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 March 31, 2022
OR
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

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)

+1 (646) 905-3974
(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, 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 42,511,357 shares of common stock outstanding as of May 6, 2022.

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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 10-Q are based upon information available to our management as of the date of this 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 investigational COMP360 psilocybin therapy, including statements regarding the timing of initiation and completion of trials or studies and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- our reliance on the success of our investigational COMP360 psilocybin therapy;
- the timing, scope or likelihood of regulatory filings and approvals;
- our expectations regarding the size of the eligible patient populations for COMP360 psilocybin therapy, 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 therapists to administer COMP360 psilocybin therapy;
- our ability to implement our business model and our strategic plans for our business and our investigational COMP360 psilocybin therapy;
- our ability to identify new indications for COMP360 beyond our current primary focuses on treatment-resistant depression, or TRD, and post-traumatic stress disorder, or PTSD;
- our ability to identify, develop or acquire digital technologies to enhance our administration of our investigational COMP360 psilocybin therapy;
- our ability to leverage our technology and drug development candidates to advance new psychedelic compounds in other areas of unmet mental health need;
- our ability to successfully establish and maintain Centres of Excellence and our ability to achieve our goals with respect to the Centre for Mental Health Research and Innovation;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the pricing, coverage and reimbursement of our investigational COMP360 psilocybin therapy, if approved;
- the scalability and commercial viability of our manufacturing methods and processes;
- the rate and degree of market acceptance and clinical utility of our investigational COMP360 psilocybin therapy, in particular, and psilocybin-based therapies, in general;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;

- our expectations regarding potential benefits of our investigational COMP360 psilocybin therapy and our therapeutic approach generally;
- our expectations around regulatory development paths and with respect to Controlled Substances Act designation;
- 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;
- regulatory developments in the United States, 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 estimates regarding expenses, capital requirements and needs for additional financing;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain qualified employees and key personnel;
- the effect of global financial, economic and geopolitical effects, including rising interest rates, foreign exchange fluctuations and inflation;
- the effect of the ongoing COVID-19 pandemic, including any current or future mitigation efforts and 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 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 10-Q and our other filings with 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 the securities laws of the United States, 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 mental health care 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;
- Failure to obtain the substantial additional funding we need to complete the development and commercialization of our investigational COMP360 psilocybin therapy or any future therapeutic candidates may force us to delay, limit or terminate certain or all of our product discovery, therapeutic development, research operations or commercialization efforts;
- Raising additional capital may cause dilution to holders of our ordinary shares or ADSs, restrict our operations or require us to relinquish rights to COMP360 or any future therapeutic candidates;
- We are dependent on the successful development of our investigational COMP360 psilocybin therapy. We cannot give any assurance that COMP360 will successfully complete clinical trials or receive regulatory approval, which is necessary before it can be commercialized;
- COMP360 is, and any future therapeutic candidates we may develop in the future 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, may adversely affect the results of our business operations and our financial condition, both during clinical development and post approval. In addition, during the review process of COMP360, and prior to approval, the US Food and Drug Administration, or FDA and/or other regulatory bodies may require additional data, including with respect to whether COMP360 has abuse potential, which may delay approval and any potential rescheduling process;
- Adverse publicity or public perception regarding psilocybin or our current or future investigational therapies using psilocybin may negatively influence the success of these therapies;
- Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of COMP360 psilocybin therapy or any future therapeutic candidates are prolonged or delayed, we or our current or future collaborators may be unable to obtain required regulatory approvals for, and therefore unable to commercialize, COMP360 psilocybin therapy or any future therapeutic candidates on a timely basis or at all;
- 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 psilocybin therapy 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;
- Research and development of drugs targeting the central nervous system are 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 therapies on our own or with suitable collaborators;
- The future commercial success of our investigational COMP360 psilocybin therapy or any future therapeutic candidates will depend on the degree of market access and acceptance of our potential therapies among healthcare professionals, patients, healthcare payors, health technology assessment bodies and the medical community at large;
- Our business and commercialization strategy depends on our ability to identify, qualify, prepare, certify and support third-party therapy sites offering any approved therapy and any inability to do this will limit our commercialization prospects and harm our business, financial condition and results of operations;

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

- Intellectual property rights of third parties could adversely affect our ability to develop or commercialize our investigational therapies, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our investigational therapies. 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;

- 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;

- Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our investigational COMP360 psilocybin therapy or any future therapeutic candidates and could have a material adverse effect on our business;

- We rely on third parties to supply and manufacture the psilocybin and psilocin incorporated in COMP360 and expect to continue to rely on third parties to supply and manufacture any of our future therapeutic candidates, and we will rely on third parties to manufacture these substances for commercial supply, if approved. If any third-party provider fails to meet its obligations to manufacture COMP360 or our future therapeutic candidates, or fails to maintain or achieve satisfactory regulatory compliance, the development of such substances and the commercialization of any therapies, if approved, could be stopped, delayed or made commercially unviable, 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. We do not sponsor these IISs, and we encourage the open publication of all IIS findings. Any failure by a third party to meet its obligations with respect to the clinical development of our investigational COMP360 psilocybin therapy or any of our 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 raise 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;

- A pandemic, epidemic, or outbreak of an infectious disease, or new variant of the ongoing COVID-19 pandemic, 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;

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

- 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;

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

- We previously identified and subsequently remediated material weaknesses in our internal control over financial reporting. We may identify future material weaknesses in our internal controls over financial reporting. If we are unable to remedy these material weaknesses, or if we fail to establish and maintain effective internal controls, we may be unable to produce accurate and timely 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.

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)

	March 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 243,684	$ 273,243
Restricted cash	104	104
Prepaid income tax	—	332
Prepaid expenses and other current assets	22,764	21,621
Total current assets	266,552	295,300
NON-CURRENT ASSETS:		
Investment	508	525
Property and equipment, net	415	398
Operating lease right-of-use assets	3,056	3,696
Deferred tax assets	1,232	766
Other assets	334	213
Total assets	$ 272,097	$ 300,898
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 2,054	$ 2,564
Accrued expenses and other liabilities	7,480	10,308
Operating lease liabilities - current	2,146	2,235
Total current liabilities	11,680	15,107
NON-CURRENT LIABILITIES		
Operating lease liabilities - non-current	843	1,379
Total liabilities	12,523	16,486
Commitments and contingencies (Note 12)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, £0.008 par value; 42,464,566 and 42,019,874 shares authorized, issued and outstanding at March 31, 2022 and December 31, 2021, respectively	440	435
Deferred shares, £21,921.504 par value; one share authorized, issued and outstanding at March 31, 2022 and December 31, 2021	28	28
Additional paid-in capital	448,271	444,750
Accumulated other comprehensive income	1,647	8,840
Accumulated deficit	(190,812)	(169,641)
Total shareholders' equity	259,574	284,412
Total liabilities and shareholders' equity	$ 272,097	$ 300,898

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 March 31,	
	2022	2021
OPERATING EXPENSES:		
Research and development	$ 15,362	$ 6,884
General and administrative	10,058	6,718
Total operating expenses	25,420	13,602
LOSS FROM OPERATIONS:	(25,420)	(13,602)
OTHER INCOME (EXPENSE), NET:		
Other income	134	1
Foreign exchange gains (losses)	1,333	(643)
Benefit from R&D tax credit	2,922	1,557
Total other income, net	4,389	915
Loss before income taxes	(21,031)	(12,687)
Income tax expense	(140)	(28)
Net loss	(21,171)	(12,715)
Other comprehensive (loss) income:		
Foreign exchange translation adjustment	(7,193)	1,988
Comprehensive loss	(28,364)	(10,727)
Net loss per share attributable to ordinary shareholders—basic and diluted	$ (0.50)	$ (0.35)
Weighted average ordinary shares outstanding—basic and diluted	42,036,563	36,569,290

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		DEFERRED SHARES £21,921.504 PAR VALUE		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL SHAREHOLDERS' EQUITY
	SHARES	AMOUNT	SHARES	AMOUNT	AMOUNT	AMOUNT	AMOUNT	AMOUNT
Balance at December 31, 2020	**35,930,331**	**$ 367**	**1**	**$ 28**	**$ 279,480**	**$ 14,585**	**$ (97,899)**	**$ 196,561**
Exercise of share options	581,328	6	—	—	992	—	—	998
Issuance of shares due to options exercised in previous year	232,227	3	—	—	(3)	—	—	—
Share-based compensation expense	—	—	—	—	1,666	—	—	1,666
Unrealized gain on foreign currency translation	—	—	—	—	—	1,988	—	1,988
Net loss	—	—	—	—	—	—	(12,715)	(12,715)
Balance at March 31, 2021	**36,743,886**	**$ 376**	**1**	**$ 28**	**$ 282,135**	**$ 16,573**	**$ (110,614)**	**$ 188,498**
Balance at December 31, 2021	**42,019,874**	**$ 435**	**1**	**$ 28**	**$ 444,750**	**$ 8,840**	**$ (169,641)**	**$ 284,412**
Exercise of share options	376,158	4	—	—	393	—	—	397
Vesting of restricted stock units	68,534	1	—	—	—	—	—	1
Share-based compensation expense	—	—	—	—	3,128	—	—	3,128
Unrealized loss on foreign currency translation	—	—	—	—	—	(7,193)	—	(7,193)
Net loss	—	—	—	—	—	—	(21,171)	(21,171)
Balance at March 31, 2022	**42,464,566**	**$ 440**	**1**	**$ 28**	**$ 448,271**	**$ 1,647**	**$ (190,812)**	**$ 259,574**

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)

	Three Months Ended March 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (21,171)	$ (12,715)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	54	35
Non-cash gain on foreign currency remeasurement	(219)	(171)
Non-cash share-based compensation	3,128	1,666
Non-cash lease expenses	550	269
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(1,386)	(2,751)
Deferred and prepaid tax assets	(135)	—
Other assets	(311)	7
Operating lease liabilities	(538)	(269)
Accounts payable	(445)	2,432
Accrued expenses and other liabilities	(2,650)	(2,281)
Net cash used in operating activities	(23,123)	(13,778)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(82)	(70)
Net cash used in investing activities	(82)	(70)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of options	189	998
Payment of deferred offering costs	—	(40)
Net cash provided by financing activities	189	958
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(6,543)	2,083
Net decrease in cash, cash equivalents and restricted cash	(29,559)	(10,807)
Cash, cash equivalents and restricted cash, beginning of the period	273,347	190,356
Cash, cash equivalents and restricted cash, end of the period	243,788	$ 179,549
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Proceeds from exercise of options not yet received and recorded in other current assets	$ 208	$ —
Deferred offering costs included in prepaid expenses and other current assets	$ 835	$ 524
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 1,049

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

	Three Months Ended March 31,	
	2022	2021
Cash and cash equivalents	$ 243,684	$ 179,520
Short-term restricted cash	104	29
Total cash, cash equivalents and restricted cash	$ 243,788	$ 179,549

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 mental health care company dedicated to accelerating patient access to evidence-based innovation in mental health. The Company is developing psilocybin therapy through late-stage clinical trials in Europe and North America for patients with treatment-resistant depression.

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

The Company has funded its operations primarily with proceeds from the sale of its convertible preferred shares, the issuance of convertible notes, and more recently through the sale of American Depository Shares, or ADSs, in connection with the September 2020 IPO and its $154.8 million May 2021 follow-on offering. On October 8, 2021, the Company entered into a Sales Agreement with Cowen and Company, LLC ("Cowen"), under which the Company may issue and sell from time to time up to $150.0 million of its ADSs, each representing one ordinary share, through Cowen as the sales agent. Sales of the Company's ADSs, if any, will be made at market prices. The Company has not yet sold any ADSs under this at-the-market offering. The Company has incurred recurring losses since its inception, including net losses of $21.2 million and $12.7 million for the three months ended March 31, 2022 and 2021, respectively. In addition, as of March 31, 2022, the Company had an accumulated deficit of $190.8 million. The Company expects to continue to generate operating losses for the foreseeable future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

The Company believes the cash and cash equivalents on hand as of March 31, 2022 of $243.7 million will be sufficient to fund its operating expenses and capital expenditure requirements into 2024. There can be no assurance that the Company will be able to secure debt or equity financing or generate revenue on terms acceptable to the Company, on a timely basis or at all. 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.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying 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, 2021, 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 as of March 31, 2022, the results of its operations and comprehensive loss and its cash flows for the three months ended March 31, 2022 and 2021.

The results for the three months ended March 31, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022, any other interim periods, or any future years or periods. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2021, 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 24, 2022.

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.

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, the prepayment and accrual for research and development expenses, discount rates for leases, the fair value of ordinary shares before IPO, share-based compensation and the research and development tax credit. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. The Company does not currently have any cash equivalents.

Restricted Cash

Restricted cash as of March 31, 2022 and December 31, 2021 represents a collateral deposit for employee credit cards.

Investment

The investment does not have readily determinable fair value and it is carried at cost, less impairment, adjusted for subsequent changes to estimated fair value up to the original cost, in circumstances where the Company does not have the ability to exercise significant influence or control over the operating and financial policies of the investee.

Fair Value of Measurements

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.

- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques

The carrying amounts reflected in the condensed consolidated balance sheets for the Company's cash and cash equivalents, restricted cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate fair value because of the short-term nature of these instruments.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk consist primarily of cash and cash equivalents. The Company places cash and cash equivalents in established financial institutions. The Company has no significant off-balance-sheet risk or concentration of credit risk, such as foreign exchange contracts, options contracts, or other foreign hedging arrangements.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets, which are as follows:

	Estimated Useful Life
Lab equipment	5 years
Office equipment	3-5 years
Furniture and fixtures	3 years
Leasehold improvements	Shorter of useful life or remaining lease term

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the condensed consolidated statements of operations and comprehensive loss. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of Long-Lived Assets

The Company evaluates assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. The Company has not recognized any impairment losses or had triggering events related to its underlying assets for the three months ended March 31, 2022 and 2021.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision maker, the Company's Chief Executive Officer, views the Company's operations and manages its business as a single operating segment; however, the Company operates in two geographic regions: the United Kingdom, or UK, and the United States. The Company's fixed assets are primarily located in the UK. The Company's singular concentration is focused on accelerating patient access to evidence-based innovation in mental health.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, share-based compensation and benefits, travel, and external costs of outside vendors engaged to conduct clinical development activities, clinical trials and the cost to manufacture clinical trial materials.

Research Contract Costs, Prepayments and Accruals

The Company has entered into various research and development-related contracts with research institutions and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records prepayments and accruals for estimated ongoing research costs and receives updated estimates of costs and amounts owed on a monthly basis from its third-party service providers. When evaluating the adequacy of the prepayments and accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted cost estimates from third-party service providers. Estimates are made in determining the prepaid and accrued balances at the end of any reporting period. Actual results could

differ from the Company's estimates. The Company's historical prepayments and accrual estimates have not been materially different from the actual costs.

Share-Based Compensation

The Company accounts for all share-based payment awards granted to employees and non-employees as share-based compensation expense at fair value. The Company grants equity awards under its share-based compensation programs, which may include share options and restricted ordinary shares. The measurement date for employee and non-employee awards is the date of grant, and share-based compensation costs are recognized as expense over the requisite service period, which is the vesting period, on a straight-line basis. Share-based compensation expense is classified in the accompanying condensed consolidated statements of operations and comprehensive loss based on the function to which the related services are provided. The Company recognizes share-based compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur.

On October 1, 2021, the Company launched the Share Incentive Plan, or the SIP, and Employee Share Purchase Plan, or the ESPP, through which employees can purchase shares at a discounted price. We estimated the fair value of stock options and shares to be issued under the SIP and ESPP using the Black-Scholes option-pricing model on the date of grant. The fair value of shares to be issued under these plans are recognized and amortized on a straight-line basis over the purchase period, which is generally six months.

There have been no performance conditions attached to the share options granted by the Company to date. The fair value of each share option grant is estimated on the date of grant using the Black-Scholes option pricing model. See Note 9 for the Company's assumptions used in connection with option grants made during the periods covered by these condensed consolidated financial statements. Assumptions used in the option pricing model include the following:

Expected volatility. The Company lacks sufficient company-specific historical and implied volatility information for its ordinary shares. Therefore, it estimates its expected share volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price.

Expected term. The expected term of the Company's share options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options.

Risk-free interest rate. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods that are approximately equal to the expected term of the award.

Expected dividend. Expected dividend yield of zero is based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future.

Fair value of ordinary shares. Given the absence of an active market for the Company's ordinary shares prior to the IPO, the Company and the board of directors of the Company, the members of which the Company believes have extensive business, finance, and venture capital experience, were required to estimate the fair value of the Company's ordinary shares at the time of each grant of a stock-based award. The grant date fair value of restricted ordinary shares and share options were calculated based on the grant date fair value of the underlying ordinary shares. The Company calculated the fair value of the ordinary shares in accordance with the guidelines in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the "Practice Aid". The Company's valuations of ordinary shares were prepared using a market approach, based on precedent transactions in the shares, to estimate the Company's total equity value using an option-pricing method, or OPM. After the Company's IPO, the fair value of ordinary shares is determined by reference to the closing price of ADSs on the Nasdaq Global Select Market on the day prior to the grant.

The OPM derives an equity value such that the value indicated for ordinary shares is consistent with the investment price, and it provides an allocation of this equity value to each of the Company's securities. The OPM treats the various classes of ordinary shares as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the ordinary shares have value only if the funds available for distribution to shareholders exceeded the value of the share liquidation preferences of ordinary shares with senior preferences at the time of the liquidity event. Key inputs into the OPM calculation included the risk-free rate, expected time to liquidity and volatility. A reasonable discount for lack of marketability was applied to the total equity value to arrive at an estimate of the total fair value of equity on a non-marketable basis.

Leases

Effective January 1, 2021, the Company adopted ASU No. 2016-02, Leases (Topic 842), as amended, using the modified retrospective method and utilizing the effective date as its date of initial application, with prior periods presented in accordance with previous guidance under ASC 840, Leases, or ASC 840. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable. Entities may elect not to separate lease and non-lease components. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and to allocate all the contract consideration to the lease component only. All the Company's leases are classified as operating leases.

Lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts has not been readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. As the Company does not have a rating agency-based credit rating, quotes were obtained from lenders to establish an estimated secured rate to borrow based on Company and market-based factors as of the respective lease measurement dates. The Company has elected not to recognize leases with an original term of one year or less on the balance sheet. The Company typically only includes the non-cancelable lease term in its assessment of a lease arrangement unless there is an option to extend the lease that is reasonably certain of exercise. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

Operating lease costs are recognized on a straight-line basis over the lease term, and they are categorized within research and development and general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss. The operating lease cash flows are categorized under net cash used in operating activities in the condensed consolidated statements of cash flows.

Foreign Currency Translation

The Company maintains its condensed consolidated financial statements in its functional currency, which is Pound Sterling. Monetary assets and liabilities denominated in currencies other than the functional currency are translated into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. The Company recorded foreign exchange gains of approximately $1.3 million and foreign exchange losses of approximately $0.6 million for the three months ended March 31, 2022 and 2021, respectively. These gains and losses arise from U.S. dollars which are held in a financial institution in one of our UK subsidiaries that has a functional currency of Pound Sterling.

For financial reporting purposes, the condensed consolidated financial statements of the Company have been presented in the U.S. dollar, the reporting currency. The financial statements of entities are translated from their functional currency into the reporting currency as follows: assets and liabilities are translated at the exchange rates at the balance sheet dates, expenses and other income (expense), net are translated at the average exchange rates and shareholders' equity is translated based on historical exchange rates. Translation adjustments are not included in determining net loss but are included as a foreign exchange adjustment to other comprehensive income, a component of shareholders' equity.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the condensed consolidated financial statements or in its tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the condensed consolidated financial statements and tax basis of assets and liabilities substantively enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that deferred tax assets will be recovered in the future to the extent management believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a

charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes in the condensed consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed as the amount of benefit to recognize in the condensed consolidated financial statements. The amount of benefit that may be used is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate, as well as the related net interest and penalties. As of March 31, 2022 and December 31, 2021, the Company has not identified any uncertain tax positions.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying condensed consolidated statements of operations and comprehensive loss. As of March 31, 2022 and December 31, 2021 no accrued interest or penalties are included on the related tax liability line in the condensed consolidated balance sheets.

Benefit from Research and Development Tax Credit

As a company that carries out extensive research and development activities, the Company benefits from the UK research and development tax credit regime under the scheme for small or medium-sized enterprises, or SME. Under the SME regime, the Company is able to surrender some of its trading losses that arise from qualifying research and development activities for a cash rebate of up to 33.35% of such qualifying research and development expenditure. The Company meets the conditions of the SME regime. Qualifying expenditures largely comprise employment costs for research staff, consumables, outsourced contract research organization costs and utilities costs incurred as part of research projects. Certain subcontracted qualifying research and development expenditures are eligible for a cash rebate of up to 21.67%. A large portion of costs relating to research and development, clinical trials and manufacturing activities are eligible for inclusion within these tax credit cash rebate claims.

The Company is subject to corporate taxation in the UK. Due to the nature of the business, the Company has generated losses since inception. The benefit from research and development, (“ R&D”), tax credits is recognized in the condensed consolidated statements of operations and comprehensive loss as a component of other income (expense), net, and represents the sum of the research and development tax credits recoverable in the UK.

The UK research and development tax credit is fully refundable to the Company and is not dependent on current or future taxable income. As a result, the Company has recorded the entire benefit from the UK research and development tax credit as a benefit which is included in net loss before income tax and accordingly, not reflected as part of the income tax provision. If, in the future, any UK research and development tax credits generated are needed to offset a corporate income tax liability in the UK, that portion would be recorded as a benefit within the income tax provision and any refundable portion not dependent on taxable income would continue to be recorded within other income (expense), net.

The Company may not be able to continue to claim research and development tax credits under the SME regime in the future because it may no longer qualify as a small or medium-sized company. In addition, the EU State Aid cap limits the total aid claimable in respect of a given project to €7.5 million which may impact the Company's ability to claim R&D tax credits in future. Further, the U.K. Finance Act of 2021 introduced a cap on payable credit claims under the SME Program in excess of £20,000 with effect from April 2021 by reference to, broadly, three times the total Pay As You Earn, or PAYE, and National Insurance Contributions, or 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 research and development expenditure in respect of connected parties, which does not exceed 15% of the total claimed. If such exception does not apply, this could restrict the amount of payable credit that we claim.

Unsurrendered UK losses may be carried forward indefinitely to be offset against future taxable profits, subject to numerous utilization criteria and restrictions. The amount that can be offset each year is limited to £5.0 million plus an incremental 50% of UK taxable profits.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in shareholders’ equity that result from transactions and economic events other than those with shareholders. For the three months ended March 31, 2022 and 2021, the component of accumulated other comprehensive loss is foreign currency translation adjustment.

Net Loss per Share

The Company has reported losses since inception and has computed basic net loss per share attributable to ordinary shareholders by dividing net loss attributable to ordinary shareholders by the weighted-average number of ordinary shares outstanding for the period, without consideration for potentially dilutive securities. The Company computes diluted net loss per ordinary share after giving consideration to all potentially dilutive ordinary shares, including unvested restricted shares and outstanding options. Because the Company has reported net losses since inception, these potential ordinary shares have been anti-dilutive and basic and diluted loss per share were the same for all periods presented.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standard Board, or the FASB, issued ASU No. 2016-02, Leases (Topic 842), as subsequently amended, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors), and replaces the existing guidance in ASC 840. The Company lost its Emerging Growth Company status on December 31, 2021 and adopted Topic 842 during the year-ended December 31, 2021, with an effective adoption date of January 1, 2021. Interim periods previously issued for fiscal year 2021 were reported under the legacy leasing guidance of ASC 840. The Company has elected to adopt ASC 842 by utilizing the effective date method, which resulted in a cumulative-effect adjustment to the Company's consolidated balance sheets at January 1, 2021. The Company has elected to apply the package of three expedients to all of its leases requiring (1) no reassessment of whether any expired or existing contracts are or contain leases, (2) the lease classification of any expired or existing leases, or (3) the capitalization of initial direct costs for any existing leases.

Adoption of this standard resulted in the recording of operating lease right-of-use assets and current operating lease liabilities of $1.0 million, on the Company's balance sheet on the effective date. The adoption of the standard did not have a material effect on the Company's statements of operations and comprehensive loss, statements of cash flows or accumulated deficit. Refer to Note 11 for right-of-use assets and liabilities recorded during the period ended March 31, 2022.

In December 2019, the FASB issued Accounting Standard Update, or ASU, 2019-12, "Income Taxes - Simplifying the Accounting for Income Taxes (Topic 740)," or ASU 740, which simplifies the accounting for income taxes. The new guidance removes certain exceptions to the general principles in ASC 740 such as recognizing deferred taxes for equity investments, the incremental approach to performing intra-period tax allocation and calculating income taxes in interim periods. The standard also simplifies accounting for income taxes under U.S. GAAP by clarifying and amending existing guidance, including the recognition of deferred taxes for goodwill, the allocation of taxes to members of a consolidated group and requiring that an entity reflect the effect of enacted changes in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. This guidance is effective for annual periods beginning after December 15, 2020, and interim periods thereafter; however, early adoption is permitted. The Company adopted this ASU as of January 1, 2021 and it has had no material impact on the condensed consolidated financial statements.

3. Fair Value Measurements

There are no financial instruments measured at fair value on a recurring basis as of March 31, 2022 and December 31, 2021. Management believes that the carrying amounts of the Company's condensed consolidated financial instruments, including cash and cash equivalents, restricted cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate fair value due to the short-term nature of those instruments.

4. Investment

On March 6, 2020, the Company made a strategic investment of $0.5 million to acquire an 8% (on a fully diluted basis) shareholding in Delix Therapeutics, Inc., a drug discovery and development company researching novel small molecules for use in Central Nervous System, or CNS, indications. The Company's investment in Delix Therapeutics, Inc. does not provide it with significant influence over the investee. The investment does not have a readily determinable fair value and therefore will be measured at cost minus impairment adjusted by observable price changes in orderly transactions for the identical or a similar investment of the same issuer. This investment will be measured at fair value on a nonrecurring basis when there are events or changes in circumstances that may have a significant adverse effect. An impairment loss is recognized in the condensed consolidated statements of operations and comprehensive loss equal to the amount by which the carrying value exceeds the fair value of the investment. As of March 31, 2022, no impairment loss was recognized.

5. Prepaid Expenses and Other Current Assets

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

	March 31, 2022	December 31, 2021
UK R&D tax credit	$ 12,178	$ 9,587
Prepaid insurance premium	2,117	3,359
Prepaid research and development	4,618	4,562
VAT recoverable	1,424	1,629
Deferred offering costs	817	840
Security deposit	276	274
Other current assets	1,334	1,370
	$ 22,764	$ 21,621

6. Property and Equipment, Net

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

	March 31, 2022	December 31, 2021
Lab equipment	$ 360	$ 370
Office equipment	272	315
Furniture and fixtures	63	65
Leasehold improvements	5	6
	700	756
Less: accumulated depreciation	(285)	(358)
	$ 415	$ 398

Depreciation and amortization expense were less than $0.1 million for the three months ended March 31, 2022 and 2021 respectively.

7. Accrued Expenses and Other Liabilities

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

	March 31, 2022	December 31, 2021
Accrued research and development expense	$ 1,688	$ 3,043
Accrued professional expenses	1,761	1,386
Accrued compensation and benefit costs	2,158	5,018
Payroll tax payable	708	593
Income taxes payable	207	—
Other liabilities	958	268
	$ 7,480	$ 10,308

8. Ordinary Shares

During the three months ended March 31, 2022, the Company issued in total 376,158 ordinary shares to settle share options exercised by employees and non-employees compared to 813,555 in the three months ended March 31, 2021. Of the shares issued in the three months ended March 31, 2021, 232,227 were related to options exercised in 2020 for which shares were delivered in 2021.

During the three months ended March 31, 2022, a total of 68,534 ordinary shares were issued in settlement of restricted share units, of which 10,659 vested and were issued during the three months ended March 31, 2022 and 57,875 vested but had not been issued at December 31, 2021. No restricted share units vested or were issued in the three months ended March 31, 2021.

Each ordinary share entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Ordinary shareholders are entitled to receive dividends, if any, as may be declared by the board of directors. Through March 31, 2022, no cash dividends had been declared or paid by the Company.

9. Share-Based Compensation

2017 Equity Incentive Plan

Under the Company's shareholder and subscription agreements, the Company is authorized to issue restricted shares, restricted share units, as well as options, as incentives to its employees, non-employees and members of its board of directors. To the extent such incentives are in the form of share options, the options are granted pursuant to the terms of the 2017 Equity Incentive Plan, or the 2017 Plan. In July 2019, the Company's board of directors adopted the 2017 Plan. The 2017 Plan provides for the grant of Enterprise Management Incentive, or EMI, options, to its UK employees, for the grant of options to its U.S. employees and non-employees of the Company. The 2017 Plan is administered by the board of directors.

As of March 31, 2022, the Company was authorized under the shareholder agreements to issue a total of 13,601,246 ordinary shares, including shares underlying options granted pursuant to the 2017 Plan. Forfeitures are accounted for as they occur. As of March 31, 2022, there were 533,779 shares available for issuance as incentives to the Company's employees and directors, which includes shares underlying options that may be granted from time to time subsequent to March 31, 2022 under the terms of the 2017 Plan.

Options granted under the 2017 Plan, typically vest over a three or four-year service period with 33.3% and 25% respectively, of the award vesting on the first anniversary of the commencement date and the balance vesting monthly over the remaining years. Restricted share units granted under the 2017 Plan, typically vest over a four-year service period with 25% of the award vesting on the first anniversary of the commencement date.

The options granted before June 30, 2020 were subject to 100% vesting upon the date of the listing of the Company's ordinary shares on any stock exchange. The options granted on June 30, 2020 were subject to 25% vesting upon the earlier occurrence of (i) the one year anniversary of the date of grant, or (ii) the date of the listing of the Company's ordinary shares on any stock exchange. Upon completion of the IPO, 866,268 options vested due to the accelerated vesting and a total of $3.5 million was immediately recognized in share-based compensation expense, including $1.4 million in research and development expenses and $2.1 million in general and administrative expenses.

The options granted on June 30, 2020 are subject to 25% vesting upon the earlier occurrence of (i) the one year anniversary of the date of grant, or (ii) the date of the listing of the Company's ordinary shares on any stock exchange, followed by straight line vesting for three years for the remaining 75% of the allocation until vested in full.

The restricted share units granted on June 30, 2020 are subject to 25% vesting upon the earlier of (i) the one year anniversary of the date of grant, or (ii) the first day following the six-month anniversary of the listing of the Company's ordinary shares on any stock exchange on which the closing price of the shares is 20% higher than the listing price for at least five consecutive trading days. Options granted under the 2017 Plan generally expire 10 years from the date of grant.

2020 Employee Share Purchase Plan

The Company's 2020 Employee Share Purchase Plan, "(the ESPP)", was adopted by the Board in September 2020 and approved by shareholders in September 2020 and became effective upon the effectiveness of the Company's Registration Statement on Form F-1 in connection with the IPO. The ESPP initially reserves and authorizes the issuance of up to a total of 340,053 ordinary shares to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022 and each January 1 thereafter through January 1, 2022, by the lesser of (i) 1% of the outstanding number of ordinary shares on the immediately preceding December 31 or (ii) 510,058 ordinary shares. The number of shares reserved under the ESPP is subject to change in the event of a share split, share dividend or other change in our capitalization.

On October 1, 2021, the Company launched the SIP and the ESPP, through which employees can purchase shares at a discounted price. At the end of six months, shares will automatically be purchased at the lower of the opening and closing price of the shares for the saving period minus a 15% discount.

2020 Share Option Plan

In September 2020, the Company's board of directors adopted, and the Company's shareholders approved, the 2020 Share Option Plan, or (the "2020 Plan"), which became effective upon the effectiveness of the Company's Registration Statement on Form F-1 in connection with the IPO. The 2020 Plan allows the compensation and leadership development committee to make equity-based and cash-based incentive awards to the Company's officers, employees, directors and other key persons (including consultants).

Options granted under the 2020 Plan generally expire 10 years from the date of grant and typically vest over a 4 year service period with 25% of the vesting on the first anniversary of the commencement date and the balance vesting monthly over the remaining years.

The Company initially reserved 2,074,325 of its ordinary shares for the issuance of awards under the 2020 Plan. The 2020 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by up to 4% of the outstanding number of ordinary shares on the immediately preceding December 31, or such lesser number of shares as determined by our compensation and leadership development committee. This number is subject to adjustment in the event of a sub-division, consolidation, share dividend or other change in our capitalization. The total number of ordinary shares that may be issued under the 2020 Plan was 3,755,119 shares as of March 31, 2022, of which 1,015,317 shares remained available for future grant.

The options granted in February 2022 under the 2020 Plan to employees generally expire 10 years from the date of grant. There are three potential vesting conditions for the February 2022 grants including: i) 25% per year over four year service period, ii) four year service period with 25% of the vesting on the first anniversary of the commencement date and the balance vesting monthly over the remaining years; and iii) monthly vesting over four year service period.

During the three months ended March 31, 2022 and 2021, the Company granted options to purchase 1,111,569 and 210,080 ordinary shares to employees and non-employees, respectively.

Restricted Share Units

A summary of the changes in the Company's unvested restricted share units during the three months ended March 31, 2022 are as follows:

	Number of Shares		Weighted Average Grant Date Fair Value
Unvested and Outstanding as of December 31, 2021	115,140	$	10.19
Granted	92,590	$	13.56
Vested	(10,659)	$	10.60
Forfeited	—	$	—
Unvested and Outstanding as of March 31, 2022	197,071	$	12.69

As of March 31, 2022 and March 31 2021, there was $2.3 million and $1.9 million of unrecognized compensation cost related to unvested restricted share units, respectively, which is expected to be recognized over a weighted-average period of 3.20 years and 3.10 years, respectively. The exercise price of restricted share units is at a nominal value less than £0.01 per share.

Share Options

The following table summarizes the Company's share options activity for the three months ended March 31, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	3,915,503	$ 13.53	8.64	$ 51,162
Granted	1,111,569	$ 14.81		
Exercised	(376,158)	$ 1.00		
Forfeited	(91,802)	$ 13.40		
Outstanding as of March 31, 2022	4,559,112	$ 14.59	8.79	$ 24,245
Exercisable as of March 31, 2022	1,992,397	$ 4.86	8.11	$ 20,495
Unvested as of March 31, 2022	2,566,715	$ 21.57	9.32	$ 3,750

The aggregate intrinsic value of options exercised during the three months ended March 31, 2022 and 2021 was $4.9 million and $26.1 million, respectively.

The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Company's ordinary shares for those share options that had exercise prices lower than the fair value of the Company's ordinary shares.

The weighted average grant-date fair value of share options granted was $11.38 and $26.73 per share during the three months ended March 31, 2022, and 2021, respectively.

As of March 31, 2022 and 2021, there was $35.2 million and $21.6 million of unrecognized compensation cost related to unvested share options, which is expected to be recognized over a weighted-average period of 3.18 years and3.37 years, respectively.

Share Option Valuation

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the share options granted to employees and directors during the three months ended March 31, 2022, and 2021 were as follows:

	Three Months Ended March 31,	
	2022	2021
Expected option life (years)	5.88 years	6.07 years
Expected volatility	80.20 %	67.80 %
Risk-free interest rate	1.65 %	0.72 %
Expected dividend yield	— %	— %
Fair value of underlying ordinary shares	$ 15.98	$ 44.03

Share-based Compensation Expense

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

	Three Months Ended March 31,	
	2022	2021
Research and development	1,792	801
General and administrative	1,336	865
Total stock based compensation expense	$ 3,128	$ 1,666

10. Net Loss Per Share

Basic and diluted net loss per share attributable to ordinary shareholders was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2022	2021
Numerator		
Net loss	$ (21,171)	$ (12,715)
Net loss attributable to ordinary shareholders - basic and diluted	$ (21,171)	$ (12,715)
Denominator		
Weighted-average number of ordinary shares used in net loss per share - basic and diluted	42,036,563	36,569,290
Net loss per share - basic and diluted	$ (0.50)	$ (0.35)

The Company's potentially dilutive securities, which include unvested ordinary shares, unvested restricted share units, and options granted, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of ordinary shares outstanding used to calculate both basic and diluted net loss per share attributable to ordinary shareholders is the same. The Company excluded the following potential ordinary shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to ordinary shareholders for the three months ended March 31, 2022, and 2021 because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2022	2021
Unvested ordinary shares	—	5,503
Unvested restricted share units	197,071	217,482
Share options	4,559,112	4,026,508
	4,756,183	4,249,493

11. Right of use of assets:

Eastbourne Terrace, London, UK

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

New York, NY

In May 2019, the Company entered into a lease with BioLabs for 200 rentable square feet of office space at 180 Varick Street, New York, New York 10014, United States. The lease is cancellable with 30 days' notice. This lease is accounted for as a short-term lease as the Company is not reasonably certain to extend the lease beyond twelve months and is therefore not recognized on the Company's condensed consolidated balance sheets.

Soho, London, UK

In July 2021, the Company entered into a two-year operating lease with Fora Space Limited commencing on September 1, 2021. The noncancellable term is 24 months and there is no option to extend the lease. The recurring residency fee per month is £136,200, and the Company paid a refundable deposit of £136,200 at the execution of the agreement. Additionally, at the start of each calendar year, the monthly residency fee will be subject to an automatic inflation linked increase of the previous years' amount.

San Francisco, CA

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

Denmark Hill, London, UK

In March 2022, the Company entered into an agreement for a lease with South London and Maudsley NHS Foundation Trust for land and buildings at 5 Windsor Walk, Maudsley Hospital, Denmark Hill, London, UK. The lease is currently expected to commence on May 15, 2022 and has a contractual term of five years. The rent will be £180,000 per year, with no deposit payable, and payment dates occurring once per quarter.

The following table summarizes our costs included in our condensed consolidated statements of operations and comprehensive loss related to right of use lease assets we have entered into through March 31, 2022 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Lease cost		
Operating lease cost	$ 560	$ 269
Variable lease cost	—	(45)
Short-term lease cost	86	86
	$ 646	$ 310
Other information:		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating leases	$ 578	$ 269
Weighted average remaining lease term (in years)	0.92	0.75
Weighted average discount rate	4.67 %	5.00 %

The following table summarizes the future minimum lease payments due under operating leases as of March 31, 2022, which does not include the Denmark Hill lease commencing in May 2022 (in thousands):

	March 31, 2022
2022	$ 1,658
2023	1,430
Total lease payments	$ 3,088
Less: imputed interest	(99)
Total	$ 2,989

12. 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 March 31, 2022, or 2021.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid

any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its Articles of Association, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date, and the Company has director and officer insurance that may enable it to recover a portion of any amounts paid for future potential claims.

13. Related Party Transactions

The Company receives accounting and professional services from Tapestry Networks, Inc., or Tapestry, a company affiliated with a director of the Company and the Company's Chief Executive Officer, from time to time as needed. The Company recorded accounting and professional fees of less than $0.1 million and $0.1 million for the three months ended March 31, 2022 and 2021. As of March 31, 2022 and December 31, 2021, the Company had less than $0.1 million outstanding to Tapestry.

14. Employee Benefit Plans

In the UK, the Company makes contributions to private defined contribution pension schemes on behalf of its employees. The Company paid less than $0.1 million in contributions for the three months ended March 31, 2022, and 2021.

In the United States, the Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company paid less than $0.1 million in contributions in the three months ended March 31, 2022 and 2021, respectively.

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 later 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."

Operating Results

Overview

We are a mental health care 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 suffering with mental health challenges who are not helped by existing therapies, and are pioneering the development of a new model of psilocybin therapy, in which psilocybin is administered in conjunction with psychological support. Our initial focus is on treatment-resistant depression, or TRD, a subset of major depressive disorder, or MDD, comprising patients who are inadequately served by the current treatment paradigm. Early signals from academic studies, using formulations of psilocybin not developed by us, have shown that psilocybin therapy may have the potential to improve outcomes for patients suffering with TRD, with rapid reductions in depression symptoms and effects lasting up to six months, after administration of a single high dose. We have developed a proprietary, high-purity polymorphic crystalline formulation of psilocybin, COMP360. In 2019, we completed a Phase I clinical trial administering COMP360, along with psychological support, to 89 healthy volunteers. In this trial, we observed that COMP360 was generally well-tolerated and supported continued progression of Phase IIb studies. On November 9, 2021, we announced positive topline results from our Phase IIb clinical trial evaluating COMP360 in conjunction with psychological support for the treatment of treatment-resistant depression. This is the largest, randomized, controlled, double-blind psilocybin therapy clinical trial ever completed. The topline results from the 233-participant trial showed a rapid and sustained response

for patients receiving a single dose of COMP360 psilocybin with psychological support. The trial achieved its primary endpoint for the highest dose, with a 25mg dose of COMP360 demonstrating a statistically significant ($p<0.001$) and clinically relevant reduction in depressive symptom severity after three weeks compared with the COMP360 1mg arm. We believe that COMP360 psilocybin therapy – combining COMP360 psilocybin with psychological support from specially trained therapists – could offer a new approach to depression care. We anticipate the initiation of a Phase III program in the second half of 2022.

On November 3, 2021, we announced that we will be conducting a Phase II clinical trial to assess the safety and tolerability of COMP360 psilocybin therapy in post-traumatic stress disorder (PTSD). The study expands our research pipeline in COMP360 psilocybin therapy. It is a multicenter, fixed-dose open label study and will enroll 20 participants; it will begin at The Institute of Psychiatry, Psychology & Neuroscience (IoPPN) at King's College London.

On March 24, 2022, we announced that we formed a long-term strategic partnership with South London and Maudsley NHS Foundation Trust (SLaM) and the Institute of Psychiatry, Psychology & Neuroscience (IoPPN) at King's College London to launch The Centre for Mental Health Research and Innovation which will work to accelerate psychedelic research and develop new models of care for mental health in the UK. The Centre will accelerate research of emerging psychedelic therapies, support therapist training and certification, evaluate real-world evidence, and prototype digital technologies to enable personalised, predictive and preventative care models.

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 to date primarily with proceeds from the sale of convertible preferred shares, convertible loan notes, our initial public offering, or IPO, and our Follow-On Offering of American Depositary Shares, or ADSs, representing our ordinary shares in September 2020 and May 2021, respectively. Through March 31, 2022, we had received net cash proceeds of $116.4 million from sales of our convertible preferred shares and convertible loan notes, $132.8 million from sales of ADSs in our IPO and $154.8 million from sales of ADS's in our Follow-On Offering. In October 2021, we entered into a Sales Agreement with Cowen and Company, LLC, under which we may issue and sell from time to time up to $150.0 million of our ADSs at market prices. We have not yet sold any ADSs under this at-the-market facility.

We have incurred significant operating losses since our inception. We incurred total net losses of $21.2 million and $12.7 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $190.8 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, commercialization and business development activities that, together with anticipated general and administrative expenses, will result in incurring further significant losses for at least the next several years. Our operating losses stem primarily from development of our investigational COMP360 psilocybin therapy for TRD, and we expect they will continue to increase as we increase our headcount and further develop our investigational COMP360 psilocybin therapy candidate through clinical trials for TRD and studies for PTSD, potentially including expanding into additional indications, and initiate preclinical and clinical development of additional programs for different therapeutic candidates, as well as using digital technologies and solutions to enhance our therapeutic offering. Furthermore, since the completion of our IPO, we have incurred additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from sales of 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. Our inability to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. There can be no assurances, however, that our current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

As of March 31, 2022, we had cash and cash equivalents of $243.7 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 2024. 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.

COVID-19

While great progress has been made in the fight against the ongoing COVID-19 pandemic and many health measures put in place to attempt to contain the spread of COVID-19 have been lifted, it remains a global challenge. In 2021, COVID-19 vaccines were broadly distributed and administered in certain countries, but the COVID-19 pandemic and its effects continue to evolve. The Company is unable to predict the future path or potential rate of global or regional COVID-19 resurgences, including existing or future variants, or other public health crises. The exact timing and pace of the recovery is currently indeterminable as certain markets have experienced a resurgence of COVID-19 cases, and, throughout the course of the pandemic, new variants of COVID-19 have been identified and spread significantly, resulting in additional restrictions put in place by certain governments around the world.

The COVID-19 pandemic has created uncertainties in the expected timelines for clinical stage companies. For example, COVID-19 delayed enrollment in and completion of our Phase IIb clinical trial of COMP360 psilocybin therapy. There can be no assurance that we will not experience additional enrollment delays in trials or studies. The ongoing COVID-19 pandemic or other public health crises could in the future delay enrollment in and completion of our clinical trials, also interrupt our clinical trial activities, our supply chain, our employees or the employees of research sites and service providers, such as therapists, suppliers, contract research organizations, or CROs, and contract manufacturing organizations, or CMOs.

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 foreseeable future. If our development efforts for our investigational COMP360 psilocybin therapy are successful and result in regulatory approval of COMP360, we may generate revenue in the future.

Operating Expenses

Research and Development

Research and development expenses consist primarily of:

- development costs, including expenses incurred under agreements with CROs and CMOs, investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services, as well as manufacturing scale-up expenses and the cost of acquiring and manufacturing materials for preclinical studies and clinical trials and laboratory and trial site supplies and equipment;

- personnel expenses, including salaries, related benefits and travel expense for employees engaged in research and development functions;

- non-cash share-based compensation expenses resulting from equity awards granted to employees engaged in research and development functions; and

- other expenses, including costs of outside consultants, including their fees and related travel expenses, allocated facility-related expenses such as direct depreciation costs, allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our condensed consolidated financial statements as a prepaid expense or accrued research and development expenses.

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 over the next several years as we: (i) seek to expedite the clinical development for our investigational COMP360 psilocybin therapy for TRD; (ii) fund research for our investigational COMP360 psilocybin therapy in other neuropsychiatric indications, including PTSD; (iii) seek to develop digital technologies to complement and augment our therapies, and seek to access other novel drug candidates for development

in neuropsychiatric and related indications; (iv) improve the efficiency and scalability of our third-party manufacturing processes and supply chain; and (v) build our third-party or in-house process development, analytical and related capabilities, increase personnel costs and prepare for regulatory filings related to our potential or future therapeutic candidates.

The successful development and commercialization of our investigational COMP360 psilocybin therapy is highly uncertain. This is due to the numerous risks and uncertainties associated with development and commercialization, including the following:

- successful enrollment in and completion of clinical trials and preclinical studies;
- 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;
- receiving positive data from our clinical trials that support an acceptable risk-benefit profile of COMP360 psilocybin therapy 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, 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 therapy 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 therapy 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 therapy and our future therapeutic candidates following approval.

A change in the outcome of any of these variables with respect to the development of our investigational COMP360 psilocybin therapy in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of our investigational COMP360 psilocybin therapy. For example, if the FDA, the European Medicines Agency, or EMA, the Medicines and Healthcare products Regulatory Agency, or MHRA, or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience 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

General and administrative expenses consist primarily of:

- personnel expenses, including salaries and related benefits, travel and other expenses incurred by personnel in certain executive, finance and administrative functions;
- non-cash share-based compensation expenses resulting from the equity awards granted to employees engaged in certain executive, finance and administrative functions;
- legal and professional fees, including consulting, accounting and audit services; and

- facilities and other expenses, including depreciation costs, allocated expenses for rent and maintenance of facilities, director and officer insurance and other operating costs.

We anticipate that our general and administrative expenses will continue to increase in the future as we increase our headcount to support our continued research activities and development of our investigational COMP360 psilocybin therapy.

We also anticipate we will continue to incur increased accounting, audit, legal, regulatory, compliance, and director and officer insurance costs, as well as investor and public relations expenses associated with being a public company. For example, we no longer qualify as an "emerging growth company", or EGC, and as a result will incur additional costs, including as a result of becoming a large accelerated filer. We will reassess our status as a large accelerated filer as at June 30, 2022 and may no longer hold this status if our public float does not exceed $560.0 million on that day. We will also continue to incur further costs as a result of our loss of Foreign Private Issuer, or FPI, status and resulting transition to a domestic filer effective January 1, 2022. Additionally, if and when we believe a regulatory approval of a therapeutic candidate appears likely, we anticipate an increase in payroll 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 (Expense), Net

Other Income

Other income relates to interest earned on cash balances.

Foreign exchange gains (losses)

Foreign exchange gains (losses) consists of foreign exchange impacts arising from foreign currency transactions, primarily related to U.S. dollars maintained in a bank account in a Pounds Sterling functional currency entity.

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 (expense), net. As a company that carries out extensive research and development activities, we seek to benefit from the Small and Medium Enterprise, or SME, Program. Qualifying expenditures largely comprise employment costs for research staff, consumables, a proportion of relevant, permitted sub-contract costs and certain internal overhead costs incurred as part of research projects for which we do not receive income.

Based on criteria established by Her Majesty's Revenue and Customs, or HMRC, a portion of expenditures being carried 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 three months ended March 31, 2022 and 2021. We expect such elements of expenditure will also continue to be eligible for the SME regime for future accounting periods.

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 corporate income tax liability in the UK, that portion would be recorded as a benefit within the income tax provision and any refundable portion not dependent on taxable income would continue to be recorded within other income (expense), net.

Income Tax Expense

We are subject to corporate taxation in the United States and the UK. Due to the nature of our business, we have generated losses since inception and have therefore not paid UK corporation tax. Our income tax expense represents only income taxes in the United States.

Unsurrendered UK losses 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 $144.0 million and $53.0 million as of December 31, 2021 and 2020, respectively, which is offset by a full valuation allowance.

Results of Operations

Comparison For The Three Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021 (in thousands):

	Three months ended March 31,		
	2022	2021	Change
OPERATING EXPENSES:			
Research and development	$ 15,362	$ 6,884	$ 8,478
General and administrative	10,058	6,718	3,340
Total operating expenses	25,420	13,602	11,818
LOSS FROM OPERATIONS	(25,420)	(13,602)	(11,818)
OTHER INCOME (EXPENSE), NET:			
Other income	134	1	133
Foreign exchange gains (losses)	1,333	(643)	1,976
Benefit from R&D tax credit	2,922	1,557	1,365
Total other income (expense), net	4,389	915	3,474
Loss before income taxes	(21,031)	(12,687)	(8,344)
Income tax expense	(140)	(28)	(112)
Net loss	$ (21,171)	$ (12,715)	$ (8,456)

Research and Development

The table below summarizes our research and development expenses incurred for the three months ended March 31, 2022 and 2021 (in thousands):

	Three months ended March 31,		
	2022	2021	Change
Development expenses	$ 8,818	$ 3,729	$ 5,089
Personnel expenses	4,455	1,821	2,634
Non-cash share-based compensation expense	1,792	801	991
Other expenses	297	533	(236)
Total research and development expenses	$ 15,362	$ 6,884	$ 8,478

Research and development expenses increased by $8.5 million to $15.4 million for the three months ended March 31, 2022, from $6.9 million for the three months ended March 31, 2021. The increase in research and development expenses was primarily attributable to:

- an increase of $5.1 million in external development expenses, which primarily related to increases of $3.4 million in clinical trial expenses, $0.9 million in drug development and manufacturing costs, and $0.8 million in the cost of preclinical studies to assess additional indications for our investigational COMP360 psilocybin therapy development;
- an increase of $2.6 million in personnel expenses, as a result of hiring additional personnel in our research and development departments to support the expansion of our digital activities, as well as the requirements of increased clinical activities;
- an increase of $1.0 million in non-cash share-based compensation expense due to increased staffing levels year over year, in addition to a company-wide option grant in February 2022. There was no similar company-wide grant in 2021; and
- a decrease of $0.2 million in other expenses, which was primarily related to decreased external consulting expenses.

We expect research and development costs to continue to increase substantially in the near future, consistent with our plan to advance our investigational COMP360 psilocybin therapy through clinical development.

General and Administrative

The following table summarizes our general and administrative expenses for the three months ended March 31, 2022, and 2021 (in thousands):

	Three months ended March 31,		
	2022	2021	Change
Personnel expenses	$ 3,483	$ 2,467	$ 1,016
Non-cash share-based compensation expense	1,336	865	471
Legal and professional fees	3,094	1,661	1,433
Facilities and other expenses	2,145	1,725	420
Total general and administrative expenses	$ 10,058	$ 6,718	$ 3,340

General and administrative expenses increased by $3.3 million to $10.1 million for the three months ended March 31, 2022 from $6.7 million for the three months ended March 31, 2021. The increase in general and administrative expenses was primarily attributable to the following:

- an increase of $1.0 million in personnel expenses, primarily due to an increase in headcount related to the hiring of additional personnel in general, administrative and commercial functions to support our growth initiatives, including operating as a public company;
- an increase of $0.5 million in non-cash share-based compensation expense due to increased staffing levels year on year, in addition to a company-wide option grant in February 2022. There was no similar company-wide grant in 2021;
- an increase of $1.4 million in legal and professional fees, primarily related to expenses associated with external consulting, public relations, patent applications and legal advice as well as continuing costs associated with operating as a public company, and other corporate activities as we continue to grow our business; and
- an increase of $0.4 million in facilities and other expenses, mainly attributable to an increase of $0.3 million associated with initiating our first Centre of Excellence in collaboration with the Sheppard Pratt Institute for Advanced Diagnostics and Therapeutics, “Sheppard Pratt”, in addition to an increase of $0.1 million in information technology costs as a result of continued growth.

We expect these general and administrative expenses to substantially increase consistent with our plans to increase our headcount as a result of ongoing requirements as a public company, in addition to ongoing research and development growth initiatives.

Other Income (Expense), Net

Benefit from Research and Development Tax Credit

During the three months ended March 31, 2022 and 2021, we recognized an R&D tax credit from the UK as a benefit within other income (expense), net of $2.9 million and $1.6 million, respectively. The tax credit receivable increased by $1.3 million in 2022 compared to 2021 in line with increased research and development activities.

Foreign exchange gains (losses)

Foreign exchange gains (losses) increased by $2.0 million to a gain of $1.3 million for the three months ended March 31, 2022 from a loss of $0.6 million for the three months ended March 31, 2021, primarily related to gains arising from the translation of cash balances generated from the IPO proceeds and the Follow-On Offering proceeds that were maintained in U.S. dollars, which is different from the legal entity’s functional currency (Pound Sterling) giving rise to foreign currency gains. Currently, our U.S. dollar balances are held in a pound sterling functional currency legal entity and converted as required into Pound Sterling because the predominant cash outflows are Pound Sterling. As our operating model and business matures we will continually monitor and assess our legal entity structure and whether our future cash outflows continue to be reported in Pounds Sterling or in U.S. dollars, as well as the continuing impact of foreign exchange rates on our results of operations.

Other income

Other income was $0.1 million for the three months ended March 31, 2022 and less than $0.1 million for the three months ended March 31, 2021. The increase in other income primarily related to increased interest income as a result of higher interest rates on cash deposits.

Income tax expense

The income tax expense was $0.1 million for the three months ended March 31, 2022 and less than $0.1 million for the three months ended March 31, 2021. The income tax expense was related to income tax obligations of our operating company in the United States, which generates a profit for tax purposes.

Liquidity and Capital Resources

We are a clinical-stage mental health care 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 for the foreseeable future, if at all. We have funded our operations to date primarily with proceeds from the sale of convertible preferred shares, convertible loan notes and ADSs in our IPO and our Follow-On Offering. Through March 31, 2022, we had received net cash proceeds of $116.4 million from sales of our convertible preferred shares and convertible loan notes, $132.8 million in net proceeds from sales of ADSs through our IPO, and $154.8 million in net proceeds from our Follow-On Offering. We believe our existing cash balance of $243.7 million at March 31, 2022 will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2024.

Cash Flows

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

	Three Months Ended March 31,	
	2022	2021
Net cash used in operating activities	$ (23,123)	$ (13,778)
Net cash used in investing activities	(82)	(70)
Net cash provided by financing activities	189	958
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(6,543)	2,083
Net decrease in cash, cash equivalents and restricted cash	$ (29,559)	$ (10,807)

Net Cash Used in Operating Activities

During the three months ended March 31, 2022, net cash used in operating activities was $23.1 million, primarily resulting from our net loss of $21.2 million plus a non-cash loss on foreign currency remeasurement of $0.2 million, offset by non-cash share-based compensation expense of $3.1 million, depreciation and amortization of $0.1 million, and non-cash lease expenses of $0.6 million. The net loss was also adjusted by $5.5 million related to changes in components of working capital, including a $1.4 million increase in prepaid expenses and other current assets which primarily related to the R&D tax credit receivable and prepaid research and development expense, a $0.3 million increase in other assets related to a rental deposit receivable in respect of our previous London office in addition to increased implementation costs, a $0.1 million increase in deferred and prepaid tax assets, a $3.1 million decrease in accounts payable and accrued expenses primarily related to payment of bonuses and accrued clinical trial costs at year end and a $0.5 million decrease in operating lease liabilities.

During the three months ended March 31, 2021, net cash used in operating activities was $13.8 million, primarily resulting from our net loss of $12.7 million offset by non-cash share-based compensation expense of $1.7 million while benefiting from a non-cash gain on foreign currency measurement of $0.2 million. The net loss was also adjusted by $2.6 million related to changes in components of working capital, including a $2.8 million increase in prepaid expenses and other current assets which primarily related to the R&D tax credit receivable and prepaid research and development expense, a $2.4 million increase in accounts payable primarily related to an increase in clinical trial costs and legal and professional fees, primarily related to expenses associated with operating as a public company and other corporate activities as we continue to grow our business. A $2.3 million decrease in accrued expenses primarily related to payment of bonuses, audit fees, and clinical trial costs which had been accrued at December 31, 2020.

Net Cash Used in Investing Activities

During the three months ended March 31, 2022, net cash used in investing activities was $0.1 million, primarily driven by our purchases of property and equipment, which largely consisted of lab and office equipment.

During the three months ended March 31, 2021, net cash used in investing activities was $0.1 million, primarily driven by our purchases of property and equipment, which largely consisted of operating and computer equipment.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2022 and 2021, net cash provided by financing activities was $0.2 million and $1.0 million, respectively, primarily related to the proceeds from exercise of options.

Effect of exchange rate changes on cash, cash equivalents and restricted cash

During the three months ended March 31, 2022 the effect of exchange rate changes on cash, cash equivalents and restricted cash resulted in an exchange loss of $6.5 million compared with a gain of $2.1 million in the same period in the prior year, primarily driven by movements in exchange rates from period to period, resulting in exchange (losses)/gains on cash balances which are held in entities with Pound Sterling functional currencies and translated to U.S. dollars, the reporting currency.

Funding Requirements

We expect our expenses to continue to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities, manufacturing and clinical trials of COMP360. In addition, we expect to continue to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. Our expenses will also increase as we:

- continue the clinical development of our investigational COMP360 psilocybin therapy in active clinical trial sites across Europe and North America including costs associated with conducting a Phase III program in TRD;
- prepare for the Phase II studies, including evaluating the safety and tolerability of COMP360 psilocybin therapy in patients suffering with PTSD;
- establish relationships with the network of public healthcare institutions and private clinics that will administer our investigational COMP360 psilocybin therapy;
- continue the training of qualified therapists, psychiatrists and other healthcare professionals to deliver our investigational COMP360 psilocybin therapy;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any therapeutic candidates, therapy sessions, or digital support, for which we may obtain regulatory approval, including COMP360;
- advance our commercialization strategy in Europe and North America, including using digital technologies and solutions to enhance our therapeutic offering;
- continue the research and development program for our other preclinical stage therapeutic candidates and discovery-stage programs;
- discover and/or develop additional therapeutic candidates;
- seek regulatory approvals for any therapeutic candidates that successfully complete clinical trials;
- pursue necessary scheduling-related decisions to enable us to commercialize any therapeutic candidates containing controlled substances for which we may obtain regulatory approval, including COMP360;

- explore external business development opportunities through acquisitions, partnerships, licensing deals to enhance our pipeline and add additional therapeutic candidates to our portfolio;
- 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;
- expand our operations in the United States, Europe and potential other geographies
- incur additional legal, accounting and other expenses associated with operating as a public company listed in the United States; and
- work to accelerate research of emerging psychedelic therapies through our partnership with Sheppard Pratt.

We believe our existing cash of $243.7 million at March 31, 2022 will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2024. We have based these estimates 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 preclinical testing and clinical trials for COMP360 for the treatment of TRD, and for indications outside of TRD or any future therapeutic candidates outside of TRD, including PTSD;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA, the EMA, 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 United States Drug Enforcement Agency, or DEA, individual states, and comparable foreign authorities;
- the number of potential new therapeutic candidates we identify and decide to develop, either internally through our research and development efforts or externally through acquisitions, licensing or other collaboration agreements;
- the costs involved with establishing Centers of Excellence to serve as research facilities and innovation labs, in line with our ambition to create a new mental health care model;
- the cost involved with hiring additional personnel in our research and development department to support the expansion of our digital activities;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our investigational COMP360 psilocybin therapy and future therapeutic candidates;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringements raised by third parties;
- the time and costs involved in obtaining regulatory approval for COMP360 or 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 of our future therapeutic candidates;

- selling and marketing activities undertaken in connection with the potential commercialization of our investigational COMP360 psilocybin therapy or any future therapeutic candidates, if approved, and costs involved in the creation of an effective sales and marketing organization;

- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our investigational COMP360 psilocybin therapy and future therapeutic candidates, if approved; 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, current ownership interests will be diluted. If we raise additional funds through government or third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish future revenue streams, research programs or therapeutic candidates or grant licenses on terms that may not be favorable to us. Debt financing, if available, may involve high interest rates or agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or therapeutic candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes in our significant accounting policies or critical accounting estimates during the first quarter of 2022. For a complete discussion, 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.

Emerging Growth Company Status

On April 5, 2012, the JOBS Act was enacted. The JOBS Act provides that, among other things, an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. As an emerging growth company, we elected to use the extended transition period under the JOBS Act until the earlier of the date we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements were not comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We were able to take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of our IPO or such earlier time that we are no longer an emerging growth company. As of June 30, 2021, the market value of our common stock that was held by non-affiliates exceeded $700.0 million, and, as a result, we no longer qualified for "emerging growth company" status on December 31, 2021.

We will reassess the market value of our common stock that is held by non-affiliates on June 30, 2022 in order to determine whether it exceeds $560.0 million, and whether we therefore are subject to the disclosure requirements of a large accelerated filer for the year ended December 31, 2022.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

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 the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

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 March 31, 2022. 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 disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any litigation or claims that we believe, if determined adversely to us, would have a material adverse effect on our business, operating results, financial condition or cash flows. From time to time, we may be a party to litigation or subject to claims incident to the ordinary course of business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources 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, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes thereto. Any of the following risks could materially and adversely affect our business, financial condition, or results of operations. The selected risks described below, however, are not the only risks facing us. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial may also materially and adversely affect our business, financial condition, or results of operations. The summary of the material risks associated with our business is included in the "Special Note Regarding Forward Looking Statements" on page 4 above.

Summary of the Material Risks Associated with our Business

- We are a clinical stage mental health care 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;
- Failure to obtain the substantial additional funding we need to complete the development and commercialization of our investigational COMP360 psilocybin therapy or any future therapeutic candidates may force us to delay, limit or terminate certain or all of our product discovery, therapeutic development, research operations or commercialization efforts;
- Raising additional capital may cause dilution to holders of our ordinary shares or ADSs, restrict our operations or require us to relinquish rights to COMP360 or any future therapeutic candidates;
- We are dependent on the successful development of our investigational COMP360 psilocybin therapy. We cannot give any assurance that COMP360 will successfully complete clinical trials or receive regulatory approval, which is necessary before it can be commercialized;
- COMP360 is, and any future therapeutic candidates we may develop in the future 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, may adversely affect the results of our business operations and our financial condition, both during clinical development and post approval. In addition, during the review process of COMP360, and prior to approval, the FDA and/or other regulatory bodies may require additional data, including with respect to whether COMP360 has abuse potential, which may delay approval and any potential rescheduling process;
- Adverse publicity or public perception regarding psilocybin or our current or future investigational therapies using psilocybin may negatively influence the success of these therapies;
- Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of COMP360 psilocybin therapy or any future therapeutic candidates are prolonged or delayed, we or our current or future collaborators may be unable to obtain required regulatory approvals for, and therefore unable to commercialize, COMP360 psilocybin therapy or any future therapeutic candidates on a timely basis or at all;
- 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 psilocybin therapy 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;

- Research and development of drugs targeting the central nervous system are 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 therapies on our own or with suitable collaborators;
- The future commercial success of our investigational COMP360 psilocybin therapy or any future therapeutic candidates will depend on the degree of market access and acceptance of our potential therapies among healthcare professionals, patients, healthcare payors, health technology assessment bodies and the medical community at large;
- Our business and commercialization strategy depends on our ability to identify, qualify, prepare, certify and support third-party therapy sites offering any approved therapy and any inability to do this will limit our commercialization prospects and harm our business, financial condition and results of operations;
- We currently rely on qualified therapists working at third-party clinical trial sites to administer our investigational COMP360 psilocybin therapy in our clinical trials and we expect this to continue upon approval, if any, of COMP360 or any of our future therapeutic candidates. If third-party sites fail to recruit and retain a sufficient number of therapists or effectively manage their therapists, our business, financial condition and results of operations would be materially harmed;
- Intellectual property rights of third parties could adversely affect our ability to develop or commercialize our investigational therapies, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our investigational therapies. 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;
- Psilocybin and psilocin are listed as Schedule I controlled substances under the CSA in the United States, 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;
- Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our investigational COMP360 psilocybin therapy or any future therapeutic candidates and could have a material adverse effect on our business;
- We rely on third parties to supply and manufacture the psilocybin and psilocin incorporated in COMP360 and expect to continue to rely on third parties to supply and manufacture any of our future therapeutic candidates, and we will rely on third parties to manufacture these substances for commercial supply, if approved. If any third-party provider fails to meet its obligations to manufacture COMP360 or our future therapeutic candidates, or fails to maintain or achieve satisfactory regulatory compliance, the development of such substances and the commercialization of any therapies, if approved, could be stopped, delayed or made commercially unviable, 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. We do not sponsor these IISs, and we encourage the open publication of all IIS findings. Any failure by a third party to meet its obligations with respect to the clinical development of our investigational COMP360 psilocybin therapy or any of our 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 raise 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;

- A pandemic, epidemic, or outbreak of an infectious disease, including a new variant of COVID-19, 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;
- We face substantial competition and our competitors may discover, develop or commercialize therapies before or more successfully than us, which may result in the reduction or elimination of our commercial opportunities;
- 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;
- Our business is subject to economic, political, regulatory and other risks associated with international operations; and
- We previously identified material weaknesses in our internal control over financial reporting. We may identify future material weaknesses in our internal controls over financial reporting. If we are unable to remedy these material weaknesses, or if we fail to establish and maintain effective internal controls, we may be unable to produce accurate and timely financial statements, and we may conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and the prices of our ADSs.

Risks Related to Our Financial Position and Need for Additional Capital

We are a clinical-stage mental health care 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 mental health care 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 $21.2 million, and $12.7 million, respectively, for the three months ended March 31, 2022 and March 31, 2021. As of March 31, 2022, we had an accumulated deficit of $190.8 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, commercialization and business development activities that, together with anticipated general and administrative expenses, will result in incurring further significant losses for at least the next several years. Our expected losses, among other things, may continue to cause our working capital and shareholders' equity (deficit) to decrease. We anticipate that our expenses will increase substantially if and as we, among other things:

- continue the clinical development of our investigational COMP360 psilocybin therapy for the treatment of TRD and PTSD, including initiating additional and larger clinical trials, including the anticipated initiation of a Phase III trial in TRD in the second half of 2022;
- continue to invest in the development of prodrug candidates and psychedelic compounds that could be developed into therapies;
- continue the training of therapists who are qualified to deliver our investigational COMP360 psilocybin therapy in our 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;
- establish and expand the network of public healthcare institutions and private clinics that administer COMP360 in conjunction with psychological support;
- advance our commercialization strategy in North America and Europe, including using digital technologies to enhance our proposed therapeutic offering;

- research additional indications for our investigational COMP360 psilocybin therapy and discover and develop any future therapeutic candidates;
- continue to invest in our Discovery Center and Centers of Excellence;
- seek regulatory approvals for any future therapeutic candidates that successfully complete clinical trials;
- experience heightened regulatory scrutiny;
- pursue necessary scheduling-related decisions to enable us to commercialize any future therapeutic candidates containing controlled substances for which we may obtain regulatory approval, including COMP360;
- explore external business development opportunities through acquisitions, partnerships, licensing deals to add future therapeutic candidates and technologies to our portfolio;
- 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 delays and other impacts as a result of a resurgence or emergence of new COVID-19 variants;
- expand our operations in the United States, Europe and potential other geographies 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.

To date we have funded our operations through private placements of equity and convertible notes and, since our initial public offering, or IPO, in 2020, through public equity offerings. To become and remain profitable, we will need to continue developing and eventually commercialize therapies that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of COMP360 or any future therapeutic candidates, and initiating new clinical trials, including our planned Phase III trial in TRD, training a sufficient number of qualified therapists to deliver our investigational COMP360 psilocybin therapy, using digital technologies and solutions to enhance our therapeutic offering, establishing and/or collaborating with providers to develop "Centers of Excellence" where we can conduct trainings for therapists, discovering and developing any future therapeutic candidates, obtaining regulatory approval for any future therapeutic candidates that successfully complete clinical trials, and establishing marketing capabilities. Even if any of the future therapeutic candidates that we may develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved future therapeutic candidate. We are only in the preliminary stages of most of these activities. 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 therapy 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, 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 therapy or any future therapeutic candidates. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain or all of our product discovery, therapeutic development, research operations or commercialization efforts.

We expect to require substantial additional funding in the future to sufficiently finance our operations and advance development of our investigational COMP360 psilocybin therapy or any future therapeutic candidates. We expect that our cash and cash equivalents of $243.7 million as of March 31, 2022, will enable us to fund our operating expenses and capital expenditure requirements into 2024. We have based this estimate 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 rising 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 preclinical testing and clinical trials for our current investigational psilocybin therapy program for TRD and for indications outside of TRD or any future therapeutic candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA, the EMA, 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 identify 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 allow for the research, development and potential commercialization of our investigational COMP360 psilocybin therapy and any future therapeutic candidates;
- 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 certifying therapists who are supporting or will support our clinical trials;
- the costs of establishing our Centers of Excellence and the Center for Mental Health Research, which includes conducting clinical trials, including proof of concept studies, to refine our therapeutic model;
- generating and collecting data and advancing our intellectual property portfolio; and strengthening our regional presence as a scientific and clinical resource;
- the costs of developing, testing and deploying digital technology solutions to improve the patient experience and therapeutic process;
- 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 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 therapy 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 payments from future sales of our investigational COMP360 psilocybin therapy and any future therapeutic candidates, if approved; 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 will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. 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 therapy or any future therapeutic candidate, or we may be unable to take advantage of future business opportunities. Market volatility, supply shortages resulting from the ongoing COVID-19 pandemic and conflict between Ukraine and Russia, increasing inflation and interest rates and the related U.S. and global economic impact or other economic or other factors could also adversely impact our ability to access capital as and when needed.

We cannot guarantee that future financing will be available in sufficient amounts, or on commercially reasonable terms, or at all. 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. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain 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. 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 therapy or any future therapeutic candidates.

In addition, heightened regulatory scrutiny 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 therapy or any future therapeutic candidates may adversely affect our business and operations, including without limitation, our ability to raise additional capital.

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

In July 2015, The Compass Trust Limited, a non-profit private limited company incorporated in England and Wales, was incorporated by two of our co-founders, George Goldsmith and Ekaterina Malievskaia. Its purpose was to support the research and development of psilocybin therapy for end-of-life anxiety. In June 2016, Mr. Goldsmith and Dr. Malievskaia formed COMPASS Pathways Technologies Limited, a for-profit private limited company incorporated in England and Wales, to manufacture psilocybin for the research. Later in 2016, following discussion with regulators and health technology assessment agencies, Mr. Goldsmith and Dr. Malievskaia began considering the development of psilocybin therapy for TRD, given the significant unmet need in this area. In 2017, Compass Pathways Technologies Limited was renamed Compass Pathways Limited and began to carry out clinical trial and funding activities, and The Compass Trust Limited was dissolved. In August 2020, Compass Pathways Limited was renamed COMPASS Pathfinder Limited and became, through its parent company, Compass Pathfinder Holdings Limited, a wholly owned indirect subsidiary of COMPASS Pathways plc in connection with our corporate reorganization.

To date, we have invested most of our resources in developing our investigational COMP360 psilocybin therapy, building our intellectual property portfolio, conducting business planning, raising capital and providing administrative support for these operations. We have not yet demonstrated an ability to conduct later-stage clinical trials, obtain regulatory approvals, manufacture a commercial-scale product, conduct sales and marketing activities necessary for successful product commercialization or obtain reimbursement in the countries of sale.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. 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. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Raising additional capital may cause dilution to holders of our ordinary shares or ADSs, 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, your ownership interest will be diluted and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Any indebtedness we incur would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, acquire or license intellectual property rights, declare dividends, make capital expenditures and other operating restrictions that could adversely impact our ability to conduct our business. 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 therapy 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 therapy 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 therapy or any future therapeutic candidates.

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

We are dependent on the successful development of our investigational COMP360 psilocybin therapy. 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 therapies that are approved for commercial sale and may never be able to develop marketable therapies. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to our investigational COMP360 psilocybin therapy, which is currently our only therapeutic candidate in development. Accordingly, our business currently depends on the successful regulatory approval of COMP360 and the commercialization of our investigational COMP360 psilocybin therapy. We cannot be certain that COMP360 will receive regulatory approval or that our therapy will be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of our investigational COMP360 psilocybin therapy, 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 foreign regulatory authorities. Failure to obtain regulatory approval in the United States, Europe or other jurisdictions will prevent us from commercializing and marketing our investigational COMP360 psilocybin therapy in such jurisdictions.

Even if we were to successfully obtain approval from the FDA, the EMA, 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. 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 therapy sites for the appropriate administration of our investigational COMP360 psilocybin therapy, secure adequate manufacturing, train and secure access to qualified therapists, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize our investigational COMP360 psilocybin therapy, we may not be able to generate sufficient revenue to continue our business.

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

- successful completion of clinical trials and preclinical studies;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or clearance for conducting our planned clinical trials or future clinical trials;
- successful patient enrollment in and completion of 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;
- entry into collaborations to further the development of our investigational COMP360 psilocybin therapy 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 therapy 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 following approval;
- effectively competing with companies developing and commercializing other therapies in the indications which our investigational COMP360 psilocybin therapy targets;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- 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 therapy 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 is, and any future therapeutic candidates we may develop in the future may be, subject to controlled substance laws and regulations in the territories where the product will be marketed, such as the United States, 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, 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, and prior to 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 United States, 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 United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription and may have a black box warning. Further, most, if not all, state laws in the United States classify psilocybin and psilocin as Schedule I controlled substances. For any product containing psilocybin to be available for commercial marketing in the United States, 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 United States will also require scheduling-related legislative or administrative action.

Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance. Therefore, while psilocybin and psilocin are Schedule I controlled substances, products approved by the FDA for medical use in the United States that contain psilocybin or psilocin should be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. If and 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 United States. 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 therapy in the United States. Furthermore, the FDA, DEA, or any foreign regulatory authority could require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of our investigational COMP360 psilocybin therapy 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 therapy contains psilocybin, to conduct clinical trials with COMP360 in the United States 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. We do not currently conduct any manufacturing or repackaging/relabeling of either COMP360 or its active ingredients (i.e., psilocybin) in the United States. COMP360 is imported in its fully-finished, packaged and labeled dosage form.

- **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 United States, and we would need to secure a manufacturer that would be required to obtain and maintain a separate DEA registration for that activity.

- **Manufacture in the United States**. If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the United States, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. 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 United States**. 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 update. 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.

- 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 United States 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 therapies using psilocybin may negatively influence the success of these therapies.

Therapies 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 therapies 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 therapies. For example, we may face media-communicated criticism directed at our clinical development program. Adverse publicity from psilocybin misuse may adversely affect the commercial success or market penetration achievable by our investigational COMP360 psilocybin therapy. 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 therapy 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 therapies. We may face limited adoption if third-party therapy sites, therapists, 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 therapies. 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 therapies or any similar therapies 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 therapies or any similar therapies 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 therapies. 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. If clinical trials of COMP360 or any future therapeutic candidates are prolonged or delayed, we or our current or future collaborators may be unable to obtain required regulatory approvals, and therefore we will be unable to commercialize our investigational COMP360 psilocybin therapy 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 may experience delays in completing our ongoing clinical trial and 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 delay or prevent our ability to receive marketing approval or commercialize our investigational COMP360 psilocybin therapy 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 investigator-initiated studies, 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;
- delays in or failure to recruit a sufficient number of suitable patients to participate in a trial;
- 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 therapists and appropriate third-party clinical trial sites for the conduct of psilocybin therapy sessions, including preparation, psilocybin administration and integration of the therapeutic experience;
- sufficiency of any supporting digital services that may form part of the preparation, integration or long-term follow-up relating to any therapy 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 therapy 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;
- lower than anticipated retention rates of patients and 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 the ongoing COVID-19 pandemic, 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 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 governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, on June 18, 2018, the FDA placed COMP360 on clinical hold after it reviewed our initial IND submission, citing the need for additional information regarding the structure of the psilocybin sessions, study personnel, and criteria for discharge. We submitted responsive information to our IND, and the FDA removed the clinical hold on August 8, 2018. If we experience 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 therapy 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 therapy or any future therapeutic candidates. Significant clinical trial delays could also allow our competitors to bring therapies to market before we do or shorten any periods during which we have the exclusive right to commercialize our investigational COMP360 psilocybin therapy or any future therapeutic candidates and impair our ability to commercialize our investigational COMP360 psilocybin therapy 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 therapy 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 therapy 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 and, because our investigational COMP360 psilocybin therapy is in an early stage of 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 designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

We cannot be certain that our current clinical trials 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 therapy. 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. 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 therapy. 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 become available and are subject to audit and verification procedures that could result in material changes in the final data. These 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. Interim, top-line and preliminary data from our clinical trials may change as more patient data or analyses become available. Preliminary, top-line or interim data from our clinical trials are not necessarily predictive of final results. 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.

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. 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, because COMP360 is in an early stage of development, there is 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. We have not obtained regulatory approval for COMP360. 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 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 therapy 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 therapy 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 United States 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 therapy and delivery method, including the use of third-party clinical trial sites and therapists.

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. 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. 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 candidate 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 therapies, 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. Any of the foregoing scenarios may have a negative impact on the commercial prospects for our investigational COMP360 psilocybin therapy 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 therapy 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 therapy and underlying therapeutic 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 therapies. 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 the therapy may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV 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 therapy.

If there are changes in the application of legislation, regulations or regulatory policies, or if problems are discovered with our investigational COMP360 psilocybin therapy 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 therapy 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 therapy 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 treatment emergent adverse events reported with the results of our Phase II clinical trial in TRD. 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 patients 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 therapy used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy 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 therapy, new risks and side effects associated with our therapies may be discovered. There have been other products and therapies 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 therapies from the market, and our investigational COMP360 psilocybin therapy and any future therapeutic candidates may be subject to similar risks. We might have to withdraw or recall our investigational COMP360 psilocybin therapy 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 therapy or any future therapeutic candidates if and when regulatory approvals for such therapy 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 therapy and any future therapeutic candidates.

Additionally, if our investigational COMP360 psilocybin therapy 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 therapies 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 therapy 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 therapy 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 therapy or any future therapeutic candidates.

Even if we obtain FDA, EMA or MHRA approval for COMP360 or any future therapeutic candidates that we may identify and pursue in the United States, 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 United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a 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 therapy and any future therapeutic candidates in those countries. The foreign regulatory approval process may include all of the risks associated with obtaining FDA, EMA 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 therapy and any future therapeutic candidates will be harmed.

The results of preclinical studies and early-stage clinical trials of our investigational COMP360 psilocybin therapy 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. 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, planned and ongoing clinical trials 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. 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 to impact the effectiveness of our investigational COMP360 psilocybin therapy. All of these factors may make it difficult to assess the prior use or the overall efficacy of our investigational COMP360 psilocybin therapy.

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

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Patient enrollment depends on many factors, including:

- 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 participate in our trials, including due to the perceived risks and benefits, stigma or other side effects of use of a controlled substance;

- the willingness or availability of patients to participate in our trials, including due to impacts of the ongoing COVID-19 pandemic;
- 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 therapies, including any new therapies that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient informed consents.

Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials.

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 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 will likely increase our costs, slow down COMP360 approval process and delay or potentially jeopardize our ability to commence sales of our investigational COMP 360 psilocybin therapy and generate revenue. 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, timely enrollment in 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 currently or in the future affected by the COVID-19 pandemic or which may in the future be impacted by other pandemics. Some factors from the COVID-19 pandemic that have delayed enrollment in our trial or that we believe could adversely affect enrollment in our trials in the future include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of infectious disease physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- the limitation of available participants for our trials;
- the inability of patients, therapists or physicians to come to hospitals and universities to participate in our trials, leading to delays and increased costs;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring and patient preparation and integration sessions;
- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our trials; and
- employee furlough days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with the virus or could continue to spread to additional countries, each of which may further adversely impact our clinical trials. The global outbreak of COVID-19 continues to evolve and the conduct of our trials may continue to be adversely affected, 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 therapies on our own or with suitable collaborators.

While we are currently assembling a sales and marketing infrastructure, we have limited organizational experience in the sale or marketing of therapeutic candidates. To achieve commercial success for any approved therapy, 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 therapy is approved for commercial sale, we plan on establishing our own market access and commercialization capabilities in primary markets in North America and in the EU. 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 therapies effectively or to market our therapies effectively since we have limited organizational experience in the sales and marketing of therapeutic substances. 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 therapies on our own include:

- our inability to train an adequate number of therapists to meet the demand for psilocybin therapy;
- the ability of our therapists to perform their roles consistently with our training and our guidelines for the administration of our investigational COMP360 psilocybin therapy;
- 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 therapies;
- our inability to identify a sufficient number of treatment centers in third-party therapy sites to meet the demands of our therapies;
- the lack of complementary therapies 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 therapies, the revenue or the profitability of these revenues to us could be lower than if we were to commercialize any therapies that we develop ourselves. Such collaborative arrangements may place the commercialization of any approved therapies 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 therapies 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. We may not be successful in entering into arrangements with third parties to commercialize our therapies 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 therapies effectively, to set up sufficient number of treatment centers in third-party therapy sites, or to recruit, train and retain adequate number of therapists to administer our therapies. In addition, we are exploring ways in which we can use digital technology to improve the patient experience and therapeutic outcomes of our therapies. Commercialization partners may lack incentives to promote our digital technology and we may face difficulties in implementing our digital technologies in third-party therapy sites through such third parties.

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 therapies, 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 therapy or any future therapeutic candidates will depend on the degree of market access and acceptance of our potential therapies among healthcare professionals, patients, healthcare payors, health technology assessment bodies and the medical community at large.

We may never have a therapy that is commercially successful. To date, we have no therapy authorized for marketing. Our investigational COMP360 psilocybin therapy requires further clinical investigation, regulatory review, significant market access and marketing efforts and substantial investment before it can produce any revenue. Furthermore, if approved, our therapy 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 historic media coverage of psychedelic substances, including psilocybin. Because of this history, efforts to educate the medical community and third-party payors and health technologies assessment bodies on the benefits of our investigational COMP360 psilocybin therapy may require significant resources and may never be successful, which would prevent us from generating significant revenue or becoming profitable. Market acceptance of our future therapies 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 therapy 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 therapies;
- 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 our therapy 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, the therapy;
- any potential unfavorable publicity, including negative publicity associated with recreational use or abuse of psilocybin;
- any restrictions on the use, sale or distribution of our investigational COMP360 psilocybin therapy or any future therapeutic candidates, including through REMS;
- the extent to which therapies are approved for inclusion and reimbursed on formularies of hospitals and managed care organizations; and
- whether our therapies are designated under physician treatment guidelines or under reimbursement guidelines as a first-line, second-line, third-line or last-line therapy.

If our investigational COMP360 psilocybin therapy 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 therapies 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 depends on our ability to identify, qualify, prepare, certify and support third-party therapy sites offering any approved therapy. 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 therapy or future therapies, our success will be dependent upon our ability to identify, qualify, prepare, certify and support third-party therapy sites that offer and administer our therapies. Our commercial model of delivering our investigational COMP360 psilocybin therapy will also involve third-party therapists before, during and after the psilocybin administration session, which will be hosted in one of the third-party therapy sites. We intend to commercialize our investigational COMP360 psilocybin therapy and any future therapeutic candidates by building close relationships with qualified third-party therapy sites where these therapists will administer our investigational COMP360 psilocybin therapy. 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 therapy. Any such limitations could make it impracticable or impossible for some potential patients to access our investigational COMP360 psilocybin therapy, if approved, which could limit the overall size of our potential patient population and harm our future results of operations. Although we plan to develop Centers of Excellence to train and certify such third-party therapy sites, conduct further research on and continuously improve our treatment protocol, we expect this to involve significant costs, time and resources, and our efforts may not be successful.

If we are unable to establish a sufficient network of third-party therapy sites certified under applicable standards, including regional, national, state or other applicable standards as needed to render psilocybin therapeutic services, including the certifications that such third-party therapy 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 therapists to be employed by the third-party therapy sites where the therapists administer our therapies. Third-party therapy sites could, for a number of reasons, demand higher payments for our therapies or take other actions to increase their income from selling our therapies, which could result in higher costs for payors and for our patients to get access to our therapies. For example, legal regimes may have higher levels of licensure which force us to contract with third-party therapy sites that demand higher payment rates to provide psilocybin therapeutic services. In addition, third-party therapy sites may have difficulty meeting regulatory or accreditation requirements.

Given the novel nature of our treatment, third-party therapy sites may face additional financial and administrative burdens in order to deliver any approved therapy, including adhering to a REMS plan in the United States or a Risk Management Program, or RMP, in Europe. The process for a third-party therapy site to obtain a certificate under a REMS plan can be very costly and time-consuming, which could delay a third-party therapy site's ability to provide our therapies and materially adversely affect our commercialization trajectory. Furthermore, third-party therapy sites will need to ensure that they have the necessary infrastructure and equipment in order to deliver our investigational COMP360 psilocybin therapy, such as adequate audio-visual equipment, ancillary equipment and sufficient treatment rooms. This may deter third-party therapy 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 therapy 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 therapeutic use of psilocybin, 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 therapy sites' costs of delivering our investigational COMP360 psilocybin therapy. The failure to maintain or to secure new cost-effective contracts with third-party therapy sites may result in a loss of or inability to grow our network of third-party therapy 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 qualified therapists working at third-party clinical trial sites to administer our investigational COMP360 psilocybin therapy in our clinical trials and we expect this to continue upon approval, if any, of COMP360 or any future therapeutic candidates. If third-party sites fail to recruit and retain a sufficient number of therapists or effectively manage their therapists, our business, financial condition and results of operations would be materially harmed.

We currently administer our investigational COMP360 psilocybin therapy in our clinical trials through qualified third-party therapists working at third-party clinical trial sites. However, there are currently not enough trained therapists to carry

out our investigational COMP360 psilocybin therapy at a commercial scale, and our efforts to facilitate training and certification programs for therapists, including through our planned Centers of Excellence, may be unsuccessful.

While we currently provide training to the therapists and expect to continue providing trainings in the future (either directly or indirectly through third-party providers), we do not currently employ the therapists who deliver our therapies to patients and do not intend to do so in the future. Such therapists are typically employed by the third-party therapy sites. If our investigational COMP360 psilocybin therapy or any future therapeutic candidates are approved for commercialization, third-party therapy sites may demand substantial financial resources from us to recruit and retain a team of qualified therapists to administer our investigational COMP360 psilocybin therapy or any future therapeutic candidates. If the third-party therapy sites fail to recruit, train and retain sufficient number of therapists, our ability to offer and administer our therapies will be greatly harmed, which may in turn reduce the market acceptance rate of our therapies. If this occurs, our commercialization prospects would be negatively affected and our business, financial condition and results of operations would be harmed.

Although we currently provide training and expect to continue providing training to the therapists (directly or through third-party providers), we generally rely on qualified and certified third-party therapy sites to manage the therapists and monitor the administration of our therapies and ensure that the administration process of our therapies comply with our established protocols. However, if not properly managed and supervised, there is a risk that therapists may deviate from our training protocols, fail to follow the guidelines we have established, or abuse patients during psilocybin administration sessions. The therapists might also administer unauthorized therapies 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 therapy or other therapeutic 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 therapies 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 the 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 therapies 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 psilocybin therapy or any future therapeutic 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.

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 therapy 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 therapies 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 we believe any future therapeutic candidates meets 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 FDA as breakthrough therapies, no longer meet the conditions for qualification.

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

We may seek Fast Track designation for COMP360 or any future 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 are expanding our Discovery Center, a sponsored research agreement with University of the Sciences (Pennsylvania), through collaborations with academic laboratories at UC San Diego, School of Medicine (California), the Medical College of Wisconsin (Wisconsin), and Dr. Matthias Grill, CEO of MiHKAL GmbH (Switzerland). 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.

Our business strategy includes developing Centers of Excellence, which we expect will involve significant costs, time and resources. If our efforts are unsuccessful, our business, prospects and financial condition would be adversely affected.

A key element of our business strategy involves setting up research facilities and innovation labs, which we refer to as Centers of Excellence, in key markets. We announced the establishment of our first Center of Excellence in collaboration with The Sheppard Pratt Institute for Advanced Diagnostics and Therapeutics in Baltimore, Maryland, in January 2021. We intend to use these Centers of Excellence to gather evidence to optimize our therapy model, train and certify therapists, conduct clinical trials, including proof of concept studies, develop and test digital technology solutions to improve patient experience and outcomes and pursue other activities to refine our approach to delivering our investigational COMP360 psilocybin therapy safely and cost-effectively. Our efforts to design, build and staff these 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 these 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 therapies 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 therapy 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 therapies that have been approved for commercial sale; however, the current and future use of our investigational COMP360 psilocybin therapy or any future therapeutic candidates by us and our corporate collaborators in clinical trials, and the potential sale of any approved therapies in the future, may expose us to liability claims. These claims might be made by patients who use our therapies, healthcare providers, pharmaceutical companies, our corporate collaborators or other third parties that sell our therapies. 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 therapy or any future therapeutic candidates or any prospects for commercialization of our investigational COMP360 psilocybin therapy 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 causes 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 therapies 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 therapy 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 therapies if we obtain marketing approval for our investigational COMP360 psilocybin therapy 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 United States, 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 United States, 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 medical use of "psilocybin products," including magic mushrooms, to treat mental health conditions in licensed facilities with registered therapists. Similar legislation has been passed in Washington, D.C. (November 2020), Somerville, Massachusetts (January 2021), Cambridge, Massachusetts (February 2021), and Northampton, Massachusetts (April 2021). The legalization of psilocybin without 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 therapy or any future therapeutic candidates outside the United States 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 United States, 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 therapy or any future therapeutic candidates outside of the United States, 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 United States 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. While there are currently several pending cases before various administrative and federal courts challenging these restrictions, there is no guarantee that these courts 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 corporate taxation 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 $144.0 million and $53.0 million as of December 31, 2021 and 2020, respectively. Subject to any relevant utilization criteria and restrictions (including 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 will be limited each year to £5.0 million per group plus, broadly, an incremental 50% of 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 research and development activities, we seek to benefit from the UK research and development tax relief programs, being the Small and Medium-sized Enterprises R&D tax relief program, or SME Program, and, to the extent that our projects are grant funded or relate to work subcontracted to us by third parties, the Research and Development Expenditure Credit program, or RDEC Program. Under the SME Program, we may be able to surrender the trading losses that arise from our qualifying research and development activities for a cash rebate of up to 33.35% of such qualifying research and development expenditures or carried forward for potential offset against future profits (subject to relevant restrictions). The majority of our research, clinical trials management and manufacturing development activities are eligible for inclusion within these tax credit cash rebate claims. We may not be able to continue to claim payable research and development tax credits in the future if we cease to qualify as a SME, based on size criteria concerning employee headcount, turnover and gross assets. The SME Program has been amended by the Finance Act 2021 which came into force in April

2021. This legislation introduced a cap on claims under the SME Program 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 research and development expenditure in respect of connected parties which does not exceed 15% of the total claimed. If such exception does not apply, this could restrict the amount of payable credit that we claim.

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 therapy, 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 research and development expenditures, we expect a long-term rate of corporation tax lower than the statutory to apply to us. If, however, there are unexpected adverse changes to the UK research and development 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.

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

In the United States, 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 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 March 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.

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 our products and any future approved product. On July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and identify and address any efforts to impede generic drug competition.

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 therapy and any future therapeutic candidates and, accordingly, the results of our financial operations. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

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 therapies 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 therapies 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 therapies, and other parties through which we market, sell and distribute our therapies 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.

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 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 aforementioned 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 United States, 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. 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 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. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. 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.

Additionally, in June 2018, the State of California enacted the California Consumer Privacy Act of 2018, or CCPA, which came into effect on January 1, 2020 and became enforceable by the California Attorney General on July 1, 2020. The CCPA provides new data privacy rights for consumers (as that term is broadly defined) and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA requires covered companies to provide

certain disclosures to consumers about its 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 gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has resulted in an increase in data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. There continues to be uncertainty surrounding the enforcement and implementation of the CCPA, exemplifying the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Additionally, a new California ballot initiative, the California Privacy Rights Act, or "CPRA," was passed in November 2020. Effective starting on January 1, 2023, the CPRA imposes additional obligations on companies covered by the legislation and will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The effects of the CCPA and the CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation.

The CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the United States, which could increase our potential liability and adversely affect our business. Certain other state laws impose similar privacy obligations, and we anticipate that more states may enact legislation similar to the CCPA, which provides consumers with new privacy rights and increases the privacy and security obligations of entities handling certain personal information of such consumers. The CCPA has prompted a number of proposals for new federal and state-level privacy legislation. Such proposed legislation, if enacted, may add additional complexity, variation in 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.

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 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.

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

Our clinical trial activity conducted within the Member States of the EEA is regulated by the GDPR. 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 EU, and/or (ii) carried out in the context of the activities of our establishment in any EU Member State, is subject to the GDPR which became effective on May 25, 2018, as well as other national data protection legislation in force in relevant Member States (including the Data Protection Act 2018 in the UK).

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 EEA, including the United States, 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 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 EEA to the United States. The EU-U.S. and the Swiss-U.S. Privacy Shield frameworks allowed U.S. companies that self-certify to the U.S. Department of Commerce and publicly commit to comply with specified requirements to import personal data from the EU and Switzerland. In 2020, the Court of Justice of the EU ruled that the EU-U.S. Privacy Shield is an invalid transfer mechanism, which was one of the primary mechanisms used by U.S. companies to import personal information from Europe in compliance with the GDPR's cross-border data transfer restrictions, and raised questions about whether the European Commission's Standard Contractual Clauses, or SCCs, one of the primary alternatives to the Privacy Shield, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Similarly, the Swiss Federal Data Protection and Information Commissioner has opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of data from Switzerland to the U.S, and the UK Information Commissioner's Office has stated that the Privacy Shield framework is inadequate for transfers from the UK to the U.S. Furthermore, on June 4, 2021, the European Commission issued new forms of standard contractual clauses for data transfers from controllers or processors in the EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EEA. The new forms of standard contractual clauses have replaced the standard contractual clauses that were adopted previously under the Data Protection Directive. We will be required to transition to the new forms of standard contractual clauses and doing so may require significant effort and cost. The new standard contractual clauses may also impact our business as companies based in Europe may be reluctant to utilize the new clauses to legitimize transfers of personal information to third countries given the burdensome requirements of transfer impact assessments and the substantial obligations that the new standard contractual clauses impose upon exporters. 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 applicable EU 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.

Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, and ongoing developments in the United Kingdom have created uncertainty regarding data protection regulation in the United Kingdom. Following the United Kingdom's withdrawal from the EU on January 31, 2020, pursuant to the transitional arrangements agreed to between the United Kingdom and EU, the GDPR continued to have effect in law in the United Kingdom, and continued to do so until December 31, 2020 as if the United Kingdom remained a Member State of the EU for such purposes. Following December 31, 2020, and the expiry of those transitional arrangements, the data protection obligations of the GDPR continue to apply to United Kingdom-related processing of personal data in substantially unvaried form under the so-called "UK GDPR" (i.e., the GDPR as it continues to form part of law in the United Kingdom by virtue of section 3 of the European Union (Withdrawal) Act 2018, as amended (including by the various Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019)). However, going forward, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the United Kingdom and EEA. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. 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 EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR

restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

The successful commercialization of our investigational COMP360 psilocybin therapy 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 therapy or any future therapeutic candidates, if approved, could limit our ability to market those therapies 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 therapies such as our investigational COMP360 psilocybin therapy or any future therapeutic candidates, if approved. As Schedule I substances under the CSA, psilocybin and psilocin are deemed to have no accepted medical use and therapies that use psilocybin or psilocin are precluded from reimbursement in the United States. 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 therapies 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 therapy 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 therapy 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 United States, Europe or elsewhere will be available for any therapy that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

We intend to seek approval to market our investigational COMP360 psilocybin therapy or future therapeutic candidates in both the United States 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 therapy 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 therapy or future therapeutic candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our investigational COMP360 psilocybin therapy 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 therapy is available. It is possible that a third-party payor may consider our investigational COMP360 psilocybin therapy or any future therapeutic candidates as substitutable and only offer to reimburse patients for the less expensive therapy. Even if we show improved efficacy or improved convenience of administration with our investigational COMP360 psilocybin therapy 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 therapies 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 therapy or any future therapeutic candidates, and may not be able to obtain a satisfactory financial return on therapeutic candidates that we may develop.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;

- cost-effective; and
- neither experimental nor investigational.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved therapies. In the United States, 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 therapies before they will reimburse health care providers who use such therapies. 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 therapy or any future therapeutic candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug therapies exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug therapies 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 therapies 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.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

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 therapies or put pressure on our therapeutic pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Outside the United States, 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 therapy or any future therapeutic candidates. In many countries, the prices of medical therapies are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical therapies, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our investigational COMP360 psilocybin therapy or any future therapeutic candidates. Accordingly, in markets outside the United States, the reimbursement for our therapies may be reduced compared with the United States 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. The medicines regulatory regime in respect of the EU applies to the EEA. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of therapies 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 therapies, this could prevent or delay marketing approval of our investigational COMP360 psilocybin therapy or any future therapeutic candidates, restrict or regulate post-approval activities and affect our ability to commercialize any therapies for which we obtain marketing approval.

EU drug marketing regulation may materially affect our ability to market and receive coverage for our therapies in the EU Member States. Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal therapies 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 (which is no longer a member of the EU), 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 therapy or any of our future therapeutic candidates to other available therapies 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 therapies. Historically, therapies launched in the EU do not follow price structures of the United States 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 therapies is unavailable or limited in scope or amount, our revenue from sales and the potential profitability of our investigational COMP360 psilocybin therapy or any of our future therapeutic candidates in those countries would be negatively affected.

Moreover, increasing efforts by governmental and third-party payors in the EU, the United States and elsewhere to cap or reduce healthcare costs may cause such organizations to limit coverage and the level of reimbursement for newly approved therapies and, as a result, they may not cover or provide adequate payment for our investigational COMP360 psilocybin therapy 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 therapies. We expect to experience pricing pressures in connection with the sale of our investigational COMP360 psilocybin therapy 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 therapies.

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 therapy, any future therapeutic candidate.

Risks Related to Intellectual Property

We rely on patents and other intellectual property rights to protect our investigational COMP360 psilocybin therapy, 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 and associated therapies, digital therapies, methods used to manufacture the underlying therapeutic substances, and the methods for treating patients using those substances and therapies, 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 therapy 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 therapies. As such, we do not know the degree of future protection that we will have on our proprietary therapies.

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 United States 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 therapies, in whole or in part, or that effectively prevent others from commercializing competitive technologies and therapies.

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 United States 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.

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 therapy 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 therapies 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 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 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 therapies and technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, 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 United States. We may fail in enforcing our rights, in which case our competitors and other third parties may be permitted to use our therapies without payment to us.

In addition, litigation involving our patents carries the risk that one or more of our patents will be narrowed, held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our therapies, 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 therapies, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States 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 unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the European Patent Office or 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 United States 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 (i.e., 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. 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 United States 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 therapies, third parties, including our competitors might be able to enter the market with similar or identical therapies 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 therapies, our business may be materially harmed.

In the United States, 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 therapies, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive therapies. Given the amount of time required for the development, testing and regulatory review of new investigational therapies, patents protecting such candidates and concomitant therapies might expire before or shortly after such candidates and concomitant therapies are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing therapies 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 and the FDA regulatory review process. 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 therapies sooner than we expect. As a result, our revenue from applicable therapies 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 therapy, 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 therapies for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our therapies or technologies could 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 employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our consultants, advisors and employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors and potential competitors. Some of these individuals executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we intend that our consultants, advisors and employees do not use proprietary information or know-how of their former employers while working for us, we may 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, of any such individual's former employer. Litigation may 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 therapies. 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 therapies, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our investigational therapies. 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 therapies 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 therapies 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 therapy 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 therapies or therapeutic candidate and the patent owner were to bring an infringement action against us, we may have to argue that our investigational therapies 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 our investigational therapies, 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 develop or commercialize our investigational therapies. Similarly, the targets for our investigational COMP360 psilocybin therapy 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 United States. In general, patent applications in the United States 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 therapies 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 therapies or the use of our therapies.

Third-party intellectual property right holders, including our competitors, may actively 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 therapies.

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 therapies that were held to be infringing. If possible, we might be forced to redesign our investigational COMP360 psilocybin therapy 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 therapies. 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 therapy or program, we may have to abandon development of that investigational therapy 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 therapy 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 therapies that would compete with the therapies 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 therapy 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 therapies. 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 therapy 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 therapy 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 therapy 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 United States, could be less extensive than those in the UK and the United States, 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 United States, or from selling therapies or importing therapeutic substances made using our inventions in and into the UK and the United States, 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 therapies and, further, may export otherwise infringing therapies 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 United States. These therapies 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 United States, 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.

Risks Related to Our Dependence on Third Parties

We rely on third parties to supply and manufacture the psilocybin and psilocin incorporated in COMP360 and expect to continue to rely on third parties to supply and manufacture any future therapeutic candidates, and we will rely on third parties to manufacture these substances for commercial supply, if approved. If any third-party provider fails to meet its obligations manufacturing COMP360 or our future therapeutic candidates, or fails to maintain or achieve satisfactory regulatory compliance, the development of such substances and the commercialization of any therapies, 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 and psilocin incorporated into such therapeutic candidates. We rely on, and expect to continue to rely on, CMOs for the development, manufacture and production of the psilocybin and psilocin used in our investigational therapies 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 therapies 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, 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 extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our investigational COMP360 psilocybin therapy or any future therapeutic candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. Since the beginning of the COVID-19 pandemic, three vaccines for COVID-19 have been granted Emergency Use Authorization by the FDA, two of which have been fully approved. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. 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 therapies, 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 therapies 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 therapies 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 therapies 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 CROs, 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 therapy 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 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 therapies 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 therapy 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 therapy 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 therapy 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 therapy or any future therapeutic candidates. As a result, our results of operations and the commercial prospects for our investigational COMP360 psilocybin therapy 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. 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 therapy 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, 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, 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, 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 therapy 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 therapy 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

A pandemic, epidemic, or outbreak of an infectious disease, such as the ongoing COVID-19 pandemic, 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.

We are subject to risks related to public health crises such as the COVID-19 pandemic. The pandemic and policies and regulations implemented by governments in response to the pandemic, have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical service and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The full extent to which COVID-19 will ultimately impact our business, preclinical studies, clinical trials and financial results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of COVID-19 and related variants and the actions to contain COVID-19 or treat its impact, among others. Other global health

concerns could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

In response to the COVID-19 pandemic, we took a number of temporary precautionary measures intended to help minimize the risk of the virus to our employees, including closing our executive offices and temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees and discouraging employee attendance at industry events and in-person work-related meetings, all of which could have negatively impacted upon our business. The future extent of the impact of the COVID-19 pandemic on our preclinical studies or clinical trial operations, our supply chain and manufacturing and our office-based business operations, will depend on future developments, which remain highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the emergence of additional variants, or the effectiveness of actions to contain and treat coronavirus. On March 23, 2020, we paused the enrollment of new patients into our clinical trials, including our now completed Phase IIb clinical trial of COMP360 in TRD. There can be no guarantee we will not face difficulties or additional costs in enrolling patients in future clinical trials or that we will be able to achieve full enrollment of our studies within the timeframes we anticipate, or at all.

While we are working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to the production of COMP360 and any future therapeutic candidates as a result of the COVID-19 pandemic, if the COVID-19 pandemic continues and persists for an extended period of time, we expect there could be 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. Any such supply disruptions would adversely impact our ability to initiate and complete preclinical studies or clinical trials, including disruptions in procuring items that are essential for our research and development activities and securing manufacturing slots for the products needed for such activities, our ability to generate sales of and revenue from our product candidates, if approved, and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

The COVID-19 pandemic has also affected, and may in the future affect, employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. As new variants of the COVID-19 virus continue to emerge and spread around the globe, we may experience additional disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of sites or facilities serving as our clinical trial sites and staff supporting the conduct of our clinical trials, including our trained therapists, or absenteeism due to the COVID-19 pandemic that reduces site resources;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or national governments, employers and others or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events or patient withdrawals from our trials;
- limitations in employee resources that would otherwise be focused on conducting our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving authorizations from regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as the COMP360 used in our clinical trials;

- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA, the EMA, the MHRA or the other regulatory bodies to accept data from clinical trials in affected geographies outside the United States or the EU or other relevant local geography.

Any negative impact the COVID-19 pandemic has on patient enrollment or treatment or the development of our investigational COMP360 psilocybin therapy and any future therapeutic candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our investigational COMP360 psilocybin therapy and any future therapeutic candidates, if approved, increase our operating expenses, and have a material adverse effect on our financial results. The COVID-19 pandemic has also in the past caused significant volatility in public equity markets and disruptions to the United States and global economies. Increased volatility and economic dislocation may make it more difficult for us to raise capital on favorable terms, or at all. Although we experienced the impact of the COVID-19 pandemic on our business and operations, we cannot currently predict the scope and severity of any potential future business shutdowns or disruptions, should they occur. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial conditions. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also heighten many of the other risks described in this ‘‘Risk Factors’’ section, such as those relating to the timing and completion of our clinical trials and our ability to obtain future financing.

Our future growth and ability to compete effectively depends on retaining our key personnel and recruiting additional qualified personnel, and on the key personnel employed by our collaborative partners.

Our success depends upon the continued contributions of our key management, scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our therapies 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.

Certain members of our management team, including our former chief financial officer, our president and chief operating officer, and our former general counsel have recently resigned. Although we have hired a new chief financial officer and general counsel, the loss of other key managers and senior scientists could delay our research and development activities. In addition, our ability to compete in the highly competitive pharmaceutical 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 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.

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 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 development of our research programs, our investigational COMP360 psilocybin therapy and any future therapeutic candidates leave our collaborative partners, the development of our research programs, our investigational COMP360 psilocybin therapy 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 therapy sites, therapists 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 therapy sites, therapists 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 United States 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 therapy sites and us as a result of actual or alleged therapist misconduct. Although we, and the third-party therapy 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 therapy 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 therapy 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 our therapists, 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 therapies 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. Such non-profits

may be willing to provide psilocybin-based products at cost or for free, undermining our potential market for COMP360. In addition, a number of for-profit biotechnology companies or institutions are specifically pursuing the development of psilocybin to treat mental health illnesses, including TRD. 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 therapies for the treatment of mental health illnesses, such as depression, will increase. If any of our competitors is granted an NDA for their psychedelic-assisted therapies before us and manages to obtain approval for a broader indication, and thus access a wider patient population, we may face more intensified competition from such potential psychedelic-assisted therapies and increased difficulties in winning market acceptance of our investigational COMP360 psilocybin therapy 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 therapies 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 therapy. There are a number of companies that currently market and sell products or therapies, or are pursuing the development of products or therapies, 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 therapies and have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market superior products or therapies. In addition, many of these 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, EMA or MHRA approval for alternative or superior products. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

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 therapies that are more effective, more convenient, more widely used and less costly or have a better safety profile than our therapies and these competitors may also be more successful than we are in manufacturing and marketing their therapies. Additionally, there can be no assurance that our competitors are not currently developing, or will not in the future develop, technologies and therapies that are equally or more economically attractive as our investigational COMP360 psilocybin therapy or any future therapeutic candidates. Competing alternative therapies or technology platforms may gain faster or greater market acceptance than our therapies or technology platforms and medical advances or rapid technological development by competitors may result in our investigational COMP360 psilocybin therapy 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 therapy 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, therapies, 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 therapy sites, therapists, patients and collaborators, and to our ability to attract clinics to become our third-party therapy sites offering our therapies. The promotion of our brand 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 therapy sites, therapists and patients, could harm our reputation and brand and make it substantially more difficult for us to attract new third-party therapy sites, therapists and patients. If we do not successfully maintain, protect or enhance our reputation and brand recognition, our business may not grow and we could lose our relationships with third-party therapy sites, therapists and patients, which would harm our business, financial condition and results of operations.

Our current and potential future digital technologies may not be successful, which may adversely affect our business, financial condition and results of operations.

We currently employ or are developing digital technologies to collect data, educate patients and therapists, collect digital phenotyping information, and harness artificial intelligence. We are expanding our research into digital technology to complement and augment our current or future investigational therapies, and may work with technology companies or other third parties to acquire or develop new technologies. Our efforts to develop or acquire these technologies will involve significant time, costs, and other resources, and may divert our management team's attention and focus from executing on other key elements of our strategy. If our efforts to develop or acquire these digital technologies are unsuccessful, it may have a materially adverse impact on our business, future prospects and financial position.

Our current or future digital technology solutions could compromise sensitive information related to our business, patients, healthcare professionals, therapists, third-party therapy 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 current and future digital technology solutions may involve the collection, storage, usage or disclosure of sensitive data, including protected health information, or PHI, and other types of personal data or personally identifiable information, or PII. We may also process and store, and use additional third parties to process and store, sensitive information including intellectual property and other proprietary business information of ours and our third-party collaborators.

We may also be 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 physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, and employee or contractor error, negligence or malfeasance, could create system disruptions, shutdowns or unauthorized disclosure or modifications of confidential information, causing member health information to be accessed, acquired or altered

without authorization or to become publicly available. We utilize third-party service providers for important aspects of the collection, storage and transmission of client, user and 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 take certain administrative and technological safeguards to address these risks, such as by requiring outsourcing contractors who handle or subcontract the handling of client, user and patient information for us to enter into agreements that contractually obligate those contractors and any subcontractors to use reasonable efforts to safeguard PHI, other PII, and other sensitive information. 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.

A security breach or privacy violation that leads to disclosure or unauthorized use or modification of, or that prevents access to or otherwise impacts the confidentiality, security, or integrity of, member 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, cause us to incur significant costs for remediation, fines, penalties, notification to individuals and for measures intended to repair or replace systems or technology and to prevent future occurrences, potential increases in insurance premiums, and require us to verify the accuracy of database contents, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations 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 platform, and could suffer a loss of clients or users or a decrease in the use of our platform, and we may suffer loss of reputation, adverse impacts on client, user and investor confidence, financial loss, governmental investigations or other actions, regulatory or contractual penalties, and other claims and liability. In addition, security 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 may lead to increased harm.

Any such breach or interruption of our systems or any of our third-party information technology partners, could compromise our networks or data security processes and sensitive information could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost 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 of member 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 perform our services, provide member assistance services, conduct research and development activities, collect, process, and prepare company financial information, provide information about our current and future therapeutic candidates and engage in other user and clinician education and outreach efforts. Any such 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.

Our current operations are headquartered in one location, and we or the third parties upon whom we depend may be adversely affected by unplanned 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 and San Francisco in the United States. 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 therapy or any future therapeutic candidates or interruption of our business operations. Such unplanned 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. For risks in connection with the COVID-19 pandemic, see " *—A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital and our ability to conduct regular business and our financial results*."

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 therapy 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 therapy 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 therapy 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;
- delays in entering into strategic relationships with respect to development or commercialization of our investigational COMP360 psilocybin therapy or any future therapeutic candidates;
- 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 any of our investigational COMP360 psilocybin therapy or any future therapeutic candidates;
- negative publicity or public perception of the use of psilocybin therapy as a treatment therapy;

- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- the trading volume of our ADSs on Nasdaq;
- sales of our ADSs by us, members of our senior management and directors or our 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, and market conditions and overall market volatility in the United States or the UK as a result of the COVID-19 pandemic or other pandemics 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. Broad market and industry factors may significantly affect the market price of our common stock unrelated to our actual operating performance. 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 $10.50 to an intraday high of $61.69 for the period beginning September 18, 2020, our first day of trading on The Nasdaq Global Market, through March 31, 2022. 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.

Our executive officers, directors and certain significant shareholders own a substantial number of our ordinary shares (including ordinary shares represented by ADSs) and, as a result, may be able to exercise control over us, including the outcome of shareholder votes. Certain of our directors and officers hold interests in one of these shareholders and these shareholders may have different interests from us or your interests.

Based upon our ordinary shares outstanding as of April 19, 2022, our executive officers, directors, greater than five percent shareholders and their affiliates beneficially own approximately 45% of our ordinary shares and ADSs. Depending on the level of attendance at our general meetings of shareholders, these shareholders either alone or voting together as a group may be in a position to determine or significantly influence the outcome of decisions taken at any such general meeting. Any shareholder or group of shareholders controlling more than 50% of the share capital present and voting at our general meetings of shareholders may control any shareholder resolution requiring a simple majority, including the appointment of board members, certain decisions relating to our capital structure, the approval of certain significant corporate transactions and amendments to our Articles of Association. Among other consequences, this concentration of ownership may prevent or discourage unsolicited acquisition proposals that our shareholders may believe are in their best interest as shareholders. Some of these persons or entities may have interests that are different than those of our other shareholders. For example, because many of these shareholders purchased their ordinary shares at prices substantially below the price at which ADSs were sold in our initial public offering have held their ordinary shares for a longer period, they may be more interested in selling our company to an acquirer than other investors or they may want us to pursue strategies that deviate from the interests of other shareholders.

For more information regarding our principal shareholders and their affiliated entities, see the sections titled “Security Ownership of Certain Beneficial Owners and Management” and “Certain Relationships and Transactions with Related Parties” in our definitive proxy statement for the 2022 Annual General Meeting of Shareholders.

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. 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 are not treated as holders of our ordinary shares.

Holders of ADSs are not treated as holders of our ordinary shares, unless they withdraw the ordinary shares underlying their ADSs in accordance with the deposit agreement and applicable laws and regulations. The depositary is the holder of the ordinary shares underlying our ADSs. Holders of ADSs therefore do not have any rights as holders of our ordinary shares, other than the rights that they have pursuant to the deposit agreement.

Holders of our ADSs will 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 will not be able to exercise voting rights attaching 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.

Most of the members of our senior management and certain members of our board of directors are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtain in U.S. courts against them or us based on civil liability provisions of the U.S. federal securities laws.

The United States 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 United States, 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 United States. 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, is an issue for the court making such decision. 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.

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 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 euros on our ordinary shares represented by ADSs could also decline.

Holders of ADSs may not be able to participate in equity offerings we may conduct from time to time.

Certain shareholders and holders of ADSs, including those in the United States, 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. 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.

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 United States 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 United States 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 United States 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 United States 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.

If we were classified as a passive foreign investment company, it 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 under "Taxation—Material U.S. Federal Income Tax Considerations for U.S. Holders") 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. No assurances regarding our PFIC status can be provided for the current 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 be treated as CFCs, 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.

We believe that we were classified as a CFC for the 2021 taxable year. However, 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., and particularly now that we no longer qualify as an emerging growth company, 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, we are required to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending December 31, 2021. As a large-accelerated filer, we also require an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. 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 as a result of this, 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 common stock 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 common stock and cause us to incur additional expenses.

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 United States and most of our directors and senior management reside outside the United States.

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 most of our senior management and certain of our directors reside, outside of the United States. As a result, it may not be possible to serve process within the United States 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 United States. As a result, it may not be possible for investors to effect service of process within the United States 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.

The United States 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 United States, 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 entertain original 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.

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, is subject to determination by the court making such decision. 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.

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 authority from our shareholders to allot additional shares for a period of five years from September 11, 2020 was included in the ordinary resolution passed by our shareholders on September 11, 2020, which authorization 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 authority from our shareholders to disapply preemptive rights for a period of five years was included in the special resolution passed by our shareholders on September 11, 2020, 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, will not apply if our place of central management and control remains outside of the UK (or the Channel Islands or the Isle of Man).

We believe that our place of central management and control is not currently in the UK (or the Channel Islands or the Isle of Man) for the purposes of the jurisdictional criteria of the Takeover Code. Accordingly, we believe that we are not currently subject to the Takeover Code and, 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.

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 September 17, 2020, 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.

Our business and results of operations may be negatively impacted by the UK's withdrawal from the EU.

On June 23, 2016, the UK held a referendum in which a majority of voters approved an exit from the EU, or Brexit, and the UK formally left the EU on January 31, 2020. There was a transition period during which EU pharmaceutical laws continued to apply to the UK, which expired on December 31, 2020. However, the EU and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently aligns in the most part with EU regulations, however it is possible that these regimes will diverge in the future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. For example, the new Clinical Trials Regulation which became effective in the EU on January 31, 2022 and provides for a streamlined clinical trial application and

assessment procedure covering multiple EU Member States has not been implemented into UK law, and a separate application will need to be submitted for clinical trial authorization in the UK. In addition, as we are headquartered in the UK, it is possible that Brexit may impact some or all of our current operations. For example, Brexit will impact our ability to freely move employees from our headquarters in the UK to other locations in the EU and it will impact the ability of EU therapists to move freely to the UK in order to complete part of their training or work on our clinical trials there. Furthermore, if other EU Member States pursue withdrawal, barrier-free access among the EEA overall could be diminished or eliminated.

The long-term effects of Brexit will depend in part on how the terms of the TCA continue to take effect in practice and the terms of any further agreements the UK makes with the EU. Such a withdrawal from the EU is unprecedented, and it is unclear how the restrictions on the UK's access to the European single market for goods, capital, services and labor, or single market, and the wider commercial, legal and regulatory environment, will impact our future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the UK in the long term.

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.

We previously identified material weaknesses in our internal control over financial reporting. We may identify future material weaknesses in our internal control over financial reporting. If we are unable to remedy these material weaknesses, or if we fail to establish and 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.

During the preparation of our 2019 financial statements, management identified three material weaknesses 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.

Specifically we identified that we lacked a sufficient number of trained professionals with an appropriate level of accounting knowledge, training and experience to:

- design and maintain formal accounting policies, procedures and controls over the fair presentation of our financial statements;
- analyze, record and disclose complex accounting matters timely and accurately, including share-based compensation arrangements and other non-routine transactions; and
- design and maintain controls over the preparation and review of account reconciliations, journal entries and financial statements including maintaining appropriate segregation of duties.

In response to the material weaknesses, we have since recruited an experienced finance team, which is further supported by appropriately qualified external advisers, including third-party professional accounting consulting firms to advise on accounting for and presentation of technical and complex non-routine transactions, as well as the calculation and review of tax liabilities and research and development tax credits.

- The Company has designed and now maintains formal accounting policies, procedures and controls to ensure the fair presentation of our financial statements;

- The Company is now identifying, analyzing, recording and disclosing complex accounting matters in a timely and accurate manner; and
- The Company has designed and is maintaining controls over the preparation and review of account reconciliations, journal entries and financial statements including maintaining appropriate segregation of duties.

These enhancements to our internal controls over financial reporting have operated for a sufficient period of time, and management's evaluation of such controls indicates that such controls are effective. Although we have determined that the previously identified material weaknesses were remediated as of December 31, 2020, 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*."

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 pound sterling (except that the functional currency of our U.S. subsidiary is the U.S. dollar) and the majority of our operating expenses are paid in pound sterling. 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 United States. As a result, our business and the price of our ADSs may 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 financial statements appearing 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.

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 income tax returns in multiple jurisdictions. Our consolidated effective 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 those related to the Organisation 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 initiatives); the practices 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, 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, Her Majesty's Revenue & Customs, or 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 income 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.

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 therapies 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 therapies 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. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies 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 and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA 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 therapies.

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 United States 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 United States 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 United States, the first to file a patent application was entitled to the patent. After March 16, 2013, under the AIA, the United States 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 United States 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 United States 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 inflation, political instability in particular in foreign economies and markets, and the potentially severe continued United States and global economic impact caused by the ongoing COVID-19 pandemic;
- 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 United States and EU;
- 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 cyber security or cyber security 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 security 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. Cyber incidents have been increasing in sophistication and frequency and can include third parties gaining access to employee or customer data using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks, ransomware, card skimming code, and other deliberate attacks and attempts to gain unauthorized access. Whilst we conduct periodic penetration testing and perform continuous security monitoring, as the techniques used by computer programmers 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.

Additionally, it is also possible that unauthorized access to customer data may be obtained through inadequate use of security controls by customers, suppliers or other vendors. While we are not currently aware of any material impact from recent attacks such as SolarWinds, Log4j, and Kaseya, new information on the scope of such attacks is continuing to emerge. While we continue to devote time and resources on the remediation of such risks, there is the possibility of a material impact from such an attack in the future.

While we have not, to our knowledge, experienced any such material system failure or security breach 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 security 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 therapy 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 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.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Key national economies, including the United States and UK, have been affected from time to time by economic downturns or recessions, supply chain constraints, rising inflation, restricted credit, poor liquidity, reduced corporate profitability, volatility in credit, equity and foreign exchange markets, bankruptcies, rising interest rates and overall uncertainty with respect to the economy. For example, while we do not have activities in Russia and Ukraine, the ongoing conflict and any further escalation of geopolitical tensions related to this conflict has and could result in, among other things, supply disruptions, fluctuations in foreign exchange rates and increased volatility in financial markets, any of which 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 is the Pound Sterling, but we report our financial results in U.S. dollars. For example, increasing interest rates in the United States to respond to inflationary pressures and market volatility has and could lead to further foreign currency fluctuations which could negatively impact our results of operations and financial condition. In addition, increased 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.

ITEM 2. UNREGISTERED SALE OF EQUITY SECURITIES AND USE OF PROCEEDS

Use of IPO Proceeds

On September 17, 2020, the Registration Statement on Form S-1 (File No. 333-248484) relating to our IPO was declared effective by the SEC. There has been no material change in the planned use of proceeds from our IPO as described in our IPO prospectus.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

ITEM 5. OTHER INFORMATION

Not applicable

ITEM 6. EXHIBITS

The documents listed in the Exhibit Index of this Quarterly Report 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).				
10.1#*	Master Research Collaboration Agreement by and among COMPASS Pathfinder Limited, King's College London and South London and Maudsley NHS Foundation Trust, dated March 22, 2022				
10.2	Form of Restricted Share Unit Award Agreement for Company Employees under the 2020 Share Option and Incentive Plan.	Form 8-K	001-39522	10.1	2/4/2022
10.3	Form of Non-Qualified Share Option Agreement for Company Employees under the 2020 Share Option and Incentive Plan.	Form 8-K	001-39522	10.1	2/4/2022
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.)				

Certain confidential portions of this Exhibit were omitted by means of marking such portions with the Mark because the identified confidential portions are (i) not material and (ii) would be competitively harmful if publicly disclosed.

* Filed herewith

** The certifications furnished in Exhibit 32.1 and 32.2 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 Act of 1934 the registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized.

COMPASS PATHWAYS PLC

Date: May 10, 2022

By: /s/ George Goldsmith
George Goldsmith
Chief Executive Officer
(Principal Executive Officer)

Date: May 10, 2022

By: /s/ Michael Falvey
Michael Falvey
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

MASTER RESEARCH COLLABORATION AGREEMENT

Dated as of March 22, 2022

By and Among

COMPASS Pathfinder Limited,

King's College London

And

South London and Maudsley NHS Foundation Trust

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MASTER RESEARCH COLLABORATION AGREEMENT

THIS MASTER RESEARCH COLLABORATION AGREEMENT, dated as of March 22, 2022 (the "**Effective Date**"), is made by and among:

(1) COMPASS Pathfinder Limited a company incorporated in England and Wales under company number 10229259, with its registered offices at 3rd Floor, 1 Ashley Road, Altrincham, Cheshire, WA14 2DT, United Kingdom (**"COMPASS"**); and

(2) King's College London, with its registered offices at Strand Building, Strand Campus, Strand, London, WC2R 2LS, United Kingdom ("**KCL**"); and

(3) South London and Maudsley NHS Foundation Trust, with its registered offices at Bethlem Royal Hospital, Monks Orchard Road, Beckenham BR3 3BX, United Kingdom ("**SLaM**").

RECITALS

WHEREAS, COMPASS is a mental health care company dedicated to accelerating patient access to evidence-based innovation in mental health, with a vision to cultivate a world of mental wellbeing and transform the patient experience in mental health care;

WHEREAS, KCL is an internationally renowned university delivering exceptional education and world-leading research, and is dedicated to driving positive and sustainable change in society and realizing its vision of making the world a better place;

WHEREAS, SLaM is part of an academic health sciences centre called King's Health Partners with KCL, and Guy's and St Thomas' NHS Foundation Trust and King's College Hospital NHS Foundation Trust, and is a leader in improving health and well-being – locally, nationally and globally;

WHEREAS, COMPASS, KCL and SLaM have collaborated with each other on psilocybin therapies, psychedelic therapies, and other mental health initiatives over the past several years, which efforts have highlighted to each of them a deep commitment to a shared vision of cultivating a world of mental well-being;

WHEREAS, the Parties wish to strengthen this commitment by entering into a strategic collaboration with an overarching goal of accelerating patient access to evidence-based innovation in mental health care by driving forward research in psilocybin therapy and other novel psychedelic therapies ("**Collaboration Mission**");

WHEREAS, to advance the Collaboration Mission, the Parties contemplate a mutually agreed Master Activity Plan outlining the five (5) Pillars of interlocking collaborative activities designed to achieve the collective vision of mental healthcare transformation and outlining the parties' activities across the different Pillars;

WHEREAS, this MRCA will set forth the governance provisions, coordination, guiding principles, overall framework, umbrella terms and conditions, objectives, and commitments for the implementation of the Master Activity Plan through each of the activity Pillars;

WHEREAS, the Project Contracts will set forth principles and terms and conditions specific to the Projects laid out in the accompanying Collaboration Plans; and

WHEREAS, it is understood that not all the Parties will participate in each Project and the Participating Parties may enter into one or more separate Project Contracts to effect the Collaboration Mission.

NOW, THEREFORE, in consideration of the foregoing premises and the covenants contained herein, the receipt and sufficiency of which are acknowledged, the Parties hereby agree as follows:

Article 1
DEFINITIONS AND INTERPRETATION

1.1 Defined Terms: Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

"**Academic Parties**" means each of KCL and SLaM.

"**Affiliate**" means any person or entity that controls, is controlled by, or is under common control with a specified person or entity. For purposes of this definition, "control" is presumed to exist if one or more of the following conditions are satisfied: (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) (or, if fifty percent (50%) or less, the maximum ownership interest permitted by law) of the stock having the right to vote for the election of directors, (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) (or, if fifty percent (50%) or less, the maximum ownership interest permitted by law) of the equity or income interest, or (iii) in the case of any entities, the direct or indirect ownership or control (by contract, operation of law or otherwise) of the power to direct the management and policies of any entity.

"**Agreement**" means this MRCA and any exhibits and Schedules attached hereto as each of the foregoing may be amended from time to time.

"**Alliance Manager**" has the meaning set forth in Clause 3.6.

"**Applicable Law**" means all laws, ordinances, rules, directives and regulations of any kind whatsoever of any governmental or regulatory authority of a country, in each case to the extent applicable to the respective activities of each Party under this Agreement.

"**Background IP**" means, with respect to a Party, all Intellectual Property Rights that (a) with respect to this Agreement is (i) controlled by a Party prior to the Effective Date or (ii) [***], created, [***] by or for a Party after the Effective Date [***] of this Agreement; and (b) with respect to any Project Contract is (i) controlled by a Party prior to the effective date of such Project Contract or (ii) [***], created, [***] by or for a Party after the effective date of such Project Contract that is outside of the scope of such Project Contract.

"**Business Day**" means any day except Saturday, Sunday or a day on which commercial banks are closed in London, England.

"**Calendar Quarter**" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

"**Calendar Year**" means each respective period of twelve (12) consecutive months ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

"**Claim**" has the meaning set forth in Clause 11.1.

"**Collaboration Mission**" has the meaning set forth in the Recitals.

"**Collaboration Opportunity**" has the meaning set forth in Clause 3.1.3(d).

"**Collaboration Plan**" has the meaning set forth in Clause 2.1.3. Each Collaboration Plan shall be deemed to be the [***] of each Party.

"**Commercialization**" means any and all activities directed to the marketing, [***], and sale of a product or therapy.

"**COMPASS**" has the meaning set forth in the preamble.

"**Confidential Information**" means (a) the terms of this Agreement, and (b) any technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, Know-How, Intellectual Property, and other information that is disclosed by one Party to another Party pursuant to this Agreement (including information disclosed prior to the Effective Date), [***] and regardless of whether such information is in written, oral, electronic, or other form.

"**Control**" or "**Controlled**" means, (i) with respect to any Intellectual Property Right and a Party or its Affiliate, the ability of such Party or its Affiliate (whether by ownership or license, other than pursuant to a license granted under this Agreement), as applicable, to assign, transfer or grant access to, or a license or sublicense of, or grant the ability to prosecute, maintain or enforce, such item or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party or (ii) with respect to change of control "Control" has the meaning given in section 1124 of the Corporation Tax Act 2010.

"**Controller"** shall have the meaning given it in the Data Protection Laws.

"**Data Protection Laws**" means all applicable legislation relating to data protection and privacy as applicable to the Parties and/or this Agreement including without limitation, the EU General Data Protection Regulation 2016/679 (GDPR), the GDPR in such form as incorporated into the laws of the United Kingdom (UK GDPR), the Data Protection Act 2018, and any associated implementing legislation and regulations in EEA member states or otherwise; and any guidance, guidelines, codes of practice, approved codes of conduct or approved certification mechanisms issued by any relevant data protection supervisory authority; in each case, as in force and applicable, and as amended, supplemented or replaced from time to time.

"Data Subject" shall have the meaning given it in the Data Protection Laws.

"**Development**" means with respect to any product, any and all internal and external research, development and regulatory activities regarding such product.

"**Designated Officers**" means in respect of each one of the Parties, the individuals appointed by each of the Parties as Designated Officers who shall have the authority to bind the entity, as notified by the Parties to each other from time to time.

"**Design and Development Management Costs**" means the costs [***] in relation to the management of the design, development and refurbishment of properties known as 5 Windsor Walk and Bethlem Hospital, the estimates of which are set out in Schedule 9 (Estimated Management Costs).

"**Disclosing Party**" has the meaning set forth in Clause 6.1.

"**Dispute**" has the meaning set forth in Clause 14.1.

"EIR" means the Environmental Information Regulations 2004 (as amended).

"**External Funding**" means any funding or assistance provided for any Project or to any Party for use in respect of any Project by a Third Party.

"**FCA**" has the meaning set forth in Clause 6.7.2.

"**Financial Contribution**" means with respect to a Project, the financial contribution to be made by a Participating Party[***], includes any Investment Amount.

"**Finance Subcommittee**" has the meaning set forth in Clause 3.1.4.

"**FOIA**" means the Freedom of Information Act 2000 (as amended).

"**Force Majeure Event**" has the meaning set forth in Clause 17.4.

"**Indemnified Party**" has the meaning set forth in Clause 11.4.

"**Indemnifying Party**" has the meaning set forth in Clause 11.4.

"Information Commissioner" shall have the meaning given it in the Data Protection Laws.

"**Insolvency Event**" means any Party:

(a) suspends, or threatens to suspend, payment of its debts or is unable to pay its debts as they fall due or admits inability to pay its debts or is deemed unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986;

(b) commences negotiations with all or any class of its creditors with a view to rescheduling any of its debts, or makes a proposal for or enters into any compromise or arrangement with any of its creditors other than (being a company) for the sole purpose of a scheme for a solvent amalgamation of that other party with one or more other companies or the solvent reconstruction of that other party;

(c) applies to court for, or obtains, a moratorium under Part A1 of the Insolvency Act 1986;

(d) a petition is filed, a notice is given, a resolution is passed, or an order is made, for or in connection with the winding up of that Party other than for the sole purpose of a scheme for a solvent amalgamation of that other party with one or more other companies or the solvent reconstruction of that Party; and/or

(e) suspends or ceases, or threatens to suspend or cease, carrying on all or a substantial part of its business.

"**Intellectual Property Rights**" means any Patents, Know-How, rights to inventions, trademarks, service marks, registered designs, copyrights, including copyrights in any Software, trade secrets, database rights, design rights, rights to use and protect Confidential Information.

"**Investment Amount**" means the amount of funding to be provided by COMPASS to a Participating Party upon the achievement of one or more milestones by one or more of the Parties as described in the Master Activity Plan.

"**IP and Data Governance Subcommittee**" has the meaning set forth in Clause 3.1.4.

"**JCC**" has the meaning set forth in Clause 3.2.1.

"**JSC**" has the meaning set forth in Clause 3.1.1.

"**KCL**" has the meaning set forth in the preamble.

"**Know-How**" means any information and materials, whether tangible or intangible, including discoveries, improvements, modifications, processes, methods, assays, designs, protocols (including clinical trial protocols), practices, formulas, data, inventions, algorithms, techniques, governmental or regulatory information, forecasts, profiles, strategies, plans, results, know-how and trade secrets (in each case, regardless of whether patentable, copyrightable or otherwise), but excluding [***].

"**Lease"** means the lease relating to the property known as 5 Windsor Walk and/or the lease relating to the new building to be constructed at the property known as Bethlem Hospital to be entered into between the Participating Parties in respect of the Model Clinic Pillar attached hereto as Schedule 4 and Schedule 5 respectively.

"**Location**" has the meaning set forth in Clause 2.2.1(i).

"**Loss**" has the meaning set forth in Clause 11.1.

"Master Activity Budget" or "MAP Budget" has the meaning given in Clause 2.1.2.

"Master Activity Plan" has the meaning set forth in Clause 2.1(b). The Master Activity Plan shall be attached hereto in Schedule 1 of this Agreement.

"**MRCA**" shall mean this Master Research Collaboration Agreement as amended from time to time.

"**Participating Party**" means each Party that has entered into a Project Contract, as applicable with respect to a Project.

"**Party**" means each of SLaM, KCL and COMPASS and any Person who becomes a party to this Agreement pursuant to Clause 17.2, and together the "**Parties**."

"**Patent Rights**" means all patents, patent applications or provisional patent applications, utility models and utility model applications, design patents or registered industrial designs and design applications or applications for registration of industrial designs, and all substitutions, divisionals, continuations, [***], continued prosecution applications, requests for continued examinations, reissues, reexaminations, revalidations, registrations, supplementary protection certificates and extensions thereof, in any country of the world. For clarity, any Patent Rights shall include any future Patent Rights that claim priority to or common priority with such Patent Rights or requests for continued examinations, foreign counterparts, and the like of any of the foregoing.

"**Party Vote**" has the meaning set forth in Clause 3.7.1.

"**Permitted Recipients**" has the meaning set forth in Clause 6.3.

"**Permitted Territories**" means the United Kingdom (UK), the European Economic Area (EEA), or another country deemed adequate for the transfer of Personal Data (as applicable) by the UK or European Commission (for EEA transfers) pursuant to Data Protection Laws.

"**Person**" means any individual, unincorporated organization or association, entity, governmental authority or governmental agency.

"Personal Data" shall have the meaning given it in the Data Protection Laws.

"**Pillar**" means activities associated with each of the key subject matter areas of interest in achieving the Collaboration Mission, as described more specifically in the applicable Collaboration Plan set out in Schedule 2.

"**Pillar Progress Plan**" has the meaning set forth in Clause 3.1.3(t).

"**Pre-Trial Activities**" means, in relation to a Project under the Sponsored Research Pillar and a Project under the Investigator Initiated & Academic Studies Pillar, a set of protocols and activities to be carried out by one or more of the Participating Parties to a Project in preparation for a clinical trial and prior to those Parties entering into a Project Contract in respect of that Project. By way of example, the following activities may constitute Pre-Trial Activities: review and confirmation of target population and recruitment strategy; review of resource and capacity in the facilities (and upon completion of development works, 5 Windsor Walk and or Bethlem Hospital as appropriate); review of resource capacity in pharmacy; review of resource capacity in support departments as applicable (e.g. neuroimaging).

"Processing" shall have the meaning given it in the Data Protection Laws.

"Processor" shall have the meaning given it in the Data Protection Laws.

"**Prohibited Act**" means, a Party:

(a) offering, giving, or agreeing to give the other Parties (or any of their officers, employees or agents) any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining of performance of this Agreement or any other contract with the other Parties, or for showing or not showing favour or disfavour to any person in relation to this Agreement or any other contract with the other Parties; and

(b) in connection with this Agreement, paying or agreeing to pay any commission, other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the other Party or Parties; or

(c) committing an offence under the Bribery Act 2010.

"**Project**" means [***] each separate and distinct project to be implemented [***] as contemplated in the applicable Collaboration Plan, and as described more specifically in such applicable Project Plan and the relevant Project Contract.

"**Project Budget**" has the meaning set forth in Clause 4.2.

"**Project Contract**" means [***] a separate written agreement entered into by the applicable Participating Parties [***].

"**Project Manager**" has the meaning set forth in Clause 2.2.1.

"**Project Period**" has the meaning set forth in Clause 2.2.4.

"**Project Plan**" means, with respect to a Project, a written document that sets forth the activities to be conducted pursuant to such Project.

"**Project Start Date**" means with respect to a Project, the date on which the Project commences as set forth in the applicable Project Contract.

"**Public Release**" has the meaning set forth in Clause 9.2.

"**Receiving Party**" has the meaning set forth in Clause 6.1.

"**Request for Information**" means a request for information or an apparent request under the FOIA or the EIR.

"**Restricted Third Party**" means any person (i) whose business activities involve or relate to arms, gambling, pornography or tobacco or (ii) who is the subject of any sanctions imposed by the governments of [***].

"**SLaM**" has the meaning set forth in the preamble.

"**Software**" means computer programs and other software, modules, routines, libraries, macros, scripts, portals, platforms, source code, object code, binary code, executable code, methodologies, algorithms, architecture, structure, software engines, display screens, utilities, user interfaces, layouts, development tools, instructions, templates, data formats, database management code and databases.

"**Study Drug**" means [***], [***] drug candidate(s) as described in the applicable Project Plan.

"**Subcommittee**" means any subcommittees formed by the JSC or a JCC pursuant to Clause 3.1.4.

"**Success Criteria**" means any objective criteria or milestone used for the determination of the successful completion of a Project or Pillar, as applicable.

"**Territory**" means, with respect to a Pillar, the countries in the world that are identified in the applicable Collaboration Plan, as applicable, together with their respective territories and possessions.

"**Third Party**" means any Person other than a Party or its Affiliates.

"**VAT**" means value added tax chargeable under the Value Added Tax Act 1994, or any tax replacing that tax.

"**Working Group**" has the meaning set forth in Clause 3.4.

"**Works**" means all records, reports, documents, papers, drawings, designs, transparencies, photos, videos, graphics, logos, typographical arrangements, software programs, inventions, ideas, discoveries, developments, improvements or innovations and all materials embodying them in whatever form, including but not limited to hard copy and electronic form, prepared by the Parties in connection with this Agreement.

1.2 Headings shall not affect the interpretation of this Agreement.

1.3 A person includes a natural person, corporate or unincorporated body (whether or not having separate legal personality).

1.4 The Schedules form part of this Agreement and shall have effect as if set out in full in the body of this Agreement. Any reference to this Agreement includes the Schedules.

1.5 A reference to a company shall include any company, corporation or other body corporate, wherever and however incorporated or established.

1.6 Unless the context otherwise requires, words in the singular shall include the plural and in the plural shall include the singular.

1.7 Unless the context otherwise requires, a reference to one gender shall include a reference to the other genders.

1.8 Unless expressly provided otherwise in this Agreement, reference to legislation or a legislative provision is a reference to it as amended, extended or re-enacted from time to time.

1.9 Unless expressly provided otherwise in this Agreement, a reference to legislation or a legislative provision shall include all subordinate legislation made from time to time under that legislation or legislative provision.

1.10 Any obligation on a Party not to do something includes an obligation not to allow that thing to be done.

1.11 References to a document in agreed form are to that document in the form agreed by the parties as at the Effective Date.

1.12 References to Clauses, Schedules and Articles are to the clauses, Schedules and Articles of this Agreement.

1.13 Any words following the terms including, include, in particular, for example or any similar expression shall be interpreted as illustrative and shall not limit the sense of the words preceding those terms.

Article 2
STRATEGIC COLLABORATION

1.1 Strategic Collaboration Plans and Overall Approach.

1.1.1 MRCA. The Parties intend this MRCA to serve as the master agreement allowing the Parties to define the overall structure and process for the collaboration activities spawned from the Master Activity Plan [***] all of which are intended to govern the activities contemplated under each of the MAP and Collaboration Plans. Project Contracts (detailed in Clause 2.2. below) will reference this MRCA [***]. Notwithstanding anything to the contrary herein, all Project Contracts shall be consistent with the terms and conditions of this MRCA unless expressly agreed otherwise by all the Parties and expressly stated in the relevant Project Contract making specific reference to this Section 2.1.1, and all Project Plans shall be consistent with advancing the activities outlined in the MAP and associated Collaboration Plan.

1.1.2 Master Activity Plan. The Parties will agree to an initial overarching master plan [***] budget ("**MAP Budget**") the Parties currently posit as reasonably necessary to achieve the mutually agreed Collaboration Mission ("**Master Activity Plan**" or "**MAP**" attached as Schedule 1). The Master Activity Plan will initially be comprised of [***] Pillars representing the key subject matters of interest to advance the Collaboration Mission. This MRCA and the MAP will serve as a high-level vehicle to guide coordination, timing, and execution between the Pillars, as well as certain financial incentives to achieve the mutually agreed Collaboration Mission milestones. The Parties will coordinate through the JSC to oversee any amendments to the MAP or MAP Budget, including any additions or removal of Pillars or budgetary changes.

1.1.3 Collaboration Plans. Each Pillar in the MAP will have a detailed Collaboration Plan outlining each of the Projects consistent with the MAP Budget reasonably necessary to achieve each of the Pillar-specific Collaboration Missions; including [***] as outlined in Schedule 2 ("**Collaboration Plan**"). The JCC responsible for such Pillar shall coordinate the generation of an initial Collaboration Plan for each Pillars (accompanied by a budget consistent with the MAP Budget allocation) and within six (6) months of the Effective Date submit such Collaboration Plan to the JSC for approval. The [***] Collaboration Plans tied to each of the initial Pillars shall be set forth in Exhibit A-E of Schedule 2. It is anticipated that the JCC will continue to evolve their respective Collaboration Plans with additional Projects as the Collaboration Mission advances through their Pillar. The Parties

will coordinate through the requisite JCC to oversee any amendments to the Collaboration Plans, including any additions or removal of Projects. Any substantive amendment to a Collaboration Plan shall be subject to JSC approval. Any budget changes will be handled at the MAP and MAP Budget level.

1.1.4 Project Plans. Each Project outlined in the Collaboration Plan shall be operationalized through a Project Contract and a Project Plan. The Parties contemplate that there will be one or more Projects to be completed under each Pillar by one or more Participating Parties. Matters generally expected to be addressed in each Project Plan are outlined in Schedule 3. The Participating Parties in the Project shall prepare a Project Plan. The JCC responsible for the Pillar that spawns the Project shall review the Project Plan to ensure that it is consistent with the MAP, the relevant Collaboration Plan, and is an appropriate allocation of the MAP Budget for such Pillar and, if acceptable, approve such Project Plan.

1.2 Projects Contracts; Pillar Specific Project Contract Templates

1.1.1 Generally.

(a) Participating Parties and shall implement a JCC approved Project Plan and the mutually agreed budget [***]

(b) Each Project Contract implementing a Project Plan shall include:

(i) [***]

(ii) [***]

(iii) [***]

(iv) [***]

(v) [***]

(vi) [***]

(vii) [***]

(viii) [***]

(ix) [***]

(x) [***]

1.1.2 Sponsored Research Pillar. Under Sponsored Research Pillar, the relevant Collaboration Plan (Schedule 2, Exhibit A) will provide for a series of Projects in which COMPASS will be responsible [***] for the clinical study as shall be set forth in a JCC approved Project Plan and the mutually agreed budget (aligned with the MAP Budget). COMPASS and one or more Participating Parties will enter into a Sponsored Research Project Contract to execute on such Project Plan ("**Sponsored Research Agreement**" or "**SRA**"). The SRA shall take substantially the form of the template contract set out in Schedule 7 of this MRCA [***]. Accordingly, each of the Parties agrees that any amendments, changes, updates and variations to that template contract which are made [***] from time to time shall be deemed to be incorporated into the document set out at Schedule 7 so that any new SRA shall include any such amendments, changes, updates and variations; provided however, any such amendments, changes, updates or variations which are made to the template contract shall not apply to any pre-existing SRA unless the relevant Participating

Parties make any specific amendments [***] to the relevant SRA; further provided, any such amendments, changes, updates or variations which are made to the template contract shall not be adopted to the extent they are inconsistent with the terms and conditions of this MRCA unless expressly agreed otherwise by all the Parties and expressly stated in the relevant Project Contract making specific reference to this Section 2.2.2.

1.1.3 Model Clinic Pillar. Under the Model Clinic Pillar, the Collaboration Plan (Schedule 2, Exhibit B) will provide for a series of Projects in which the Parties will work together to design and build model psychedelic treatment clinics incorporating, among other things, COMPASS Know-How and design, as set forth in a JCC approved Project Plan and the mutually agreed budget (aligned with the MAP Budget). It is anticipated that one or more Participants Parties will enter into a series of [***] Project Contracts on commercially reasonable terms and conditions and in accordance with the budget to implement Project Plans. As of the Effective Date, the contemplated [***] Project Contracts include:

(a) in relation to the property at Maudsley Hospital, Denmark Hill, London SE5 8A2 also known as 5 Windsor Walk, [***]

(b) in relation to the building to be constructed on the Bethlem Hospital site [***]

(c) [***]

1.1.4 Real World Data/Evidence Pillar. Under the Real World Data Pillar, the Collaboration Plan (Schedule 2, Exhibit C) will provide for a series of Projects in which the Participating Parties will collaborate on performing [***] analysis of existing patient data sets as shall be set forth in a JCC approved Project Plan and the mutually agreed Project Budget (aligned with the MAP Budget). One or more Participating Parties will enter into a Project Contract on commercially reasonable and customary terms [***]. If appropriate, a Project Contract shall be subject to the standard governance procedures and approvals of the Clinical Record Interactive Search ("CRIS") application and the Participating Parties will generate a suitable template agreement to address ongoing Projects which shall be added to Schedule 5.

1.1.5 Training Pillar. Under the Training Pillar, the Collaboration Plan (Schedule 2, Exhibit D) will provide for a series of Projects in which the Participating Parties will collaborate to advance [***] therapist course offerings to train the next generation of therapists, clinicians, and research in the delivery of [***] psychedelic therapies as shall be set forth in a JCC approved Project Plan and the mutually agreed budget (aligned with the MAP Budget). The Project Contract shall take substantially the form of an agreement to be attached upon the finalization of the applicable Collaboration Plan.

1.1.6 Investigator Initiated & Academic Studies Pillar. Under Investigator Initiated & Academic Studies Pillar, the relevant Collaboration Plan (Schedule 2, Exhibit E) will provide for a series of Projects in which an Academic Party will be responsible for designing certain clinical trials and serving as the regulatory sponsor for the clinical study as shall be set forth in a JCC approved Project Plan and the mutually agreed budget (aligned with the MAP Budget). The IIS Project Contract shall take substantially the form of an agreement set out in Schedule 8 of this Agreement.

1.1.7 Material Transfer Agreement. In the event a Participating Party agrees to the transfer any biological, chemical or other physical material (including any Study Drug) not otherwise covered in the governing Project Contract to any of the other Participating Parties, such transfer shall be subject to the terms of a separate Materials Transfer Agreement to be entered into by the applicable Participating Parties in substantially the standard form of agreement the transferring Participating Party uses for material transfer and, in any event, standard and customary in the industry.

Article 3
GOVERNANCE

1.1 Joint Steering Committee.

1.1.1 Formation and Purpose of the JSC. Promptly, but not more than thirty (30) days after the Effective Date, the Parties shall establish a Joint Steering Committee ("**JSC**") to serve as [***] decision-making body for the activities to be conducted by the Parties pursuant to this MRCA with respect to the strategic collaboration. The Parties anticipate that the JSC will not be involved in [***], but shall serve as the [***]decision-making body during the Term of this MRCA. The JSC may establish Subcommittees (defined below) as set forth in Clause 3.1.4 below. For clarity, the JSC shall not have any authority beyond the specific matters set forth in this Clause 3.1, and in particular shall not have any power to [***] waive a Party's compliance with this MRCA.

1.1.2 Membership. Each Party will designate up to [***] representatives with appropriate knowledge, expertise, and decision-making authority to serve as members of the JSC. The JSC will be comprised of an equal number of representatives from each of COMPASS, KCL and SLaM. Each Party may replace its JSC representatives at any time upon written notice to the other Party. Each of the Parties will designate one of its JSC members as one of the co-chairpersons of the JSC. [***] The lead co-chairperson or their designee, in collaboration with the Alliance Managers, shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within thirty (30) days thereafter. Such minutes shall not be finalized until all JSC members have had an adequate opportunity to review and confirm the accuracy of such minutes.

1.1.3 Specific Responsibilities of the JSC. The JSC shall have the following responsibilities with respect to the collaboration:

(a) manage the overall strategic alignment among the Parties with respect to the collaboration under this MRCA and maintain the relationships among the Parties;

(b) manage the overall strategic alignment among the Parties with respect to each Pillar and across the Pillars;

(c) manage the overall strategic alignment among the Parties and approve a Master Activity Plan consistent with the Pillars, to be amended from time to time as needed or agreed upon;

(d) evaluate and identify additional opportunities for the Parties to collaborate that are consistent with the Collaboration Mission (a "**Collaboration Opportunity**");

(e) for each Collaboration Opportunity, determine by which Pillar such Collaboration Opportunity would be governed;

(f) evaluate and determine whether there should be any changes to the scope of the Collaboration Mission, including any corresponding changes to the scope or mission of a Pillar;

(g) determine whether to extend the time needed to finalize each of the Collaboration Plans for each of the Pillars in accordance with Clause 2.1(c);

(h) determine whether any amendments should be made to any of the Collaboration Plans with respect to the overall goals and scope of a Pillar;

(i) encourage and facilitate communication and the flow of information between the Parties with respect to their respective activities relating to the Development and Commercialization of any products in connection with or arising under this MRCA;

(j) oversee the JSC's Subcommittees, including the Joint Collaboration Committees, and ensuring effective participation in each such Subcommittee's operations by any of its members;

(k) assign responsibilities that may fall within the purview of more than one Subcommittee to a particular Subcommittee or more than one Working Group to a particular Working Group, as further defined in Clause 3.1.4;

(l) establish such additional Subcommittees and Working Groups as it deems necessary to achieve the objective and intent of this MRCA;

(m) establish and delegate specifically defined duties to any additional subcommittees the JSC decides to form and any other operational committees or ad hoc subcommittees;

(n) serve as an initial forum for discussion of any strategies, issues or disputes relating to patent and other intellectual property matters;

(o) resolve any issues or disputes on matters escalated to the JSC by any subcommittees, committees or groups established pursuant to this Clause 3 on an informal basis and in good faith prior to the initiation of escalation or other formal dispute resolution mechanisms hereunder, including any matters relating to the withdrawal of a Participating Party;

(p) review, discuss, and determine whether to approve any amendments to the Master Activity Plan or a Collaboration Plan for a Pillar proposed by a Party or the JCC;

(q) review, discuss, and determine whether to approve any amendments to the Master Activity Budget and the Project Budgets [***];

(r) review the progress reports on the activities conducted pursuant to a Collaboration Plan for a Pillar (each, a "**Pillar Progress Plan**") as submitted by the applicable JCC in accordance with Clause 3.2.3;

(s) review each Pillar Progress Plan and coordinate and manage the pace of activities to be completed under each Collaboration Plan [***] review and resolve any disputes of any Subcommittee or Working Group;

(t) address any other matters referred to the JSC by the terms of this MRCA; and

(u) perform such other functions as appropriate to further the purposes of this MRCA as determined by the Parties in writing.

1.1.4 Formation and Dissolution of Subcommittee(s). From time to time, in addition to the Joint Collaboration Committees and working groups described in Clause 3.4 below, the JSC may in its discretion, establish additional subcommittees from time to time to handle specific matters within the scope of the JSC's area of authority and responsibility (each, a "**Subcommittee**"), and no Subcommittee's authority and responsibility may be greater than that of the JSC itself. Each Subcommittee shall have such authority and responsibility as determined by the JSC at the time of formation of such Subcommittee and from time to time thereafter. The JSC shall determine when each Subcommittee shall be

dissolved. [***] ("**IP and Data Governance Subcommittee**"). For each of the aforementioned Subcommittees, COMPASS shall appoint a co-chairperson who shall be responsible for calling meetings, preparing, and circulating an agenda in advance of any meeting, and preparing and issuing minutes of each meeting within thirty (30) days thereafter and presenting the Subcommittee's recommendations and reports to the JSC.

1.2 Joint Collaboration Committee.

1.1.1 Formation and Purpose of the JCC. Promptly, but not more than thirty (30) days after the approval of a Master Activity Plan, the Parties shall establish a Joint Collaboration Committee ("**JCC**") for each Pillar that will have the responsibilities set forth in Clause 3.2.3 below. Each JCC will coordinate, oversee and monitor each of the Parties' activities under this MRCA with respect to the applicable Pillar.

1.1.2 Membership. Each Party will designate up to three (3) representatives with appropriate knowledge, expertise, and decision-making authority to serve as members of each JCC. The JCC will be comprised of an equal number of representatives from each of COMPASS, KCL and SLaM. Each Party may replace its JCC representatives at any time upon written notice to the other Parties. [***]. The lead co-chairperson or their designee shall be responsible for calling meetings, preparing, and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within thirty (30) days thereafter. Such minutes will not be finalized until all JCC members have had an adequate opportunity to review and confirm the accuracy of such minutes.

1.1.3 Specific Responsibilities of the JCC. Each JCC shall have the following responsibilities with respect to the applicable Pillar:

(a) review capital investment activities of each of the Parties and coordinate the activities of each of the Parties under such Pillar as set forth in the applicable Collaboration Plan, Project Plans and Project Contracts;

(b) discuss and attempt to address any scientific or technical issues arising in the course of each Party's Development and Commercialization activities with respect to any deliverables in connection with or arising under such Pillar;

(c) evaluate, review and propose any amendments to the Collaboration Plan for such Pillar for review and approval by the JSC;

(d) determine the scope of each separate and distinct Project to be entered into by the applicable Parties with respect to the Pillar, including any subsequent expansion or other modification of such Project;

(e) determine the applicable Participating Parties, to be included in the applicable Project;

(f) review, discuss, and determine whether to approve the Projects proposed to the JCC by any one of the Parties and accompanying budgets prepared by the applicable Participating Parties for a Project, and any amendments to the Project Plans or accompanying budgets;

(g) determine when the Project Managers should be appointed for a particular Project and appoint the Project Managers;

(h) for each Project, establish and delegate specifically defined duties to the Project Managers for such Project;

(i) review, discuss, and determine whether to approve any Project Contracts to be entered into by the Participating Parties as contemplated under the Collaboration Plan;

(j) review, discuss, and determine whether to approve each Project Plan developed by the applicable Project Managers for a Project;

(k) review, discuss, and determine whether to propose to the JSC any amendments to the Collaboration Plan for its Pillar;

(l) review the progress reports on the collaboration activities submitted by the Project Managers in accordance with Clause 3.3.2(e);

(m) address any issues or disputes arising from the conduct of the activities with respect to the Pillar;

(n) establish such additional Working Groups as it deems necessary to achieve the objective and intent of the applicable Project; and

(o) perform such other functions as appropriate to further the purposes of this MRCA as determined by the Parties.

1.3 Project Managers.

1.1.1 Appointment of the Project Managers. Promptly, but not more than thirty (30) days after the JCC approves a Project, the Participating Parties shall appoint a Project Manager for such Project that will have the responsibilities set forth in Clause 3.3.2 below. The Project Managers will coordinate, oversee and monitor each of the Participating Parties' activities under this MRCA for the applicable Project.

1.1.2 Specific Responsibilities of the Project Managers. The responsibilities of the Project Managers will be, with respect to the applicable Projects, to:

(a) assist the JCC to oversee all activities for the Project to be conducted by or on behalf of each of the Participating Parties;

(b) facilitate information sharing and cooperation among the Participating Parties with respect to the Project activities;

(c) prepare the initial Project Plan and any accompanying preliminary budgets for such Project for review and approval by the JCC;

(d) review and prepare amendments or updates to the applicable Project Plans [***];

(e) prepare regular progress reports of all Project activities and submit to the applicable JCC;

(f) resolve any disputes between the Participating Parties as to whether any Success Criteria for a Project has been met; and

(g) perform such other functions as appropriate to further the purposes of this MRCA as determined by the Parties.

1.4 Working Groups. From time to time, the Parties, the JSC or the JCC may establish working groups (each, a "**Working Group**") to oversee particular subject matters that crossover between Pillars and/or Projects. Each Working Group shall undertake the activities allocated to it herein or delegated to it by the Committee to which it reports. During

the process of establishing a Working Group, such Working Group and the Committee to which it reports shall agree regarding which matters such Working Group will resolve on its own and which matters such Working Group will advise the Committee regarding (and with respect to which such advice-specific matters the Committee will resolve); provided, that the Parties acknowledge and agree that each Working Group is intended to function primarily in a supporting role providing advice to the Committee to which it reports, but that each Working Group will be best positioned to provide expedited guidance and decisions regarding certain operational matters as determined by the Committee to which such Working Group reports.

1.5 Meetings.

1.1.1 General. Each Committee will hold meetings at such times as it elects to do so, but in no event will such meetings be held less frequently than once per Calendar Quarter, unless otherwise agreed by the Parties. Each Committee will meet alternatively at COMPASS's facilities, KCL's facilities, and SLaM's facilities or at such Locations as the Parties or the applicable Participating Parties may otherwise agree. Meetings of each Committee may be held by audio or video teleconference with the consent of each Party. The Alliance Manager of each Party will attend each meeting of any Committee as a non-voting participant. Each Party will be responsible for all of its own expenses of participating in any Committee meeting.

1.1.2 Meeting Agendas. Each Party will disclose to the other Parties the proposed agenda items along with appropriate information at least five (5) Business Days in advance of each meeting of each Committee; provided that under exigent circumstances requiring any such Committee's input, a Party may provide its agenda items to the other Parties within a lesser period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Parties consents to such later addition of such agenda items or the absence of a specific agenda for such Committee meeting.

1.6 Alliance Managers. Each of the Parties will appoint one or more individuals to manage Development and Commercialization obligations between the Parties (each, an "**Alliance Manager**"). The role of the Alliance Managers is to act as a single point of contact between the Parties. The Alliance Managers will attend all JSC meetings and the Alliance Managers or their respective designees will attend all Subcommittee meetings and will support the co-chairpersons of the JSC and each Subcommittee in the discharge of his or her responsibilities. Alliance Managers will be non-voting participants in all JSC and Subcommittee meetings. An Alliance Manager may bring any matter to the attention of the JSC or any Subcommittee if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will designate its initial Alliance Manager promptly after the Effective Date and each Party may change its designated Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Alliance Manager will also:

(a) be the point of first referral in all matters of conflict resolution;

(b) provide a single point of communication for seeking consensus between the Parties regarding key strategy and plan issues;

(c) identify and bring disputes to the attention of the JSC in a timely manner;

(d) plan and coordinate cooperative efforts and internal and external communications; and

(e) take responsibility for ensuring that governance activities, such as the conduct of required JSC and Subcommittee meetings and production of meeting minutes, occur as set forth in this MRCA, and that the relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

1.7 Decision-Making.

1.1.1 General Decision-Making Process. Each Party's representatives on the JSC, each JCC, and each Subcommittee will, collectively, have one vote (each, a "**Party Vote**") on all matters brought before such committee [***]. The JSC, each JCC, and each Subcommittee will make decisions as to matters within its jurisdiction by [***] Party Vote, which may be reflected in the minutes of the committee meeting or by an action by written consent signed by the co-chairperson appointed by each Party or his or her designee identified in writing. If the JSC cannot agree on a matter for which the JSC has decision-making authority within fifteen (15) days after the matter was first considered by the JSC, then [***], and (iv) for all other matters, Clause 3.7.2 shall apply. Notwithstanding any provision to the contrary set forth in this MRCA, none of the JSC, any JCC, nor any Subcommittee will have the authority to amend, modify, or waive compliance with this MRCA, which may only be implemented pursuant to a written amendment to this MRCA signed by all of the Parties. Except as otherwise expressly set forth in this MRCA, the phrase "determine," "designate," "approve," or "determine whether to approve" by the JSC, a JCC, or any Subcommittee and similar phrases used in this MRCA will mean approval in accordance with this Clause 3.7, including the escalation and tie-breaking provisions herein. For the avoidance of doubt, matters that are specified in Clause 3.1.3, Clause 3.2.3 and Clause 3.3.2, to be reviewed and discussed (as opposed to reviewed, discussed, and approved) do not require any agreement or decision by the Parties and are not subject to the voting and decision-making procedures set forth in this Clause 3.7.1.

1.1.2 Decisions of the JSC. The JSC has the authority to resolve disputes within the jurisdiction of any JCC or any Subcommittee relating to matters specifically delegated to it or expressly specified in this MRCA and with respect to any other matter agreed to by the Parties in writing. The JSC has no authority other than the authority expressly provided under this MRCA. The JSC will use reasonable endeavours, in compliance with this Clause 3.7.2 to promptly resolve any such matter for which it has authority. Subject to Clause 3.7.1, if, after the use of reasonable endeavours, the JSC is unable to resolve any such matter referred to it by any JCC or Subcommittee or any matter with respect to the matters within the scope of the JSC's authority or any other disagreement between the Parties that may be referred to the JSC, in each case, within a period of for [***] Business Days, then a Party may refer such matter for resolution in accordance with Article 14.

1.8 Authority. In furtherance thereof, each Party will retain the rights, powers and discretion granted to it under this MRCA and no such rights, powers or discretion will be delegated to or vested in the JSC, Subcommittee or any Working Group unless such delegation or vesting of rights is expressly provided for in this MRCA or the Parties expressly so agree in writing.

1.9 ELT Coordination. At least once per Calendar Year during the Term, unless the Parties agree otherwise, members of each Party's executive leadership team will meet (via audio or visual teleconference or in person) to discuss the activities conducted by the Parties with respect to the strategic collaboration under this MRCA.

Article 4
FINANCIAL CONTRIBUTION AND PAYMENT

1.1 General. The general principles relating to the funding of the Master Activity Plan, the Collaboration Plans, and Project Plans are set forth in the Master Activity Plan Budget or the Project Budgets in accordance with this Article 4.

1.2 Budget Management. The Parties shall fund the Master Activity Plan in accordance with the Master Activity Plan Budget (which allocates budget to each of the Pillars). In turn, each Project shall be allocated a budget of its own from the budget allocated to the Project Contract from which that Project stems ("**Project Budget**"). The Finance Subcommittee shall coordinate [***] of the end of each Calendar Quarter each JCC shall deliver to the Finance Subcommittee a report detailing (and including all necessary supporting documentation) the actual Project spend versus the budgeted amounts for the previous Calendar Quarter ("**Budget Report**"). Each Budget Report will be considered Confidential Information [***]. If the actual spend in the previous Calendar Quarter is lower than the budgeted spend, the Finance Subcommittee shall provide for a credit to that Project Budget [***]. Any continuous [***] during the Project of up to [***] will automatically be rolled over and applied to the subsequent Calendar Quarters so that any underspend against budget in a relevant year or other period of four Calendar Quarters will be carried forward into the next year or the next Calendar Quarter as the case may be. If the actual spend in the previous Calendar Quarter is higher than the budgeted spend, the Finance Subcommittee shall, provided that the difference is within ten percent (10%) of the budgeted amount, credit such difference from the MAP Budget for such Pillar to the relevant Project Budget. In the event the difference is greater than ten percent (10%) (either over or under), the Finance Subcommittee will review the Project Budget in toto to determine if the funds can be reallocated within the relevant Calendar Quarters to cover the overage or adjust for the underage. If they are unable to adjust the full budget to accommodate the overage or underage, the matter will be referred to the JCC for resolution. The JCC shall deliver a final reconciliation Budget Report to the Finance Subcommittee detailing the actual Project spend versus the budgeted amounts for the entire term of the Project. If the actual total spend is lower than the total budgeted spend, the Finance Subcommittee shall credit such underspend to the MAP Budget for such Pillar. For avoidance of doubt, if the actual total Project spend is [***]. Participating Parties agree to use the funds in accordance with the budget and nothing in this Agreement shall be interpreted to require each of the Participating Parties to fund more than its share of a budget without their express written agreement.

1.3 Expenses. With respect to each Project, none of the Participating Parties shall be responsible for any cost or expenses not included in the approved Project Budget in the corresponding Project Contract, further provided, unless expressly provided otherwise in the Project Plan:

1.1.1 none of the Participating Parties shall charge any pass-through costs not included in the budget without the prior written consent of the other Participating Parties; and

1.1.2 to the extent that a Participating Party charges any pass-through costs to another Participating Party, no mark-up (including any mark-up to any exchange rate used to convert the currency of any payments) shall be added.

1.4 Project Expense Reports. The Parties will ensure that the applicable Project Managers prepare and submit an account of all income and expenditure in connection with the Projects quarterly to the corresponding JCC.

1.5 Design and Development Management Costs. The Parties agree that the Project Budget for the Model Clinical Pillar shall include the Design and Development Management Costs, [***]. In consideration of SLaM undertaking project management activities in relation to the design, development and refurbishment of the property known as Maudsley Hospital or 5 Windsor Walk and new build at the Bethlem Hospital site, [***]. The Parties acknowledge that the amounts set out in Schedule 9 (Estimated Management Costs) are estimates only. In the event the actual costs incurred by SLaM in the provision of the project management activities contemplated in this Clause 4.5 [***].

1.6 Milestone Payments Across Pillars. The applicable Party(ies) shall promptly notify the JSC in writing following the achievement of all applicable milestone(s) [***]. If

such milestone is achieved prior to or on the corresponding Target Date as defined and set forth in the Master Activity Plan, the Finance Subcommittee shall coordinate payment for the milestone payment in the amount equal to the corresponding Investment Amount (if applicable), and within thirty (30) days after COMPASS's receipt of any invoice in respect of the applicable Investment Amount, COMPASS shall remit the applicable Investment Amount to [***]. For avoidance of doubt, COMPASS is not obligated to pay any amounts to any of the other Participating Parties under [***] unless and until the JSC confirms that the applicable milestones set forth in [***] have been successfully achieved. Each of the Parties shall act reasonably when determining whether or not a milestone has been achieved.

1.7 Payments Among Parties within a Specific Pillar. Within a specific Pillar, the Finance Subcommittee shall ensure that payments between the Parties shall be made in accordance with the financial terms as set forth in the Project Budget and as implemented by the corresponding Project Contracts.

1.8 Pre-Trial Activities Costs. Where the relevant Participating Parties have undertaken the Pre-Trial Activities but have not entered into a Project Contract (for example, due to a failure to obtain the required regulatory approvals for the relevant clinical trials), the Participating Party that has incurred reasonable and documented costs in respect of the Pre-Trial Activities in advance of entering into the Project Contract and the paying Participating Party has expressly agreed to such Pre-Trial Activities being performed in advance of entering into a Project Contract, Participating Party shall invoice and the paying Participating Party shall reimburse such Participating Party for such costs in accordance with Clause 4.12.

1.9 External Funding. Unless otherwise stated in the relevant Project Contract, for any Project where there is External Funding, the allocation of the External Funding will be as set out in the corresponding Project Plan unless the applicable Participating Parties unanimously agree otherwise in writing. Claims for any External Funding will be made through the Project Managers for such Project. Each of the Participating Parties will provide sufficient information to the Project Managers to allow the appropriate Participating Party to claim the External Funding (the "**Funding Receiving Party**") [***]. Each of the Participating Parties will certify its claims for any External Funding in such way as may be necessary to allow the Funding Receiving Party to give any certificate required by the Funding Body in relation to those claims.

1.10 Records. Each Party will keep complete and accurate accounts of its expenditures on the activities contemplated by this Agreement. Such books and records shall be maintained for at least seven (7) years following the latter of termination or completion of the Project and shall be made available for inspection, copying and audit by the other Parties, upon reasonable notice by the other Participating Parties, for the sole purpose of determining the accuracy of amounts invoiced thereunder.

1.11 VAT. Unless any VAT exemption applies, all amounts are exclusive of VAT which the Party making the Financial Contribution will pay at the rate from time to time prescribed by law.

1.12 Invoices and Payment. With respect to each Project, all invoices must include an invoice number, date, and itemized reconciliation to the line item of the relevant budget. Invoices shall be sent to each Parties' designated contact person(s) with a copy to the Finance Subcommittee. Unless expressly provided otherwise in a Project Contract, all payments due under this Agreement shall be made within [***] to the designated bank account of the applicable Academic Party in U.K. pound sterling.

1.13 Late Payment. If any Party fails to make any undisputed payment due to another Party under this Agreement, without prejudice to any other right or remedy available to that other Party, that other Party may charge interest (both before and after any judgement) on the amount outstanding, on a daily basis at the rate of four (4) percent per annum above the base rate of Barclays Bank PLC from time to time in force. That interest will be

calculated from the date of the last date for payment to the actual date of payment, both dates inclusive, and will be compounded quarterly. The Party that is late paying will pay that interest on demand. No Party shall have the right to offset any amount owed to such Party by another Party under one Project against any amounts owed by such Party to the other Party under any other Project(s).

1.14 Inspection. The Parties will ensure that each JCC allows an independent chartered accountant appointed by any Party, at that Party's expense, to examine the accounts and records relating to any Project under such JCC's supervision provided:

1.1.1 at least fourteen (14) days written notice is given in advance to such JCC or the Project Managers;

1.1.2 the inspection or examination takes place during normal working hours; and

1.1.3 the Party appointing the accountant and the accountant will keep confidential any information that it may acquire in the exercise of its rights under this Clause 4.12.

1.15 Accountant Appointment. Any Party to which another Party is obliged to make payments under the Project Contracts may appoint an independent chartered accountant, at its own expense, to examine the accounts and records of the Party which is obliged to make payments to it provided:

1.1.1 at least fourteen (14) days written notice is given in advance to the Party whose accounts and records are to be inspected;

1.1.2 the inspection or examination takes place during that Party's normal working hours; and

1.1.3 the inspecting Party and the accountant will keep confidential any information that it may acquire in the exercise of its rights under this Article 4.

Article 5
OTHER REGULATORY & COMPLIANCE MATTERS

1.1 Compliance with Law. Each Party shall comply with all Applicable Laws. Each Party shall provide to each of the other Parties any and all information, reasonably requested by such other Party to enable such other Party to comply with Applicable Law requirements.

1.2 Cooperation. The Parties will confer and cooperate with one another through the JSC or the JCC (or as directed by the JSC, through a Subcommittee) and in accordance with this Agreement with respect to all matters relating to this Agreement.

1.3 Restrictions and Approvals. To the extent there are any restrictions as to the performance of the activities in a certain Territory as specifically set forth in the Collaboration Plan, the Participating Parties shall comply with such restrictions. Each of the Participating Parties shall obtain and maintain all regulatory approvals, licences, consents and approvals necessary to allow it to carry out the tasks allotted to it in the corresponding Project Contract.

Article 6
CONFIDENTIALITY

1.1 Term of Confidentiality Obligations. Except as otherwise provided in this Article 6, during the Term of this Agreement and [***] expiration of this Agreement

thereafter (or, for any trade secret of the Disclosing Party, for so long as such Confidential Information qualifies as a trade secret of the Disclosing Party under Applicable Law), each Party (the "**Receiving Party**") agrees that it will keep the disclosing party's (the "**Disclosing Party**") Confidential Information confidential and use it solely in accordance with the terms and conditions of this Agreement.

1.2 Confidentiality and Non-Use Obligations. Each Party agrees that all Confidential Information disclosed to such Party or any of such Party's Affiliates by or on behalf of the Disclosing Party or an Affiliate of the Disclosing Party:

1.1.1 will not be used by the Receiving Party or its Permitted Recipients except as [***] in order to further the purposes of this Agreement; and

1.1.2 will be maintained in confidence by the Receiving Party and such Party's Affiliates, with a degree of care that is not less than the Receiving Party typically exercises with respect to its own Confidential Information and in any case with not less than reasonable care.

1.3 Disclosures to Permitted Recipients. Each Party agrees that such Party and such Party's Affiliates will provide Confidential Information received from the Disclosing Party or an Affiliate of the Disclosing Party only on a need-to-know basis and only to the Receiving Party's and its Affiliates' employees, directors, consultants, and advisors (collectively, "**Permitted Recipients**"), solely under conditions of confidentiality and non-use at least as stringent as the conditions imposed by this Agreement, and provided that each Party will remain responsible for any failure by its Permitted Recipients to treat such information and materials as required under Clause 6.2. Neither Party shall allow access to the Confidential Information of the other Party to any Permitted Recipient who does not require such access in order to accomplish the purposes of this Agreement. Receiving Party and its Affiliates will use at least the same standard of care as it uses to protect its own most valuable confidential information, and in any case not less than reasonable care, to ensure that its Permitted Recipients do not disclose or make any unauthorized use or disclosure of the Confidential Information of the Disclosing Party.

1.4 Exceptions to Confidential Information Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information will not apply to the extent that Receiving Party can demonstrate that the Disclosing Party's Confidential Information:

1.1.1 was known or used by the Receiving Party or such Party's Affiliates prior to its date of disclosure to the Receiving Party other than under an obligation of confidentiality or non-use at the time of disclosure;

1.1.2 becomes available to the Receiving Party from a Third Party, other than the Disclosing Party, that lawfully has possession of and the right to disclose such Confidential Information without the breach of any contractual, legal or fiduciary obligation to the Disclosing Party or any Third Party;

1.1.3 at the time of disclosure hereunder was generally available to the public or known to parties reasonably skilled in the field to which such information pertains, or was otherwise part of the public domain, at the time of its disclosure to the Receiving Party;

1.1.4 after disclosure hereunder becomes generally available to the public, except through breach of this Agreement by, or other act or omission of, the Receiving Party; or

1.1.5 is independently developed by or for the Receiving Party, as evidenced by contemporaneous written records, without reference to or reliance upon the Confidential Information of the Disclosing Party.

Specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information will not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

1.5 Trade Secrets, Responsibility for Compliance with Confidentiality and Non-use Obligations.

1.1.1 The Receiving Party will be responsible for any intentional misuse, misappropriation of trade secrets or breach of this Article 6 by the Receiving Party, its Affiliates, or its Permitted Recipients of the Disclosing Party's Confidential Information.

1.1.2 The Receiving Party will promptly notify the Disclosing Party in writing of the Receiving Party becoming aware of any actual or threatened disclosure, intentional misuse, misappropriation of trade secrets or other actual or threatened breach of this Article 6 by any other Person.

1.6 Cooperation. If at any time the Disclosing Party brings, or investigates the possibility of bringing, any claim against any Person for intentional misuse, misappropriation of trade secrets or breach of this Article 6, then the Receiving Party, upon the request and at the expense of the Disclosing Party, will cooperate with and assist the Disclosing Party in the investigation or pursuit of such claim, and provide the Disclosing Party with any information in the possession of the Receiving Party that may be of use to the Disclosing Party in the investigation or pursuit of such claim.

1.7 Authorized Disclosures of Provisions of Agreement. A Receiving Party may disclose Confidential Information of a Disclosing Party or the terms of this Agreement to the extent that such disclosure is:

1.1.1 made in response to a valid order of a court of competent jurisdiction or other governmental authority of competent jurisdiction, provided that the Receiving Party will (i) notify the Disclosing Party of any such disclosure requirement or request as soon as practicable; (ii) cooperate with and reasonably assist the Disclosing Party (at the Disclosing Party's cost) if the Disclosing Party seeks a protective order or other remedy in respect of any such disclosure; (iii) furnish only that portion of the Confidential Information which is responsive to such requirement or request; and (iv) mark any such outgoing communication as "**Confidential**."

1.1.2 otherwise required by Applicable Law (including any securities law or regulation or the rules of a securities exchange or as a requirement in filing for an International Nonproprietary Name (INN) or the like) including by the rules or regulations of the Financial Conduct Authority (the "**FCA**") or similar regulatory agency in a country other than the U.K., or of any stock exchange or other securities trading institution; provided that the Party subject to such disclosure requirement will, if reasonably practicable under the circumstances, provide the other Party with a reasonable opportunity to review and comment in advance on the disclosing Party's proposed disclosure and such disclosing Party will consider in good faith any comments thereon provided by the other Party. Such Party will exercise at least a reasonable standard of care and take commercially reasonable steps to protect Confidential Information of the Disclosing Party and disclose only such portion of Confidential Information of the Disclosing Party, if at all, as is reasonably required to be

disclosed; further provided, that the Disclosing Party will provide the Receiving Party with reasonable notice of such disclosure in advance thereof to the extent practicable;

1.1.3 made by the Receiving Party to governmental authorities as required in connection with any application, filing, or similar requests from Regulatory Authorities; provided, however, that reasonable measures will be taken to assure confidential treatment of such information; and provided, further, that the Confidential Information disclosed will be limited to that information required in connection with such application, filing, or similar request from Regulatory Authorities;

1.1.4 made by the Receiving Party, in the performance of this Agreement or in connection with the exploitation of any product, to Affiliates, collaboration partners, permitted sublicensees and their respective employees, consultants, contractors, representatives or agents, each of whom has a need to know such Confidential Information in order to perform the Receiving Party's obligations or exercise the Receiving Party's rights under this Agreement and whom, prior to disclosure, must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Clause 6, provided that the Receiving Party will use diligent efforts to cause such Persons to comply with the restrictions on use and disclosure in this Clause 6 and will be liable for and indemnify the Disclosing Party for any breach of such Persons;

1.1.5 each Party shall have the right to disclose such terms to investors, bona fide potential investors, collaborators, business partners, sublicensee(s), bona fide potential business partners, lenders, bona fide potential lenders, acquirers, bona fide potential acquirers, and investment bankers in connection with licensing, financing and acquisition activities, and due diligence processes related to such activities, provided that any such Third Party has entered into a written obligation with the Disclosing Party to treat such information and materials as confidential on terms no less restrictive than those set forth herein (and each Party will remain responsible for any failure by any of the foregoing Persons, to whom a Receiving Party may disclose Confidential Information, to comply with such terms);

1.1.6 a disclosure of the terms of this Agreement made in accordance with Clause 9.2 (Publication, Publicity); and

1.1.7 In the event that this Agreement will be included in any report, statement or other document filed by COMPASS or an Affiliate of COMPASS with the FCA or similar regulatory agency in a country other than the U.K. or any stock exchange or other securities trading institution, COMPASS will use, or will cause such Affiliate, as the case may be, to use, reasonable endeavours to obtain confidential treatment from the FCA, similar regulatory agency, stock exchange or other securities trading institution of any Academic Parties' proprietary technical data, Know-How, and trade secrets concerning any Academic Parties' proprietary methods, Academic Parties' equipment and techniques, Academic Parties' facilities and its design and operation, as well as financial information or other information of a competitive or confidential nature, and will include in such confidentiality request such provisions of this Agreement as may be reasonably requested by such Academic Parties.

1.8 Remedies. The Receiving Party acknowledges that a breach by it of any of the terms of this Agreement would cause irreparable harm to the Disclosing Party for which the Disclosing Party could not be adequately compensated by money damages. Accordingly, the Receiving Party agrees that, in addition to all other remedies available to the Disclosing Party in an action at law, in the event of any breach or threatened breach by the Receiving Party of the terms of this Agreement, the Disclosing Party will, without the necessity of proving actual damages or posting any bond or other security, be entitled to seek temporary and permanent injunctive relief, including, but not limited to, specific performance of the terms of this Agreement.

1.9 No Licenses. Except as expressly provided in Article 8 hereof, no right or license, either express or implied, is granted under any Intellectual Property Right or by virtue of the disclosure of Confidential Information under this Agreement, or otherwise. The Parties agree that each Party has and will retain sole and exclusive rights of ownership in and to any Confidential Information of such Party.

Article 7
DATA PROTECTION

1.1 General. Each of the Parties acknowledges and agrees the following in relation to Personal Data processed in connection with this MRCA:

1.1.1 except as contemplated under this Article 7, a Project Contract or any data sharing agreement agreed between the Parties, including substantially in the form set out in Schedule 6, each of the Parties intends that it will not share any Personal Data with any of the other Parties, or any Third Party Controllers, as a result of the Collaboration Mission given effect to by this MRCA or otherwise;

1.1.2 the sharing of Personal Data in respect of a particular Project which is entered into pursuant to the Sponsored Research Pillar or the Investigator Initiated & Academic Studies Pillar, shall be governed by the relevant Project Contract entered into by the Participating Parties;

1.1.3 if one or more of the Parties intends to share with or transfer to one or more of the other Parties, or any Third Party, any Personal Data in respect of a particular Project which is entered into pursuant to the Model Clinic Pillar, the Real World Data / Evidence Pillar (solely to the extent it applies to the CRIS dataset) or the Training Pillar, except to the extent such data is generated or shared under the Sponsored Research Pillar or the Investigator Initiated & Academic Studies Pillar, that such sharing or transferring of Personal Data will be governed and regulated by the provisions of a data sharing agreement to be entered into by the relevant Parties, in substantially the form of the template data sharing agreement set out in Schedule 6, unless the Parties, acting reasonably, agree otherwise; and

1.1.4 any Project Contract entered into by one or more of the Parties, in accordance with Clause 7.1(c) above shall set out which of the Parties is a Controller, Joint Controller or Processor under Data Protection Laws (as applicable to each Project).

1.4 Joint Controllership. Where any Project Contract entered into in relation to Clause 7(1)(c) above indicates that any of the Academic Parties are joint Controllers with COMPASS with regards to any of the Personal Data processed pursuant to this MRCA, the Parties shall agree a responsibility matrix in writing prior to carrying out any processing of Personal Data contemplated under the relevant Project Contract. This responsibility matrix shall set out each of the relevant Party's responsibility for performing the obligations imposed on Controllers under Data Protection Laws (particularly relating to transparency and Data Subject rights) and shall be appended to the relevant Pillar Overview Plan once agreed. The Parties shall agree a written summary of this responsibility matrix which can be made available to Data Subjects on request.

Article 8
INTELLECTUAL PROPERTY RIGHTS

1.1 Ownership Generally. Ownership of Intellectual Property Rights shall be governed by the relevant Project Contract between the Participating Parties; notwithstanding, as among the Parties:

1.1.1 COMPASS owns [***] in and to COMPASS's Background IP;

1.1.2 KCL owns [***] in and to KCL's Background IP; and

1.1.3 SLaM owns [***] in and to SLaM's Background IP.

1.2 Works. The Parties acknowledge that during the Term of this Agreement and pursuant to the Collaboration Plans, the Parties will be creating and developing Works and other deliverables. For each Project, the Parties' respective Intellectual Property Rights ownership (including joint ownership where applicable) and licences in respect of these Works and deliverables shall be governed by [***].

1.3 Commercialization of Products. All Commercialization matters shall be determined on a Project-by-Project basis and set forth in the applicable Collaboration Plan or Project Plan and Project Contract, including [***].

Article 9
PUBLICATION AND PUBLICITY

1.1 Publication. COMPASS agrees that the Academic Parties and the employees of the Academic Parties shall be permitted to present at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results arising under this Agreement subject to this Article 9 and the publication policy described in the applicable Collaboration Plan provided that any material for public dissemination will be submitted to COMPASS for review at least sixty (60) days (or the time limit specified in the applicable Collaboration Plan if longer) prior to submission for publication, public dissemination, or review by a publication committee.

1.1.1 Each Academic Party agrees, and shall ensure that their representatives agree, that all reasonable comments made by COMPASS in relation to a proposed publication by such Academic Parties and their representatives shall be considered by the Academic Parties in good faith prior to the publication.

1.1.2 Each Academic Party acknowledges that COMPASS may present at symposia, national or regional professional meetings, and publish in journals, theses or dissertations, or otherwise of their own choosing, [***]. In the event COMPASS coordinates a multi-centre publication, the participation of the representatives of any Academic Party as a named author shall be determined in accordance with COMPASS's policy and generally accepted standards for authorship as further set out in Clause 9.1.4. If any representatives of any of the Academic Parties is a named author of the multi-centre publication, such person shall have access to the clinical trial data from all clinical trial sites as necessary to participate fully in the development of the multi-centre publication.

1.1.3 During the period for review of a proposed publication referred to in Clause 9.1 above, COMPASS shall be entitled to make a reasonable request to the Academic Parties that publication be delayed for a period of up to three (3) months from the date of first submission to COMPASS in order to enable COMPASS to take steps to protect its proprietary information and/or Intellectual Property Rights and Know How and the Academic Parties shall not unreasonably withhold their consent to such a request. The Academic Parties shall not unreasonably withhold or delay their consent to a request from COMPASS for an additional delay of up to a maximum further three (3) months if, in the reasonable opinion of COMPASS, COMPASS's proprietary information and/or Intellectual Property Rights and Know How might otherwise be compromised or lost.

1.1.4 Any publication made in connection with this Agreement shall give each Party and its personnel appropriate credit and/or recognition for co-authorship in accordance with academic standards for contributions made by such Party or its personnel, provided that authorship involving any of the Parties' personnel is subject to that Party's prior consent.

1.1.5 Except as expressly provided in this Agreement, none of the Parties shall use the name, logo, or trademark of any other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without prior written approval of such other Party in each instance, which approval shall not be unreasonably withheld, conditioned, or delayed. Notwithstanding the foregoing, the Parties shall be free to disclose, without the requirement of each of the other Party's prior written consent, the existence of this Agreement, the identity of the other Parties, and a general description of the Projects. The restrictions imposed by this Clause 9.1.5 shall not prohibit each of the Parties from making any disclosure identifying the other Parties that, in the reasonable opinion of the disclosing Party's counsel, is required by Applicable Law.

1.2 Publicity; Press Releases. Notwithstanding Clause 6.7 of this Agreement, upon the execution of this Agreement, the Parties shall have the option to issue a mutually agreed joint press release regarding the subject matter of this Agreement. After such initial joint press release, none of the Parties shall issue a press release or public announcement relating to this Agreement without [***] except that a Party may issue such a press release or public announcement if the contents of such press release or public announcement have previously been made public other than through a breach of this Agreement.

1.1.1 The Parties recognize that either Academic Party may from time-to-time desire to issue press releases, public statement, or disclosures regarding the activities conducted, or the data, information, or results generated, pursuant to this Agreement ("**Public Release**"). In such event, such Academic Party shall provide COMPASS with a written copy (or an outline of any proposed oral disclosure) of the proposed Public Release for review and approval as soon as practicable prior to publication or disclosure thereof. The Parties shall consult with each other reasonably and in good faith with respect to the text, content, and timing of such Public Release prior to the issuance thereof. Any Public Release will present data, information, or results disclosed therein in a factual, balanced, and non-misleading manner that discloses any limitations in the study design. In addition, such Public Release will also disclose information regarding possible conflicts of interest, including, by way of example, funding or other support from a Third Party.

1.1.2 If COMPASS reasonably requests modifications to the Public Release to prevent disclosure of trade secret or proprietary business information, failing to disclose conflicts of interest, or failing to present the data, information, or results in a factual, balanced, and non-misleading manner (acting reasonably), the Academic Parties shall edit such Public Release to prevent the disclosure of such information prior to publication or disclosure of such Public Release. COMPASS may not unreasonably withhold, condition, or delay consent to such Public Release by [***]; provided however either Academic Party may make disclosures to any applicable regulatory authority as it determines, based on advice of counsel, which is reasonably necessary to comply with Applicable Laws. In such event, such Academic Party shall provide COMPASS with advance notice of legally required disclosures to the extent practicable, and to the extent possible [***].

1.1.3 No other Public Release shall be made, either directly or indirectly, by either Academic Party without first obtaining the written approval of COMPASS; provided however, once any Public Release has been approved in accordance with this Clause 9.2, then such Academic Party may appropriately communicate information contained in such permitted Public Release.

1.1.4 [***]. In no event shall the Academic Parties present COMPASS in a manner that would materially denigrate or diminish the goodwill associated with the COMPASS trademark and tradename.

1.1.5 Except as required by Applicable Law, none of the Parties shall make any representations or commitments on any of the other Party's behalf, nor use any of the

other Party's name or trademarks in any public disclosure, without such other Party's prior written permission which such other Party may withdraw at any time.

Article 10
REPRESENTATIONS AND WARRANTIES

1.1 Representations of Authority. Each Party represents and warrants that it has full corporate right, power and authority to enter into this Agreement and Project Contracts and to perform its respective obligations under this Agreement and that it has the right to grant to the other Parties the licenses and sublicenses (as applicable) granted pursuant to this Agreement.

1.2 Consents. Each Party represents and warrants that all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by it as of the Effective Date in connection with the execution, delivery and performance of this Agreement and the activities contemplated hereby have been obtained by the Effective Date.

1.3 No Conflicts. Each Party represents and warrants to the other Parties that, notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder and intellectual property transferred, including any licenses and sublicenses to be granted by such Party pursuant to this Agreement (a) do not conflict with or violate any requirement of Applicable Law or regulations existing as of the Effective Date and applicable to such Party and (b) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date.

1.4 Enforceability. Each Party represents and warrants to the other Parties that, as of the Effective Date, this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms.

1.5 Exclusivity Covenant. Each of the Parties acknowledges that, pursuant to the Lease relating to the new building to be constructed at the Bethlem Hospital, [***]

10.5.1 Maudsley Hospital or 5 Windsor Walk. Notwithstanding anything to the contrary in this Agreement, during the term of the Maudsley Hospital (4 Windsor Walk) Lease, none of the Academic Parties shall, directly or indirectly, use such leased premises [***]. When (i) the Bethlem Hospital facility is available for use for trials or research [***]

10.5.2 Bethlem Hospital. Notwithstanding anything to the contrary in this Agreement, during the term of the Bethlem Hospital Lease, none of the Academic Parties shall, directly or indirectly, use such leased premises [***]; further provided that as between the parties, such permission shall remain within its sole discretion. Further provided and solely for clarity, in relation to the Bethlem Hospital site, it is understood that SLaM reserves certain rights to occupy parts of that building [***]. Upon expiration or termination of the Bethlem Hospital Lease [***].

1.6 Commitment of Efforts. During the Term, each of the Parties shall dedicate adequate resources in a timely manner, to fulfil its obligations under this Agreement and such obligations shall, in respect of each of the Academic Parties include without limitation a requirement to cause its investigators and other medical personnel to dedicate adequate time and efforts to enable each of the Academic Parties to fulfil its obligations under this Agreement.

Article 11
INDEMNIFICATION AND LIMITATION OF LIABILITY

1.1 Indemnification by COMPASS. COMPASS will indemnify KCL and SLaM and each of their directors, officers, employees, representatives and agents against any and all damages, loss, actions, costs, and expenses (including the cost of reasonable legal and/or professional fees) (collectively, "**Losses**") in connection with any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims and demands of Third Parties ("**Claims**") to the extent arising from or resulting from any negligence or material breach by COMPASS of this Agreement provided, however, that the foregoing indemnity obligation will not apply to the extent that such Losses arise out of or result from any activities for which either KCL or SLaM is obligated to indemnify COMPASS under Clauses 11.2 and 11.3.

1.2 Indemnification by KCL. KCL will indemnify COMPASS and SLaM and each of their directors, officers, employees, representatives and agents against any and all Losses in connection with any and all Claims to the extent arising from or resulting from any negligence or material breach by KCL of this Agreement provided, however, that the foregoing indemnity obligation will not apply to the extent that such Losses arise out of or result from any activities for which either COMPASS or SLaM is obligated to indemnify KCL under Clauses 11.1 and 11.3.

1.3 Indemnification by SLaM. SLaM will indemnify COMPASS and KCL and each of their directors, officers, employees, representatives and agents against any and all Losses in connection with any and all Claims to the extent arising from or resulting from any negligence or material breach by SLaM of this Agreement provided, however, that the foregoing indemnity obligation will not apply to the extent that such Losses arise out of or result from any activities for which either COMPASS or KCL is obligated to indemnify SLaM under Clauses 11.1 and 11.2.

1.4 Indemnification Procedure. Upon receipt of notice of any Claim that may give rise to a right of indemnity from any Party hereto, another Party seeking indemnification (the "**Indemnified Party**") will give prompt written notice thereof to such Party, (the "**Indemnifying Party**") of the Claim for indemnity. Such Claim for indemnity will indicate the nature of the Claim and the basis therefor. Promptly after a Claim is made for which the Indemnified Party seeks indemnity, the Indemnified Party will [***] provided that:

1.1.1 the Indemnified Party will have the right to participate in the defense of any such Claim at its own cost and expense;

1.1.2 the Indemnifying Party will conduct the defense of any such Claim with due regard for the business interests and potential related liabilities of the Indemnified Party; and

1.1.3 the Indemnifying Party will, prior to making any settlement, consult with the Indemnified Party as to the terms of such settlement.

The Indemnifying Party will not, in defense of any such Claim, settle or consent to an adverse judgment in any such claim, demand, action or other proceeding that adversely affects the rights or interests of any Indemnified Party or imposes additional obligations (financial or otherwise) on such Indemnified Party, without the prior express written consent of such Indemnified Party, such consent not to be unreasonably withheld, conditioned or delayed. After notice to the Indemnified Party of the Indemnifying Party's election to assume the defense of such Claim, the Indemnifying Party will only be liable to the Indemnified Party for such reasonable legal or other expenses subsequently incurred by the Indemnified Party in connection with the defense thereof at the request of the Indemnifying Party. As to those Claims with respect to which the Indemnifying Party does not elect to assume control of the defense, the Indemnifying Party will be liable for all reasonable legal or other expenses incurred by the Indemnified Party in connection with the defense thereof and the Indemnified Party will afford the Indemnifying Party an opportunity to participate in such defense at the Indemnifying Party's own cost and expense, and will not settle or otherwise dispose of any of

the same without the consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed. If requested by the Indemnifying Party, the Indemnified Party agrees to cooperate with the Indemnifying Party and its counsel in contesting any Third Party Claim which the Indemnifying Party defends, or, if (a) appropriate and related to the Third Party Claim in question and (b) reasonable in the judgment of the Indemnifying Party, in making any counterclaim against the Person asserting the Third Party Claim, or any cross complaint against any Person.

1.5 Limitations of Liability.

1.1.1 No Party shall limit or exclude its liability in respect of:

(a) death or personal injury caused by negligence;

(b) fraud or fraudulent misrepresentation; or

(c) any liability which cannot be limited by Applicable Law.

1.1.2 SUBJECT TO CLAUSE 11.5.1 AND OTHER THAN FOR BREACH OF ARTICLE 6 (CONFIDENTIALITY) OR ARTICLE 7 (DATA PROTECTION) OF THIS AGREEMENT, EACH PARTY'S LIABILITY UNDER THIS AGREEMENT HOWSOEVER ARISING WILL NOT EXCEED THE AMOUNT PAID OR PAYABLE UNDER THIS AGREEMENT. FOR AVOIDANCE OF DOUBT, THE PROVISIONS RELATING TO THE PARTIES' LIABILITY IN RESPECT OF THE PROJECTS SHALL BE SET OUT IN THE RELEVANT PROJECT CONTRACT.

1.1.3 INDIRECT LOSS. IN NO EVENT WILL ANY PARTY BE LIABLE TO THE OTHER PARTIES FOR ANY INDIRECT, SPECIAL OR CONSEQUENTIAL, LOSS (INCLUDING BUT NOT LIMITED TO, LOSS OF PROFITS, LOSS OF BUSINESS OPPORTUNITY, LOSS OF BUSINESS, OR LOST SAVINGS) WHETHER ARISING IN TORT OR ON ANY OTHER BASIS.

1.1.4 No Additional Remedies. Notwithstanding anything to the contrary set forth herein or in any Project Contract, (a) all claims (whether directly between or among the Parties thereto or any Third Party claims) arising out of the activities or subject matter of such Project Contract shall be resolved solely by such Project Contract; (b) no Party shall have any rights or recourse under this Agreement if such claim can be addressed by such Project Contract; and (c) no Party shall have any right or recourse with respect to any claims directly between or among the Parties or any Third Party claims under both this Agreement and the Project Contract.

1.6 Insurance. Each Party will, at its own expense, obtain and maintain insurance (or in the case of SLaM where relevant, equivalent arrangements through schemes operated by the National Health Service Litigation Authority) with respect to the activities under this Agreement in such amount and subject to such deductibles and other limitations customarily maintained by similar entities. Each Party will provide a copy of such insurance policy to the other Parties upon request.

1.7 Inspection. Subject to applicable regulations and restrictions, including those related to patient privacy and insurance requirements, each Party shall allow the other Parties or their representatives or property insurance company representatives, at any time with reasonable advance notice, to inspect, test, observe the testing of, or examine fire protection and security equipment, systems, and procedures.

1.8 Certificates. Each Party shall on request provide certificates of insurance evidencing the above coverage to the other Parties. Each Party shall list the other Parties as additional insured on the commercial general liability and umbrella policies. None of the

Parties shall materially change or cancel any of the insurance certificates relating to this Agreement without providing thirty (30) days' prior written notice to the other Parties.

Article 12
TERM AND TERMINATION

1.1 Term and Termination. The Term of this Agreement shall begin on the Effective Date and shall terminate on a [***] at the later of (a) ten (10) years; or (b) the termination or expiration of all Project Contracts in such Pillar ("**Term**"). The Parties may agree to extend the Term by written agreement of all of the Parties. Each Project Contract may be terminated in accordance with its terms and shall govern the effects of termination of such Project. Notwithstanding anything to the contrary set forth herein, this MRCA may be terminated by a Party as follows:

1.1.1 immediately upon the delivery of written notice by one Party to another Party, if any other Party is in material breach of any of the provisions of this MRCA or any Project Plan and such breach is capable of being cured and is not cured within [***] after receipt of written notice identifying such breach [***]; or

1.1.2 if all of the Collaboration Plans are not timely agreed-upon pursuant to Clause 2.1(c); or

1.1.3 if a Party experiences an Insolvency Event; or

1.1.4 if a Party has committed a Prohibited Act.

1.2 Termination by Academic Parties. The Academic Parties may terminate this Agreement with immediate effect on a written notice to COMPASS if a change of Control occurs where the party acquiring Control of COMPASS is a Restricted Third Party.

1.3 Termination for Patent Challenge by COMPASS. In the event that Institution or Trust, directly or indirectly, brings, assumes, or participates in, or knowingly, wilfully or recklessly assists in bringing, a dispute or challenge, to the validity, patentability, priority, inventorship, ownership or enforceability of any Patent Rights controlled by COMPASS [***], then COMPASS shall be entitled to terminate this Agreement in its entirety immediately upon written notice to the other Parties.

Article 13
EFFECTS OF TERMINATION

1.1 General. Upon expiration or termination of this MRCA, all rights and licenses granted by any Party under this MRCA shall immediately terminate (except to the extent necessary to conduct wind-down activities). As soon as reasonably practicable but no later than six (6) months from the Effective Date, the Parties shall work together through the JSC and each of the JCCs in good faith to adopt a plan to wind-down activities [***], including overseeing the termination or completion of any ongoing Projects and the disposition of rights and obligations pursuant to Project Contracts ("**Wind-down Plan**"). The Wind-down Plan shall be appended to this Agreement. The Wind-down Plan will provide for any activities that are ongoing as of the effective date of termination or expiration (if any) in a [***] in compliance with all Applicable Laws. Further it will provide for (i) the disposition of any Confidential Information or Know How not accounted for in each of the Project Contracts, if any; and (ii) a mechanism by which all activities [***] may be transitioned to COMPASS or its designee. The Parties shall review the Wind-down Plan each year and if required, amend the Wind-down Plan in accordance with the provisions of this Agreement.

1.2 Survival. Expiration or termination of this MRCA or any Project for any reason will not relieve the Parties of any obligation accruing prior to such expiration or

termination and any other provision that by its terms is intended to survive termination or expiration of this MRCA or such Project, together with any definitions used or schedules referenced therein, will survive termination or expiration of this MRCA or such Project.

1.3 Return of Confidential Information. Unless otherwise expressly provided for in the Wind-down Plan, upon any expiration or termination of this MRCA, each Party will, at the other Parties' option, promptly return or destroy any of such other Parties' Confidential Information (including all Know-How) in its possession or control within [***] of the date of termination; provided, however, that each Party may retain: (a) a single archival copy of the Confidential Information [***], or to perform its obligations, under the surviving provisions of this MRCA (including, without limitation any and all license or sublicense rights expressly made to survive termination or expiration hereof); and (b) any portion of the Confidential Information of the other Parties which a Party is required by Applicable Law to retain.

1.4 Other Effects of Termination. Effects of termination specific to a particular [***] Project upon termination of this MRCA in its entirety, shall be set forth in the applicable [***] Project Contract.

Article 14
DISPUTE RESOLUTION

1.1 General. The Parties recognize that disputes as to certain matters may arise from time to time during the Term of this Agreement that relate to a Party's rights or obligations hereunder (a "**Dispute**"). It is the desire of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation, except as otherwise provided herein. The Parties agree to follow the procedures set forth in this Article 14 if and when a dispute arises under this Agreement. The Parties shall negotiate in good faith and use commercially reasonable efforts to settle any Dispute under this Agreement.

1.2 Escalation

1.1.1 Referral to the Joint Steering Committee. If the JSC, in consultation with the Alliance Managers, does not resolve any Dispute submitted to it for resolution pursuant to Clause 3.7.2 within [***] Business Days after such submission, or in the event that the JSC deadlocks on any other matter within its jurisdiction and such deadlock exists for [***] Business Days (each, an "**Unresolved Committee Matter**"), such matter shall be resolved pursuant to Clause 14.2.2.

1.1.2 Referral to the Designated Officers. With respect to (a) Unresolved Committee Matters and (b) upon written notice by a Party to another Party, all other disputed matters outside the jurisdiction and authority of the Committees shall be referred to the Designated Officers for resolution. The Designated Officers shall meet for attempted resolution by good faith negotiations within [***] Business Days after such matter is referred to the Designated Officers.

1.1.3 Unresolved Officer Disputes. If any disputed matter is not resolved by the Designated Officers within [***] Business Days after such matter is referred to them, or such longer period as the Designated Officers may collectively agree, then such matter shall be resolved as set forth in Clause 14.3.

1.3 Dispute Resolution Procedure. If the Parties have not resolved the Dispute in accordance with Clause 14.2.3, then the Parties will attempt to settle such dispute by mediation in accordance with the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure or any other model mediation procedure as agreed by the Parties. To initiate a mediation, a Party may give notice in writing (a "**Mediation Notice**") to the other Parties requesting mediation of the dispute and shall send a copy thereof to CEDR or an

equivalent mediation organisation as agreed by the Parties asking them to nominate a mediator with experience in the pharmaceutical industry. Based on mediator availability, the mediation shall commence within twenty (20) Business Days of the mediator being named. Neither Party will [***]. Thereafter, Paragraph 14 of the CEDR Model Mediation Procedure will apply (or the equivalent paragraph of any other model mediation procedure agreed by the Parties). The Parties will co-operate with any person appointed as mediator, providing them with such information and other assistance as they shall require and will [***].

1.4 Alternative Action. With respect to any dispute subject to this Article 14, the parties agree that: (i) any relevant time period related to the matter that is that subject of such dispute shall be [***] during any dispute resolution proceeding pursuant to this Article 14; (ii) any provision of Applicable Law notwithstanding, they will not request [***] against any Party; (iii) the provisions of this Article 14 shall not prohibit either Party from seeking [***] to restrain any breach or threatened breach of this Agreement at any time; and (iv) nothing in this Article 14 shall in any way affect the Parties' right to terminate this Agreement in accordance with any of its terms or to [***].

Article 15
FREEDOM OF INFORMATION AND ENVIRONMENTAL INFORMATION REGULATIONS

1.1 General. For clarity, any and all agreements entered into pursuant to this Agreement between the Parties as shall be subject to this Article 15. No Academic Party shall be in breach of this Agreement if it makes disclosures of information in accordance with FOIA or EIR in accordance with this Article 15.

1.2 COMPASS Obligations. COMPASS acknowledges that each Academic Party may be subject to the requirements of FOIA and EIR. COMPASS shall:

1.1.1 provide all necessary assistance and cooperation as reasonably requested by any of the Academic Parties to enable the relevant Academic Party to comply with its obligations under the FOIA and EIR;

1.1.2 transfer to the relevant Academic Party all Requests for Information it receives relating to activities under this Agreement as soon as practicable and in any event within two (2) Business Days of receipt;

1.1.3 use reasonable efforts to provide the relevant Academic Party with a copy of all information belonging to the relevant Academic Party requested in the Request For Information which is in its possession or Control, in the form that the relevant Academic Party reasonably requires within five (5) Business Days (or such other period as the relevant Academic Party may reasonably specify) of the relevant Academic Party's request for such Information; and

1.1.4 not respond directly to a Request for Information unless authorised in writing to do so by the relevant Academic Party or required by Applicable Law.

1.3 Disclosure. COMPASS acknowledges that each Academic Party may be required under the FOIA or EIR to disclose information (including Confidential Information). Each of the Academic Parties shall promptly notify COMPASS of a Request for Information (in accordance with the Cabinet Office's Freedom of Information Code of Practice issued under section 45 of the FOIA) and its intended response to the request. The Academic Party will be responsible for determining in its discretion what information it will disclose in compliance with FOIA or EIR; provided, however, [***] that any Confidential Information disclosed will be limited to that information which is legally required to be so disclosed by such FOIA or EIR.

1.4 Co-operation of the Academic Parties. Each of the Academic Parties shall co-operate with the other Academic Party in relation to any Requests for Information to the extent required in order to enable the other Academic Party to comply with any Request for Information under FOIA or EIR.

Article 16
PROHIBITED ACTS

1.1 Prohibited Acts. The Parties must not commit any Prohibited Act. If any of the Parties or its employees or agents (or anyone acting on its or their behalf) commits any Prohibited Act in relation to activities contemplated by this Agreement with or without the knowledge of the other Parties, the Parties so affected will be entitled:

1.1.1 to terminate this Agreement under Clause 12.1.4 and to recover from the Party that committed the Prohibited Act the amount of any loss resulting from the termination; and

1.1.2 to recover from the Party that committed the Prohibited Act the amount or value of any gift, consideration or commission concerned; and

1.1.3 to recover from the Party that committed the Prohibited Act any loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence.

Article 17
MISCELLANEOUS

1.1 Notices. All notices or communication required or permitted to be given by either Party hereunder shall be deemed sufficiently given if delivered in person, mailed by registered mail or certified mail, return receipt requested, or sent by overnight courier to the other Party at its respective address set forth below or to such other address as one Party shall give notice of to the other from time to time hereunder. Mailed notices shall be deemed to be received on the third (3rd) Business Day following the date of mailing. Notices sent by overnight courier shall be deemed received the day delivered by the courier (provided it maintains a record tracking the date of delivery). Notices delivered in person shall be deemed received as of the date of delivery:

If to COMPASS:

Fora SoHo, 2nd floor
33 Broadwick St, London W1F 0DQ
United Kingdom
Attn: [***]
E-mail: [***]

with a copy to:

3rd Floor, 1 Ashley Road,
Altrincham, Cheshire, WA14 2DT,
United Kingdom
Attn: Legal
E-mail: [***]

If to KCL:

Institute of Psychiatry, Psychology & Neuroscience (IoPPN)
King's College London, Room E2.09, PO72 De Crespigny Park, Denmark Hill, London SE5 8AF

United Kingdom
Attn: [***]
E-mail: [***]

If to SLaM:

South London and Maudsley NHS Foundation Trust
Trust Headquarters, 1st Floor, Maudsley Hospital, Denmark Hill, London SE5 8AZ, United Kingdom
Attn: [***]
E-mail: [***]

With a copy to:

[***]
Attn: [***]
E-mail: [***]

Except where notice is required to be given under this Agreement, it is understood and agreed that this Clause 17 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

1.2 Assignment. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by a Party without the prior written consent of the other Parties, such consent not to be unreasonably withheld, conditioned or delayed; provided, however, that any Party may assign this Agreement without the other Parties' consent [***]; and provided, further, that the relevant Affiliate assignee, Third Party assignee or surviving entity assumes in writing all of the assigning Party's obligations under this Agreement, provided however, notwithstanding the foregoing, in the event that such Third Party [***], then the prior written consent of the Academic Parties shall be required to any assignment or transfer to that Third Party of COMPASS's rights and / or obligations under this Agreement, such consent not to be unreasonably withheld, conditioned or delayed.

The assigning Party (except if it is not the surviving entity) will remain jointly and severally liable with the relevant Affiliate or Third Party assignee under this Agreement. Any attempted assignment not in accordance with this Clause 17.2 shall be null and void and of no legal effect. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. Subject to the foregoing, the terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns.

1.3 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) that, insofar as practical, implement the purposes of this Agreement.

1.4 Force Majeure. Neither Party will be deemed to be in breach of this Agreement as a result of default, delay or failure to perform by such Party that results from any cause beyond the reasonable control of such Party that could not reasonably be foreseen by such Party, including without limitation, fire, earthquake, acts of God, acts of war, terrorism, strikes, lockouts, or other labor disputes, riots, civil disturbances, actions or inactions of governmental authorities (except actions in response to a breach of Applicable

Laws by such Party), epidemics or pandemics (including COVID-19 and its variants (a "**Force Majeure Event**"). In the event of any such Force Majeure Event, the Party affected will promptly notify the other Party, will use commercially reasonable efforts to overcome such Force Majeure Event, and will keep the other Party informed with respect thereto. The Party not subject to such Force Majeure Event may terminate this Agreement with respect to any Project if [***].

1.5 Governing Law. This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement or the breach thereof (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by, and enforced in accordance with, the laws of England and Wales and each Party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).

1.6 Entire Agreement; Amendments. This Agreement, together with any exhibits or schedules attached hereto (each of which is hereby incorporated herein by reference), sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all agreements, understanding, promises and representations made prior to the date hereof, whether written or oral, with respect thereto are hereby superseded and of no further force and effect. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein or as may be agreed otherwise in writing by the parties. No amendment or modification of this Agreement will be binding upon the Parties unless made in writing, makes specific reference to this Clause 17, and duly executed by authorized representatives of both Parties.

1.7 Waiver. A Party's consent to or waiver, express or implied, of any other Party's breach of its obligations hereunder shall not be deemed to be or construed as a consent to or waiver of any other breach of the same or any other obligations of such breaching Party. Party's failure to complain of any act, or failure to act, by the other Party, to declare the other Party in default, to insist upon the strict performance of any obligation or condition of this Agreement or to exercise any right or remedy consequent upon a breach thereof, no matter how long such failure continues, shall not constitute a waiver by such Party of its rights hereunder, of any such breach, or of any other obligation or condition. A Party's consent in any one instance shall not limit or waive the necessity to obtain such Party's consent in any future instance and in any event no consent or waiver shall be effective for any purpose hereunder unless such consent or waiver is in writing and signed by the Party granting such consent or waiver.

1.8 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

1.9 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law.

1.10 Business Day Requirements. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.

1.11 Performance by Affiliates. Each Party may use one (1) or more of its Affiliates to perform its obligations and duties hereunder and such Affiliates are expressly

granted certain rights herein; provided that each such Affiliate shall be bound by the corresponding obligations of such Party and such Party shall remain liable hereunder for the prompt payment and performance of all of their respective obligations hereunder.

1.12 Further Actions. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

1.13 Counterparts, Electronic Execution. This Agreement may be in three or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Furthermore, the words "execution," "signed," "signature," and words of similar import in the Agreement shall be deemed to include electronic or digital signatures or the keeping of records in electronic form, each of which shall be of the same effect, validity, and enforceability as manually executed signatures or a paper-based recordkeeping system, as the case may be, to the extent and as provided for under Applicable Law.

In Witness Whereof, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

COMPASS PATHFINDER LIMITED

By:__

Name:__

Title:__

SOUTH LONDON AND MAUDSLEY NHS FOUNDATION TRUST

By:__

Name:__

Title:__

KING'S COLLEGE LONDON

By:__

Name:__

Title:_____

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, George Goldsmith, 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: May 10, 2022

/s/ George Goldsmith

George Goldsmith
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, Michael Falvey, 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: May 10, 2022

/s/ Michael Falvey

Michael Falvey
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, George Goldsmith, 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 March 31, 2022 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: May 10, 2022

By: /s/ George Goldsmith

George Goldsmith

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, Michael Falvey, 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 March 31, 2022 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: May 10, 2022

By: /s/ Michael Falvey

Michael Falvey

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.