 30, 2025, compared to the same period in 2024, primarily as a result of proceeds from the 2025 Financing for the issuance of ADSs and the Pre-funded Warrants of $140.4 million, partially offset by the proceeds from the issuance of ordinary shares to settle warrants exercised 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 late-stage development program 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 plans for NDA submission and commercial launch;
- initiate and advance a late-stage development program 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;
- may in the future invest in further discovery efforts and/or develop additional therapeutic candidates;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any therapeutic candidates for which we may obtain regulatory approval, including COMP360;
- advance our commercialization strategy;
- establish and expand the network of public healthcare institutions and private clinics that administer our investigational COMP360 psilocybin treatment if approved;
- seek regulatory approvals for any future therapeutic candidates that successfully complete clinical trials;
- 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 September 30, 2025, we had cash and cash equivalents of $185.9 million. We believe that our existing cash and cash equivalents will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2027. 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 NDA submission, including potential accelerated NDA submission, and related preparations for commercial launch;
- 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 nonclinical 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 new 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 to the size needed to prepare for the potential commercialization of our investigational COMP360 psilocybin treatment and future therapeutic candidates, including increases to personnel costs;
- the costs of developing sales and marketing capabilities to target public and private healthcare providers and clinic networks in major markets;
- the costs of training and qualifying healthcare professionals to monitor and safeguard participants receiving our investigational COMP360 psilocybin treatment in our Phase 3 program and other clinical trials;
- the costs of establishing and 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 digital technology solutions to improve the patient experience and therapeutic process via third-party vendors 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, and 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

During the first nine months of 2025, our significant accounting policies or critical accounting estimates have been updated to include warrant liabilities, as described below. For a complete discussion of our other significant accounting policies and critical accounting estimates, see the "Critical Accounting Policies and Significant Judgments and Estimates" section of the Management's Discussion and Analysis of Financial Condition and Results of Operation in our Form 10-K for the year ended December 31, 2024, which we filed with the SEC on February 27, 2025.

Warrant 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 condensed 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 condensed 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.

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 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in market risk exposures that affect the disclosures presented in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2024.

ITEM 4. CONTROLS AND PROCEDURES

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 September 30, 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.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended September 30, 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. 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 1A. RISK FACTORS

You should carefully consider the following risk factors as well as the other information included in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our condensed 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 $194.0 million and $111.8 million for the nine months ended September 30, 2025 and 2024. As of September 30, 2025, we had an accumulated deficit of $728.7 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 and ADS Warrants, which were issued in January 2025 and 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. 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 and commercial launch;
- initiate and advance a late-stage development program 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 a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any therapeutic candidates for which we may obtain regulatory approval, including COMP360;
- advance our commercialization strategy;
- establish and expand the network of public healthcare institutions and private clinics that 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.

We will need substantial additional funding to complete the development and commercialization of our investigational COMP360 psilocybin treatment or any future therapeutic candidates. 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.

We expect to require substantial additional funding in the future to sufficiently finance our operations and to complete the development and commercialization of our investigational COMP360 psilocybin treatment or any future therapeutic candidates. Under the terms of the 2025 ADS Warrants, following the time when the 2025 ADS Warrants become exercisable and provided the closing price of our ADSs is above the warrant exercise price of $5.7960 per ADS for at least three consecutive trading days, we may elect to force the exercise of some or all of the 2025 ADS Warrants. If we force the exercise of all of the 2025 ADS Warrants, we would receive an additional $203.2 million in gross proceeds. However, we cannot predict if we will have the ability to force the exercise of the 2025 ADS Warrants. We are only permitted to force the exercise of the 2025 ADS Warrants following the public release of the 26-week results from our COMP005 clinical study and only if the closing price of our ADSs is greater than the 2025 ADS Warrant exercise price of $5.7960 per ADS for each of the three consecutive trading days prior to the delivery of the forced exercise notice. Therefore, we have not included any anticipated proceeds from such exercises of the 2025 ADS Warrants in our estimate of our cash runway. In addition, if the outstanding 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 $185.9 million as of September 30, 2025, will enable us to fund our operating expenses and capital expenditure requirements into 2027. 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, the majority of which are subject to further Phase 3 data;
- the design, size and timing of the late-stage development program in PTSD that we plan to initiate;
- 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 to the size needed to prepare for the potential commercialization of our investigational COMP360 psilocybin treatment and any future therapeutic candidates, including increases to personnel costs;
- the costs of developing sales and marketing capabilities in the long-term 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 Phase 3 program and other clinical trials;
- the costs of establishing and 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, and 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, the volatile capital markets environment, lower prices for many securities, fluctuating inflation and interest rates, concerns about potential recessionary factors may affect our ability to raise additional funding, including through the exercise for cash of the 2025 ADS Warrants and/or 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 (whether from the continued government shutdown or reduced resources) 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 a minimum cash balance of $22.5 million 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 September 30, 2025, we had 12,324,700 outstanding PIPE Warrants. 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 our 2025 Financing, we issued and sold an aggregate of 35,059,448 2025 ADS Warrants which have an exercise price of $5.7960 per ADS. The 2025 ADS Warrants are not yet exercisable and will become exercisable following the public release of the 26-week results from our COMP005 clinical study. 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, in whole or in part, by delivering a notice of forced exercise to the holders if our ADS price is above the warrant exercise price, which is $5.7960, for the three prior consecutive trading days prior to the delivery of the forced exercise notice. Even though we have the right to force the exercise of the 2025 ADS Warrants, the 2025 ADS Warrants may never become exercisable and even if the 2025 ADS Warrants become exercisable, the closing price of our ADSs may never exceed the exercise price of the 2025 ADS Warrant for three consecutive trading days during the exercise period, in which case we would not be able to force the exercise of the 2025 ADS Warrants. In addition, there is no guarantee holders will elect to exercise the 2025 ADS Warrants, in the event we are not able to or choose not to force the exercise of such warrants. We believe that

whether the holders elect to exercise the 2025 ADS Warrants is 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 2025 ADS Warrants prior to their expiration. Thus, the 2025 ADS Warrants may expire unexercised and we may never receive any additional proceeds.

In addition, the PIPE Warrants and the 2025 ADS Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the PIPE Warrants and 2025 ADS Warrants, respectively, in which case we would not receive any additional proceeds. If the PIPE Warrants and the 2025 ADS Warrants are not exercised for cash, or only a portion of the PIPE Warrants or the 2025 ADS 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 2025 Financing, we issued and sold 11,044,720 Pre-funded Warrants, of which 8,700,000 remain outstanding as of September 30, 2025. Each Pre-funded Warrant will be exercisable until it is fully exercised and by means of 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 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 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 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 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 and/or the 2025 ADS 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, 2025 ADS Warrants and the Pre-funded Warrants were exercised, we would issue 56,178,370 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 a minimum cash balance of $22.5 million 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 and intend in the future to 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.

The remaining tranche of term loans under our Loan Agreement with Hercules, in an amount up to $20.0 million, is available solely at the lender's discretion and is only available during the interest-only period, which ends on January 2, 2026. If these conditions are met, the remaining tranche may be borrowed in drawings of a minimum of $5.0 million each. Without the satisfaction of certain customary conditions, we will not be eligible to draw additional funds under the remaining tranche. 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 remaining 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 June 30, 2023, we entered into a Loan Agreement with Hercules for an aggregate principal amount of up to $50.0 million, of which the first tranche of $30.0 million was funded at closing. 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 at least $22.5 million of cash in accounts subject to a control agreement in favor of Hercules during the period that commenced on July 1, 2024 and at all times thereafter, provided that if we have achieved certain performance milestones, the minimum cash covenant shall not apply on any day that our market capitalization is at least $750.0 million measured on a consecutive 15-calendar 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 an 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 completion of our Phase 3 trials in TRD and successful patient enrollment in and completion of 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 Phase 3 program and other 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**. If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the U.S., our contract manufacturers 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 additional 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 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 Phase 3 program and other clinical trials, including preparation, the COMP360 administration session, and post-administration follow-up (integration);
- 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 proposed amendments to the European Union regulations related to pharmaceutical product development and marketing currently under consideration, which, once approved, 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 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 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 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 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 June 2025, we reported top-line primary endpoint results from the COMP005 trial, which is our first Phase 3 trial in our Phase 3 program in TRD, and the full results and safety data from this Phase 3 trial in TRD or the results and safety data from the Phase 3 COMP006 trial, which is our second Phase 3 trial in TRD, may not be consistent with the preliminary or top-line 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 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 currently under consideration, which, once approved, 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 FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes.

We have in the past 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 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 FDA throughout the conduct of the Phase 3 trials and submitting a proposal for rolling submission and request for rolling review. 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 FDA grants our request for a rolling review, COMP360 may not experience a faster review or approval compared to conventional FDA procedures. 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, 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

psychological support provided with 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 clinical trial 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 planned 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 planned 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 planned 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. 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 FDA for review, successfully obtain FDA approval, secure federal and state rescheduling for COMP360, and build a sales and marketing organization before we can produce 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 REMS;
- 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 through 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 is expected take effect in 2028. 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 $339.7 million and $252.3 million as of December 31, 2024 and 2023, 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, 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, 2023 and before April 1, 2024, under the SME Program, we may be able to surrender the trading losses that arise from our qualifying R&D activities 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. For accounting periods starting on or after April 1, 2024, the SME and RDEC regimes have been merged, which will impact us for the first time from 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.

The SME Program, and the new merged scheme, incorporate 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 from April 1, 2023 onwards, which are approximately 27.0% for qualifying expenditure and approximately 17.5% for qualifying subcontracted expenditure (paid to an unconnected subcontractor) under the SME program. 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 year ended December 31, 2023, the Company was uncertain whether it would meet the R&D intensity condition and therefore be eligible for the enhanced effective rate due to uncertainties over the ability to net off an exchange gain and loss arising on an intercompany loan when calculating aggregate expenditure, which was not covered by HMRC guidance. It sought clarity from HMRC in the form of a non-statutory clearance and received a positive response in April 2025. Therefore for the year ended December 31, 2023 the Company filed a resubmission claim relating to the year ended December 31, 2023 at the enhanced rate, which resulted in an increase in its R&D tax relief claim of $4.0 million.

As the Company 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 to continue to be able to claim at the enhanced rate in that year, it must also be loss making and qualify as a small or medium sized enterprise (SME).

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 will therefore impact 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 expenditures.

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.

The UK tax authority, His Majesty's Revenue & Customs, or 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, 2024.

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, which 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; and 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.

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, 2024.

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.

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.

Laws similar to the CCPA have been passed or proposed in numerous other states, including Colorado, Virginia, Utah, Connecticut, New Jersey, New Hampshire and more. Such laws add complexity, vary requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states will make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Several states are also specifically regulating health 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, and a similar law is awaiting the governor's signature in New York. 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.

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 (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 and could potentially impact the UK's adequacy decision granted by the European Commission. The respective provisions and enforcement of the EU GDPR and UK GDPR continue to diverge, creating additional regulatory uncertainty. This evolving regulatory landscape could increase legal risk, complexity and cost to our handling of personal data and may require us to adapt our privacy and data security compliance programs to account for increasing 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, 2024.

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 most foreign countries, including many 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 psychological support, 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 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. 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 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, the EMA, 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 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 necessarily 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. 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. 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. For example, on October 28, 2024, our board of directors authorized a strategic reorganization, which included a reduction in workforce, including some senior management roles. This reorganization including first exploring the potential externalization of our digital technologies and associated employees and then executing a reduction in workforce for the digital technologies team in May 2025, has caused and may in the future cause additional attrition and affect employee morale. Additionally, as we are operating with fewer employees than we have in prior periods, we face additional risk that we might not be able to execute on our strategic plans which may have an adverse effect on our business, financial condition, and operating results. If we are not successful in managing these transitions or 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, 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 expansion of our operations may lead to significant costs and may divert our management and business development resources. 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 administering our treatments. 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 is expected to enroll approximately 240 adult patients. 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 Cybin Inc., and other psychedelic compounds to treat mental health illnesses, including TRD. Cybin is conducting a 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 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, EC 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 not be successful, 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, collect digital phenotyping information, and record and transcribe audio data. We use certain internally developed digital technologies in the conduct of our clinical trials and we continuously maintain, evaluate and improve the performance, security and reliability. In addition, we may rely significantly on third-parties in the future to provide us with digital technology services. 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. 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.

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, cybersecurityincidents, 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, 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 would 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. For example, at the onset of the COVID-19 pandemic, we paused the enrollment of new patients into our clinical trials. In the future, we could also experience 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 patients in 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 the sale of ADSs held by holders from our PIPE offering or the exercise of the 2025 ADS Warrants and/or the PIPE 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 October 31, 2025. 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.

Many 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. Whilst 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 a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2023 and we believe that we were not a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2024. However, no assurances regarding the determination of our PFIC status can be provided for the 2023 taxable year, the 2024 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" 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. 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 2024 taxable year. However, no assurances regarding the determination of our CFC status can be provided for the 2024 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.

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 (Hague Service Convention), to which the U.S. and the UK are both signatories. Whilst 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 the Company's 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 the Company. 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 the Company's place of central management and control will no longer be relevant in determining whether the Takeover Code applies to the Company. From

February 3, 2027, the Takeover Code will only apply to the Company 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.

Risks Related to Our Controls Over Financial Reporting

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. 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 reveal 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. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ADSs.

If we fail to maintain effective internal controls, we may be unable to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our ADS price.

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. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. 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. We cannot assure you that we will not identify other material weaknesses or deficiencies, which could negatively impact our results of operations in future periods.

More generally, if we are unable to meet the demands that have been placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results in future periods, or report them within the timeframes required by law or stock exchange regulations. Failure to comply with the Sarbanes-Oxley Act, when and as applicable, could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses or significant deficiencies, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities. 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.*"

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 cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information, and the trading price of our stock may decline.

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 and could in the future be adversely affected by general conditions in the global economy, geopolitics and in 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. For example, on April 16, 2025, the U.S. Department of Commerce announced an investigation under Section 232 of the Trade Expansion Act of 1962 into imports of pharmaceuticals and pharmaceutical ingredients and the impact of these imports on U.S. national security culminating in a decision by the President whether to take action to remedy any identified threats, including by imposing additional tariffs. The statute provides that the Commerce Department report must be completed within 270 days of initiation and that the President must decide whether to act within 90 days of receiving the report. 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 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, the turmoil in the banking system, such as the turmoil seen in early 2023 with the appointment of the FDIC as a receiver for several U.S. banks, and the announcement of the imposition of tariffs by the U.S. and other countries has in the past 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, the Trump administration, or any new administration have in the past and 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. Although we are still evaluating the impact of the OBBBA on our business, 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. 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. Currently, federal agencies in the United States are operating under a federal government shutdown due to expiration of the continuing resolution that expired on September 30, 2025 and certain federal agencies, such as the FDA and SEC, have had to furlough critical employees and stop critical activities. The duration of the current government shutdown is unknown. 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.

With the change in the U.S. presidential administration in 2025, there is substantial uncertainty as to whether and how 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. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidate. 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.

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 beginning on October 1, 2025, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Currently, federal agencies in the U.S. are operating under a federal government shutdown due to expiration of the continuing resolution that expired on September 30, 2025. The duration of the current government shutdown is unknown. Without appropriation of additional funding to federal agencies, our business operations relating to our product development activities for the U.S. market could be impacted.

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. Future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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.

While we have not, to our knowledge, experienced any such material system failure or security breach that caused interruptions to our operations to date, if such an 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 2. UNREGISTERED SALE OF EQUITY SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES

Issuer Purchases of Equity Securities

The following table summarizes the surrenders of our equity securities during the three months ended September 30, 2025:

Period	Total Number of Shares Purchased(a)	Average Price Paid per Share(a)	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Programs
July 1 to July 31, 2025	—	—	—	—
August 1 to August 31, 2025	6,366.00	$4.34	—	—
September 1 to September 30, 2025	—	—	—	—
Three Months Ended September 30, 2025	6,366.00	$4.34	—	—

(a) Represents ordinary shares surrendered to the Company to satisfy tax withholding obligations in connection with the vesting of equity awards under our equity incentive plans.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Rule 10b5-1 Trading Plans

During the three months ended September 30, 2025, none of our directors or executive officers adopted, modified, or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement” as such terms are defined in Item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

The documents listed in the Exhibit Index of this Quarterly Report on Form 10-Q are incorporated by reference or are filed with this Quarterly Report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

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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).				
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 Principal Financial Officer.				
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.)				

* Filed herewith

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Quarterly Report on Form 10-Q 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.

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: November 4, 2025

By: /s/ Kabir Nath
Kabir Nath
Chief Executive Officer
(Principal Executive Officer)

Date: November 4, 2025

By: /s/ Teri Loxam
Teri Loxam
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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 Quarterly Report on Form 10-Q 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: November 4, 2025

/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 Quarterly Report on Form 10-Q 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: November 4, 2025

/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 Quarterly Report on Form 10-Q of COMPASS Pathways plc for the period ended September 30, 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 Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of COMPASS Pathways plc.

Date: November 4, 2025

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 Quarterly Report on Form 10-Q of COMPASS Pathways plc for the period ended September 30, 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 Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of COMPASS Pathways plc.

Date: November 4, 2025

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.