

PROSPECTUS

**4,000,000 American Depositary Shares  
Representing 4,000,000 Ordinary Shares**



We are offering 4,000,000 American Depositary Shares, or ADSs, of COMPASS Pathways plc. Each ADS represents one ordinary share, nominal value £0.008 per ordinary share, of COMPASS Pathways plc. The ADSs may be evidenced by American Depositary Receipts, or ADRs.

Our ADSs are listed on the Nasdaq Global Select Market under the symbol "CMPS." The last reported sale price of our common stock on The Nasdaq Global Select Market on April 29, 2021 was \$38.96 per share.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and a "foreign private issuer" under applicable U.S. Securities and Exchange Commission rules. As such, we have elected to comply with certain reduced public company reporting requirements.

**Our business and investment in our ADSs involve significant risks. These risks are described under the caption "Risk Factors" beginning on page 10 of this prospectus.**

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER ADS		TOTAL	
<b>Public offering price</b>	\$	<b>36.00</b>	\$	<b>144,000,000</b>
<b>Underwriting discounts and commissions<sup>(1)</sup></b>	\$	<b>2.16</b>	\$	<b>8,640,000</b>
<b>Proceeds, before expenses, to COMPASS Pathways plc</b>	\$	<b>33.84</b>	\$	<b>135,360,000</b>

(1) See the section titled "Underwriting" for additional information regarding compensation payable to the underwriters. We have agreed to reimburse the underwriters for certain expenses in connection with the offering.

We have granted the underwriters an option for a period of 30 days to purchase up to 600,000 additional ADSs from us at the public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the ADSs against payment in New York, New York on May 4, 2021.

***Joint Book-Running Managers***

**Cowen**

**Evercore ISI**

**Berenberg**

***Lead Managers***

**Cantor**

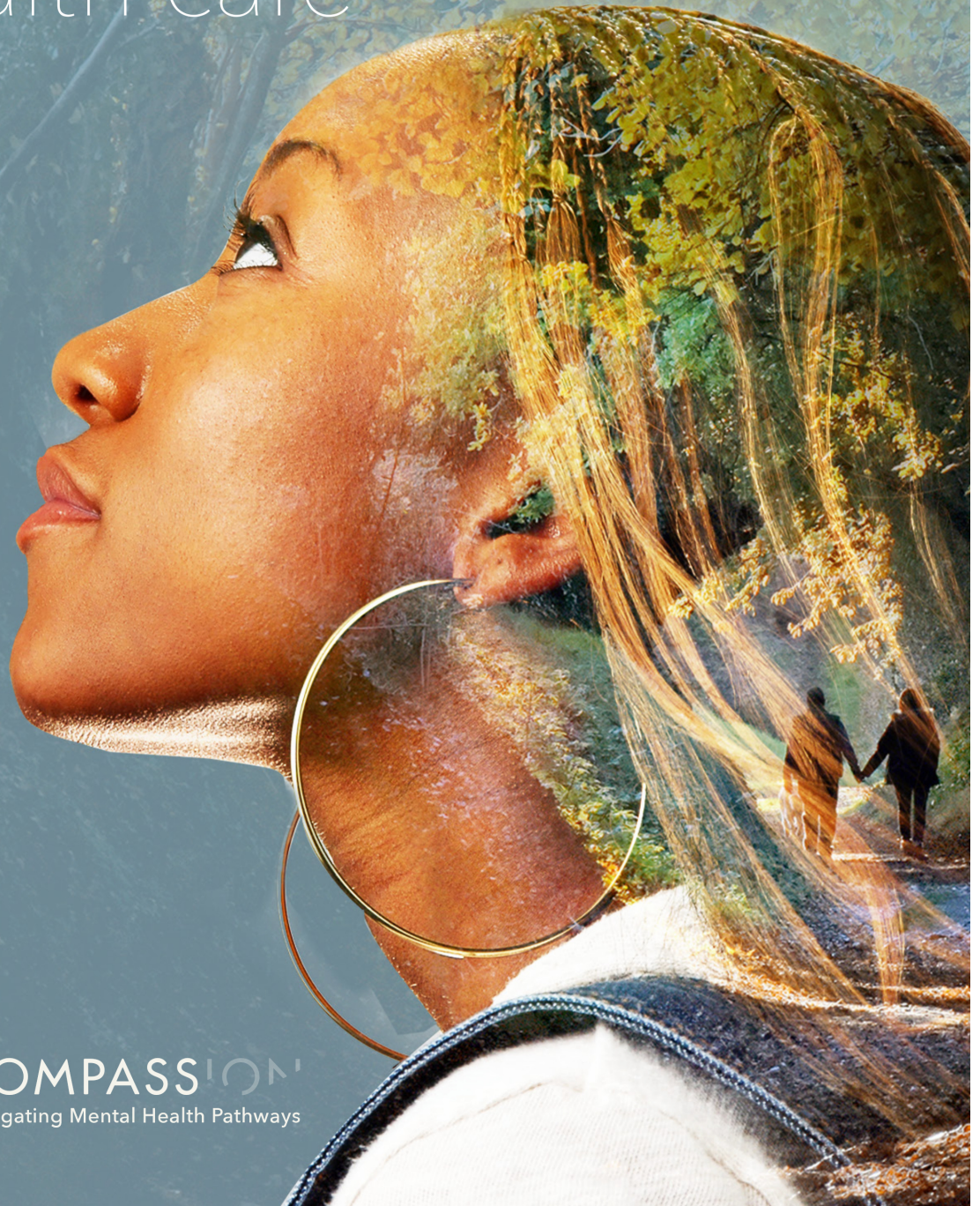
**BTIG**

Prospectus dated April 29, 2021

# Transforming mental health care



COMPASSION  
Navigating Mental Health Pathways





Everyone has a story



Our vision is a world  
of mental wellbeing

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Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, ADSs only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any free writing prospectus is accurate only as of its date regardless of its time of delivery or of any sale of ADSs. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States, or U.S.: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction, other than the United States, where action for that purpose is required. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the ADSs and the distribution of this prospectus outside the United States.

We are incorporated under the laws of England and Wales. Under the rules of the U.S. Securities and Exchange Commission, or the SEC, we are considered a "foreign private issuer." As a foreign private issuer, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act.



## **ABOUT THIS PROSPECTUS**

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to the terms “COMPASS Rx Limited,” “COMPASS Pathfinder Holdings Limited,” “COMPASS Pathways plc,” “the company,” “we”, “us” and “our” refer to (i) COMPASS Pathfinder Holdings Limited (and, where the context requires, its subsidiaries) prior to the completion of the share exchange effected on August 7, 2020 as part of our corporate reorganization that we completed in connection with our initial public offering, (ii) COMPASS Rx Limited (and, where the context requires, its subsidiaries) following the completion of the share exchange effected on August 7, 2020 as part of our corporate reorganization, but prior to the re-registration of COMPASS Rx Limited as a public limited company and the change of its name to COMPASS Pathways plc, and (iii) COMPASS Pathways plc (and, where the context requires, its subsidiaries) following COMPASS Rx Limited's re-registration as a public limited company and change of its name to COMPASS Pathways plc on August 21, 2020.

We own various trademark registrations and applications, and unregistered trademarks, including COMPASS and COMPASS PATHWAYS and our corporate logo. All other trade names, trademarks and service marks of other companies appearing in this prospectus are the property of their respective holders. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ®, ™ or RTM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

## **PRESENTATION OF FINANCIAL INFORMATION**

We maintain our books and records in pounds sterling, our results are subsequently converted to U.S. dollars and we prepare our consolidated financial statements in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, as issued by the Financial Accounting Standards Board, or FASB. All references in this prospectus to “\$” are to U.S. dollars and all references to “£” are to pounds sterling. Unless otherwise indicated, certain U.S. dollar amounts contained in this prospectus have been translated into pounds sterling at the rate of £1.00 to \$1.3662, which was the noon buying rate of the Federal Reserve Bank of New York on December 31, 2020. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as of that or any other date.

We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them. We have historically conducted our business through COMPASS Pathfinder Holdings Limited, and therefore our historical consolidated financial statements through December 31, 2019 present the consolidated results of operations of COMPASS Pathfinder Holdings Limited. For periods beginning after January 1, 2020, our consolidated financial statements present the consolidated results of operations of COMPASS Pathways plc.



## PROSPECTUS SUMMARY

*This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider in making your investment decision. Before investing in our ADSs, you should carefully read this entire prospectus, including the matters set forth under the sections of this prospectus captioned “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this prospectus.*

### 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, the largest randomized, controlled trial with psilocybin therapy to date. In this trial, we observed that COMP360 was generally well-tolerated and supported continued progression of Phase IIb studies. We are currently evaluating COMP360 in conjunction with psychological support in a Phase IIb trial and we plan to report data from this trial in late 2021. We believe that a single dose of our COMP360 monotherapy with psychological support from specially trained therapists could offer a new approach to depression care.

### Market Opportunity and Existing Treatments

Globally, more than 320 million people suffer with MDD. The economic burden of MDD in the United States, accounting for comorbid physical and psychiatric conditions, is estimated to be over \$200 billion per year. TRD, a condition affecting the approximately 100 million patients worldwide who are not helped after two or more existing depression treatments, has even greater economic and societal cost than non-TRD MDD. TRD patients are often unable to perform daily tasks, are more likely to receive disability or welfare benefits and more frequently have co-occurring conditions compared with non-TRD MDD patients. Direct medical costs for TRD patients are estimated to be two to three times higher than for non-TRD MDD patients, caused by, among other factors, increased rates of hospitalization and longer average hospital stays. In addition, there is approximately a seven-fold increase in suicide rate for TRD patients compared with non-TRD MDD patients.

Patients suffering with depression are treated through a variety of approaches, each of which can have significant shortcomings in certain subsets of patients. Most pharmacotherapies for depression employ the same mechanism of action, targeting the modulation of the brain’s neurotransmitter monoamine levels, and have exhibited limited efficacy in a significant portion of patients and can result in high relapse rates. There are only two pharmacotherapies specifically approved for TRD in the U.S.: esketamine, and a combination of olanzapine (an atypical antipsychotic) and fluoxetine (a selective serotonergic reuptake inhibitor). Esketamine was recently approved by the U.S. Food and Drug Administration, or FDA. Mixed efficacy and limited durability were observed in clinical trials as well as potential side effects including dissociation and cognitive impairment. The olanzapine-fluoxetine combination has also shown mixed efficacy and can commonly lead to side effects such as dizziness, drowsiness and weight gain. In addition to pharmacotherapies, various forms of somatic intervention are also used, although these treatments tend to be invasive and/or onerous, and there are limited data supporting their long-term benefit. Psychotherapy is another common treatment approach, but it requires

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

### **Potential of Psilocybin Therapy in Mental Health Conditions**

Psilocybin is considered a serotonergic hallucinogen and is an active ingredient in some species of mushrooms. While classified as a Schedule I drug, there is an accumulating body of evidence that psilocybin may have beneficial effects on depression and other mental health conditions. Therefore, the FDA and the U.S. Drug Enforcement Administration, or DEA, have permitted the use of psilocybin in clinical studies for the treatment of a range of psychiatric conditions. In 2018, we received Breakthrough Therapy designation from the FDA for COMP360 for the treatment of TRD.

We believe that our investigational COMP360 psilocybin therapy may confer beneficial effects in depression and other mental health conditions through COMP360's mechanism of action on the central nervous system, or CNS. By activating the 5-hydroxytryptamine (serotonin) 2A, or 5-HT<sub>2A</sub>, receptor, psilocybin and its active metabolite psilocin induce a range of downstream effects that may cause important, sustained changes in brain function. These effects include altered extracellular release of serotonin and dopamine, changes in brain network connectivity, and increased levels of neuroplasticity, whereby the nervous system is able to reorganize its structure, function, and connections, all of which we believe contribute to our psilocybin therapy's potential to generate rapid-onset and sustained positive mood effects.

The potential of psilocybin therapy in mental health conditions has been demonstrated in a number of academic-sponsored studies over the last decade. In these early studies, it was observed that psilocybin therapy provided rapid reductions in depression symptoms after a single high dose, with antidepressant effects lasting for up to at least six months for a number of patients. These studies assessed symptoms related to depression and anxiety through a number of widely used and validated scales. The data generated by these studies suggest that psilocybin is generally well-tolerated and has the potential to treat depression when administered with psychological support.

### **Our Psilocybin Therapy – COMP360**

COMP360 is our proprietary psilocybin formulation that includes our pharmaceutical-grade polymorphic crystalline psilocybin, optimized for stability and purity. Our investigational COMP360 psilocybin therapy comprises administration of our COMP360 with psychological support from specially trained therapists with specific professional and educational qualifications. We believe this support, or therapy, is an integral element of psilocybin therapy. The psilocybin administration session lasts approximately six to eight hours, with patients supported by therapists in a non-directive manner. Psilocybin administration sessions are preceded by preparation sessions, in which patients are given a thorough orientation, and followed by integration sessions to help patients process the range of emotional and physical experiences facilitated by COMP360 administration.

In 2019, we completed a Phase I trial in 89 healthy volunteers, the largest controlled trial of psilocybin to date, with our investigational COMP360 psilocybin therapy. In this trial, we observed that COMP360 was generally well-tolerated and supported continued progression of Phase IIb studies. The trial also showed the feasibility of simultaneous administration of COMP360 to up to six people in the same facility, with 1:1 therapist support, which we believe will accelerate future clinical trials and commercial scale-up upon potential regulatory approval. In August 2020, the FDA approved our request for a 1:1 model of therapist support and we intend to use this model in future clinical trials. We previously conducted a series of *in vitro* and *in vivo* toxicology studies, including tests for genotoxicity and cardiotoxicity. We are now undertaking an additional series of safety pharmacology and toxicity studies, to be completed prior to commencement of our anticipated Phase III program.



We are currently conducting a randomized controlled Phase IIb clinical trial in 216 patients suffering with TRD, in 22 sites across North America and Europe. This dose-finding trial is investigating the safety and efficacy of COMP360 combined with psychological support, for the treatment of TRD, and aims to determine the optimal dose of COMP360, with three doses (1mg, 10mg, 25mg) being explored. The primary endpoint of this clinical trial is to evaluate the efficacy of COMP360, as assessed by the change in the Montgomery-Åsberg depression rating scale, or MADRS, a widely accepted scale for depression that has been used as a primary endpoint in pivotal trials of other depression treatments. This trial has been designed to capture a statistically significant reduction in MADRS. We plan to report data from this trial in late 2021.

We are using digital technology in this trial, including an online portal to help patients prepare for their psilocybin experience, and a web-based “shared knowledge” interactive platform to complement therapist training. We are also collecting digital phenotyping information through the measurement of human-smartphone interactions. After the trial, these data will be compared with information collected from validated psychiatric scales, such as MADRS, to develop potential digital applications to help anticipate relapse of depression. In the future we plan to expand our research into additional digital technologies to complement and augment our therapies.

The need for innovation in mental health care is significant, given that the current paradigm is ineffective for millions of people. Our vision is a world of mental wellbeing – a world in which mental health isn’t simply the absence of mental illness, but the ability to flourish. We want to help reduce the stigma surrounding mental health, to acknowledge that “everyone has a story,” and to create a system of care for all who are not helped by the existing system and existing therapies.

### **Our Strategy**

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

- Advance our investigational COMP360 psilocybin therapy for the treatment of TRD.
- Expand our investigational COMP360 psilocybin therapy into new indications and explore other compounds and therapies to address areas of unmet need.
- Maximize the reach and value of our investigational COMP360 psilocybin therapy by creating a new model for mental health care.
- Use digital technology to improve access to and impact of our investigational COMP360 psilocybin therapy.

### **Corporate Information**

We were originally incorporated as a private limited company under the laws of England and Wales in June 2020 under the name COMPASS Rx Limited to become a holding company for COMPASS Pathfinder Holdings Limited. COMPASS Rx Limited was subsequently re-registered as a public limited company in August 2020 and renamed COMPASS Pathways plc. COMPASS Pathfinder Holdings Limited was originally incorporated under the laws of England and Wales in June 2017. Our registered office is located at 3rd Floor, 1 Ashley Road, Altrincham, Cheshire, WA14 2DT, United Kingdom, and our telephone number is +1 (646) 905-3974. Our website address is [www.compasspathways.com](http://www.compasspathways.com). We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

### **Summary of Risk Factors**

Our business is subject to a number of risks of which you should be aware before making an investment decision. You should carefully consider all of the information set forth in this prospectus and, in

particular, should evaluate the specific factors set forth in the section titled “Risk Factors” before deciding whether to invest in our ADS. These risks 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;
- Exchange rate fluctuations may materially affect our results of operations and financial condition;
- 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 the product 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, 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 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 is particularly difficult, which makes it difficult to predict and understand why the drug has a positive effect on some patients but not others;
- We have never commercialized a therapeutic candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our therapies on our own or with suitable collaborators;
- 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 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;
- 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 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;
- 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 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, 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, 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;
- Our business is subject to economic, political, regulatory and other risks associated with international operations;
- If you purchase our ADSs in this offering, you will experience substantial and immediate dilution; 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 our ADS price.

### **Implications of Being an Emerging Growth Company and a Foreign Private Issuer**

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. An emerging growth company may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include, but are not limited to:

- an option to present only two years of audited financial statements in addition to any required interim financial statements and correspondingly specified reduced Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure in this prospectus; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. See “Management's Discussion and Analysis of Financial Condition and Results of Operations—Emerging Growth Company Status.”

We may take advantage of these exemptions for up to five years from the date of our initial public offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earlier to occur of: (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.07 billion or more; (ii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three-year period; (iii) the date on which we are deemed to be a large accelerated filer under the rules of the SEC; or (iv) December 31, 2025. We may choose to take advantage of some but not all of these exemptions.

In addition, under the JOBS Act, emerging growth companies can take advantage of an extended transition period for complying with new or revised accounting standards.

We report under the Exchange Act as a non-U.S. company with “foreign private issuer” status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act, we will continue to be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations with respect to a security registered under the Exchange Act;
- the requirement to comply with Regulation FD, which requires selective disclosure of material information;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K upon the occurrence of specified significant events.

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer. As a result, some investors may find our ADSs less attractive, which could result in a less active trading market for our ADSs or more volatility in the price of our ADSs.



## THE OFFERING

ADSs offered by us	4,000,000 ADSs, each representing one ordinary share.
Option to purchase additional ADSs	We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to an additional 600,000 ADSs from us.
Ordinary shares (including ordinary shares represented by ADSs) to be outstanding immediately after this offering	39,930,331 ordinary shares (or 40,530,331 ordinary shares if the underwriters exercise in full their option to purchase an additional 600,000 ADSs).
American Depositary Shares	Each ADS represents one ordinary share, nominal value £0.008 per share. The depositary will be the holder of the ordinary shares underlying the ADSs, and you will have the rights of an ADS holder or beneficial owner (as applicable) as provided in the deposit agreement among us, the depositary and all holders and beneficial owners of ADSs issued thereunder. To better understand the terms of our ADSs, you should carefully read the section in this prospectus titled "Description of American Depositary Shares." We also encourage you to read the deposit agreement, which is filed as an exhibit to the registration statement of which this prospectus forms a part.
ADS depositary	Citibank, N.A.
Custodian	Citibank, N.A. (London Branch)
Use of proceeds	We estimate that the net proceeds to us from this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, to be approximately \$134.4 million (or \$154.7 million if the underwriters exercise in full their option to purchase an additional 600,000 ADSs) based on the public offering price of \$36.00 per ADS. We intend to use the net proceeds from this offering (i) to fund clinical trials, therapist training and other activities to support the development of our investigational COMP360 psilocybin therapy through completion of all ongoing trials through the end of Phase II meetings with the FDA; (ii) to fund research and clinical development activities related to our investigational COMP360 psilocybin therapy to support the progression of COMP360 as a therapy for other neuropsychiatric indications and further our mechanistic understanding of psilocybin; (iii) to fund our general business development activities, including strategic investments which may aid us in developing digital technologies to complement and augment our therapies, as well as potentially providing access to other novel drug candidates for development in neuropsychiatric and related indications; and (iv) to fund general and administrative expenses, working capital and other general corporate purposes. See "Use of Proceeds" for a more complete description of the intended use of proceeds from this offering.

Dividend Policy	We do not anticipate paying any cash dividends in the foreseeable future. See “Dividend Policy” for more information.
Risk factors	See “Risk Factors” beginning on page 10 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our ADSs.
Nasdaq Global Select Market symbol	“CMPS.”

The total number of our ordinary shares (including ordinary shares represented by ADSs) to be outstanding after this offering is based on 35,930,331 of our ordinary shares outstanding as of December 31, 2020, and excludes:

- 4,430,340 ordinary shares issuable upon the exercise of options for ordinary shares outstanding as of December 31, 2020, with a weighted-average exercise price of \$5.61 per share;
- 217,481 ordinary shares issuable upon the vesting of unvested restricted stock units outstanding as of December 31, 2020;
- an additional 1,178,547 ordinary shares that are available for future issuance under our 2020 Option Plan; and
- an additional 340,053 ordinary shares that are available for future issuance under our ESPP.

Unless otherwise indicated, all information contained in this prospectus also reflects and assumes:

- no issuance or exercise of outstanding options after December 31, 2020; and
- no exercise by the underwriters of their option to purchase up to 600,000 additional ADSs in this offering.

## SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables present the summary consolidated financial data as of the dates and for the periods indicated. We derived the summary consolidated statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020 and the selected consolidated balance sheet data as of December 31, 2019 and 2020 from our audited consolidated financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information contained in those statements. We prepare our consolidated financial statements in accordance with United States generally accepted accounting principles, or U.S. GAAP, as issued by the Financial Accounting Standards Board, or FASB. Our historical results are not necessarily indicative of our future results. You should read this data together with our consolidated financial statements and related notes appearing elsewhere in this prospectus and the information under the sections titled "Capitalization" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	YEAR ENDED DECEMBER 31,	
	2019	2020
	(in thousands, except share and per share data)	
<b>Consolidated Statement of Operations and Comprehensive Loss Data:</b>		
Operating expenses:		
Research and development	\$ 12,563	\$ 23,366
General and administrative	8,616	28,027
Total operating expenses	21,179	51,393
Loss from operations	(21,179)	(51,393)
Other income	73	319
Foreign exchange losses	(81)	(11,702)
Fair value change of convertible notes	(1,139)	(1,771)
Benefit from R&D tax credit	2,729	4,245
Total other income (expense), net	1,582	(8,909)
Loss before income taxes	(19,597)	(60,302)
Income tax benefit (expense)	(15)	(32)
Net loss	(19,612)	(60,334)
Other comprehensive (loss) income:		
Foreign exchange translation adjustment	337	14,683
Comprehensive loss	\$ (19,275)	\$ (45,651)
Net loss per share attributable to ordinary shareholders — basic and diluted	\$ (2.62)	\$ (3.55)
Weighted-average ordinary shares outstanding — basic and diluted	7,476,422	16,991,664



## RISK FACTORS

*Investing in our American Depositary Shares, or ADSs, involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in this prospectus before making an investment decision. Our business, financial condition and/or results of operations could be materially and adversely affected if any of these risks occur, and as a result the trading price of our ADSs could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us may also adversely affect our business.*

*This prospectus also contains forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors.*

### **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 \$60.3 million, and \$19.6 million, respectively, for the fiscal years ended December 31, 2020 and December 31, 2019. As of December 31, 2020, we had an accumulated deficit of \$97.9 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 treatment-resistant depression, or TRD, including initiating additional and larger clinical trials;
- 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;
- seek additional indications for our investigational COMP360 psilocybin therapy and discover and develop any future therapeutic candidates;
- continue to invest in our Discovery Centers 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 the spread of the coronavirus disease of 2019, or COVID-19, which we refer to as the COVID-19 pandemic;
- 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 public company listed in the U.S.

Prior to our initial public offering, or IPO, we funded our operations through private placements of equity and convertible notes. 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, 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 U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, the UK's medicines regulator, the Medicines and Healthcare products Regulatory Agency, or 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 the net proceeds from this offering, together with our cash and cash equivalents of \$190.3 million as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements through 2023. 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, 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 U.S. Drug Enforcement Administration, or 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, which includes conducting clinical trials, including proof of concept studies, to refine our therapeutic model;
- generating and collecting data and intellectual property; and strengthening our regional presence as a scientific and clinical resource;

- the costs of developing and testing digital technology solutions to improve the patient experience;
- 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 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 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 resulting from the COVID-19 pandemic and the related U.S. and global economic impact 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. In addition, we anticipate that any regulatory approval of COMP360 may include specific requirements or restrictions on the involvement or conduct of trained therapists in the administration of our investigational COMP360 psilocybin therapy and we have not yet received any specific guidance from the FDA, the EMA, the MHRA or other regulatory bodies regarding such requirements or restrictions. 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 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;
- enforcing and defending intellectual property rights and claims; and
- complying with laws and regulations, including laws applicable to controlled substances.

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 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 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 will likely be determined to have a high potential for abuse and therefore required to be administered at our trial sites, which could limit commercial uptake. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.
- 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 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, 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 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.***

From time to time, 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, 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. There can be no assurance that deaths or serious side effects will not occur, even in a clinical setting. To date, four patients have experienced suspected, unexpected serious adverse reactions, or SUSARs. All patients and study teams remain blinded to the dose received. One patient experienced a SUSAR of adjustment disorder more than a month after administration, which led to hospitalization. The event was adjudicated by the investigator to be moderate in severity and possibly related to study medication. A second patient experienced a SUSAR of suicidal ideation several weeks after administration which required hospitalization and was adjudicated by the investigator to be severe and possibly related to study medication. A third patient experienced a SUSAR of suicidal ideation with some intent to act, without specific plan, several weeks after administration. The investigator assessed the event as moderate in intensity and possibly related to study medication. We were also notified of a patient death that occurred in August 2020, more than two months after the patient was administered COMP360 supplied by us to an IIS involving MDD patients at the University of Zurich. The patient had shown improvement in symptoms, without side effects, following administration. Based on this and other available information, including the 72 days that elapsed between

administration of COMP360 (which has a half-life of approximately three hours) and the reported death, a report by the investigator that the death is unlikely to be related to COMP360 and opinion by the patient's psychiatrist that the death is unrelated to COMP360, we consider the death unlikely to be related to COMP360. There can, however, be no assurance that the death was unrelated. More recently, a fourth patient experienced a SUSAR; during the study screening phase the subject's anxiety increased whilst tapering off their existing depression therapy medication, but suicidal ideation without intent to act remained absent. Directly after the study drug dosing session the subject reported fleeting suicidal thoughts and on the day following dosing the subject reported suicidal ideation with some intent to act, without specific plan, due to increased feelings of anxiety that occurred during the dosing session. Antidepressant medication was restarted and hospitalization was not required. The investigator assessed the event as possibly related to study medication; the DSMB will be notified of this event, for assessment, as part of our regular reporting. 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.

***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. For example, in 2019, both Rapastinel and SAGE-217, two new drugs targeting MDD, failed to meet their primary endpoints in Phase III trials. ALKS 5461, another new drug targeting MDD, was rejected by FDA in 2019 after its Phase III trials as FDA required additional clinical data to provide substantial evidence of effectiveness. 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. Moreover, most of the patients we treat in clinical trials with COMP360 have previously been treated with other drugs or therapies, including serotonergic antidepressants and we believe that the prior use of these drugs or therapies concurrently or up to two weeks prior to administration may interfere with the mechanism of action of or response to our investigational COMP360 psilocybin therapy. 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 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 affected by the COVID-19 pandemic or which may in the future be impacted by this or 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 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 state 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 state 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 states 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.

***A 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), and the Medical College of Wisconsin (Wisconsin). 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 U.S., and similar controlled substance legislation in other countries and any significant breaches in our compliance with these laws and regulations, or changes in the laws and regulations may result in interruptions to our development activity or business continuity.***

Psilocybin and psilocin are categorized as Schedule I controlled substances under the CSA, Schedule 1 drugs under the UK's Misuse of Drugs Regulations 2001 and are similarly categorized by most states and foreign governments. Even assuming that COMP360 or any future therapeutic candidates containing psilocybin or psilocin are approved and scheduled by regulatory authorities to allow their commercial marketing, the ingredients in such therapeutic candidates would likely continue to be Schedule I, or the state or foreign equivalent. Violations of any federal, state or foreign laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges and penalties, including, but not limited to, disgorgement of profits, cessation of business

activities, divestiture, or prison time. This could have a material adverse effect on us, including on our reputation and ability to conduct business, our financial position, operating results, profitability or liquidity or the market price of our publicly traded ADSs. In addition, it is difficult for us to estimate the time or resources that would be needed for the investigation or defense of any such matters or our final resolution because, in part, the time and resources that may be needed are dependent on the nature and extent of any information requested by the applicable authorities involved, and such time or resources could be substantial. It is also illegal to aid or abet such activities or to conspire or attempt to engage in such activities. An investor's contribution to and involvement in such activities may result in federal civil and/or criminal prosecution, including, but not limited to, forfeiture of his, her or its entire investment, fines and/or imprisonment.

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

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

Despite the current status of psilocybin and psilocin as Schedule I controlled substances in the 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. 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 \$53.0 million and \$17.7 million as of December 31, 2020 and 2019, 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. Recent proposed changes to the SME Program, which are scheduled to begin from April 2021, will cap the available claim under the SME Program to a multiple of payroll taxes (broadly, three times the total PAYE and NICs liability of the company). This cap may limit the value we can 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.

Among the provisions of the ACA of importance to our potential therapeutic candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs, apportioned among these entities according to their market share in certain



government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;

- expansion of eligibility criteria for Medicaid programs, a Federal and state program which extends healthcare to low income individuals and other groups, by, among other things, allowing states to offer Medicaid coverage to certain individuals and adding new eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program, which requires that drug manufacturers provide rebates to states in exchange for state Medicaid coverage for most of the manufacturers' drugs by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans (i.e., a type of Medicare healthcare plan offered by private companies);
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of the types of entities eligible for the 340B drug discount program, which requires drug manufacturers to provide outpatient drugs to eligible healthcare organizations and covered entities at significantly reduced prices;
- establishment of the Medicare Part D coverage gap discount program, which requires manufacturers to provide a 50% point-of-sale-discount (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 1, 2019) off the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;
- creation of a new non-profit, nongovernmental institute, called the Patient-Centered Outcomes Research Institute, to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation within the Centers for Medicare & Medicaid, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the U.S. Supreme Court. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what effect further changes to the ACA would have on our business, especially under the Biden administration.

Other legislative changes have been proposed and adopted since the ACA was enacted. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. For example, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. The Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. However, these

Medicare sequester reductions have been suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the BBA amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”.

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, including 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. These laws include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act, or the FCA. The definition of the “remuneration” under the federal Anti-Kickback Statute has

been interpreted to include anything of value. Further, courts have found that if “one purpose” of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. On December 2, 2020, the Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. These rule (with exceptions) became effective January 19, 2021;

- the federal civil and criminal false claims laws, such as the FCA, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the U.S. federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (i.e., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements, in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information and their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state

attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include certain payments and other transfers of value made during the previous year to certain non-physician providers, such as physician assistants and nurse practitioners;
- analogous state laws and regulations, including the following: state anti-kickback and false claims laws, which may be broader in scope than their federal equivalents, and which may apply to our business practices, including research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- the European and other foreign law equivalents of each of these laws, including reporting requirements detailing interactions with and payments to healthcare providers, and privacy-related requirements in Europe and other jurisdictions.

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.**

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 EU General Data Protection Regulation, or 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 European Union 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. Our clinical trial activity conducted within the member states of the European Union is regulated by the GDPR. In addition, we are subject to evolving and strict rules on the transfer of personal data out of the European Union to the United States. For example, evolution of laws governing the cross-border transfer of data, such as the invalidation of the EU–U.S. Privacy Shield, creates additional uncertainty around the legality and logistics of such transfers. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any future European activities. We could be adversely affected if we fail to comply fully with all of these requirements.

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 European Union 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)). 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. Furthermore, the relationship between the United Kingdom and the EEA in relation to certain aspects of data protection law remains somewhat uncertain. For example, it is unclear whether transfers of personal data from the EEA to the United Kingdom will be permitted to take place on the basis of a future adequacy decision of the European Commission, or whether a "transfer mechanism," such as the Standard Contractual Clauses, will be required. For the meantime, under the post-Brexit Trade and Cooperation Agreement between the European Union and the United Kingdom, or the TCA, it has been agreed that transfers of personal data to the United Kingdom from European Union Member States will not be treated as "restricted transfers" to a non-EEA country for a period of up to four months from January 1, 2021, plus a potential further two months extension, or the extended adequacy assessment period. This will also apply to transfers to the United Kingdom from EEA Member States, assuming those Member States accede to the relevant

provision of the TCA. Although the current maximum duration of the extended adequacy assessment period is six months it may end sooner, for example, in the event that the European Commission adopts an adequacy decision in respect of the United Kingdom, or the United Kingdom amends the UK GDPR and/or makes certain changes regarding data transfers under the UK GDPR/ Data Protection Act 2018 without the consent of the European Union (unless those amendments or decisions are made simply to keep relevant United Kingdom laws aligned with the European Union's data protection regime). If the European Commission does not adopt an 'adequacy decision' in respect of the United Kingdom prior to the expiry of the extended adequacy assessment period, from that point onwards the United Kingdom will be an "inadequate third country" under the GDPR and transfers of data from the EEA to the United Kingdom will require a "transfer mechanism," such as the Standard Contractual Clauses.

Additionally, as noted above, the United Kingdom has transposed the GDPR into United Kingdom domestic law by way of the UK GDPR with effect from January 2021, which could expose us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. Also, following the expiry of the post-Brexit transitional arrangements, the United Kingdom Information Commissioner's Office is not able to be our "lead supervisory authority" in respect of any "cross border processing" for the purposes of the GDPR. For so long as we are unable to, and/or do not, designate a lead supervisory authority in an EEA member state, with effect from January 1, 2021, we are not able to benefit from the GDPR's "one stop shop" mechanism. Amongst other things, this would mean that, in the event of a violation of the GDPR affecting data subjects across the United Kingdom and the EEA, we could be investigated by, and ultimately fined by the United Kingdom Information Commissioner's Office and the supervisory authority in each and every EEA member state where data subjects have been affected by such violation. Other countries have also passed or are considering passing laws requiring local data residency and/or restricting the international transfer of data.

***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. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example in 2020, former President Trump announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. Although a number of these and other proposed measures may require authorization to become effective, and the Biden administration may reverse or otherwise change these measures, Congress may seek new legislative measures to control drug costs.

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 European Economic Area, or the EEA, which comprises the EU member states as well as Norway, Iceland and Liechtenstein. 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 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 our contracts involve 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, contract manufacturing organizations, or 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. Two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized in the coming months. 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. 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 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 COVID-19 pandemic originated in Wuhan, China, in December 2019 and has since spread to a large number of countries, including the United States and most European countries. The pandemic and policies and regulations implemented by governments in response to the pandemic, often directing businesses and governmental agencies to cease non-essential operations at physical locations, prohibiting certain nonessential gatherings and ceasing non-essential travel have also 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 the actions to contain COVID-19 or treat its impact, among others. Global health concerns, such as the COVID-19 pandemic, 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 have taken 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 negatively affect our business. The 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 are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of the COVID-19 pandemic, 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 ongoing Phase IIb clinical trial of COMP360 in TRD. While we have since partially resumed enrollment, there can be no guarantee we will not be forced to pause enrollment again, 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 will 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 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. For example, the IISs at the University of Copenhagen and at the University of Zurich were both placed on hold. As COVID-19 continues to be present 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 caused significant volatility in public equity markets and disruptions to the United States and global economies. This increased volatility and economic dislocation may make it more difficult for us to raise capital on favorable terms, or at all. Although we have begun to experience the impact of the COVID-19 pandemic on our business and operations, we cannot currently predict the scope and severity of any potential business shutdowns or disruptions. 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.

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

***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 digital technologies to collect data, educate patients and therapists, collect digital phenotyping information, and harness artificial intelligence. We also plan to expand 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, 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,



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 an additional office in New York in the U.S. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents, including events of civil unrest that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our investigational COMP360 psilocybin 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 any 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 this Offering and Ownership of Our ADSs**

***An active and liquid market for our ADSs may not be sustained, which could harm the market price of our ADSs and you may not be able to resell your ADSs at or above the public offering price.***

We completed our initial public offering, or our IPO, in September 2020. Prior to that time, there was no public trading market for our ADSs or ordinary shares. Although we have completed our IPO and our ADSs are listed and trading on the Nasdaq Global Select Market, an active trading market for our ADSs may not be sustained. If an active trading market for our ADSs is not sustained, it may be difficult for existing shareholders to sell our ADSs without depressing the market price for our securities or at all. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling ADSs and may impair our ability to acquire other companies or assets by using our ADSs as consideration.

Following this offering, our ADSs may not trade at a price equal to or greater than the public offering price of \$36.00 per ADS. In the absence of a sustained active trading market for our ADSs, investors may not be able to sell their ADSs at or above the initial offering price or at the time that they would like to sell.

***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 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 \$22.51 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 April 23, 2021. If the market price of our ADSs after this offering does not exceed the offering price, 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 26, 2021, our executive officers, directors, greater than five percent shareholders and their affiliates beneficially own approximately 61.5% 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, and the approval of certain significant corporate transactions. 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 “Related Party Transactions” and “Principal Shareholders.”

***Participation in this offering by our existing shareholders and/or their affiliated entities may reduce the public float for our ADSs.***

To the extent our existing shareholders who are our affiliates or their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our ADSs after this offering, which is the number of ADSs that are not held by our officers, directors and affiliated shareholders. A reduction in the public float could reduce the number of ADSs that can be traded at any given time, which could adversely impact the liquidity of our ADSs and depress the price at which you may be able to sell ADSs purchased in this offering.

***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.

***We have broad discretion in the use of the net proceeds from the offering and may not use them effectively.***

Our board of directors will have broad discretion in the application of the net proceeds from the offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ADSs. The failure by our board of directors to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our ADSs to decline and delay the development of our investigational COMP360 psilocybin therapy or any future therapeutic candidates. Pending their use, we may invest the net proceeds from the offering in a manner that does not produce income or that loses value.

***If securities or industry analysts do not 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. There can be no assurance that analysts will continue to cover us, or provide favorable coverage. If no or few securities or industry analysts cover our company, the trading price of our ADSs would be negatively impacted. 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, or downgrades our ADSs, demand for our ADSs could decrease, which could cause the price of our ADSs or trading volume to decline.

***Future sales of our securities by existing shareholders could depress the market price of our ADSs.***

If our existing shareholders sell, or indicate an intent to sell, substantial amounts of our securities in the public market, the trading price of the ADSs could decline significantly and could decline below the public offering price in this offering. Upon completion of this offering, and assuming no exercise of the underwriters' option to purchase additional ADSs, we will have 39,930,331 outstanding ordinary shares (including ordinary shares represented by the ADSs), and holders of approximately 50.7% of our ordinary shares will be subject to a 90-day contractual lock-up. The representatives of the underwriters may permit us and the holders of the lock-up shares to sell shares or ADSs prior to the expiration of the lock-up agreements. See "Underwriting." After the lock-up agreements pertaining to this offering expire, and based on the number of ordinary shares (including ordinary shares represented by ADSs) outstanding upon completion of this offering, these approximately 20,233,420 additional ordinary shares will be eligible for sale in the public market, all of which shares are held by directors and certain members of our executive management and will be subject to volume limitations under Rule 144 under the Securities Act

of 1933, as amended, or the Securities Act, for sales in the United States. In addition, ordinary shares subject to outstanding options under our equity incentive plans and the ordinary shares reserved for future issuance under our equity incentive plans are eligible for sale in the public market in the future, subject to volume limitations applicable to affiliates and the lock-up agreements described in the “Shares and ADSs eligible for future sale” section of this prospectus.

***If you purchase our ADSs in the offering, you will experience substantial and immediate dilution.***

If you purchase our ADSs in this offering at the offering price of \$36.00, you will experience substantial and immediate dilution of \$27.72 per ADS in the net tangible book value after giving effect to the offering at the public offering price of \$36.00 per ADS, because the price that you pay will be substantially greater than the net tangible book value per ADS that you acquire. You will experience additional dilution upon exercise of any outstanding options to purchase ordinary shares under our equity incentive plans with exercise prices lower than the public offering price. For a further description of the dilution that you will experience immediately after the offering, see the section of this prospectus titled “Dilution.”

***Holders of our ADSs are not treated as holders of our ordinary shares.***

By participating in this offering you will become a holder of ADSs with underlying ordinary shares in a company incorporated under English law. 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. See "Description of American Depositary Shares—Share Dividends and Distributions—How will I receive dividends and other distributions on the ordinary shares underlying my ADSs—Rights to Receive Additional Ordinary Shares."

***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.

Based on the current and expected composition of our income and assets and the value of our assets, we do not expect to be a PFIC for the 2020 taxable year. However, no assurances regarding our PFIC status can be provided for the 2020 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, including this offering.

For further discussion of the PFIC rules and adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see the section titled “Taxation—Material U.S. Federal Income Considerations for U.S. Holders” in this prospectus. 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 2020 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 are an “emerging growth company” and are availing ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our ADSs less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs the price of our ADSs may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last

day of the fiscal year (i) in which we have total annual gross revenue of \$1.07 billion; (ii) following the fifth anniversary of the date of the completion of our IPO; or (iii) in which we are deemed to be a "large accelerated filer," which requires the market value of our ordinary shares that is held by non-affiliates to exceed \$700.0 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three-year period. We cannot predict if investors will find our ADSs less attractive because we rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile.

***As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.***

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices as opposed to those requirements that would otherwise be required by Nasdaq for domestic U.S. issuers. Following our home country governance practices allows us to follow English corporate law and the Companies Act 2006 with regard to certain corporate governance matters as opposed to the requirements that would otherwise apply to U.S. companies listed on Nasdaq may provide less protection to our shareholders than what is accorded to investors under the Nasdaq rules applicable to domestic U.S. issuers.

As a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements. Our officers, directors and principal shareholders are also exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act and we are exempt from filing quarterly reports with the SEC under the Exchange Act. Moreover, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information, although we have voluntarily adopted a corporate disclosure policy substantially similar to Regulation FD. These exemptions and leniencies will reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic issuer.

In accordance with our Nasdaq listing, our audit and risk committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act, and Rule 10A-3 of the Exchange Act. Because we are a foreign private issuer, however, our audit and risk committee is not subject to additional Nasdaq requirements applicable to listed U.S. companies, including an affirmative determination that all members of the audit and risk committee are "independent," using more stringent criteria than those applicable to us as a foreign private issuer. Furthermore, Nasdaq's corporate governance rules require listed U.S. companies to, among other things, seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares, which we are not required to follow as a foreign private issuer. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

***We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.***

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2021.

In the future, we would lose our foreign private issuer status if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if more than 50% of our securities are held by U.S. residents and more than 50% of the

members of our executive committee or members of our board of directors are residents or citizens of the United States, we could lose our foreign private issuer status.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

***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.***

As an English public company listed in the U.S., and particularly after 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. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an “emerging growth company.” We have recently commenced the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 in the event we are required to include such attestation for the fiscal year ending December 31, 2021, but we may not be able to complete our evaluation, testing, and any required remediation in a timely fashion once initiated. Our compliance with Section 404 will require that we incur substantial expenses and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. In this regard, we need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and

improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe, that our internal controls over financial reporting are effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***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 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” 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 depository 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  $\frac{1}{3}$ %) 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. After nearly three years of negotiation and political and economic uncertainty, the UK's withdrawal from the EU became effective on January 31, 2020. Under the terms of the withdrawal agreement, the UK continued to be subject to the laws and obligations applicable to all EU members during a transitional period which ended on December 31, 2020, including laws related to trade and data privacy and pharmaceuticals, while the future relationship between the UK and the EU was formally negotiated. The UK and the EU have signed a EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and will become formally applicable once ratified by both the UK and the EU. This agreement provides details on how some aspects of the UK and EU's relationship will operate going forwards, however there are still many uncertainties, and certain key issues (for example, in respect of financial services) have yet to be addressed. This lack of clarity on future UK laws and regulations and their interaction with the EU laws and regulations may negatively impact foreign direct investment in the UK, increase costs, depress economic activity and restrict access to capital. Brexit may affect our results of operations in a number of ways, including increasing currency exchange risk, generating instability in the global financial markets or negatively impacting the economies of the UK and Europe. 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, now that the transition period is over, Brexit will impact our ability to freely move employees from our headquarters in the UK to other locations in Europe and it will impact the ability of European 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 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 current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the UK. In addition to the foregoing, our UK operations support our current and future operations and clinical activities in the EU and EEA and these operations and clinical activities could be disrupted by Brexit.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations as a result of Brexit. The UK will lose the benefits of global trade agreements negotiated by the EU on behalf of its member states, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. Since the regulatory framework in the UK covering quality, safety and efficacy of therapeutic substances, clinical trials, marketing authorization, commercial sales and distribution of therapeutic substances is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime with respect to the approval of COMP360 or any future therapeutic candidates in the UK. For instance, now the transition period has expired, Great Britain will no longer be covered by the centralized procedures for obtaining EEA-wide marketing authorization from the EMA and a separate process for authorization of drug products will be required in Great Britain, resulting

in an authorization covering the UK or Great Britain only. For a period of two years from January 1, 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a UK marketing authorization. A separate application will, however, still be required. The MHRA has published a series of guidance notes on how the process for authorization of medicines will now work; however exactly what implications this will have in practice remain unclear. It remains to be seen how Brexit will impact regulatory requirements for therapeutic candidates and therapies in the UK in the long term. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would delay or prevent us from commercializing our investigational COMP360 psilocybin therapy or future therapeutic candidates in the UK and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK and/or EU for COMP360 or any future therapeutic candidates, which could significantly and materially harm our business. Even prior to any change to the UK's relationship with the EU, the announcement of Brexit had created economic uncertainty surrounding the terms of Brexit and its consequences could adversely impact customer confidence resulting in customers reducing their spending budgets on our investigational COMP360 psilocybin therapy or any future therapeutic candidates, if approved, which could adversely affect our business, financial condition, results of operations and could adversely affect the market price of our ADSs.

We expect that following the transition period, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replicate or replace, including those related to data privacy and the regulation of medicinal products, as described above. Any of these effects of Brexit, and others we cannot anticipate, could negatively impact our business and results of operations.

### **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 have been 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 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. subsidiaries 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 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 through April 2020. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. Since March 2020, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections and resumed inspections in China and India in early 2021. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Should the FDA determine that a manufacturing or bioresearch monitoring 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 appropriate, the agency has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.



Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. Additionally, as of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic; however, the FDA may not be able to continue its current pace and review timelines could be extended. 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 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 limited operating history, we are still in the process of implementing our internal security measures. Our internal computer systems, which are managed entirely 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. Because 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 impact that the recent SolarWinds supply chain attack had on our business, this is a recent event, and the scope of the attack is yet unknown. Therefore, there is residual risk that we may experience a security breach arising from the SolarWinds supply chain attack.

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. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, including due to the impact of the COVID-19 pandemic, could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy 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 economic climate and financial market conditions could adversely impact our business.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Use of Proceeds,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Business,” contains express or implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Act of 1934, as amended, that involve substantial risks and uncertainties. All statements other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objections of managements, are forward looking statements. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “contemplate,” “estimate,” “predict,” “potential,” “continue” and “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future, although not all forward-looking statements contain these identifying words. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements and opinions contained in this prospectus are based upon information available to our management as of the date of this prospectus 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. Furthermore, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the timing, progress and results of COMP360, 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, 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 focus on treatment resistant depression;
- our ability to identify, develop or acquire digital technologies to enhance our administration of our investigational COMP360 psilocybin therapy;
- our ability to successfully establish and maintain Centers of Excellence;

- 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 expectations related to the use of proceeds from this offering;
- 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 the COVID-19 pandemic, including 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 (“CFC”) or a passive foreign investment company (“PFIC”) under the Internal Revenue Code of 1986, as amended, for current and future periods;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act and as a foreign private issuer;
- the future trading price of the ADSs and impact of securities analysts’ reports on these prices; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the section titled “Risk Factors,” that we believe may cause our actual results or events to differ materially from those expressed or implied by our forward-looking statements. Moreover, we operate in a 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 prospectus. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, 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. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this prospectus are made as of the date of this prospectus, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law. We qualify all of our forward-looking statements by these cautionary statements.



## USE OF PROCEEDS

We estimate that the net proceeds to us in this offering will be \$134.4 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, based on a public offering price of \$36.00 per ADS. If the underwriters exercise their option to purchase 600,000 additional ADSs in full, we estimate that the net proceeds to us from this offering will be \$154.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We expect to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$155.0 million to fund clinical trials, therapist training and other activities to support the development of our investigational COMP360 psilocybin therapy for treatment-resistant depression through completion of all ongoing trials and our end of Phase II meeting with the FDA, and to prepare and initiate our Phase III program;
- approximately \$30.0 million to fund research and clinical development activities related to our investigational COMP360 psilocybin therapy to support the progression of COMP360 as a therapy for other neuropsychiatric indications and further our mechanistic understanding of psilocybin;
- approximately \$45.0 million to fund our general business development activities, including strategic investments which may aid us in developing digital technologies to complement and augment our therapies, as well as potentially providing access to other novel drug candidates for development in neuropsychiatric and related indications; and
- the remainder to fund general and administrative expenses, working capital and other general corporate purposes.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional businesses, technologies, products or assets. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to develop product candidates and commercialize approved products can be difficult and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, any collaborations that we may enter into with third parties for our therapeutic candidate and any unforeseen cash needs. Our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering and our existing cash and cash equivalents, we estimate that such funds will be sufficient to fund our operations and capital expenditure requirements through the end of 2023, although there can be no assurance in that regard. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Pending our use of proceeds from this offering, we plan to invest these net proceeds in a variety of capital preservation instruments, including short-term, interest bearing obligations and investment-grade instruments.

## **DIVIDEND POLICY**

We have never declared or paid any cash dividend, and we do not anticipate declaring or paying any cash dividends in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. See the section titled “Risk Factors—Risks Related to the Offering and Ownership of Our ADSs—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 English law, among other things, we may only pay dividends if we have sufficient distributable reserves (on a non-consolidated basis), which are our accumulated realized profits that have not been previously distributed or capitalized less our accumulated realized losses, so far as such losses have not been previously written off in a reduction or reorganization of capital.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2020 on:

- an actual basis, and
- on an as adjusted basis giving effect to the sale of 4,000,000 ADS in this offering at the public offering price of \$36.00 per ADS, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. Cash is not a component of our total capitalization. You should read this information together with our consolidated financial statements and related notes appearing elsewhere in this prospectus and the information set forth under the sections titled “Use of Proceeds” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of December 31, 2020	
	Actual	As adjusted
	(in thousands, except share and per share amounts) (expressed in U.S. Dollars, unless otherwise stated)	
Cash	\$ 190,327	\$ 324,727
Shareholders' equity (deficit):		
Ordinary shares, nominal value £0.008 per share; 35,930,331 shares issued and outstanding, actual; 39,930,331 shares issued and outstanding, as adjusted	367	411
Deferred shares	28	28
Additional paid-in capital	279,480	413,836
Accumulated other comprehensive (loss) income	14,585	14,585
Accumulated deficit	(97,899)	(97,899)
Total shareholders' equity (deficit)	196,561	330,961
Total capitalization	\$ 196,561	\$ 330,961

The number of ordinary shares outstanding in the table above does not include:

- 4,430,340 ordinary shares issuable upon the exercise of options for ordinary shares outstanding as of December 31, 2020, with a weighted-average exercise price of \$5.61 per share;
- 217,481 ordinary shares issuable upon the vesting of unvested restricted stock units outstanding as of December 31, 2020;
- an additional 1,178,547 ordinary shares that are available for future issuance under our 2020 Option Plan; and
- an additional 340,053 ordinary shares that are available for future issuance under our ESPP.

## DILUTION

If you invest in our ADSs in this offering, your interest will be immediately diluted to the extent of the difference between the public offering price per ADS in this offering and the as adjusted net tangible book value per ADS after this offering. Dilution results from the fact that the public offering price per ADS is substantially in excess of the net tangible book value per ADS.

As of December 31, 2020, our net tangible book value was \$196.0 million, or \$5.46 per ordinary share (equivalent to \$5.46 per ADS). Our net tangible book value per ADS represents total tangible assets (excluding fixed asset investments) less total liabilities, divided by the aggregate number of ordinary and deferred shares outstanding on December 31, 2020.

After giving effect to the sale of 4,000,000 ADSs in this offering at a public offering price of \$36.00 per ADS, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value at December 31, 2020 would have been \$8.28 per ordinary share, or \$8.28 per ADS. This represents an immediate increase in as adjusted net tangible book value of \$2.82 per ADS to existing investors and immediate dilution of \$27.72 per ADS to new investors. The following table illustrates this dilution to new investors purchasing ADSs in this offering:

Public offering price per ADS	\$36.00
Historical net tangible book value per ADS as of December 31, 2020	\$5.46
Increase attributable to new investors purchasing ADSs in this offering	\$2.82
As adjusted net tangible book value per ADS as of December 31, 2020	\$8.28
Dilution per share to new investors purchasing ADSs in this offering	\$27.72

If the underwriters exercise their option to purchase additional ADSs in full, the as adjusted net tangible book value per ADS after the offering would be \$8.65, the increase in net tangible book value per ADS to existing shareholders would be \$3.19 and the immediate dilution in net tangible book value per ADS to new investors in this offering would be \$27.35.

The above discussion and tables are based on 35,930,331 ordinary shares issued and outstanding as of December 31, 2020 and exclude:

- 4,430,340 ordinary shares issuable upon the exercise of options for ordinary shares outstanding as of December 31, 2020, with a weighted-average exercise price of \$5.61 per share;
- 217,481 ordinary shares issuable upon the vesting of unvested restricted stock units outstanding as of December 31, 2020;
- an additional 1,178,547 ordinary shares that are available for future issuance under our 2020 Option Plan; and
- an additional 340,053 ordinary shares that are available for future issuance under our ESPP.

To the extent that options are issued under our 2020 Option Plan or shares are issued under our ESPP, or we issue additional ordinary shares or ADSs in the future, there will be further dilution to investors participating in this offering.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and our expectations with respect to liquidity and capital resources, includes forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, those risks and uncertainties described in "Risk Factors" and "Special Note Regarding Forward-Looking Statements" in this prospectus. Our actual results could differ materially from the results described in or implied by these forward-looking statements.

### 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, the largest randomized controlled trial with psilocybin therapy to date. In this trial, we observed that COMP360 was generally well-tolerated and supported continued progression of Phase IIb studies. We are currently evaluating COMP360 in conjunction with psychological support in a Phase IIb trial and we plan to report data from this trial in late 2021. We believe that a single dose of our COMP360 monotherapy with psychological support from specially trained therapists could offer a new approach to depression care.

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 and our initial public offering, or the IPO, of American Depositary Shares, or ADSs, representing our ordinary shares. Through December 31, 2020, we had received net cash proceeds of \$116.4 million from sales of our convertible preferred shares and convertible loan notes and \$132.8 million from sales of ADSs through our IPO, which was completed in September 2020, after deducting underwriting discounts and commissions and other offering expenses.

We have incurred significant operating losses since our inception. We incurred total net losses of \$60.3 million and \$19.6 million, respectively, for the years ended December 31, 2020 and 2019. As of December 31, 2020, we had an accumulated deficit of \$97.9 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 through clinical trials for TRD, potentially including expanding into additional indications, and initiate preclinical and clinical development of

additional programs for different therapeutic candidates. 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 December 31, 2020, we had cash and cash equivalents of \$190.3 million. We believe that our existing cash and cash equivalents, together with the proceeds of this offering, will be sufficient for us to fund our operating expenses and capital expenditure requirements through to 2023. 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.

The ongoing impacts and spread of the coronavirus disease, or COVID-19, which we refer to as the COVID-19 pandemic, and the policies and regulations implemented by governments in response to the pandemic have had a significant impact, both directly and indirectly, on the global economy and our business and operations, including in particular the interruption of our clinical trial activities and potential interruption to our supply chain. For example, the COVID-19 pandemic had previously delayed enrollment in our ongoing Phase IIb clinical trial of COMP360 psilocybin therapy. While we have resumed enrollment in this trial, the impact of COVID-19 has delayed our anticipated completion date of this trial, with data now expected in late 2021, and there can be no assurance that, despite the approval and administration of vaccines, we will not experience additional enrollment delays as the virus, including new strains or variants thereof, continues to spread globally. The development of our investigational COMP360 psilocybin therapy could continue to be disrupted and materially adversely affected in the future by the COVID-19 pandemic or other epidemics or outbreaks of an infectious disease. If the disruptions due to the COVID-19 pandemic continue, our planned future clinical development for our investigational COMP360 psilocybin therapy could also be delayed due to government orders and site policies on account of the pandemic, and some patients may be unwilling or unable to travel to study sites, enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our therapeutic candidate. Furthermore, the COVID-19 pandemic could affect our employees or the employees of research sites and service providers, including therapists employed by trial sites involved in our clinical trial of COMP360 psilocybin therapy, on whom we rely as well as those of companies with which we do business, including our suppliers, contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, thereby disrupting our business operations. Quarantines and travel restrictions imposed by governments in the jurisdictions in which we and the companies with which we do business could materially impact the ability of employees to access preclinical and clinical sites, manufacturing sites and offices. We have implemented and continue to maintain work-at-home policies and may experience limitations in employee resources. Our increased reliance on personnel working from home may negatively impact productivity, increase the potential risks of data privacy or security breaches, or disrupt, delay, or otherwise adversely impact our business.

We continue to assess our business plans and the impact the COVID-19 pandemic may have on our 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 we rely, or to raise financing to support the development of our investigational COMP360 psilocybin therapy. No assurances can be given that this analysis will enable us to avoid further impacts from the COVID-19 pandemic, including downturns in

business sentiment generally or in our sector in particular. We cannot currently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties on whom we rely or with whom we conduct business 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 adversely impacted.

## 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 Expenses*

Research and development expenses consist primarily of:

- development costs, including expenses incurred under agreements with contract research organizations and contract manufacturing organizations, or CROs and CMOs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing materials for preclinical studies and clinical trials, the costs of laboratory and trial site supplies and equipment;
- personnel expenses, including salaries, related benefits and travel expense for employees engaged in research and development functions;
- share-based compensation expenses resulting from equity awards granted to employees engaged in research and development functions; and
- other expenses, including costs related to compliance with regulatory requirements, costs of outside consultants, including their fees, share-based compensation 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 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) 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; (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 U.S. Food and Drug Administration, or 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 Expenses*

General and administrative expenses consist primarily of:

- personnel expenses, including salaries and related benefits, travel and other expenses incurred by personnel in executive, finance and administrative functions;
- share-based compensation expenses resulting from the equity awards granted to employees engaged in 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, maintenance of facilities 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. 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 losses*

Foreign exchange losses consists of foreign exchange gain or loss arising from foreign currency transactions.

- *Fair Value Change of Convertible Notes*

Fair value change of convertible notes relates to the convertible notes issued during the year ended December 31, 2019, which were converted to Series B convertible preferred shares in April 2020.

- *Benefit from Research and Development Tax Credit*

Benefit from research and development, or 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 years ended

December 31, 2020 and 2019. 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) benefit 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 \$53.0 million and \$17.7 million as of December 31, 2020 and 2019, respectively.

## **Results of Operations**

### **Comparison of the Years Ended December 31, 2020 and 2019**

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,		Change
	2020	2019	
Operating expenses:			
Research and development	\$ 23,366	\$ 12,563	\$ 10,803
General and administrative	28,027	8,616	19,411
Total operating expenses	51,393	21,179	30,214
Loss from operations	(51,393)	(21,179)	(30,214)
Other income (expense), net:			
Other income	319	73	246
Foreign exchange losses	(11,702)	(81)	(11,621)
Fair value change of convertible notes	(1,771)	(1,139)	(632)
Benefit from R&D tax credit	4,245	2,729	1,516
Total other income (expense), net	(8,909)	1,582	(10,491)
Loss before income taxes	(60,302)	(19,597)	(40,705)
Income tax expense	(32)	(15)	(17)
Net loss	(60,334)	(19,612)	(40,722)

### Research and Development Expenses

The table below summarizes our research and development expenses incurred for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,		Change
	2020	2019	
Development expenses	\$ 11,553	\$ 7,568	\$ 3,985
Personnel expenses	4,563	2,702	1,861
Non-cash share-based compensation expense	6,336	1,817	4,519
Other expenses	914	476	438
Total research and development expenses	<u>\$ 23,366</u>	<u>\$ 12,563</u>	<u>\$ 10,803</u>

Research and development expenses increased by \$10.8 million to \$23.4 million for the year ended December 31, 2020, from \$12.6 million for the year ended December 31, 2019. The increase in research and development expenses was primarily attributable to:

- an increase of \$4.0 million in development expenses, which primarily related to increases of \$2.8 million in clinical trial expenses and \$1.8 million in the cost of preclinical studies to assess additional indications for our investigational COMP360 psilocybin therapy development, offset by a decrease of \$0.1 million in therapist training costs and \$0.5 million in drug development costs;
- an increase of \$1.9 million in personnel expenses, as a result of hiring 22 additional personnel in our research and development department to support the requirements of increased clinical and preclinical activities;
- an increase of \$4.5 million in non-cash share-based compensation reflecting a significant charge due in part to 1,015,813 options that were granted in May 2020 to our President and Chief Business Officer and which fully vested during the year ended December 31, 2020, resulting in the recognition of \$9.5 million in share-based compensation expense, \$2.4 million, or 25%, of which was allocated to research and development expenses based on the time spent supporting research and development activities. In addition, the vesting of certain other options accelerated upon completion of our IPO in accordance with the option grant terms, resulting in the recognition of \$3.5 million in share-based compensation expense, \$1.4 million of which was allocated to research and development expenses based on the time spent supporting research and development activities. The remaining increase in non-cash share-based compensation of \$0.7 million resulted from recurring monthly vesting of existing option grants in addition to further share option grants made to recruit and retain staff to support the increase in our overall research and development activities; and
- an increase of \$0.4 million in other expenses, which was primarily related to increases in consulting expenses.

### General and Administrative Expenses

The following table summarizes our general and administrative expenses for years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,		Change
	2020	2019	
Personnel expenses	\$ 6,084	\$ 3,599	\$ 2,485
Non-cash share-based compensation expense	11,647	1,436	10,211
Legal and professional fees	6,827	2,657	4,170
Facilities and other expense	3,469	924	2,545
Total general and administrative expenses	\$ 28,027	\$ 8,616	\$ 19,411

General and administrative expenses increased by \$19.4 million to \$28.0 million for the year ended December 31, 2020 from \$8.6 million for the year ended December 31, 2019. The increase in general and administrative expenses was primarily attributable to the following:

- an increase of \$2.5 million in personnel costs, primarily due to an increase in headcount related to the hiring of 16 additional personnel in general and administrative functions to support our growth initiatives, including our transition to becoming a public company;
- an increase of \$10.2 million in non-cash share-based compensation reflecting a significant charge due in part to 1,015,813 options that were granted in May 2020 to our President and Chief Business officer which fully vested during the year ended December 31, 2020, resulting in the recognition of \$9.5 million in share-based compensation expense, \$7.1 million, or 75%, of which was allocated to general and administrative expenses based on the time spent on general and administrative activities. In addition, the vesting of certain other options accelerated upon the IPO in accordance with the option grant terms, resulting in the recognition of \$3.5 million in share-based compensation expense, \$2.1 million of which was allocated to general and administrative expenses based on the time spent supporting general and administrative activities. The remaining increase of \$1.0 million in non-cash share-based compensation also resulted from recurring monthly vesting of existing option grants in addition to further share option grants made to recruit and retain staff to support the requirements of increased general, administrative and commercial activities;
- an increase of \$4.2 million in legal and professional fees, primarily related to the preparation of our IPO (\$1.8 million) and our other corporate activities as we continue to grow our business; and
- an increase of \$2.5 million in facilities and other expenses, including rent (\$0.6 million), depreciation (\$0.1 million), IT supplies and services (\$0.3 million), subscriptions (\$0.1 million) and insurance (\$1.1 million) in addition to a number of additional individually immaterial other expenses

### Total Other Income (Expense), Net

- Benefit from Research and Development Tax Credit

During the years ended December 31, 2020 and 2019, we recognized an R&D tax credit from the UK as a benefit within other income (expense), net for \$4.2 million and \$2.7 million, respectively. The tax credit receivable increased in 2020 compared to 2019 in line with increased research and development activity.

- *Fair value change of convertible notes*

The change resulted from the fair value change of the convertible notes which increased by \$0.7 million to \$1.8 million during the year ended December 31, 2020 from \$1.1 million during the year ended December 31, 2019. The convertible notes automatically converted into preferred shares upon completion of the Series B raise on April 17, 2020, which were then converted to ordinary shares upon IPO on September 22, 2020.

- *Foreign exchange losses*

Foreign exchange losses increased by \$11.6 million to \$11.7 million for the year ended December 31, 2020 from \$0.1 million for the year ended December 31, 2019, primarily related to an increase in exchange losses arising from the translation of cash balances generated from the issuance of Series B convertible preferred shares during the second quarter of 2020 and the issuance of ADSs upon our IPO that were maintained in USD, which was different from the legal entity's functional currency (GBP), giving rise to foreign currency losses. Currently, the legal entity which holds USD is a pounds sterling functional currency legal entity as the predominant cash outflows in the entity are pounds 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 in pounds sterling or in US dollars.

- *Other income*

Other income increased by \$0.2 million to \$0.3 million for the year ended December 31, 2020 from \$0.1 million for the year ended December 31, 2019, mainly due to a \$0.2 million increase in interest income as a result of higher cash balances due to completing both the Series B and IPO funding.

- *Income tax expense*

The income tax expense was less than \$0.1 million for the year ended December 31, 2020 and 2019. The income tax expense was related to income tax obligations of our operating company in the U.S., 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. Through December 31, 2020, we had received net cash proceeds of \$116.4 million from sales of our convertible preferred shares and convertible loan notes and \$132.8 million net proceeds from sales of ADSs through our IPO after deducting underwriting discounts and commissions and other offering expenses. We anticipate that we will need to raise additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

## Cash Flows

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

	Year Ended December 31,	
	2020	2019
Net cash used in operating activities	\$ (41,380)	\$ (17,813)
Net cash used in investing activities	(628)	(165)
Net cash provided by financing activities	194,155	18,379
Effect of exchange rate changes on cash, cash equivalents and restricted cash	13,225	1,676
Net increase (decrease) in cash	\$ 165,372	\$ 2,077

### Net Cash Used in Operating Activities

During the year ended December 31, 2020, net cash used in operating activities was \$41.4 million, primarily resulting from our net loss of \$60.3 million, offset by non-cash share-based compensation expense of \$18.0 million, a \$0.2 million increase in deferred tax assets, depreciation and amortization of \$0.1 million and a loss due to the change in fair value of our convertible notes of \$1.8 million. The net loss was also adjusted by \$0.7 million related to changes in components of working capital, including a \$4.5 million increase in prepaid expenses and other assets which primarily related to the R&D tax credit receivable and prepaid insurance, and a \$3.9 million increase in accounts payable and accrued expenses which related to increased research and development expenses, incurred in our preclinical and clinical trials and increased general and administrative spending resulting from increased professional and legal expenses we incurred in conjunction with our preparation for becoming a public company.

During the year ended December 31, 2019, net cash used in operating activities was \$17.8 million, primarily resulting from our net loss of \$19.6 million, offset by non-cash share-based compensation of \$3.3 million and the loss due to the change in fair value of our convertible notes of \$1.1 million. The net loss was also adjusted by \$2.7 million related to changes in components of working capital, including a \$3.4 million decrease in prepaid expenses and other assets which related to the R&D tax credit receivable, and a \$0.8 million increase in accounts payable and accrued expenses which relate to increased research and development expenses incurred on our preclinical and clinical trials and increased general and administrative spending resulting from increased professional and legal expenses we have incurred in conjunction with our preparation for becoming a public company.

### Net Cash Used in Investing Activities

During the year ended December 31, 2020, net cash used in investing activities was \$0.6 million, comprising a \$0.1 million in purchase of property and equipment and a \$0.5 million investment 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 indications.

During the year ended December 31, 2019, net cash used in investing activities was \$0.2 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 year ended December 31, 2020, net cash provided by financing activities was \$194.2 million, primarily related to \$61.3 million net cash proceeds from our sale and issuance of Series B convertible preferred shares and \$132.8 million net cash proceeds from our sale and issuance of ADSs upon the IPO.

During the year ended December 31, 2019, net cash provided by financing activities was \$18.4 million, consisting of net cash proceeds from our issuance of convertible notes in 2019.



**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 psilocybin therapy. 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;
- establish and expand the network of public healthcare institutions and private clinics that 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;
- 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 the COVID-19 pandemic;
- expand our operations in the United States, Europe and potential other geographies; and
- incur additional legal, accounting and other expenses associated with operating as an English public company listed in the United States.

In addition, the Sarbanes-Oxley Act, as well as rules adopted by the Securities and Exchange Commission, or SEC, requires public companies to implement specified corporate governance practices. Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will first be required to furnish a report by our management on our internal control over financial reporting for the year ending December 31, 2021. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will continue to engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe our existing cash and cash equivalents of \$190.3 million at December 31, 2020, together with the net proceeds from this offering, will be sufficient for us to fund our operating expenses and capital expenditure requirements through to 2023. 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 psilocybin therapy for the treatment of 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 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 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. 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 agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or therapeutic candidates that we would otherwise prefer to develop and market ourselves.

### **Critical Accounting Policies and Significant Judgments and Estimates**

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

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing at the end of this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

#### ***Accrued Research and Development Expenses***

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments if necessary. To date, such adjustments have not been material.

The estimate of accrued research and development expense is dependent, in part, upon the receipt of timely and accurate reporting from CROs, CMOs, and other third-party service providers. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials; and
- CMOs in connection with drug substance and drug product formulation of preclinical study and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense.

Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

#### ***Research and Development Incentives and Receivables***

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

The UK R&D tax credit is fully refundable to us and is not dependent on current or future taxable income. As a result, we have recorded the entire benefit from the UK R&D tax credit as a benefit which is included in our net loss before income tax and accordingly, not reflected as part of our income tax provision. If, in the future, any UK R&D tax credits generated are needed to offset a 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.

As a company we carry out extensive R&D activities and, therefore, benefit from the UK R&D tax credit regime under the scheme for SMEs. Under the SME regime, we are able to surrender some of our trading losses that arise from qualifying R&D activities for a cash rebate of up to 33.35% of such qualifying R&D expenditure. We meet the conditions of the SME regime. Qualifying expenditures largely comprise employment costs for research staff for which an estimate of time spent directly or indirectly supporting the pursuit of R&D activities is made, consumables, outsourced contract research organization costs and utilities costs incurred as part of our research projects. Certain subcontracted qualifying R&D expenditures are eligible for a cash rebate of up to 21.67%. A large portion of costs relating to R&D, clinical trials and manufacturing activities are eligible for inclusion within our tax credit cash rebate claims.

We have recorded a benefit from the R&D tax credit in other income, net of \$4.2 million and \$2.7 million for the years ended December 31, 2020 and 2019, respectively.

The refund is denominated in pounds sterling and, therefore, the receivable is remeasured into U.S. dollars as of each reporting date. As of December 31, 2020 and 2019, our tax incentive receivable from the UK government was \$4.6 million and \$4.8 million, respectively.

### **Share-Based Compensation**

We measure non-cash share-based awards granted to employees, non-employees and directors based on the fair value on the date of the grant. Forfeitures are accounted for as they occur. We issue non-cash share-based awards with service-based vesting conditions. For equity awards that vest based on a service condition, the non-cash share-based compensation expense is recognized on a straight-line basis over the requisite service period.

#### *Determination of the Fair Value of the Ordinary Shares*

The fair value of our Ordinary Shares is determined based on the quoted market price of our common stock.

Prior to our IPO, as there was no public market for our ordinary shares, the estimated fair value of our ordinary shares was determined by our board of directors as of the date of each grant, with input from management, considering our most recently available third-party valuations of our ordinary shares, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. After a public trading market for our ordinary shares was established following the closing of our IPO, it was no longer necessary for our board of directors to estimate the fair market value of our ordinary shares in connection with our accounting for granted equity awards.

#### *Determination of the Fair Value of the Share Options*

We measure share options granted to employees and members of our board of directors for their services as directors based on the fair value on the date of the grant and recognize the corresponding compensation expense of those share options over the requisite service period, which is generally the vesting period of the respective share options. We have only issued share options with service-based vesting conditions and record the expense for these awards using the straight-line method.

We estimate the fair value of each share options grant using the Black-Scholes option-pricing model, which uses as inputs the estimated fair value of our ordinary shares and assumptions we make for the volatility of our ordinary shares, the expected term of our share options, the risk-free interest rate for a period that approximates the expected term of our share options and our expected dividend yield.

We determined the assumptions for the Black-Scholes option-pricing model as discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

- **Fair Value of Our Ordinary Shares.** Prior to our IPO, our ordinary shares were not publicly traded, and therefore we estimated the fair value of our ordinary shares, as discussed in "Determination of the Fair Value of Ordinary Shares" above.
- **Expected Volatility.** Because we do not have a trading history of our ordinary shares, the expected volatility was derived from the average historical stock volatilities of several public companies within our industry that we consider to be comparable to our business over a period equivalent to the expected term of the share-based awards. We expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded share price.

If any of the assumptions used in the Black-Scholes model change significantly, share-based compensation for future awards may differ materially compared with the awards granted previously.

#### **Valuation of Convertible Notes**

The convertible notes were valued using a scenario-based discounted cash flow analysis. Two primary scenarios were considered and probability weighted to arrive at the valuation conclusion for each convertible note. The first scenario considered the value impact of conversion at the stated discount to the issue price if we raise over £25.0 million in an equity financing before the first anniversary of the issuance date, or the Qualified Financing, while the second scenario assumed the convertible notes are held to maturity. As of the issuance date of the convertible notes, an implied yield was calculated such that the probability weighted value of the convertible note was equal to the principal investment amount. The average implied yield of previously issued convertible notes is carried forward and used as the primary discount rate for subsequent valuation dates.

We determined the fair value of the convertible notes based on the proceeds received for the convertible notes; the terms of the convertible notes, including the rate at which the notes convert into the Qualified Financing securities; the probability and timing of a qualified equity financing; and the fair value of the underlying convertible preferred shares. Estimates and assumptions impacting the fair value measurement include the probability of a qualified equity financing as defined in the convertible notes' agreement, the expected timing of such event, and the then fair value of our convertible preferred shares. We estimated the probability and timing of the qualified equity financing based on our assumptions and knowledge of specified events at issuance and as of each reporting date.

#### **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 have 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 may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We may 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. We would cease to be an emerging growth company if we have more than \$1.07 billion in annual revenue, we have more than \$700.0 million in market value of our stock held by non-affiliates or we issue more than \$1.0 billion of non-convertible debt securities over a three-year period.

We intend to rely on certain of the other exemptions and reduced reporting requirements provided by the JOBS Act. As an emerging growth company, we are not required to, among other things, (i) provide an auditor's 127 attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), or (ii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis).

#### **Trend Information**

Other than as disclosed elsewhere in this prospectus, we are not aware of any trends, uncertainties, demands, commitments or events for the period from January 1, 2020 to December 31, 2020 that are reasonably likely to have a material adverse effect on our other income (expense), net, liquidity or capital resources, or that caused the disclosed financial information to be not necessarily indicative of future operating results or financial conditions. For a discussion of trends, see "Operating Results" and "Liquidity and Capital Resources."

## Off-Balance Sheet Arrangements

As of December 31, 2020, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K, such as the use of unconsolidated subsidiaries, structured finance, special purpose entities or variable interest entities.

## Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business, which are principally limited to interest rate fluctuations and foreign currency exchange rate fluctuations. We maintain significant amounts of cash and cash equivalents that are in excess of federally insured limits in various currencies, placed with one or more financial institutions for varying periods according to expected liquidity requirements.

### *Interest Rate Risk*

As of December 31, 2020, we held cash of \$190.3 million. Our exposure to interest rate sensitivity is impacted by changes in the underlying United States and UK bank interest rates. Our surplus cash has been invested in interest-bearing savings and money market accounts from time to time. We have not entered into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, which is predicated on capital preservation of investments with short-term maturities, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our portfolio, and therefore we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

### *Foreign Currency Exchange Risk*

We maintain the consolidated financial statements of COMPASS Pathways plc in pounds sterling, but for financial reporting purposes our consolidated financial statements have been presented in U.S. dollars, the reporting currency. 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 consolidated statement of comprehensive loss. We recorded foreign exchange losses of \$11.7 million and \$0.1 million for the years ended December 31, 2020 and December 31, 2019, respectively. 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, revenue and expenses are translated at the average exchange rates and shareholders' equity (deficit) 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 loss, a component of shareholders' equity (deficit).

We do not currently engage in currency hedging activities in order to reduce our currency exposure, but in the future we will maintain a spread of deposits in U.S. dollars, pounds sterling and euros to broadly reflect our expected expenditures in those currencies over time, to provide a natural hedge against the impact of foreign exchange rate movements, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.



### Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2020 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

As of December 31, 2020	Total	Less than 1 Year	1 to 2 Years	3 to 5 Years	More than 5 Years
Operating lease commitments	\$ 1,020	\$ 1,020	\$ —	\$ —	\$ —
Total	\$ 1,020	\$ 1,020	\$ —	\$ —	\$ —

As further discussed in Note 2 to our consolidated financial statements appearing elsewhere in this prospectus, we have not yet adopted ASU No. 2016-02 (Topic 842) Leases, and in accordance with accounting principles generally accepted in the United States, or U.S. GAAP, the obligations listed above relate to expenses associated with future periods that are not currently reflected in our consolidated balance sheets.

We enter into contracts in the normal course of business with CROs and other third-party vendors for clinical trials, clinical and commercial supply manufacturing, support for pre-commercial activities, research and development activities and other services and therapeutic candidates for our operations. Our agreements generally provide for termination within 30 days' notice. Such agreements are cancelable contracts and not included in the table of contractual obligations and commitments.

## BUSINESS

### 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, the largest randomized, controlled trial with psilocybin therapy to date. In this trial, we observed that COMP360 was generally well-tolerated and supported continued progression of Phase IIb studies. We are currently evaluating COMP360 in conjunction with psychological support in a Phase IIb trial and we plan to report data from this trial in late 2021. We believe that a single dose of our COMP360 monotherapy with psychological support from specially trained therapists could offer a new approach to depression care.

Globally, more than 320 million people suffer with MDD. The economic burden of MDD in the United States, accounting for comorbid physical and psychiatric conditions, is estimated to be over \$200 billion per year. TRD, a condition affecting the approximately 100 million patients worldwide who are not helped after two or more existing depression treatments, has even greater economic and societal cost than non-TRD MDD. TRD patients are often unable to perform daily tasks, are more likely to receive disability or welfare benefits and more frequently have co-occurring conditions compared with non-TRD MDD patients. Direct medical costs for TRD patients are estimated to be two to three times higher than for non-TRD MDD patients, caused by, among other factors, increased rates of hospitalization and longer average hospital stays. In addition, there is approximately a seven-fold increase in suicide rate for TRD patients compared with non-TRD MDD patients.

Patients suffering with depression are treated through a variety of approaches, each of which can have significant shortcomings in certain subsets of patients. Most pharmacotherapies for depression employ the same mechanism of action, targeting the modulation of the brain's neurotransmitter monoamine levels, and have exhibited limited efficacy in a significant portion of patients and can result in high relapse rates. There are only two pharmacotherapies specifically approved for TRD in the U.S.: esketamine, and a combination of olanzapine (an atypical antipsychotic) and fluoxetine (a selective serotonergic reuptake inhibitor). Esketamine was recently approved by the U.S. Food and Drug Administration, or FDA. Mixed efficacy and limited durability were observed in clinical trials as well as potential side effects, including dissociation and cognitive impairment. The olanzapine-fluoxetine combination has also shown mixed efficacy and can commonly lead to side effects such as dizziness, drowsiness and weight gain. In addition to pharmacotherapies, various forms of somatic intervention are also used, although these treatments tend to be invasive and/or onerous, and there are limited data supporting their long-term benefit. Psychotherapy is another common treatment approach, but it requires a significant time commitment and is subject to large variability in availability and administration. Despite the range of treatments and therapies available for depression, patients suffering with TRD continue to be underserved, prolonging a significant health, social and economic burden. We believe patients suffering with TRD need a paradigm-shifting treatment that can deliver rapid and sustained relief of their depression.

Psilocybin is considered a serotonergic hallucinogen and is an active ingredient in some species of mushrooms. While classified as a Schedule I drug, there is an accumulating body of evidence that

psilocybin may have beneficial effects on depression and other mental health conditions. Therefore, the FDA and the U.S. Drug Enforcement Administration, or DEA, have permitted the use of psilocybin in clinical studies for the treatment of a range of psychiatric conditions. In 2018, we received Breakthrough Therapy designation from the FDA for COMP360 for the treatment of TRD.

We believe that our investigational COMP360 psilocybin therapy may confer beneficial effects in depression and other mental health conditions through COMP360's mechanism of action on the central nervous system, or CNS. By activating the 5-hydroxytryptamine (serotonin) 2A, or 5-HT<sub>2A</sub>, receptor, psilocybin and its active metabolite psilocin induce a range of downstream effects that may cause important, sustained changes in brain function. These effects include altered extracellular release of serotonin and dopamine, changes in brain network connectivity, and increased levels of neuroplasticity, whereby the nervous system is able to reorganize its structure, function, and connections, all of which we believe contribute to our psilocybin therapy's potential to generate rapid-onset and sustained positive mood effects.

The potential of psilocybin therapy in mental health conditions has been demonstrated in a number of academic-sponsored studies over the last decade. In these early studies, it was observed that psilocybin therapy provided rapid reductions in depression symptoms after a single high dose, with antidepressant effects lasting for up to at least six months for a number of patients. These studies assessed symptoms related to depression and anxiety through a number of widely used and validated scales. The data generated by these studies suggest that psilocybin is generally well-tolerated and has the potential to treat depression when administered with psychological support.

COMP360 is our proprietary psilocybin formulation that includes our pharmaceutical-grade polymorphic crystalline psilocybin, optimized for stability and purity. Our investigational COMP360 psilocybin therapy comprises administration of our COMP360 with psychological support from specially trained therapists with specific professional and educational qualifications. We believe this support, or therapy, is an integral element of psilocybin therapy. The psilocybin administration session lasts approximately six to eight hours, with patients supported by therapists in a non-directive manner. Psilocybin administration sessions are preceded by preparation sessions, in which patients are given a thorough orientation, and followed by integration sessions to help patients process the range of emotional and physical experiences facilitated by COMP360 administration.

In 2019, we completed a Phase I trial in 89 healthy volunteers, the largest controlled trial of psilocybin to date, with our investigational COMP360 psilocybin therapy. In this trial, we observed that COMP360 was generally well-tolerated and supported continued progression of Phase IIb studies. The trial also showed the feasibility of simultaneous administration of COMP360 to up to six people in the same facility, with 1:1 therapist support, which we believe will accelerate future clinical trials and commercial scale-up upon potential regulatory approval. In August 2020, the FDA approved our request for a 1:1 model of therapist support and we intend to use this model in future clinical trials. We previously conducted a series of *in vitro* and *in vivo* toxicology studies, including tests for genotoxicity and cardiotoxicity. We are now undertaking an additional series of safety pharmacology and toxicity studies, to be completed prior to commencement of our anticipated Phase III program.

We are currently conducting a randomized controlled Phase IIb clinical trial in 216 patients suffering with TRD, in 22 sites across North America and Europe. This dose-finding trial is investigating the safety and efficacy of COMP360 combined with psychological support, for the treatment of TRD, and aims to determine the optimal dose of COMP360, with three doses (1mg, 10mg, 25mg) being explored. The primary endpoint of this clinical trial is to evaluate the efficacy of COMP360, as assessed by the change in the Montgomery-Åsberg depression rating scale, or MADRS, a widely accepted scale for depression that has been used as a primary endpoint in pivotal trials of other depression treatments. This trial has been designed to capture a statistically significant reduction in MADRS. We plan to report data from this trial in late 2021. We are using digital technology in this trial, including an online portal to help patients prepare for their psilocybin experience, and a web-based "shared knowledge" interactive platform to

complement therapist training. We are also collecting digital phenotyping information through the measurement of human-smartphone interactions. After the trial, these data will be compared with information collected from validated psychiatric scales, such as MADRS, to develop potential digital applications to help anticipate relapse of depression. In the future we plan to expand our research into additional digital technologies to complement and augment our therapies.

The need for innovation in mental health care is significant, given that the current paradigm is ineffective for millions of people. Our vision is a world of mental wellbeing – a world in which mental health isn't simply the absence of mental illness, but the ability to flourish. We want to help reduce the stigma surrounding mental health, to acknowledge that “everyone has a story,” and to create a system of care for all who are not helped by the existing system and existing therapies.

## OUR STRATEGY

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

- **Advance our investigational COMP360 psilocybin therapy for the treatment of TRD, including initiating additional and larger clinical trials.** We are conducting a randomized controlled Phase IIb clinical trial in 216 TRD patients. We plan to report data from this trial in late 2021, and if successful, we intend to follow with a Phase III registrational program.
- **Expand our investigational COMP360 psilocybin therapy into new indications and explore other compounds and therapies to address areas of unmet need.** We believe that our investigational COMP360 psilocybin therapy may confer beneficial effects in other mental health and neurological conditions. We are generating preclinical and clinical data to further our mechanistic understanding and explore the potential benefits of our psilocybin therapy in other indications. We are performing some of these studies ourselves and some through collaborations with academic institutions, including through investigator-initiated studies (signal-generating studies using our COMP360 psilocybin) and through our Discovery Center, which is carrying out preclinical research into new compounds. The outcomes of these studies will inform which indications, compounds and therapies we may pursue.
- **Maximize the reach and value of our investigational COMP360 psilocybin therapy by creating a new model for mental health care.** We retain global development and commercialization rights for our investigational COMP360 psilocybin therapy and are developing a commercial rollout plan, working with payors to enable reimbursement and with health systems to enable broad patient access. We plan to set up research facilities and innovation labs, which we refer to as Centers of Excellence, in key markets. Through these, we also intend to gather evidence to optimize our therapy model, training and certification of therapists, and prototype digital technology solutions to improve patient experience and outcomes. In January 2021, we established our first Center of Excellence, with The Sheppard Pratt Institute for Advanced Diagnostics and Therapeutics, in Baltimore, Maryland, in the United States. We believe this will give us a firm foundation from which to grow and develop potential new models as we seek to expand access to our investigational COMP360 psilocybin therapy, if approved.
- **Use digital technology to improve access to and impact of our investigational COMP360 psilocybin therapy.** We are exploring ways to use digital technology to make our therapeutic model more scalable, and to improve patient experience and outcomes. We plan to build upon the technologies we currently use in our Phase IIb clinical trial, which include a patient portal to help patients prepare for their experience, and a web-based “shared knowledge” interactive platform to complement our face-to-face and clinical therapist training. In our Phase IIb trial, we are collecting patient data in a remote setting using mobile technologies and using a third-party technology that tracks human-smartphone interactions. After the trial, this data will be compared

with information collected from validated psychiatric scales, such as MADRS, to develop potential digital applications to help detect early signs of post-treatment relapse and model the course of disease. We are also developing solutions using AI-assisted therapist feedback and monitoring. We are building an in-house digital team with experts in digital technology, engineering, and AI, which we refer to as augmented intelligence as well as artificial intelligence. We will continue to collaborate with other digital companies to research, develop and ultimately commercialize proprietary digital technology solutions that have the potential to complement and augment our investigational COMP360 psilocybin therapy. We believe this may enable us to offer a personalized, preventative and predictive care model.

### **Our Market Opportunity**

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

#### ***MDD and TRD Prevalence***

MDD is a condition characterized by a persistent feeling of sadness and heightened negative emotions. It is considered a unipolar condition, suggesting a distinction between MDD and bipolar depression, the latter of which is often associated with an emotional state fluctuating between depression and hypomania or mania. MDD is a chronic, relapsing, recurring and serious mental health condition associated with high mortality rates, morbidity and diminished quality of life. The World Health Organization, or WHO, estimates that more than 320 million people worldwide are suffering with MDD and that MDD currently accounts for an average of 7.5% of years of life lost due to disability globally, as defined by disability-adjusted life years, or DALYs, or the sum of years of healthy life lost to either mortality or non-fatal illness or impairment.

Due to the limitations of existing treatments, nearly one-third of those suffering with MDD are not adequately helped after two or more existing depression treatments. This condition is referred to as TRD. We estimate the TRD population to be approximately 100 million people globally, based on the most recently available data in 2010. To date, only two pharmacotherapies have been approved specifically for the treatment of TRD in the U.S.

The following table indicates the worldwide estimated patient populations suffering with new onset MDD, persistent MDD and TRD, and the primary treatment options available.

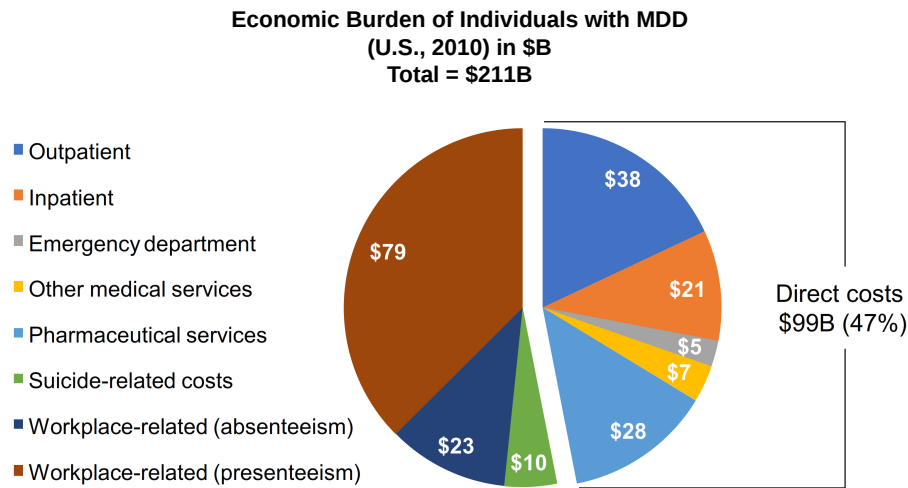
Treatment pathway stage	New onset depression Major depressive disorder (MDD)	Persistent depression Major depressive disorder (MDD)	Treatment-resistant depression (TRD)
Line of therapy	First line	Second line	Third line +
Patients (worldwide)	320 million	200 million	100 million (~33% of total)
Available treatments	<ul style="list-style-type: none"> <li>• Antidepressants</li> <li>• Psychological interventions eg, CBT*</li> </ul>	<ul style="list-style-type: none"> <li>• Antidepressants</li> <li>• Antidepressant combinations</li> <li>• Psychological interventions</li> </ul>	<ul style="list-style-type: none"> <li>• Antidepressants</li> <li>• Augmentation therapy (antidepressants, mood stabilizers, anticonvulsants, atypical antipsychotics, esketamine)</li> <li>• Ketamine</li> <li>• Somatic therapy (rTMS*, tDCS*, ECT*, DBS*)</li> <li>• High-intensity psychological interventions</li> </ul>
% relapse	60-70%	50-75%	80-90%

\* CBT = cognitive behavioral therapy; rTMS = repetitive transcranial magnetic stimulation; tDCS=transcranial direct current stimulation; ECT=electroconvulsive therapy; DBS=deep brain stimulation

### ***Economic and Societal Burden***

The economic burden of MDD in the United States, accounting for comorbid physical and psychiatric conditions, is estimated to be over \$200 billion per year as of 2010. Approximately 47% of this figure is attributable to direct costs including outpatient, inpatient, emergency, medical and pharmaceutical cost, while the rest is attributable to indirect costs, including loss of productivity, absenteeism and suicide. Between 2005 and 2010, the economic burden of MDD rose by \$37.3 billion, an increase of 21.5%. A large proportion of this increase can be attributed to direct costs such as outpatient and inpatient medical services, with an increase of 27.5% from \$77.5 billion in 2005 to \$98.9 billion in 2010. This figure

demonstrates that the economic burden of MDD is large and we believe it is likely to continue to grow over time.



TRD has a greater economic and societal cost than non-TRD MDD. TRD patients are often unable to perform daily tasks, are less productive at work and have higher rates of unemployment. They are also more likely to receive disability or welfare benefits than non-TRD MDD patients. Employees suffering with TRD have higher rates of workplace absenteeism compared with those without a mental health condition. In addition, co-occurring conditions, such as hypertension, anemia and diabetes, are more common in TRD patients versus non-TRD MDD patients.

Direct medical costs for TRD patients are estimated to be two to three times higher than for non-TRD MDD patients. An analysis from commercial claims and Medicare/Medicaid data in the United States points to average annual healthcare costs of between \$17,000 and \$25,000 per TRD patient per year. This compares with less than \$10,000 per year for non-TRD MDD patients. TRD patients have higher prescriptions costs, more doctor visits and increased rates of hospitalization. TRD patients also have, on average, twice the number of inpatient visits compared with non-TRD MDD patients and, on average, their hospital stay is approximately 36% longer.

Every year, approximately 800,000 people die from suicide globally. For each adult suicide death, estimates suggest there may have been more than 20 other attempts. There is approximately a seven-fold increase in the suicide rate for TRD patients compared with non-TRD MDD patients. Research conducted in 2018 suggests that the proportion of patients suffering with TRD attempting suicide at least once during their lifetime could be as high as 30%.

**Existing Therapies for Depression**

Because depression has biological, social, psychological, environmental, genetic, and stress-related determinants, many of which co-occur, treatment options are wide-ranging and often combined. Current pharmacological and non-pharmacological treatments, such as antidepressants and psychotherapy, respectively, are well-established and efficacious for a subset of MDD patients. However, many patients experience relapses. Clinicians lack high-quality evidence and often rely on a trial and error approach, course correcting as patients experience these relapses or difficult side effects. Experts are beginning to recommend a shift to more multi-modal treatments where different types of therapy are delivered concomitantly (i.e., a mix of pharmacotherapy, psychological/behavioral, and device interventions).



Patients suffering with TRD are treated through a variety of approaches, each of which is associated with significant shortcomings. Consequently, there remains a need for a fast-acting, tolerable treatment that provides a durable response. Despite the condition's largely heterogeneous nature, most pharmacotherapies for depression use the same mechanism of action, targeting the modulation of the brain's neurotransmitter monoamine levels. As evidenced by the low response and high relapse rates, these treatments are not effective for a large number of patients. Various forms of somatic intervention are also used, although there is limited data supporting their long-term benefit. Esketamine, a newly approved TRD therapy, demonstrated mixed efficacy in its pivotal clinical trials, with rapid relapse rates even with adjunctive antidepressants and protracted withdrawal reactions. We believe currently available options do not adequately meet the needs of patients suffering with TRD and there is a significant need for a new therapeutic approach.

The following table includes representative ranges and approximate costs for existing treatments of depression as well as their methods of delivery.

Therapy	Route	Frequency and duration	Strategy	Reimbursement <sup>1</sup>	Approximate annual cost per patient <sup>2</sup>
Antidepressants: SSRI/SNRI*	Oral	1/day, chronic	Mono/ Adjunctive therapy	Broad	\$500 - 900
Atypical antipsychotics	Oral	1/day - chronic	Adjunctive therapy	Broad	\$3,000 - 9,000
CBT	Face-to-face or online	10-20 sessions, 3-4 months	Mono/ Adjunctive therapy	Broad	Averaging \$1,000
Esketamine	Intranasal	Up to 56 sessions/year, under supervision of a healthcare professional	Adjunctive therapy	Limited	\$33,000 - 49,000
Ketamine	Intravenous	Up to 9 injections	Adjunctive therapy	No	\$2,500 - 5,000
rTMS	Magnetic brain stimulation without anesthesia	5 sessions/ week, 4-5 weeks	Mono/Adjunctive therapy	Limited	\$6,000 - 12,000
ECT	Electric brain stimulation under anesthesia	3 sessions/ week, 4+ weeks	Mono/Adjunctive therapy	Limited	\$5,000 - 15,000
VNS	Electric pulses sent to the brain	Duration varies from patient to patient – stimulator must first be implanted and given at a starting low dose every 5 minutes from day to night	Mono/Adjunctive therapy	Limited	\$40,000 - 45,000 for surgical implementation (excluding costs of post-operative device adjustments)
DBS	Electrical impulses to the brain through implanted electrodes	3-6 hour operations; follow up visits	Mono/Adjunctive therapy	Limited	\$200,000 - 250,000 for surgical implementation (excluding costs of battery replacements required every 12-24 months costing ~\$95,000 for hardware replacement and surgery)

**Key:** orange: established common pharmacotherapies for depression; blue: common psychotherapy for depression; grey: novel pharmacotherapies for depression; green: somatic therapies for depression

\* SSRI = selective serotonergic reuptake inhibitor; SNRI =serotonergic norepinephrine reuptake inhibitor

1. Government reimbursement or private insurance coverage; 2. Assumes one treatment course over the year, direct treatment cost only (not total healthcare costs); 3. Based on a year of treatment, 150mg/day, augmentation with fluoxetine for U.S. or citalopram for UK

### ***Pharmacotherapies***

There are five main categories of antidepressants available on the market. These are selective serotonergic reuptake inhibitors, or SSRIs, and serotonergic norepinephrine reuptake inhibitors, or SNRIs, atypical antidepressants, monoamine oxidase inhibitors, or MAOIs, and tricyclic antidepressants, or TCAs. These are frequently used in first- and second-line treatment of depression and can also be used after this point. Studies have shown that approximately 50% of patients are not helped by their initial antidepressant treatment. This figure rises to as high as 70% for subsequent treatments.

Currently approved antidepressants have significant limitations, including delayed onset of action, poor therapy adherence rates and various side effects. The onset of action for the most commonly used antidepressants is typically between two and three weeks. Adherence levels are relatively low, with approximately 50% of individuals in primary and psychiatric care not adhering to their prescribed antidepressant medication.

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

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

### ***Psychotherapies (Including Cognitive Behavioral Therapy, or CBT)***

Psychotherapy is a form of talk therapy often recommended as first-line treatment in mild depression and often used as adjunctive therapy for MDD patients. Two frequently used psychotherapies for depression are CBT and interpersonal therapy, or IPT. CBT focuses on changing negative thought and behavior patterns. IPT also looks at negative thoughts and behaviors, but only as they apply to interpersonal relationships and social functioning. The incremental efficacy of psychotherapy in more severe cases and in later lines of treatment remains questionable. Psychotherapeutic approaches can be effective for many individuals but require a significant time commitment from patients and are subject to variability in their availability and delivery.

### ***Esketamine/Ketamine***

Ketamine is an NMDA receptor antagonist that has been used for several decades in sedation, anesthesia and chronic pain. The S-enantiomer of ketamine, esketamine, is administered intranasally as a spray and has recently been approved by the FDA to treat TRD. There are mixed efficacy results associated with the use of esketamine. Ketamine and esketamine require multiple administration sessions and are associated with a high abuse potential. Esketamine treatments typically need to be frequently administered, in a controlled environment under medical supervision. This frequency makes administration costly for payors and burdensome for patients, resulting in limited clinical adoption and patient access.

### ***Somatic Therapies***

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

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

Based on early signals from psilocybin therapy studies (not involving the use of COMP360), which showed a rapid reduction in depression symptoms and effects lasting up to six months for some patients following administration of a single high dose, we believe psilocybin therapy has the potential to transform the current paradigm for TRD and other mental health and neurological conditions.

## **Psilocybin Therapy**

### ***History of Psilocybin Usage***

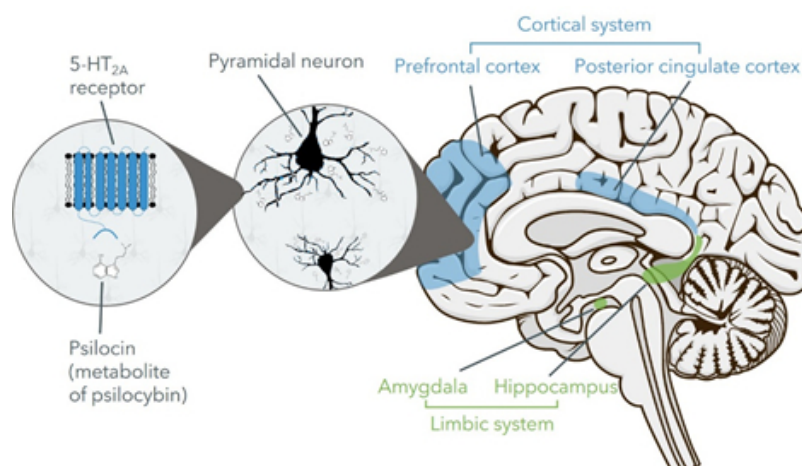
Psychedelics are a class of psychoactive drugs that act primarily through an agonist action on neurotransmitter receptors and cause psychological, visual and auditory changes, as well as an altered state of consciousness. Prior to psychedelics being classified as Schedule I drugs in the early 1970s, clinical research in psychedelics was widespread, with more than 40,000 patients suffering with mental health conditions participating in clinical studies and case reports. Accumulating evidence suggests that many psychedelic drugs may have psychopharmacological effects on the brain, including increasing the number, density and connections of neurons. This body of evidence has driven a resurgence of interest in the evaluation of psychedelic drugs for therapeutic use to treat a range of mental health conditions. A number of major academic institutions - Imperial College London, Johns Hopkins University, and Mount Sinai Health System - have established dedicated psychedelic research centers in the last two years.

Psilocybin is considered a serotonergic hallucinogen, along with other tryptamines such as dimethyltryptamine, or DMT, ergolines such as lysergic acid diethylamide, or LSD, and phenethylamines such as mescaline. It is an active ingredient in some species of mushrooms and was first isolated from psilocybe mushrooms by Dr. Hofmann and synthesized in the late 1950s. While classified as a Schedule I drug, the FDA and DEA began permitting the use of psilocybin in clinical studies for the treatment of a range of psychiatric conditions in the 1990s. Psilocybin has been researched as a potential treatment for a range of CNS diseases for over 60 years.

### ***Mechanism of Action***

There is an accumulating body of evidence that psilocybin may have beneficial effects on depression and other mental health conditions. We believe the benefits of psilocybin are largely derived from its mechanism of action. As shown in the graphic below, by activating a distinct set of receptors in brain areas critical to mood and cognition, psilocybin acts to induce a range of downstream effects that may have important, sustained effects on brain function. In this way, evidence of the molecular, cellular, and

systemic effects of psilocybin in the CNS supports the potential for psilocybin in the treatment of mental health conditions.



1. Stimulation of 5-HT<sub>2A</sub> receptors results in downstream cascades via G-protein signaling.
2. Altered extracellular release of dopamine leads to enhanced positive mood.
3. Down-regulation of the default mode network, or DMN, and de-synchronization of cortical activity as well as the emergence of new patterns of functional connectivity across the brain.
4. Sustained cellular changes leading to neuroplasticity and "window of opportunity" for therapy.

#### *Molecular Effects of Psilocybin: Partial Agonism of Serotonin Receptors*

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

#### *Cellular Effects: Activation of Downstream Signaling Cascades*

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

#### *Local Circuit-Level Effects: Neurotransmitter Release and Neuroplasticity*

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

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

Alterations in neurotransmitter release are another local circuit-level consequence of psilocin that may be relevant to its psychoactive and mood effects. Specifically, evidence from rodent studies suggests that psilocybin may alter extracellular release of serotonin and dopamine in brain areas such as the prefrontal cortex. By virtue of the extracellular neurotransmitter release changes in certain brain areas, which have established roles in, for example, executive function, psilocybin may drive positive mood effects.

#### *Systemic Effects: Changes in Brain Activity and Functional Connectivity*

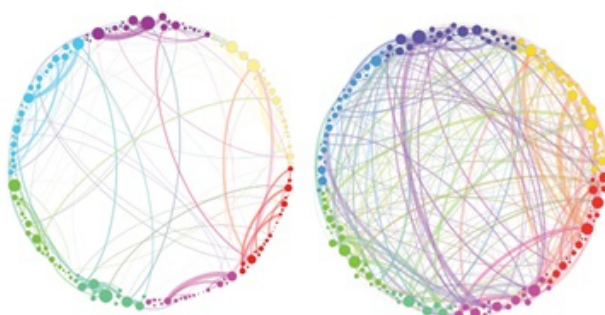
At the systemic level, psilocybin has been shown to alter the synchronicity of neuronal activation within and between different brain networks, during the psychedelic experience and afterwards. One network that has displayed altered functioning after psilocybin treatment in recent studies is the default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

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

### Simplified Visualization of the Acute Changes in Brain Network Connectivity

Placebo

Psilocybin



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

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

### Psilocybin Academic Studies

The therapeutic potential of psilocybin in depressive and anxiety conditions has been demonstrated in a number of academic-sponsored studies over the last decade. In these studies, psilocybin, when administered in conjunction with psychological support, provided rapid reductions in depression symptoms after a single high dose, with antidepressant and anxiolytic effects occurring on the day of administration and lasting up to the six-month follow-up period for a number of participants. These studies used a range of widely used and validated scales to assess symptoms related to depression and anxiety. Some of these scales are self-reported and others are rated by clinicians.

These studies have shown psilocybin to be generally well-tolerated, with low toxicity and no serious adverse events, or SAEs, reported. The low toxicity profile of psilocybin is corroborated by early non-clinical studies that indicate that very high levels of psilocybin, in excess of 200mg/kg when administered intravenously, are required to induce toxic effects in rodents. A 2004 study estimated a lethal dose to be 6,000mg of psilocybin in an average, healthy 70kg adult, which vastly exceeds a therapeutic dose range.

Psilocybin is categorized as a Schedule I drug in the U.S. and a Class A drug in the UK, due to its abuse potential reported in the 1960s. However, despite evidence of recreational use of natural sources of psilocybin, a recent and comprehensive review used the structure of the eight factors of the U.S. Controlled Substance Act to assess the abuse potential of medically administered psilocybin. It suggested that in a medical context psilocybin does not have a high abuse potential and that there is no clear evidence for a physical dependence potential, based on animal and human data.



The totality of these data suggest that psilocybin therapy may exhibit clinical activity in patients with depression and anxiety, when administered with psychological support from specially trained therapists. The table below summarizes the key findings from academic-sponsored studies that we believe support the use of psilocybin therapy for treating mental health conditions. Only the most recently reported of these studies, conducted at Imperial College London, which reported findings in April 2021, used COMP360 psilocybin supplied by the Company.

	University of California Los Angeles Grob et al (2011) (n=12) <sup>(a)</sup>	New York University Ross et al (2016) (n=29) <sup>(a)</sup>	Johns Hopkins Griffiths et al (2016) (n=51) <sup>(a)</sup>	Imperial College London Carhart-Harris et al (2016, 2018) (n=20) <sup>(a)</sup>	Johns Hopkins Davis et al (2020) (n=24) <sup>(a)</sup>	Imperial College London Carhart-Harris et al (2021) (N=59)
Disorder	Anxiety related to advanced-stage cancer	Anxiety or depression related to cancer	Anxiety or depression in life-threatening cancer	TRD	MDD	MDD
Design	Double-blinded, placebo-controlled	Randomized, double-blinded, placebo-controlled	Randomized, double-blinded	Open-label	Randomized	Randomized, double-blinded study with active comparator arm
Dose	14mg/70kg	21mg/70kg	Low (1 or 3mg/70kg) High (22 or 30mg/70kg)	10mg and subsequently 25mg	20mg/70kg (first) 30mg/70kg (second) <sup>(b)</sup>	Psilocybin arm: Two psilocybin 25mg doses, 3 weeks apart plus daily placebo tablets for 6 weeks  Escitalopram arm: Two psilocybin 1mg doses, 3 weeks apart plus daily escitalopram tablets for 6 weeks (10mg for first 3 weeks, 20 mg for final 3 weeks)
Outcome measures	BDI, STAI, POMS	HADS, BDI, STAI	GRID-HAM-D, HAM-A	QIDS-SR-16	GRID-HAM-D	QIDS-SR-16, HAM-D-17, MADRS
Safety findings	No SAEs attributed to psilocybin administration	No SAEs attributed to psilocybin administration	No SAEs attributed to psilocybin administration	No SAEs attributed to psilocybin administration; only mild and transient adverse events	No SAEs attributed to psilocybin administration	No SAEs attributed to psilocybin administration
Efficacy findings	<ul style="list-style-type: none"> <li>• <b>BDI</b>: 30% improvement at 1 and 6 months vs baseline and significant reduction from mild to minimal depression</li> <li>• <b>POMS</b>: Trend reduced adverse mood at week 2, returned to baseline at 6 months</li> <li>• <b>STAI</b>: Sustained decrease in trait anxiety sub-score at every time point for 6 months</li> </ul>	<ul style="list-style-type: none"> <li>• Significant reductions (mild/moderate to normal/minimal) in HADS, BDI and STAI measures</li> <li>• ~60-80% of participants continued with clinically significant responses<sup>(c)</sup> on depression and anxiety measures</li> </ul>	<ul style="list-style-type: none"> <li>• At 5 weeks and 6 months, 92% and 79% of high-dose participants, respectively, continued to show clinically significant responses<sup>(c)</sup> on depression and anxiety measures</li> </ul>	<ul style="list-style-type: none"> <li>• QIDS-SR-16 scores showed significant improvement at all post-treatment time points</li> <li>• Max effect at 5 weeks with 65% response (including 20% remission)</li> <li>• No patients sought conventional antidepressant treatment within 5 weeks after psilocybin therapy</li> </ul>	<ul style="list-style-type: none"> <li>• 71% of participants had a clinically significant response in depression scores at both 1 and 4 weeks. 58% and 54% achieved clinical remission at 1 and 4 weeks respectively</li> </ul>	<ul style="list-style-type: none"> <li>• QIDS-SR-16 total score at six weeks showed a two point difference (95% confidence interval (CI), -5 to 0.9) favoring the psilocybin group compared with the escitalopram group</li> <li>• For the clinician rated scales, the MADRS, showed a 7.2 point treatment difference (95% CI, -12.1 to -2.4) favoring psilocybin, while the HAM-D-17 showed a 5.3 point treatment difference (95% CI, -8.2 to -2.4) favoring psilocybin</li> <li>• 70% of participants were responders at week 6 in the psilocybin arm versus 48% in the escitalopram arm. 57% of participants were remitters at week 6 in the psilocybin arm versus 29% in the escitalopram arm</li> </ul>

(a) "N" numbers indicate the number of patients that completed at least one administration session. In some studies, not all administration sessions and/or follow-up measures were completed for all patients. Reasons provided for patients not

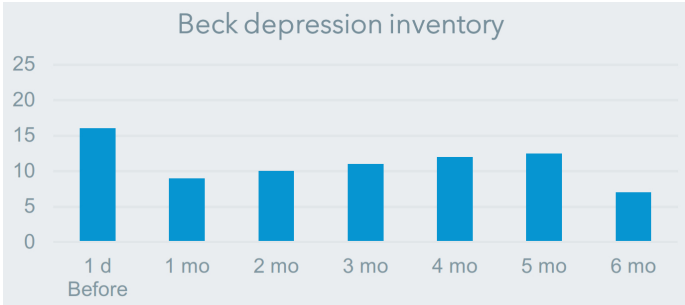
- completing the studies included patients becoming too ill due to cancer progression, death due to cancer, or resumption of antidepressant medications.
- (b) Some patients received the 20mg/70 kg dose again for their second dose.
- (c) As used herein, "clinically significant response" is defined as a >50% reduction in depression or anxiety scores relative to baseline. "Clinical remission" in the Davis et al study is defined as GRID-HAMD scores <7. "Remission" in the Carhart-Harris et al. 2021 study is defined as QIDS-SR-16 score ≤5. Responses and remission shown for Davis et al study are for "Immediate treatment" group that had already received psilocybin therapy.

Abbreviations: BDI, Beck Depression Inventory; GRID-HAM-D, GRID Hamilton Depression Rating Scale; HADS, Hospital Anxiety and Depression Scale; HAM-A, Hamilton Anxiety Rating Scale; HAM-D, Hamilton Depression Rating Scale; STAI, State-Trait Anxiety Inventory; MADRS, Montgomery-Asberg Depression Rating Scale; POMS, Profile of Mood States questionnaire; QIDS-SR-16, Quick Inventory of Depressive Symptomatology

**University of California Los Angeles, Grob et al, 2011 - Existential Distress: Feasibility and Safety for Cancer Patients**

In this 2011 study, 12 patients with anxiety related to advanced stage cancer (defined as diagnosis of acute stress disorder, generalized anxiety disorder, anxiety disorder due to cancer, or adjustment disorder with anxiety) underwent two experimental sessions spaced several weeks apart. In one session, each patient received 14mg/70kg psilocybin and in the other session each patient received a placebo control (250mg niacin), and the order in which they were administered was randomized. The BDI, POMS and STAI scoring scales were assessed one day before, one day after, and two weeks after each session. Each measure was assessed again once a month for up to six months after the final session. There was a trend showing decreased BDI scores at two weeks compared to one day before the first session. BDI scores were reduced by almost 30% at one month after the second treatment. This change was sustained and became significant at six months. The POMS indicated a trend for reduced adverse mood tone at two weeks after the first session compared to one day prior to psilocybin treatment. Although no significant changes were observed on the STAI state anxiety score, a sustained decrease that was significant at one and three-months post-treatment was evident on the STAI trait anxiety score. No SAEs were attributed to psilocybin administration.

**Significant Reduction in BDI Scores at Six Months Post Treatment Compared with Baseline**

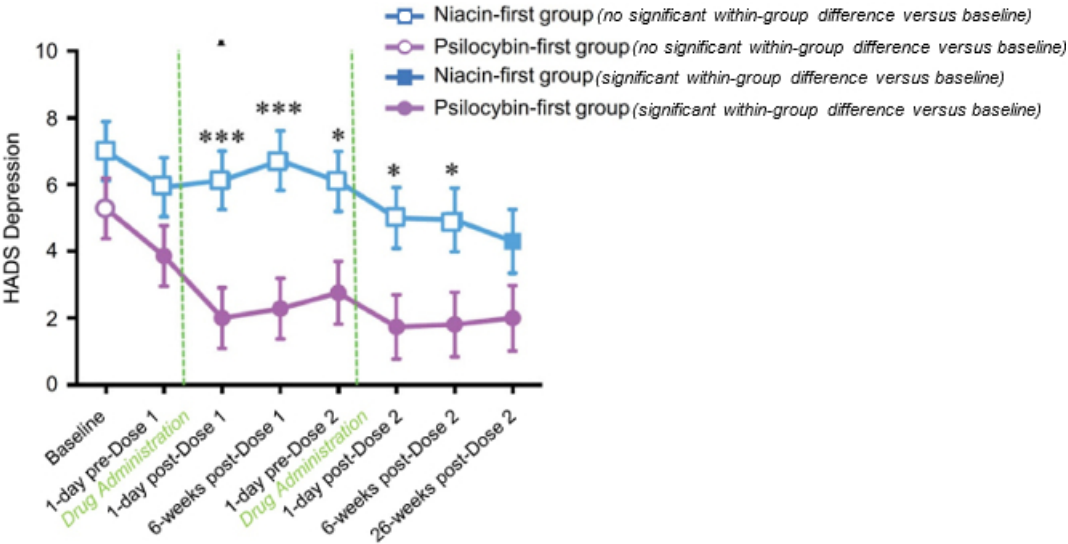


Graph displays changes in depression severity represented by Beck Depression Inventory (BDI) score between baseline and six months following second administration session. A reduction in BDI score was reported at the six month timepoint, compared to baseline. Effect sizes not reported. P-value = 0.03, calculated by performing a t-test to compare the six month score with one day before the first administration. Adapted from Grob et al 2011.

**New York University, Ross et al, 2016 – Existential Distress**

This 2016 study recruited 29 patients with life-threatening cancer and clinically significant anxiety or depression (defined as a primary diagnosis of acute stress disorder, generalized anxiety disorder, anxiety disorder due to cancer, or adjustment disorder with anxiety and/or depression). Patients underwent two administration sessions, one in which 21mg/70kg psilocybin was administered and one in which they received a placebo (250mg niacin). The administration sessions were spaced seven weeks apart and the order in which they were administered was randomized. Baseline measurements were collected two to four weeks prior to the first session. Statistically significant reductions in measures of anxiety and depression were observed up to 26 weeks following the second dose in patients who received psilocybin first, compared with baseline. Although no significant changes were observed in the placebo-first group prior to crossover, these patients also experienced statistically significant, sustained reductions in a majority (five out of six) of anxiety and depressions measures following psilocybin treatment. At 26 weeks following the final treatment, both groups exhibited antidepressant or anxiolytic, or reduction of anxiety, response rates of 60-80% across a variety of measures, including BDI remission and response rates as well as HADS, as demonstrated in the following graphic. No SAEs were attributed to psilocybin administration.

**Statistically Significant Decrease in HADS Depression Scores at 26 Weeks Post Treatment**



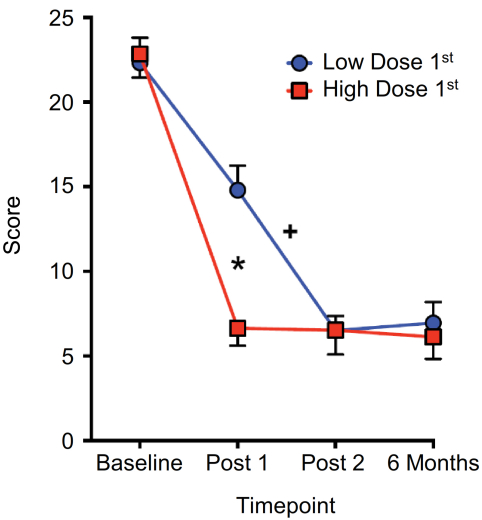
Graph illustrates changes in mean HADS Depression scores in niacin-first (blue) and psilocybin-first (purple) groups between baseline and 26-weeks after second treatment. The psilocybin-first group exhibited significant reductions in depressed symptoms compared to the placebo group after the first administration session. The niacin-first group also showed significant reductions in depressive symptoms 26 weeks after receiving psilocybin compared with baseline. \*p<0.05, \*\*p<0.01, \*\*\*p<0.001, calculated by performing between-group t-tests. Solid symbols indicate significant within-group differences versus baseline. Data shown as mean ± Standard Error (SE). Adapted from Ross et al, 2016.

**Johns Hopkins University, Griffiths et al, 2016 - Existential Distress**

This 2016 study enrolled 51 patients with life-threatening cancer and a Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) diagnosis that included anxiety and/or mood symptoms. The patients were randomized to receive either a low (1 or 3mg/70kg) or a high (22 or 30mg/70kg) dose of psilocybin first. At a second administration session five weeks later, patients who had received the low dose first were given a high dose, whereas the high-dose first group were given a low dose of psilocybin. In the high-dose first group, psilocybin treatment resulted in significant reductions in measures of depression and anxiety at five weeks following the first session. Of the high-dose first group, 92% showed a clinically significant response (≥50% reduction in GRID-HAMD depression scores relative

to baseline) at this five-week timepoint, compared with 32% of the low-dose first group. These significant changes were sustained at the six-month follow-up in both groups, with 79% of the high-dose first group and 77% of the low-dose first group continuing to show clinical response. More than two thirds of patients described psilocybin therapy as among the top five most meaningful experiences of their lives, alongside the birth of a child or the death of a parent, six months after their psilocybin therapy session. No SAEs were attributed to psilocybin administration.

**Statistically Significant Reductions in Depression and Anxiety (GRID-HAMD) Sustained Six Months Post Treatment**

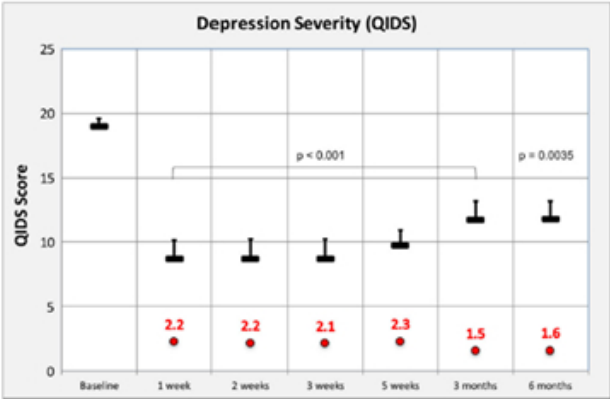


Graph displays changes in GRID-HAMD scores between baseline and six months following first treatment, in groups receiving psilocybin low dose first or psilocybin high dose first. These changes demonstrate the antidepressant effect of psilocybin in this population and supported greater efficacy for the high dose of psilocybin. \*p<0.05 and +p<0.05, calculated using planned comparison t-tests. Asterisk indicates significant difference between the groups following session 1 (Post 1) and cross denotes significant difference between scores at Post 1 and Post 2 timepoints in the group that received the psilocybin low dose first. Data shown as mean ± SEM. Adapted from Griffiths et al, 2016.

**Imperial College London, Carhart-Harris et al, 2016, 2018 - TRD**

In this study, conducted in 2016, 20 TRD patients with moderate to severe depression were dosed with 10mg psilocybin and 25mg psilocybin in two separate administration sessions that occurred one week apart. All patients received the lower dose in the first session. Among the 19 patients who completed the entire follow-up period, a statistically significant reduction in depressive symptoms was observed for up to six months, compared with baseline. The maximum effect size (on the QIDS-SR-16) was observed at five weeks post-treatment, at which point nine patients met the criteria for response (≥50% reduction in BDI score compared with baseline). No patients had sought conventional antidepressant treatment within five weeks of receiving the high psilocybin dose. Only mild and transient adverse events were observed and no SAEs were attributed to psilocybin administration.

Significant Reduction in Depressive Symptoms Observed up to Six Months Post Treatment

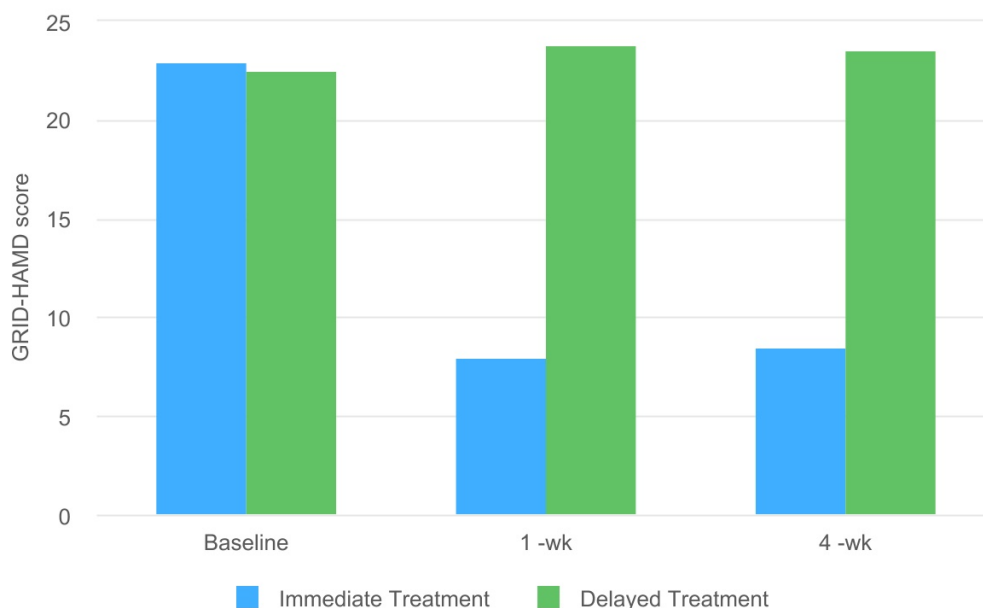


Graph shows changes in depression severity represented by QIDS score between baseline and six months after the second treatment. These changes demonstrated a significant reduction in depressive symptoms following psilocybin treatment in TRD. Effect size comparing pre- to post-treatment scores is represented by Cohen's *d* values in red. Adapted from Carhart-Harris et al 2018.

Johns Hopkins University, Davis et al, 2020 - MDD

This study analyzed data from a total of 24 MDD patients who were randomized into two groups. One group received treatment immediately following baseline measurements ("immediate treatment"), while a waitlist control group received treatment eight weeks after baseline measurements ("delayed treatment"). Each patient received 20mg/70kg psilocybin in a first session and either 20 or 30mg/70kg psilocybin in a second administration session. The authors reported significant differences between the two treatment groups in depressive symptoms measured using the GRID-HAMD at one and four weeks post-treatment (when the "delayed treatment" group were still awaiting their first administration session), caused by a decrease in scores of the "immediate treatment" group. In addition, at four weeks following treatment, 71% and 54% of study participants met the criteria for clinically significant response (>50% reduction in GRID-HAMD depression scores relative to baseline) and remission (GRID-HAMD scores <7), respectively.

### Significant Reduction in Depressive Symptoms Observed up to Four Weeks Post Treatment in Immediate Treatment Group Compared with Delayed Treatment Group

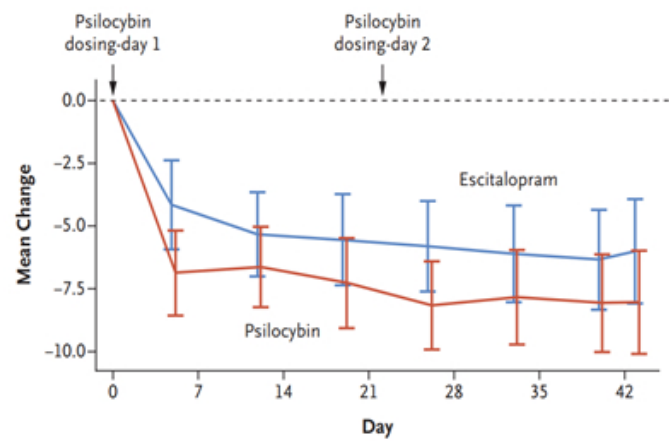


Graph shows depression severity represented by GRID-HAMD score between baseline and at one and four weeks post-treatment of the "immediate treatment" group. Effect size (Cohen's d): 1 week = 2.5, 4 weeks = 2.6. Graph created based on data from Davis et al 2020.

#### ***Imperial College London, Carhart-Harris et al, 2021- MDD***

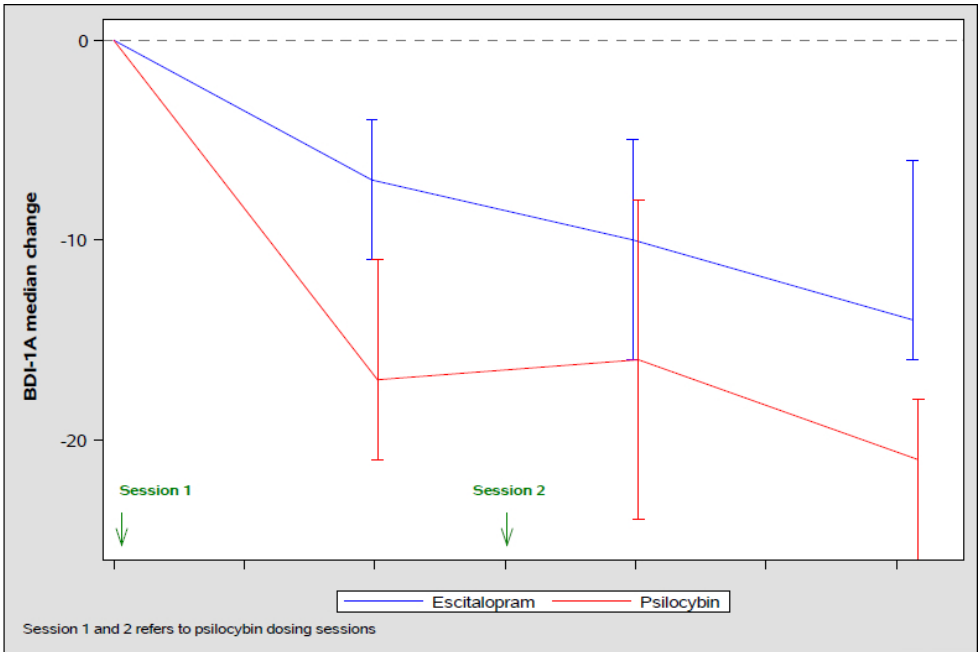
This study was a randomized, double-blind clinical trial, with the aim to compare the efficacy of COMP360 with a six week course of the selective serotonin reuptake inhibitor (SSRI), escitalopram, for major depressive disorder (MDD). The study enrolled 59 MDD patients who were randomized into two groups. The psilocybin group received two 25mg doses of COMP360, at 3 week intervals, together with psychological support and a daily placebo tablet; the escitalopram based group received daily administration of 10mg escitalopram for the first 3 weeks titrated to 20mg for the following 3 weeks, together with two low doses (1 mg) of COMP360 at 3 week intervals, together with psychological support. Results signaled positive activity of COMP360 compared with escitalopram. The primary outcome measure, the change from baseline in the 16-item, self-report Quick Inventory of Depressive Symptomatology (QIDS-SR-16) total score at six weeks showed a two point difference favoring the psilocybin group compared with the escitalopram group, but was not statistically significant (95% confidence interval (CI), -5 to 0.9). Secondary measures showed improvement on depression rating outcome measures for psilocybin and escitalopram, with psilocybin showing numerical benefits compared with the SSRI. On the clinician-rated depression scales, the change from baseline at week six on the Montgomery-Asberg Depression Rating Scale (MADRS), showed a 7.2 point treatment difference (95% CI, -12.1 to -2.4) favoring psilocybin, while the 17-item Hamilton Depression Rating Scale (HAM-D-17) showed a 5.3 point treatment difference (95% CI, -8.2 to -2.4) favoring psilocybin. Response rates (a 50% or greater reduction on the QIDS-SR-16 total score from baseline) at week six were 70.2% for the psilocybin arm compared with 48.0% for the escitalopram arm, and remission rates (defined as a QIDS-SR-16 total score  $\leq 5$ ) at week six were 57.1% and 29.1%, respectively. Such secondary endpoints were uncorrected for multiplicity. COMP360 psilocybin was well-tolerated. Adverse event rates and severity were comparable across both groups; there were no serious adverse events.

Change from baseline on the QIDS-SR-16



Primary outcome measure: the change from baseline in QIDS-SR-16 total score at 6 weeks showed a two point difference favoring the psilocybin vs escitalopram group

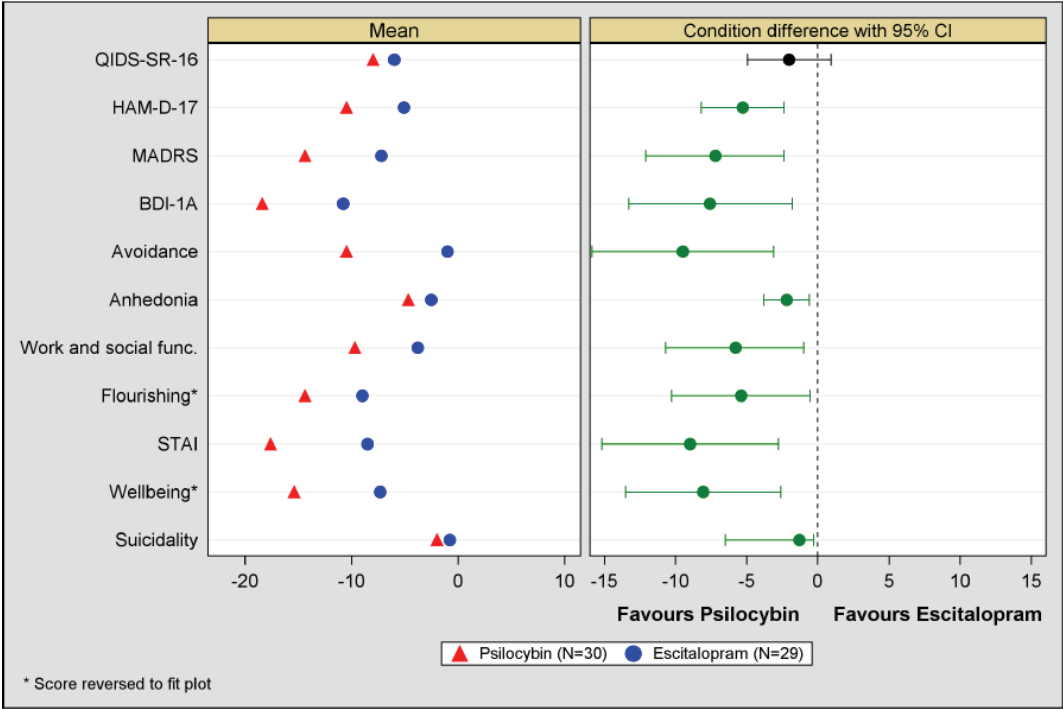
Change from baseline on the BDI-1A the psilocybin vs escitalopram group



Secondary clinical outcome measure: the change from baseline in BDI-1A total score difference favoring the psilocybin vs escitalopram group

Mean change for primary and secondary outcomes with confidence intervals: all clinical outcome measures at week 6





Secondary measures: positive activity of both psilocybin and escitalopram, with psilocybin showing numerical advantages compared with the SSRI

**Our Investigational Psilocybin Therapy - COMP360**

**Clinical Summary**

Our psilocybin therapy combines the pharmacological effects of psilocybin with psychological support from specially trained therapists who are present throughout the psilocybin administration session. We have developed a proprietary stabilized, high-purity polymorphic crystalline synthesized formulation of psilocybin, COMP360, and are investigating the effectiveness of this psilocybin therapy initially in TRD.

We are currently conducting a large-scale randomized controlled Phase IIb clinical trial of our psilocybin therapy in 216 patients suffering with TRD, in 22 sites in 10 countries in North America and Europe. This dose-finding trial is investigating the safety and efficacy of COMP360 in TRD, and aims to determine the optimal dose of COMP360, with three doses (1mg, 10mg, 25mg) being explored.

In our Phase I clinical trial in 89 healthy participants, completed in 2019, we observed that COMP360 was generally well-tolerated, with no serious adverse events and no clinically-relevant negative short- or longer-term effects on cognition or emotional processing. According to analyses in this exploratory study, for the duration of the trial, there were no negative effects on cognition (measured up to four weeks from administration) based on a range of validated measures from the Cambridge Neuropsychological Test Automated Battery, or emotional processing (measured up to 12 weeks from administration), based on widely accepted clinical and academic tests.

### *Psilocybin Therapy Protocol*

Our psilocybin therapy comprises administration of COMP360 with psychological support from specially trained therapists. Psychological support is designed to facilitate patient safety and optimal therapeutic outcomes.

Our psilocybin therapy takes place over a period of several weeks, and comprises:

- **Preparation:** The objectives of the preparation sessions are to establish a therapeutic alliance between the patient and therapist, and to demonstrate and practice the skills of self-directed inquiry and experiential processing, which we believe are critical for embracing the psychedelic experience in the psilocybin administration session. We have created an online preparation platform for patients where they can remind themselves what to expect from the experience and how to prepare for it.
- **Psilocybin administration session:** A psilocybin administration session lasts approximately six to eight hours and a therapist and assisting therapist are present throughout the session. The therapist's goal during the session is to establish psychological safety, minimizing anxiety and encouraging openness to all emerging experiences. The session takes place in a room designed to be ambient, comfortable and calming. Patients wear eyeshades to help them focus internally, lie on a bed, and listen to a carefully curated music playlist through a high-quality sound system and earphones. After the acute effects of psilocybin subside, patients are evaluated for safety and discharged.
- **Post-administration integration:** The objectives of integration sessions are to help patients process the range of emotional and physical experiences facilitated by the psilocybin session and to generate insights that can lead to cognitive and behavioral changes. We believe psilocybin therapy can give patients a sense of agency, whereby they feel separate from their symptoms and empowered to make changes in their lives.

We require our therapists to have specific professional and educational backgrounds. All therapists must be registered mental health professionals, such as mental health nurse practitioners, clinical psychologists, and psychiatrists with experience in counselling or psychotherapy. We have established a therapist training program designed by experts from the fields of psychology, psychiatry and psychedelic therapy research, and to date have trained more than 65 therapists and assisting therapists to work at the sites conducting our Phase IIb clinical trial.

Our method of psychological support is based on our current understanding of psilocybin's potential to generate new insights and perspectives leading to reduced rigidity in thinking. This modification of thought patterns can be uncomfortable or anxiety-provoking. Therapists refrain from intervening with the patient's experience, unless required for safety reasons. Such an approach differs from some forms of psychotherapy which can be more directive and interventional. Our therapist training program sets out a formal and scalable methodology for psychological support in psilocybin therapy. It will continue to evolve as we progress COMP360 psilocybin therapy through clinical trials, but this manualized approach to the training program is an important first step in reducing variation in psychological support and setting out a framework for training and evaluation of this support. Details of the program were published in February 2021 in the peer-reviewed journal *Frontiers in Psychiatry*.

### **Preclinical and Clinical Experience**

#### *Preclinical Studies*

We previously conducted a series of *in vitro* and *in vivo* toxicology studies, including tests for studies evaluating genotoxicity and cardiotoxicity. The results of these studies allowed us to begin our Phase IIb clinical trial in TRD. We are currently undertaking an additional series of safety pharmacology and toxicity studies, to be completed prior to commencement of our anticipated Phase III program.

**Phase I: Healthy Volunteers Trial**

In 2019, we completed a Phase I clinical trial of COMP360 administered along with psychological support in healthy participants. The trial recruited 89 healthy participants, of which 41 were females and 48 were males, with an average age of 36 years. This double-blind, placebo-controlled trial was the largest randomized controlled trial of psilocybin to date, and the first to simultaneously administer psilocybin, with 1:1 support from therapists in a clinical research setting. The trial was conducted at the Institute of Psychiatry, Psychology and Neuroscience, King’s College London.

**Trial Design**

Prior to administration, participants took part in a two-hour preparatory group session. Participants were randomized to three arms: placebo, 10mg or 25mg doses of COMP360 in a 1:1:1 ratio. COMP360 was administered orally and 1:1 psychological support was given to up to six participants simultaneously at the facility. Participants were followed up for 12 weeks following drug administration and completed safety assessments, using a range of validated measures of cognitive function and emotional processing.

**Key Enrollment Criteria**

Participants were males or females aged between 18 to 65 years of age. Participants with a current diagnosis or past history of schizophrenia, psychosis, bipolar disorder, delusional disorder, paranoid personality disorder, schizoaffective disorder, borderline personality disorder, major depressive disorder, panic disorder, generalized anxiety disorder, obsessive-compulsive disorder, eating disorder, or body dysmorphic disorder, were excluded. Patients with first-degree relatives with the aforementioned conditions, or a past history thereof, were also excluded. Additionally, participants were not deemed eligible if they met criteria for current, or history of, substance abuse or dependency, had taken psychiatric medications within one year of enrollment or had prior exposure to psilocybin within one year of signing the informed consent.

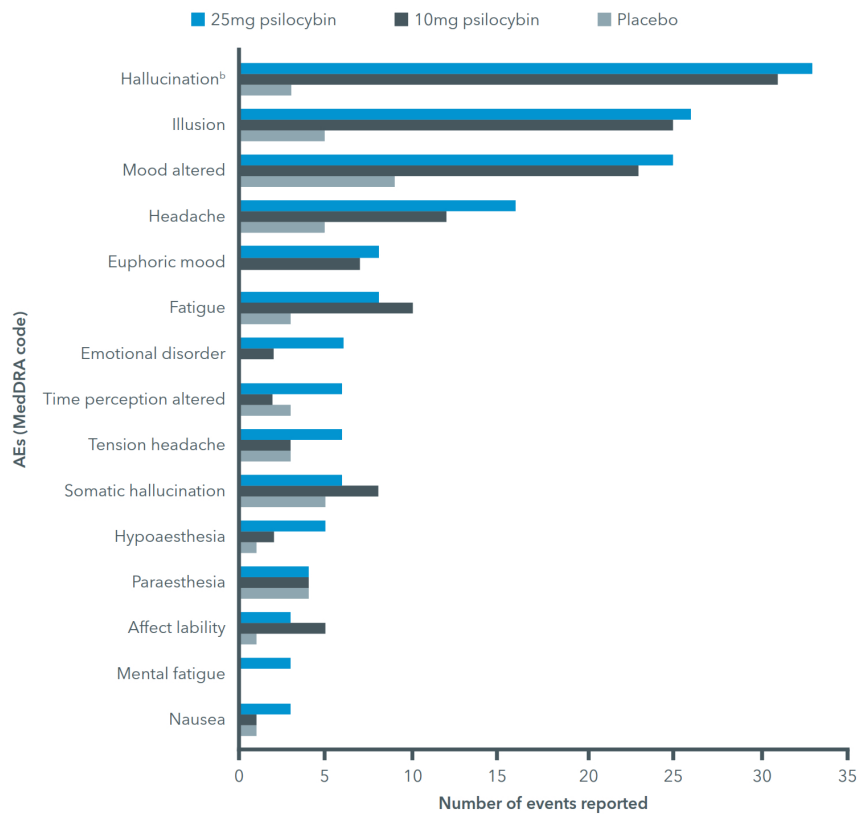
**Clinical Findings**

There were no SAEs reported, and no adverse events, or AEs, led to withdrawal. A total of 511 AEs were reported throughout the 12-week duration of the trial. The tables below summarize the most frequently reported AEs, including AE profile by treatment group, as well as ranking the most frequently reported AEs based on the 25mg psilocybin arm, by group:

	Placebo (n=29)	10mg COMP360 (n=30)	25mg COMP360 (n=30)
Total number of treatment-emergent AEs reported	91	203	217
Total number of treatment-emergent AEs reported deemed to be related or possibly related to study treatment	77	188	208

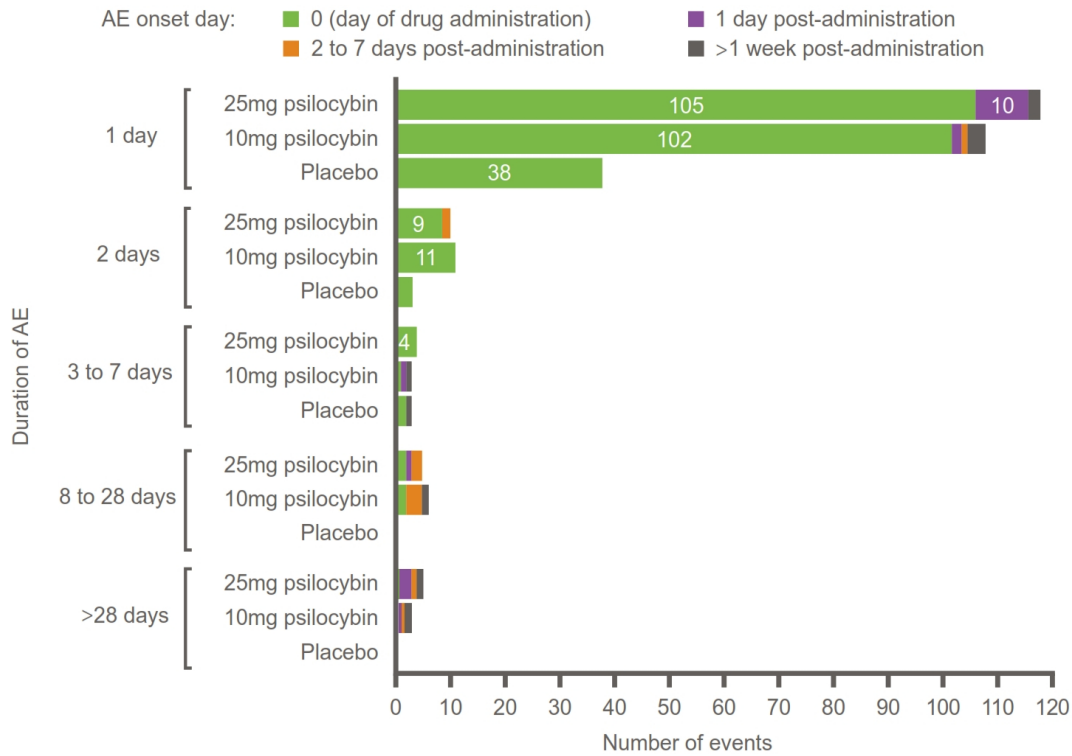
Number of treatment-emergent adverse events (AEs) reported by treatment group in our health volunteers trial.

Most Frequently Reported AEs (MedDRA Code)<sup>a</sup> in our Phase I healthy volunteers trial



<sup>a</sup> Ranked by incidence in the 25mg psilocybin group  
<sup>b</sup> Includes auditory, gustatory, olfactory, tactile, and visual hallucinations  
AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities

COMP360 induced expected psychedelic experiences that generally resolved on the day of administration. In previous third-party studies, these have been found to correlate with therapeutic effect. Of all AEs, 68% reported as starting and resolving on the day of administration. The median duration of AEs in all treatment arms across the 12-week trial was one day.



Above Figure: Most frequent AEs: onset and duration by treatment arm in our healthy volunteers trial.

There were 57 AEs reported of “mood altered,” of which only two related to negative alterations in mood. One of these was in the placebo arm (“negative mood,” which started and resolved on Day 0) and one in the 10 mg psilocybin arm (“feeling moody or sensitive,” which started on Day 2 and resolved eight days later).

	<b>25mg COMP360 (n=30)</b>	<b>10mg COMP360 (n=30)</b>	<b>Placebo (n=29)</b>
Any “mood altered” AE	15 (50.0)	13 (43.3)	6 (20.7)
Introspection	7 (23.3)	5 (16.7)	1 (3.4)
Reflections	3 (10.0)	2 (6.7)	2 (6.9)
Increased empathy	2 (6.7)	3 (10.0)	0
Sense of oneness	1 (3.3)	4 (13.3)	0
Introspection/reflection	1 (3.3)	1 (3.3)	1 (3.4)
Laughter	1 (3.3)	1 (3.3)	0
New perspective	1 (3.3)	1 (3.3)	0
Awareness of importance of considering others	1 (3.3)	0	0
Clarity of thought	1 (3.3)	0	0
Contemplative state	1 (3.3)	0	1 (3.4)
Increased compassion	1 (3.3)	0	0
Increased creativity	1 (3.3)	0	0
Increased sense of connectedness	1 (3.3)	0	0
More socially upbeat	1 (3.3)	0	0
Reflections and new perspectives	1 (3.3)	0	0
Sense of oneness and connectedness	1 (3.3)	0	0
Being less judgmental	0	1 (3.3)	0
Feeling more moody/sensitive	0	1 (3.3)	0
Feeling rested	0	1 (3.3)	0
Increased wit	0	1 (3.3)	0
Reflections and new perspectives on relationships and society	0	1 (3.3)	0
Sense of oneness	0	1 (3.3)	0
Calm	0	0	1 (3.4)
Feeling of adrenaline release	0	0	1 (3.4)
Negative mood	0	0	1 (3.4)
Unusual appreciation of music	0	0	1 (3.4)

Above Table: Reported “mood altered” AEs ranked by incidence in the 25mg psilocybin group in our healthy volunteers trial.

“Mood altered” AEs were grouped into this MedDRA preferred term post hoc, while retaining the non-MedDRA AE description originally reported by the participant/investigator.

Participants completed a range of assessments of cognitive function and emotional processing. These included a range of validated measures of cognition from the Cambridge Neuropsychological Test Automated Battery, or CANTAB, including, amongst others, tasks of spatial working memory, rapid visual information processing and paired associates learning. Small differences in cognitive outcomes were seen between the groups, but no negative trends were identified.

Assessments of emotional processing included, amongst others, tasks of social cognition such as the Pictorial Empathy Test, the Reading the Mind in the Eyes Test, the Scale of Social Responsibility, the Social Value Orientation, and the Toronto Empathy Questionnaire. There were no consistent negative trends in emotional processing outcomes to suggest that either psilocybin dose had short- or longer-term effects on these indicators.

According to analyses, we found no negative trends on cognition or emotional processing.

### Conclusions

This trial suggests that COMP360 was generally well-tolerated in healthy volunteers. There were no SAEs and analyses assessing cognitive and emotional functions showed no clinically-relevant negative short- or longer term effects on cognition or emotional processing of COMP360. The trial also showed the feasibility of simultaneous administration of COMP360 to up to six people in the same facility, with 1:1 therapist support, which we believe will accelerate future clinical trials and commercial scale-up.

### ***Phase IIb Ongoing Trial of Our Psilocybin Therapy in TRD***

We have an ongoing Phase IIb international multi-site, randomized, double-blind, dose-ranging clinical trial to assess the safety and efficacy of active doses of COMP360 (10mg or 25mg) compared with 1mg COMP360, administered with psychological support, in patients suffering with TRD. We currently have 22 trial sites in 10 countries in North America and Europe.

### Trial Design

Patients who are on serotonergic medications are expected to taper off their medicine at least two weeks prior to the baseline (Day -1) visit. Prior to administration, patients receive at least one, and up to three, preparatory sessions with an assigned therapist, in order to be informed and prepared for the psilocybin session. During the psilocybin session, a single dose of COMP360 is administered to patients. The objective is to provide a safe and supportive environment during the session. Patients receive post-administration integration sessions with their therapists in which the psychedelic experience is discussed. Patients are followed up for 12 weeks, with a visit the day after administration followed by an additional six visits, weekly for the first three weeks, and every three weeks for the remaining nine weeks.

### *Primary, Secondary and Exploratory Endpoints*

The primary endpoint of this trial is the change in the MADRS total score from baseline to Week 3. MADRS is assessed by independent raters in native language and is a widely accepted assessment of mood disorders. This variable will also be analyzed for change from baseline to Weeks 1, 6 and 12. This Phase IIb clinical trial has been powered to capture a statistically significant reduction in MADRS.

Secondary endpoints of the trial include:

- The proportion of participants with a response (defined as a  $\geq 50\%$  decrease in MADRS total score from baseline) at Week 3;
- The proportion of participants with remission (defined as a MADRS total score  $\leq 10$ ) at Week 3;
- The proportion of participants who have a sustained response at Week 12. Sustained response is defined as the proportion of patients fulfilling response criteria at any visit up to and including Week 3, that also fulfills response criteria at all subsequent visits up to and including Week 12; and
- Time to event measures: restarting of antidepressant medication for any reason, restarting medication for continuing depressive symptoms and relapse from a previously recovered state (clinical judgement, supported by QIDS-SR-16).



Safety and tolerability of COMP360 in patients suffering with TRD will be assessed based on AEs, vital signs, clinical laboratory assessments, ECG findings and suicidal ideation/behavior (measured using the Columbia-Suicide Severity Rating Scale, or C-SSRS score, at all visits).

The trial will assess exploratory endpoints including, but not limited to, quality of life (assessed using the Euro Quality of Life five dimension three level scale, EQ-5D-3L), functional impairment (Sheehan Disability Scale, SDS), psychosocial functioning (Work and Social Adjustment scale, WSAS), cognition (Digit Symbol Substitution Test, DSST), anxiety (Generalized anxiety disorder, GAD-7), and self-reported depression severity (QIDS-SR-16).

#### Enrollment Criteria

We are planning to recruit up to 216 adult patients with TRD into the trial. We define TRD patients as those who meet Diagnostic and Statistical Manual of Mental Disorders, 5<sup>th</sup> Edition, or DSM-5, diagnostic criteria for a single or recurrent episode of MDD without psychotic features, who have not responded to an adequate dose and duration of two, three, or four pharmacological treatments for the current episode of depression.

#### Current Status

Our Phase IIb trial was initiated in 2019 and patients were randomized and administered COMP360 from March 2019. In choosing our trial sites we consider the incidence of TRD in the country, and each site's experience and interest in psychedelic therapy. Our current trial sites include Stanford University, the University of California, San Diego, Kadima Neuropsychiatry Institute, University of Texas Health Science Center, Emory University School of Medicine, University of Toronto Centre for Addiction and Mental Health, New York State Psychiatric Institute, Sheppard Pratt Health System, Wolfson Research Centre, Northumberland, Tyne and Wear NHS Foundation Trust, Avon and Wiltshire Mental Health Partnership NHS Trust, Tallaght University Hospital, Kings College London Institute of Psychiatry, Psychology & Neuroscience, St. Pancras Clinical Research, Centro Clinico Champalimaud Unidade de Neuropsiquiatria, Psikiatrien I Aalborg Mølleparkvej, University Medical Centre Groningen, University Medical Centre Utrecht, Charité - Universitätsmedizin Berlin, National Institute of Mental Health Czech Republic, Leiden University Medical Center, Sant Joan De Du Serveis De Salut Mental and Institute Hospital de Mar of Medical Research. Recruitment to the trial has been impacted by COVID-19. In March 2020, we paused the inclusion of new patients into our trial. Our trial site teams have continued to identify eligible patients in order to generate a large cohort of pre-screened patients. In May 2020, we began resuming treatment-related activities at a number of our sites, as local conditions allowed, and continued to progressively resume treatment at many of our remaining sites during the second half of 2020. Our goal is to announce results for the trial by late 2021, although this objective will remain subject to the ongoing impact of COVID-19. To date, four patients have experienced suspected, unexpected serious adverse reactions, or SUSARs, which may possibly be drug-related. All patients and study teams remain blinded to the dose received. One patient experienced a SUSAR of adjustment disorder more than a month after administration, which led to hospitalization. The event was adjudicated by the investigator to be moderate in severity and possibly related to study medication. A second patient experienced a SUSAR of suicidal ideation several weeks after administration which required hospitalization and was adjudicated by the investigator to be severe and possibly related to study medication. A third patient experienced a SUSAR of suicidal ideation with some intent to act, without specific plan, several weeks after administration. The investigator assessed the event as moderate in intensity and possibly related to study medication. All three cases have been reviewed by the trial's Data Safety Monitoring Board in line with their charter, who have advised that the study should continue and that no amendments to the trial protocol are required. More recently, a fourth patient experienced a SUSAR; during the study screening phase the subject's anxiety increased whilst tapering off their existing depression therapy medication, but suicidal ideation without intent to act remained absent. Directly after the study drug dosing session the subject reported fleeting suicidal thoughts and on the day following dosing the subject reported suicidal ideation with some intent to act, without specific plan, due to increased feelings of anxiety that occurred during the dosing session. Antidepressant medication was restarted and hospitalization was not required.

The investigator assessed the event as possibly related to study medication; the DSMB will be notified of this event, for assessment, as part of our regular reporting. Since the purpose of our Phase IIb study is to establish the optimal dose of COMP360, during the final analysis of the unblinded data, we will be able to make a more detailed assessment of the safety and efficacy of COMP360 (including any dose-relationship of SUSARs to study drug) and whether there are any potential implications for the design of future clinical trials using COMP360.

#### Additional Clinical Trials

In addition to our ongoing Phase IIb trial, we are conducting the following trials:

- A Phase II trial of the safety and efficacy of COMP360 in TRD patients when administered as an adjunct to SSRIs. Based on anecdotal and case report evidence, and our current understanding of the psilocybin mechanism of action, the subjective and antidepressant effects of psilocybin in patients who have taken serotonergic antidepressants up to two weeks prior to a therapy session may be either attenuated or absent. We are conducting this study to confirm that COMP360 is best administered as a monotherapy and we intend to complete prior to initiating Phase III development; and
- A long-term follow-up study of participants taking part in the Phase II trials.

We believe the outcomes of these trials will help inform our future clinical development plans. Based on our discussions with regulators to date, we plan to conduct a Phase III registrational program, where our investigational COMP360 psilocybin therapy will likely be compared with placebo and/or an active reference arm.

#### **Expansion Opportunities**

The active metabolite of psilocybin, psilocin, is a partial agonist at several 5-HT receptors, including the 5-HT<sub>2A</sub> receptor. The 5-HT<sub>2A</sub> receptors are abundantly expressed in multiple areas of the brain that have important roles in cognitive and emotional processing and could impact a range of cognitive and mental health conditions. We therefore believe psilocybin could have transdiagnostic utility and intend to explore various expansion opportunities beyond our core program of developing our psilocybin therapy for TRD. We are also investigating the potential benefits of compounds other than psilocybin through our Discovery Center, a research collaboration with University of the Sciences in Philadelphia, Pennsylvania, US; UC San Diego, School of Medicine, in San Diego, California, US; and Medical College of Wisconsin in Milwaukee, Wisconsin, US. See “—Drug Discovery Center”.

#### *Mechanistic Studies*

We are working with academic researchers and CROs to investigate the mechanistic characteristics of psilocybin therapy. This mechanistic research includes the following:

- A study of the sustained effects of our high-purity polymorphic crystalline formulation psilocybin through the investigation of short- and long-term changes in gene expression (mRNA) and epigenetic regulation (miRNA and DNA methylation) as part of an academic collaboration with the University of Bordeaux, France;
- A preclinical academic collaboration with the University of Bristol, UK, to study the effects of our high-purity polymorphic crystalline formulation of psilocybin on affective biases, which are relevant to information processing alterations frequently observed in mood and anxiety conditions; and
- A healthy volunteers study with Imperial College London, investigating the acute and long-term psychological and brain effects of psilocybin therapy, using COMP360.

In addition, we plan to research areas such as cognition, motivation, and neuroplasticity through *in vitro* and *in vivo* models with academic researchers and CROs. These studies will further our understanding of the mechanism of action and inform our decisions over which other indications to explore, outside TRD.

#### *Other Indications: Preclinical Studies*

Through collaborations with academic institutions, we are generating preclinical and clinical data to explore the benefits of our psilocybin therapy in indications outside TRD. More than 20 new studies were completed in our preclinical program in 2020.

We work with CROs and academic institutions, including the University of Bristol and the University of Bordeaux, in conducting preclinical studies. Based on data generated from studies undertaken over the past year in preclinical disease models, we filed three Patent Cooperation Treaty, or PCT, applications in April 2020 for methods for treating certain disorders of the central nervous system and other inflammatory conditions with psilocybin. These indications included: Alzheimer's disease, autism spectrum disorder, chronic pain, epilepsy, inflammation, Parkinson's disease, attention deficit hyperactivity disorder, binge eating disorder, cluster headaches, generalized anxiety disorder, obsessive-compulsive disorder and sleep wake disorders, anxiety, eating disorders, neurocognitive disorders, autism, epilepsy, pain and sleep-wake disorders. We believe the data from the above program of pre-clinical research is also supportive of further research in the following indication areas: anorexia nervosa, bulimia nervosa, inflammatory bowel disease, panic disorder, post-traumatic stress disorder, stroke, body dysmorphic disorder, fibromyalgia, migraine, postpartum depression, social anxiety disorder and traumatic brain injury. Based on scientific and clinical relevance, and market potential, we are exploring the development of a subset of these additional potential indications towards proof-of-concept studies in humans through clinical trials.

#### *Other Indications: Investigator-Initiated Studies, or IISs*

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

We supply our IIS researchers with COMP360 and encourage the open publication of all study findings. If an IIS using COMP360 produces results with the potential to improve mental health care, we may seek to advance this research through a clinical development program, with the goal of making it available for patients, although we have no pre-existing contractual right to do so. In addition to providing our IIS researchers with COMP360, we have in the past and may continue to offer support with regulatory submissions. Through our IIS collaborations, we ultimately hope to bring more innovation to patients, as quickly and safely as possible. To date, one patient involved in an IIS has experienced a SUSAR. In September 2020, we were notified of a patient death that occurred in August 2020, more than two months after the patient was administered COMP360 supplied by us to an IIS involving MDD patients at the University of Zurich. The patient had shown improvement in symptoms, without side effects, following administration. Based on this and other available information, including the 72 days that elapsed between administration of COMP360 (which has a half-life of approximately three hours) and the reported death, a report by the investigator that the death is unlikely to be related to COMP360 and opinion by the patient's psychiatrist that the death is unrelated to COMP360, we consider the death unlikely to be related to COMP360.

### *Drug Discovery Center*

On August 5, 2020, we established a Drug Discovery Center under a sponsored research agreement with the University of the Sciences in Philadelphia, Pennsylvania, or USciences, to focus on developing optimized psychedelic and related compounds targeting the 5-HT<sub>2A</sub> receptor, which is believed to mediate the potential therapeutic effects of psychedelics. Pursuant to the agreement, USciences will perform research services on our behalf, and has granted us an exclusive, royalty bearing, worldwide license, including rights to sublicense, all jointly held intellectual property for any and all purposes, and a non-exclusive, fully paid-up, worldwide license to any pre-existing intellectual property utilized over the course of performing the services. Under the agreement, we will pay a research service fee of an estimated \$0.5 million and tiered payments upon completion of certain milestones by USciences up to an aggregate of \$0.9 million per licensed product covered by a valid claim of a patent included in the intellectual property rights licensed to us under the agreement, as well as a low single-digit royalty percentage on annual net sales of licensed products covered by a valid claim of a patent included in the intellectual property rights licensed to use under the agreement, subject to certain reductions. In addition, USciences is entitled to a low double-digit percentage of sublicense revenue for agreements entered into prior to a Phase II trial, and a mid-single-digit percentage of sublicense revenue for agreements entered into after the start of a Phase II trial. Unless earlier terminated, the agreement terminates upon the expiration or revocation of the last valid claim of any patent included in the joint intellectual property. We and USciences can terminate the agreement in the event of a material breach by the other party and failure to cure such breach within a certain period of time. Additionally, we and USciences can terminate the research service in the event of a material safety or regulatory issue with respect to the research service. We may also terminate the research service at will upon sixty (60) days prior written notice to USciences. USciences can terminate the research service if such services would materially and negatively interfere with its operations or upon the continuation of a force majeure event. There are no current licensed patents or patent applications under the sponsored research agreement.

In February 2021, we expanded the Discovery Center through collaboration with laboratories at UC San Diego, School of Medicine (San Diego, California, US), and Medical College of Wisconsin (Milwaukee, Wisconsin, US). We expect that scientists from these teams will work with COMPASS and the team from USciences, from their different locations, in a virtual network.

### *Investments*

#### *Delix Therapeutics*

On March 6, 2020 we made a strategic investment 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 CNS indications. Delix Therapeutics develops non-hallucinogenic psychoplastogens, which are molecules capable of promoting neural plasticity without hallucinogenic effects, by modifying existing psychedelics. These compounds may have potential for a range of neuropsychiatric conditions.

### **Therapist Training**

Our therapist training program has been designed by experts from the fields of psychology, psychiatry and psychedelic therapy research. We require our therapists to have specific professional and educational backgrounds. Therapists must be registered mental health professionals, such as mental health nurse practitioners, clinical psychologists, and psychiatrists with experience in counselling or psychotherapy. To date, we have trained more than 65 therapists and assisting therapists to work in our Phase IIb clinical trial. Currently, therapists are often referred to us by clinical trial sites and are employed by the sites. Details of our therapist training program were published in February 2021 in the peer-reviewed journal *Frontiers in Psychiatry*.

Our core training curriculum consists of:

- More than 10 hours of self-paced online learning through our interactive therapist training platform, including video re-enactments of preparation, psilocybin administration, and integration sessions, a psilocybin therapy manual, and an online therapist forum;
- At least five days of in-person interactive learning, led by experienced therapists;
- Clinical experience of supporting participants in at least four psilocybin experiences under the guidance of experienced therapists. Trainee therapists gain clinical experience as an assisting therapist at their site, and/or have the opportunity to sit in other psilocybin therapy studies run by our academic collaborators, including the Institute of Psychiatry, Psychology and Neuroscience, or IoPPN, at King's College London, and Sheppard Pratt Health System (Baltimore, Maryland, U.S.); and
- Ongoing professional development through 1:1 mentoring and clinical supervision by mentors. This includes feedback from mentors about therapists' fidelity to the therapeutic model from recorded video/audio footage of sessions (with participant consent).

#### *Future Model*

Our therapist training program is currently available to professionals involved in our ongoing studies. However, as we scale, we may expand our training to a larger pool of qualified mental healthcare professionals. We are in discussion with academic centers in the U.S. and Europe to establish an accredited training program for psilocybin therapists. Accrediting the training program would help enable us to meet the needs of any Phase III trials and post-approval rollout. In addition, in August 2020, the FDA approved our request for virtual face-to-face training of therapists, with immediate effect. Conducting a larger part of the therapist training virtually will facilitate the training of therapists during the COVID pandemic and training at scale in general.

#### **Using Digital Technology**

We believe digital technology will change the way in which patients access psychotherapy services and manage their mental health conditions. We anticipate mobile technology applications will enhance activities traditionally done with an in-person therapist. We also believe remote consultations will help to remove barriers to accessing treatment such as stigma or lack of transportation. Furthermore, digital tools will enable greater self-care, as they support patients managing depressive episodes on their own, and will be used to complement and augment psychotherapy and pharmacological treatments.

Working with third parties, we currently use digital technology in a number of ways:

- An online preparation platform for participants in our TRD trial to educate them and help prepare them for their psilocybin experience;
- A web-based "shared knowledge" interactive therapist training platform, complementing our comprehensive face-to-face training program;
- Collection of measurements, endpoints and outcomes in our Phase IIb clinical trial, including remote data collection using mobile devices so patients do not need to travel into study sites for all in-clinic visits;
- Collection of digital phenotyping information through the measurement of human-smartphone interactions. After our Phase IIb trial, these data will be compared with information collected from validated psychiatric scales, such as MADRS, to develop potential digital applications to help anticipate relapse of depression and model the course of disease; and

- Harnessing AI and natural language processing (speech recognition) capabilities to characterize the mechanism of change and assess therapist fidelity to our treatment protocol for psychological support. We are building an in-house digital team with experts in digital technology, engineering, and AI, which we refer to as augmented intelligence as well as artificial intelligence. We will continue to collaborate with other digital companies to research, develop and ultimately commercialize proprietary digital technology solutions that have the potential to complement and augment our investigational COMP360 psilocybin therapy. We believe this may enable us to offer a personalized, preventative and predictive care model.

## **Manufacturing and Supply**

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

## **Commercialization**

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

Upon any approval, we intend to offer a range of services to enable the safe and effective use of COMP360 with psychological support in clinical practice. These services are expected to include therapist training, information and education for patients and healthcare providers, and implementation support for treatment centers, such as guidance on procurement and installation of equipment, certification, and quality assurance.

### ***Centers of Excellence***

In line with our ambition to create a new mental health care model, we intend to establish Centers of Excellence to serve as research facilities and innovation labs. In January 2021, we established our first Center of Excellence, with The Sheppard Pratt Institute for Advanced Diagnostics and Therapeutics, in Baltimore, Maryland, in the United States.

Our potential future Centers of Excellence will be designed to model the “clinics of the future,” and through them we intend to gather evidence to shape our therapy model and prototype digital technology solutions to improve patient experience and support therapists. Methodologies developed in the Centers of Excellence will be shared with our partner clinics.

Centers of Excellence will allow us to test and establish a new blueprint for innovative care models that can be licensed or franchised to existing behavioral health providers, community mental health teams, private clinic networks, partial hospitalization programs, and intensive outpatient programs.

We intend to establish additional Centers of Excellence for several purposes, including:

- Conducting clinical trials, including proof of concept studies, to refine our therapeutic model;

- Participating in late-stage trials as a clinical trial site;
- Training and certifying therapists who are supporting or will support our clinical trials;
- Generating and collecting safety and other data, as well as (licensable) intellectual property;
- Developing and testing digital technology solutions to improve patient experience;
- Strengthening our regional presence as a scientific and clinical resource by showcasing what we believe to be the future of mental health care, fostering relationships with stakeholders including patients, providers, payors and public policymakers; and
- Refining our approach to delivering our investigational COMP360 psilocybin therapy safely and cost-effectively.

## Competition

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

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

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

We also face competition from 501(c)(3) non-profit medical research organizations, including the Usona Institute. 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.

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

Many of the pharmaceutical, biopharmaceutical and biotechnology companies with whom we may compete have established markets for their therapies and have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market superior products or therapies. In addition, many of these potential competitors have significantly greater experience than we have in undertaking non-clinical studies and human clinical trials of new therapeutic substances and in obtaining regulatory approvals of human therapeutic products. Accordingly, our

competitors may succeed in obtaining FDA, EMA or MHRA approval for alternative or superior products. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. An increasing number of companies are increasing their efforts in discovery of new psychedelic compounds.

## **Intellectual Property**

Our commercial success is closely tied to obtaining and maintaining intellectual property, or IP, rights protection in patents, trademarks and trade secrets in the EU, U.S., UK, and other jurisdictions. We continue to strategically protect our innovations with a harmonized IP strategy, combining patent protection with regulatory and market exclusivity.

### ***Patent Strategy***

Our patent strategy includes pursuing protection for our novel high-purity polymorphic crystalline psilocybin, large-scale psilocybin manufacturing processes, psilocybin formulations and compositions, and methods of treatment using psilocybin. Our patent portfolio includes six granted patents: three in the U.S., one in Germany, and two in the UK. Our portfolio also includes three pending UK patent applications, three pending U.S. continuation applications (including one allowed application), and pending applications in Australia, Brazil, Canada, China, Colombia, Eurasian Patent Organization, European Patent Office, Hong Kong, Indonesia, Israel, India, Japan, Republic of Korea, Mexico, Malaysia, New Zealand, Philippines, Saudi Arabia, Singapore, Taiwan, Thailand, and South Africa, as well as three pending Patent Cooperation Treaty, or PCT, applications. Our portfolio of patents and patent applications cover our novel crystalline polymorphic psilocybin, psilocybin formulations, methods of manufacturing psilocybin, and use of psilocybin for the treatment of psychiatric and neurological indications, including TRD and MDD, as well as a range of other indications.

We expect to receive EU market protection via a New Active Substance application to the EMA using a Centralized Procedure which provides market access across EU-28 countries in addition to Iceland, Norway and Liechtenstein. The EMA provides for eight years of data exclusivity (i.e., no generic application), an additional two years of market exclusivity (i.e., no generic marketing), as well as an additional one-year extension if one or more additional indications are identified and filed on in the eight-year window. The U.S. FDA provides for data exclusivity of four years and an additional year of market exclusivity for New Chemical Entities. In addition, if an Orange Book-listed patent is challenged, the Company would be eligible for a 30-month stay of litigation.

### ***Patents and Patent Applications***

Our first patent, U.S. Patent No 10,519,175, was granted on December 31, 2019, with claims directed to methods of treating treatment-resistant depression with oral dosage formulations of COMPASS's high-purity crystalline psilocybin. Three Third Party Observations were previously filed during the pendency of the application, each considered by the Examiner and found to not be a barrier to patentability. This patent expires October 9, 2038. A Petition for Post Grant Review of the patent was filed on February 21, 2020 and was dismissed on the merits on August 20, 2020.

Our second U.S. patent was granted on March 16, 2021 as U.S. Patent No 10,947,257, with claims to oral dosage forms of crystalline psilocybin and methods of treating major depressive disorder (MDD) with the oral dosage forms. Our third U.S. patent was granted as U.S. Patent No 10,954,259 on March 23, 2021, with claims to COMPASS's high-purity crystalline psilocybin (including the form used in COMP360), pharmaceutical formulations containing crystalline psilocybin and methods of treating MDD with the crystalline psilocybin. Our fourth US patent application, U.S. 16/679,009, is pending with method of manufacture claims that are not limited to a particular polymorph. Our fifth US patent application, U.S. 17/172,411, is allowed but not yet issued, with claims to crystalline psilocybin, pharmaceutical formulations containing crystalline psilocybin and medical uses of the crystalline psilocybin. Our sixth patent application, U.S. 17/228,936, is pending with claims directed to treatment methods using oral



dosage formulations of COMPASS's high-purity crystalline psilocybin. Patents issuing from these applications will expire October 9, 2038.

Our first German utility model, DE202018006384, was registered in March 2020, with claims covering forms of crystalline psilocybin, its use in medicine, and methods of synthesis. This patent has an expiry date of October 9, 2028.

Our first UK patent, No GB2571696, was granted in May 2020. This patent includes two independent method of manufacture claims that are not limited to a particular polymorph, as well as a product-by-process claim and a formulation claim. The Intention to Grant was sent in December 2019, and Third-Party Observations were filed in late January 2020, shortly before grant was originally scheduled. Grant of the patent was announced in the Patents Journal on May 27, 2020. This patent has an expiry date of October 8, 2037.

Our second UK patent, No GB2572023, was granted in June of 2020. This patent includes claims covering our crystalline psilocybin (including the form used in COMP360), pharmaceutical formulations of crystalline psilocybin, medical uses of crystalline psilocybin (including for treatment-resistant depression), and a method of manufacturing crystalline psilocybin. The Intention to Grant was sent in December 2019, and Third-Party Observations were filed in late January 2020. A notification of grant was mailed June 23, 2020, and grant was announced in the Patents Journal on July 22, 2020. This patent has an expiry date of June 28, 2038.

Our third UK patent application, No GB2576059, and two divisional applications, are pending, with claims directed to additional manufacturing methods and formulations of crystalline psilocybin. If granted, patents based on these applications have a projected expiry date of October 8, 2038.

Corresponding patent applications are pending in Australia, Brazil, Canada, China, Colombia, Eurasian Patent Organization, European Patent Office, Indonesia, Israel, India, Japan, Republic of Korea, Mexico, Malaysia, New Zealand, Philippines, Saudi Arabia, Singapore, Thailand, and South Africa. Any patents that may grant from these pending applications have a projected expiry date of October 9, 2038.

Three PCT applications (PCT Publication nos. WO2020/212951, WO2020/212948, and WO2020/212952) and one Taiwanese application were filed on April 17, 2020. These applications cover additional formulations, administration, therapeutic supports, digital supports, combination treatments, and methods of using a therapeutically effective amount of psilocybin or active metabolite thereof to treat a variety of additional indications, including: various anxiety disorders, headache disorders, eating disorders, major and mild neurocognitive disorders, autism, epilepsy, inflammation, ADHD, substance use disorders, inflammatory bowel disease, stroke, ALS, multiple sclerosis, anti-social personality disorder, pain, sleep-wake disorders, and bipolar type II depression. Any patents that may grant from these pending applications have a projected expiry date of April 17, 2040.

We are committed to exploring additional opportunities with psilocybin through the continuous development of novel formulations, processes, and methods for the treatment of other mental health indications. We continue to innovate and strategically protect our innovations in the following four main areas:

1. novel high-purity crystalline psilocybin polymorphs;
2. manufacturing processes for large-scale manufacture of high-purity crystalline psilocybin;
3. novel formulations and unique pharmaceutical compositions; and
4. methods of treatment using high-purity crystalline psilocybin.

Psilocybin may be efficacious for other conditions of the CNS and related therapeutic areas. We have shortlisted opportunities in a number of other indications based on unmet medical need and commercial attractiveness. Some of the work completed by independent researchers with our COMP360 might generate additional IP, and we will have to agree to the basis on which we share the development cost and potential revenue this might bring as we move studies with a promise of helping patients from the lab into clinical development. Prioritized opportunities inform animal model studies and mechanism of action studies, as well as continuing to inform and guide IP filings.

Beyond psilocybin, we will grow by focusing efforts and investment on developing IP for new indications and substances with optimal therapeutic benefit and/or minimal psychoactive effect.

#### **Trademarks**

Our trademark portfolio includes two registered UK trademarks, for COMPASS and COMPASS PATHWAYS, in Classes 05, 09, 10, 35, 41, and 44.

#### **Government Regulation**

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

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

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

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- Completion of the manufacture, under current Good Manufacturing Practices, or cGMP, conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- Submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin;

- Approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- Submission to the FDA of a New Drug Application, or NDA;
- Payment of user fees for FDA review of the NDA;
- A determination by the FDA within 60 days of its receipt of an NDA, to accept the filing for review;
- Satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- Potentially, satisfactory completion of FDA audit of the clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

### ***Preclinical Studies and Clinical Trials for Drugs***

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

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, who generally are physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, administration procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable compared to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the

clinical trial until completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than Phase I investigations, must be submitted within specific timeframes for publication on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), a clinical trials database maintained by the National Institutes of Health.

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

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

- *Phase I*—Phase I clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- *Phase II*—Phase II clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the drug's potential efficacy, to determine the optimal dosages and administration schedule and to identify possible adverse side effects and safety risks.
- *Phase III*—Phase III clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling.

Post-approval trials, sometimes referred to as Phase IV clinical trials or post-marketing studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of NDA approval.

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

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with

cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

### ***US Marketing Approval for Drugs***

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

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

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

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

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

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure

consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

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

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

#### ***Expedited Development and Review Programs for Drugs***

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

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

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review designation, once an NDA or BLA is submitted, if the drug that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the

FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review. Products are eligible for Accelerated Approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Accelerated Approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug or an indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, as a condition for Accelerated Approval, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

### **US Post-Approval Requirements for Drugs**

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

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including Phase IV clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements. Failure to comply with statutory and regulatory requirements may subject a manufacturer to legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

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

### ***Controlled Substances***

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

The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV or V — with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. COMP360, if approved in the United States, will require scheduling by the DEA before it can be marketed.

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

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled



substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics. In some cases, Schedule III non-narcotic substances may be subject to the import/export permit requirement, if necessary, to ensure that the United States complies with its obligations under international drug control treaties.

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

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

#### ***U.S. Foreign Corrupt Practices Act***

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

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

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

MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union or its member states (as well as Iceland, Norway and Liechtenstein). If we fail to comply with applicable requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### ***Clinical Trial Approval***

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the national competent authority, or NCA, of a European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee, or EC, has issued a favorable opinion in relation to the clinical trial. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the member state where they occurred.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new legislation, which will be directly applicable in all EU member states (meaning that no national implementing legislation in each European Union member state is required), aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of clinical trial applications. It is expected that the new Clinical Trials Regulation will come into effect following confirmation of full functionality of the Clinical Trials Information System, the centralized EU portal and database for clinical trials foreseen by the new Clinical Trials Regulation, through an independent audit, which is currently expected to occur in December 2021.

### ***Marketing Authorization***

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

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the EEA. Pursuant to Regulation (EC) No 726/2004, our investigational COMP360 psilocybin therapy, as a new active substance indicated for the treatment of treatment-resistant depression, will have the option to be filed through the centralized procedure. For those products for which the use of the centralized procedure is not mandatory, applicants may elect to use the centralized procedure where either the product contains a new active substance indicated for the treatment of diseases other than those on the mandatory list, or where the applicant can show that the product constitutes a significant therapeutic, scientific or technical innovation, or for which a centralized process is in the interest of public health.

Under the centralized procedure, the Committee for Medicinal Products for Human use, or the CHMP, which is the EMA's committee that is responsible for human medicines, established at the EMA is responsible for conducting the assessment of whether a medicine meets the required quality, safety and

efficacy requirements, and whether it has a positive risk/benefit/risk profile. Under the centralized procedure, the maximum timeframe for the evaluation of a MAA is 210 days from the receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

Now that the UK (which comprises Great Britain and Northern Ireland) has left the EU, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January, 1 2021. For a period of two years from January 1, 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

### **PRIME Scheme**

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

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

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

- appoints a rapporteur from the CHMP or from the Committee for Advanced Therapies (CAT) to provide continuous support and to build up knowledge of the medicine in advance of the filing of a marketing authorization application;
- issues guidance on the applicant's overall development plan and regulatory strategy;
- organizes a kick-off meeting with the rapporteur and experts from relevant EMA committees and working groups;
- provides a dedicated EMA contact person; and

- provides scientific advice at key development milestones, involving additional stakeholders, such as health technology assessment bodies and patients, as needed.

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

### ***Orphan Drug Designation***

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

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

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition which either (i) affects not more than five in ten thousand persons in the EU when the application is made, or (ii) without incentives it is unlikely that the marketing of the product in the EU would generate sufficient return to justify the necessary investment in its development. For either of these conditions, the applicant must also demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the EU or, if such method exists, the product has to be of significant benefit compared to products available for the condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized marketing authorization. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The grant of a marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for the same therapeutic indication in respect of a "similar medicinal product". A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug

designation, for example because the product is sufficiently profitable not to justify market exclusivity. There are also limited derogations from the ten-year period of market exclusivity pursuant to which the European Commission may grant a marketing authorization for a similar medicinal product in the same therapeutic indication. These are where: (i) the second applicant can establish that although their product is similar to the orphan medicinal product already authorized, the second product is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder consents to the second orphan medicinal product application; or (iii) the marketing authorization holder cannot supply enough orphan medicinal product.

### ***Pediatric Development***

In the EEA, companies developing a new medicinal product must agree upon a Pediatric Investigation Plan, or PIP, with the EMA's Pediatric Committee, or PDCO, and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies, (e.g., because the relevant disease or condition occurs only in adults). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted by the PDCO of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) even where the trial results are negative. In the case of orphan medicinal products, a two year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

### ***Regulatory Data Protection in the European Union***

In the EEA, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon grant of a marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No. 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity prevents generic and biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a marketing authorization for a period of eight years from the date on which the reference product was first authorized in the EEA. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be marketed until the expiration of the market exclusivity period. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on a MAA with a completely independent data package of pharmaceutical tests, preclinical tests and clinical trials.

### ***Periods of Authorization and Renewals***

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a re-evaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified

grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the EEA market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

### ***Controlled Drugs Classification***

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

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

### ***Regulatory Requirements After Marketing Authorization***

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

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

In addition, all new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

Furthermore, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's cGMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity.

Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products, are strictly regulated in the European Union under Directive 2001/83/EC, as amended. The advertising of prescription-only medicines to the general public is not permitted in the European Union, or in the UK under the Human Medicines Regulations 2021. Although general requirements for advertising and promotion of medicinal products are established under EU Directive 2001/83/EC as amended, the details are governed by regulations in each European Union member state (as well as Iceland, Norway and Liechtenstein) and can differ from one country to another.

### ***Brexit and the Regulatory Framework in the United Kingdom***

The UK formally left the EU (commonly referred to as “Brexit”) on January 31, 2020, however there was an initial transition period beginning on February 1, 2020, during which European Union medicinal product law remained applicable to the UK. This transition period ended on December 31, 2020. Since the regulatory framework in the UK covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the UK, as UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the UK in the long-term. The MHRA has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the UK’s regulatory position on medicinal products evolves over time.

### ***Coverage, Pricing and Reimbursement***

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

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

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



establish or maintain price levels sufficient to realize an appropriate return on our investment in product development.

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

A decision by a third-party payor not to cover or not to separately reimburse for our medical products or therapies using our products could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. If there is coverage for our product candidates, or therapies using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, will be available for our current or future product candidates, or for any procedures using such product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future. Further, if we or our collaborators develop therapies for use with our product candidates, we, or our collaborators, will be required to obtain coverage and reimbursement for these therapies separate and apart from the coverage and reimbursement we seek for our product candidates, once approved.

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

Lastly, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some EU member states provide that products may be marketed only after a reimbursement price has been agreed. Some EU member states may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Approaches between EU member states are diverging. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security



Fund. The price of medicines is negotiated with the Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Other EU member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the level of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results-based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

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

### **Other Healthcare Laws and Compliance Requirements**

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable federal and state fraud and abuse laws, as well as other healthcare laws and regulations. These laws may impact, among other things, our business or financial arrangements and relationships through which we research, as well as market, sell and distribute the psilocybin therapies for which we obtain approval. In addition, we may be subject to health information privacy regulation by both the federal government and the states in which we conduct our business. In the United States the laws that may affect our ability to operate include, among others:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare and Medicaid. The term remuneration has been interpreted broadly to include anything of value. Further, courts have found that if “one purpose” of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to significant administrative, civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA, or federal civil money

penalties statute. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. On December 2, 2020, the Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. These rule (with exceptions) became effective January 19, 2021;

- The federal civil and criminal false claims laws, such as the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented claims for payment or approval from Medicare, Medicaid, or other third-party payors, that are false, fictitious, or fraudulent; from knowingly making, using or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit property to the federal government; or from knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transferring of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of items or services reimbursable by a federal or state healthcare program;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (i.e., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its respective implementing regulations, which imposes, among other things, certain requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to business associates, those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or

injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions;

- The federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, or ACA, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include certain payments and other transfers of value made during the previous year to certain non-physician providers, such as physician assistants and nurse practitioners;
- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- Analogous state and foreign equivalents of each of the healthcare laws and regulations described above, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require pharmaceutical companies to comply with the pharmaceutical industry voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government, such as the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals; state laws that require the reporting of information related to drug pricing; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state and local laws that require the licensure and/or registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information that may be more stringent than those in the United States (such as the European Union, which adopted GDPR, which became effective on May 25, 2018), many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

The full scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued to increase their scrutiny on interactions between healthcare companies and healthcare providers, which has led to a number of significant investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including our arrangements with physicians and other healthcare providers and entities, such as our Centers of Excellence or therapists, are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including, without limitation, administrative, civil and criminal penalties,

damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), imprisonment, and additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our Centers of Excellence and therapists, are found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions.

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

***European Data Collection is Governed by Restrictive Regulations Governing the Use, Processing and Cross-border Transfer of Personal Information.***

In the event we decide to conduct future clinical trials in the European Union, we may be subject to additional privacy and data protection requirements and restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EEA, including personal health data, is subject to European Union and national level data protection and privacy laws including, most notably GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on entities that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors that will have access to personal data. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States. Entities that fail to comply with the requirements of the GDPR may be subject to very significant penalties, including potential fines of up to the greater of €20 million or 4%. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous, costly and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European personal data processing activities.

Following the United Kingdom's withdrawal from the European Union on January 31, 2020, pursuant to the transitional arrangements agreed to between the United Kingdom and European Union, 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 European Union 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)). 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. Furthermore, the relationship between the United Kingdom and the EEA in relation to certain aspects of data protection law remains somewhat uncertain. For example, it is unclear whether transfers of personal data from the EEA to the United Kingdom will be permitted to take place on the basis of a future adequacy decision of the European Commission, or whether a "transfer mechanism," such as the Standard Contractual Clauses, will be required. For the meantime, under the TCA between the European Union

and the United Kingdom, it has been agreed that transfers of personal data to the United Kingdom from European Union Member States will not be treated as “restricted transfers” to a non-EEA country for a period of up to four months from January 1, 2021, plus a potential further two months extension, or the extended adequacy assessment period. This will also apply to transfers to the United Kingdom from EEA Member States, assuming those Member States accede to the relevant provision of the TCA. Although the current maximum duration of the extended adequacy assessment period is six months it may end sooner, for example, in the event that the European Commission adopts an adequacy decision in respect of the United Kingdom, or the United Kingdom amends the UK GDPR and/or makes certain changes regarding data transfers under the UK GDPR/ Data Protection Act 2018 without the consent of the European Union (unless those amendments or decisions are made simply to keep relevant United Kingdom laws aligned with the European Union’s data protection regime). If the European Commission does not adopt an ‘adequacy decision’ in respect of the United Kingdom prior to the expiry of the extended adequacy assessment period, from that point onwards the United Kingdom will be an “inadequate third country” under the GDPR and transfers of data from the EEA to the United Kingdom will require a “transfer mechanism,” such as the Standard Contractual Clauses.

Additionally, as noted above, the United Kingdom has transposed the GDPR into United Kingdom domestic law by way of the UK GDPR with effect from January 2021, which could expose us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. Also, following the expiry of the post-Brexit transitional arrangements, the United Kingdom Information Commissioner’s Office is not able to be our “lead supervisory authority” in respect of any “cross border processing” for the purposes of the GDPR. For so long as we are unable to, and/or do not, designate a lead supervisory authority in an EEA member state, with effect from January 1, 2021, we are not able to benefit from the GDPR’s “one stop shop” mechanism. Amongst other things, this would mean that, in the event of a violation of the GDPR affecting data subjects across the United Kingdom and the EEA, we could be investigated by, and ultimately fined by the United Kingdom Information Commissioner’s Office and the supervisory authority in each and every EEA member state where data subjects have been affected by such violation. Other countries have also passed or are considering passing laws requiring local data residency and/or restricting the international transfer of data.

### **Healthcare Reform**

In the United States and in some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the ACA was enacted, which, among other things, increased rebates for drugs sold to Medicaid programs owed by most manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed organizations; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; imposes mandatory discounts for certain Medicare Part D beneficiaries in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for manufacturers’ outpatient drugs coverage under Medicare Part D; subjects drug manufacturers of certain branded prescription drugs to new annual, nondeductible fees and taxes; expanded healthcare fraud and abuse laws (including the FCA and the Anti-Kickback Statute), government investigative powers and enhances penalties for non-compliance; expands eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers’ Medicaid rebate liability; expands the entities eligible for discounts under the 340B Drug Pricing Program; created new requirements to report financial arrangements with physicians, as defined by such law, and teaching hospitals, commonly referred to as the Physician Payments Sunshine Act; created a new requirement to annually report the

identity and quantity of drug samples that manufacturers and authorized distributors of record provide to physicians; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established the Center for Medicare and Medicaid Innovation at CMS, an agency within HHS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended, especially under the Biden Administration.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. Specifically, the Joint Select Committee on Deficit Reduction was created to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2012 through 2021, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year that will, due to subsequent legislative amendments, remain in effect through 2030 unless additional Congressional action is taken. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act and subsequent legislation, the 2% Medicare sequester reductions have been suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in 2020, former President Trump announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On

January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which has also been delayed until January 1, 2023.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

### **Legal Proceedings**

From time to time, we may be a party to litigation or subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our results of operations, cash flows and financial position. 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. We were not a party to any material litigation and did not have material contingency reserves established for any liabilities as of December 31, 2020 and December 31, 2019.

### **Facilities**

We lease a facility of 4,750 square feet of office space, located at 19 Eastbourne Terrace, London, W2 6LG, United Kingdom. The lease expires in 2021. We also lease 200 square feet of office space at 180 Varick Street, New York, New York 10014, United States. The lease expires is cancellable with 30 days notice.

In New York City, we are part of the BioLabs@NYULangone incubator space on the New York University School of Medicine campus. We are also participants in the START-UP NY program, which is an initiative from the New York State Department of Economic Development. Together, BioLabs@NYULangone and START-UP NY include tax and other incentive programs for us and our local employees.

We believe our facilities are adequate for our current needs, including our short-term needs, and that suitable additional or substitute space would be available in London or New York City if needed.

## **Employees**

As of December 31, 2020, we had 61 full-time employees and one part-time employee. Of these, 13 employees hold M.D. and/or Ph.D. degrees.

Of our workforce, 37 full-time equivalent, or FTE, employees are directly engaged in research and development with the rest providing administrative, business and operations support.

None of our employees are represented by labor unions or covered by collective bargaining agreements. We have not experienced any employee litigation or claims and consider our employee relations to be good. We have a comprehensive employee engagement program in place and carry out regular surveys with our whole team to obtain feedback and ideas for improvement.



## MANAGEMENT

### Executive Officers and Directors

The following table sets forth the name, age and position of our executive officers and directors as of April 26, 2021.

NAME	AGE	POSITION(S)
<b>Executive Officers:</b>		
George Goldsmith	65	Chief Executive Officer, Co-Founder, Chair of our Board of Directors
Lars Christian Wilde	35	President, Chief Business Officer, Co-Founder
Piers Morgan	54	Chief Financial Officer
Nate Poulsen	42	General Counsel and Chief Legal Officer
Ekaterina Malievskaia, M.D.	54	Chief Innovation Officer, Co-Founder, Director
<b>Non-Executive Directors:</b>		
Florian Brand	34	Director
Jason Camm	32	Director
Annalisa Jenkins, MBBS	55	Director
Thomas Lönngren	70	Director
Linda McGoldrick	66	Director
Robert McQuade	64	Director
David Norton	70	Director
Wayne Riley	61	Director

(1) Mr. Brand, who is one of the directors appointed by ATAI Life Sciences AG pursuant to our Amended and Restated Shareholders' Agreement, has previously indicated that he intends to resign from our board due to the increase in his operational responsibilities as chief executive officer in ATAI Life Sciences AG.

### Executive Officers

*George Goldsmith* has served as our Chief Executive Officer and Chair of our board of directors since June 2017. Previously, Mr. Goldsmith served as Chairman and Chief Executive Officer at Tapestry Networks, which he co-founded in 2002, until 2005, and he continues to serve as Non-Executive Chairman. Mr. Goldsmith was Chief Executive Officer of TomorrowLab@McKinsey from 2000 to 2001, and prior to that served as Senior Advisor to McKinsey & Company from 1997 to 2000. Prior to that he served as Managing Director of the Lotus Institute after the Lotus Development Corporation's acquisition of his first company, The Human Interface Group. Mr. Goldsmith also serves on the board of directors of COMPASS Pathways Limited. Mr. Goldsmith received his bachelor's degree in Psychology from the University of Rochester and his masters in Clinical Psychology from the University of Connecticut. We believe that Mr. Goldsmith is qualified to serve on our board of directors because of his executive experience in our industry.

*Lars Christian Wilde* has served as our President since June 2019 and previously served as Chief Operating Officer since our formation. Previously, Mr. Wilde was the founder and CEO of Springlane GmbH, or Springlane, which he founded in 2012, and was a co-founder of ATAI Life Sciences AG. Prior to founding Springlane, Mr. Wilde served as an investor at Waterland Private Equity. Mr. Wilde serves as an independent member on the board of directors of Quercis Pharma AG, Sutura Therapeutics and Kanna Health Ltd. Mr. Wilde received his bachelor's degree in Business Administration from Rotterdam School of Management, Erasmus University in the Netherlands and his masters in Finance from IE Business School in Spain.

*Piers Morgan* has served as our Chief Financial Officer since March 2020. Previously, Mr. Morgan served as Chief Financial Officer of Verona Pharma plc from 2016 to 2020. From November 2015 to September 2016, Mr. Morgan was an independent consultant. From May 2014 to November 2015, Mr. Morgan was the Chief Executive Officer of C4X Discovery plc, a biotechnology company. Prior to C4X, Mr. Morgan co-founded uniQure N.V., a biotechnology company in Amsterdam, where he served as Chief Financial Officer from December 2009 to May 2014. Mr. Morgan is a director of Ikarovec Ltd and a member of the Institute of Chartered Accountants in England and Wales. Mr. Morgan received an MA in Law and Management Studies from the University of Cambridge.

*Nate Poulsen, J.D.*, is our General Counsel and Chief Legal Officer. He joined us in 2019 as our General Counsel and Head of Legal, Intellectual Property and Licensing. Previously, Mr. Poulsen worked as a lawyer with Cooley LLP since 2012. Mr. Poulsen is a registered patent attorney. Prior to beginning his legal career in 2006, Mr. Poulsen served as a medicinal chemist for NPS Pharmaceuticals, as a researcher in the Department of Neurology at Columbia Presbyterian Medical Center, and consulted on strategy in the medical device and consumer healthcare industries. Mr. Poulsen received his undergraduate degrees in mathematics, physics, and chemistry from Westminster College, an MA in pharmacology from Columbia University, MBA from Cornell University's Johnson School of Management, and JD from Fordham University School of Law.

*Ekaterina Malievskaia M.D.* has served as our Chief Innovation Officer since January 2020 and as a member of our board of directors since 2017. Prior to her role as our Chief Innovation Officer, Dr. Malievskaia served as our Head of Research and Development from January 2019 to January 2020 and as our Chief Medical Officer from June 2017 to 2019. Dr. Malievskaia served as clinical faculty at Mount Sinai School of Medicine and as a research professor in Public Health at the City University of New York. Prior to these roles, Dr. Malievskaia worked in clinical, academic and public health from 1999 until co-founding COMPASS. Dr. Malievskaia received her Doctor of Medicine from St. Petersburg Medical Academy. We believe that Dr. Malievskaia is qualified to serve on our board of directors because of her clinical practice, executive experience and public health academic background.

### **Non-Executive Directors**

*Florian Brand* has served as a member of our board of directors since March 2018. Mr. Brand intends to resign from our board of directors following completion of this offering. Mr. Brand is the Co-Founder and Chief Executive Officer of ATAI, where he has served since its inception in June 2018. From 2018 to 2019, Mr. Brand served as Chief Executive Officer of Perception Neuroscience, and from 2015 to 2018, Mr. Brand served as Managing Director of Springlane GmbH. Mr. Brand serves as a member of the board of directors of Perception Neuroscience, GABA Therapeutics, EntheogeniX Biosciences, DemeRx IB, Viridia Life Sciences, Recognigy Life Sciences, Revixia Life Sciences and IntroSpect Digital Therapeutics. Mr. Brand received his bachelor's degree in Economics from LMU Munich and his master's degree in Management from ESCP Europe, Paris. We believe that Mr. Brand is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive executive experience.

*Jason Camm* has served as a member of our board of directors since February 2020. Mr. Camm currently serves as a Managing Director and the Chief Medical Officer at Thiel Capital, where he has worked since 2013. Mr. Camm currently serves on the board of directors of The Thiel Foundation, on the supervisory board of ATAI, which is a major shareholder of our company, and on the board of advisors of the Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy at Tufts University. Mr. Camm also serves on the board of directors of several privately held biotech companies in the United States and abroad. Mr. Camm received his master's degree in Osteopathy from The British School of Osteopathy. We believe that Mr. Camm is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive medical experience.

*Annalisa Jenkins, MBBS, FRCP*, has served as a member of our board of directors since May 2018. From November 2017 until April 2019, Dr. Jenkins served as the Chief Executive Officer of PlaqueTec Ltd., a biotechnology company focusing on coronary artery disease treatment and prevention. Previously, Dr. Jenkins served as the Chief Executive Officer and a member of the board of directors of Dimension Therapeutics, Inc., a biotechnology company focused on rare and metabolic diseases associated with the liver, from September 2014 until its sale to Ultragenyx Pharmaceutical Inc. in November 2017. From October 2013 to March 2014, Dr. Jenkins served as Executive Vice President, Head of Global Research and Development for Merck Serono Pharmaceuticals, a biopharmaceutical company. Previously, from September 2011 to October 2013, she served as Merck Serono's Executive Vice President, Global Development and Medical, and was a member of Merck Serono's executive committee. Prior to that, Dr. Jenkins pursued a 15-year career at Bristol-Myers Squibb Company, a biopharmaceutical company, where, from July 2009 to June 2011 she was a Senior Vice President and Head of Global Medical Affairs. Dr. Jenkins is currently a committee member of the science board to the FDA, chairs the Court of the London School of Hygiene and Tropical Medicine and is a non-executive director of Genomics England. Dr. Jenkins serves on the board of directors of AgeX Therapeutics, Inc. (NYSE American: AGE), AvroBio, Inc. (Nasdaq: AVRO), Oncimmune Holdings plc (LSE: ONC), Affimed GmbH (Nasdaq: AFMD) and a number of privately held biotechnology and life science companies. Dr. Jenkins graduated with a degree in medicine from St. Bartholomew's Hospital in the University of London and subsequently trained in cardiovascular medicine in the UK National Health Service. Earlier in her career, Dr. Jenkins served as a Medical Officer in the British Royal Navy. We believe Dr. Jenkins is qualified to serve on our board of directors based on her industry experience in the field in which we operate and her executive experience with companies in our industry.

*Thomas Lönngren* has served as a member of our board of directors since May 2018. Mr. Lönngren currently serves as the Director at PharmaExec Consulting AB and as a Strategic Advisor at the NDA Group, which he has done since 2010. He acts as an advisor to the following companies and organizations: Artis Venture, San Francisco, US, Baren Therapeutics, San Francisco, US, Faculty member of GLG Institute (Gerson Lehrman Group), New York, US, special advisor to the Centre for Innovation in Regulatory Science (CIRS), London, UK, ScientificMed AB Stockholm, Sweden. He was the Deputy General Director of the Swedish Medical Product Agency until 2000. From 2001 until 2010, Mr. Lönngren served as the Executive Director of the European Medical Agency. He has held non-executive board positions since 2010 in Cbio Ltd, Brisbane, Analytica Ltd, Brisbane and Global Kinetic Corporation Ltd, Melbourne Australia. Mr. Lönngren received his degree in pharmacy and MSc in Social and Regulatory Pharmacy from Uppsala University. He is an Honorary Member of the Royal Pharmaceutical Society of Great Britain, Honorary Fellow of the Royal College of Physicians in Great Britain, and holds Honorary Doctorates from the University of Uppsala and University of Bath, UK. We believe that Mr. Lönngren is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive pharmaceutical consulting experience.

*Linda McGoldrick* has served as a director of our company since September 2020. In 1985, Ms. McGoldrick founded, and currently serves as Chairman and Chief Executive Officer of, Financial Health Associates International, a strategic consulting company specializing in healthcare and life sciences. From April 2019 through December 2019, Ms. McGoldrick served as President and interim Chief Executive Officer of Zillion, Inc., a health, technology and condition management company. Over her professional career, she has served in a number of leadership roles, including senior vice president and National Development director for the Healthcare and Life Sciences Industry Practices at Marsh-MMC Companies, international operations and marketing director of Veos plc, a European medical devices company, and managing director Europe for Kaiser Permanente International. In 2018, Ms. McGoldrick was appointed by the Governor of Massachusetts to serve on the state's Health Information Technology Commission. Ms. McGoldrick has served as a director of numerous publicly traded and private held companies and non-profit organizations in the U.S., UK and Europe and currently serves on the faculty of the National Association of Corporate Directors. Ms. McGoldrick received her bachelor of arts in sociology from Ohio Wesleyan University and master of social work from the University of Pennsylvania and master of business administration in management from the Wharton School, University of Pennsylvania. We

believe that Ms. McGoldrick is qualified to serve on our board of directors because of her extensive experience as a director, global business strategy leader and policy expert for U.S. and European companies and organizations.

*Robert McQuade, Ph.D.* has served as a member of our board of directors since April 2020. Dr. McQuade currently serves as the Executive Vice President & Chief Strategic Officer at Otsuka Pharmaceutical Development & Commercialization, Inc., or Otsuka, where he has served since 2004. Dr. McQuade is also the Officer and Manager of the McQuade Center for Strategic Research and Development LLC since February 2020. Dr. McQuade currently serves on the board of directors of Otsuka America Pharmaceutical, Inc., Astex Pharmaceutical, Inc., Astex Pharmaceutical, Ltd., Avanir Pharmaceuticals, Visterra, Inc., Otsuka Pharmaceutical Development & Commercialization, Inc., Medical University of South Carolina Foundation for Research and Development, The Technology Accelerator Co., and Clinical Biotechnology Research Institute. Dr. McQuade received his degree in biology from Davidson College and completed his Ph.D. in biochemistry from University of North Carolina at Chapel Hill. Prior to joining Otsuka, Dr. McQuade worked in drug discovery research at Schering-Plough Corp. and in global medical affairs at Bristol-Myers Squibb company. We believe that Dr. McQuade is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive pharmaceutical experience.

*David Norton* has served as a member of our board of directors since May 2018. Until his retirement in September 2011, Mr. Norton was Company Group Chairman, Global Pharmaceuticals for Johnson & Johnson, a public healthcare company. Mr. Norton began his Johnson & Johnson career in 1979 and held a number of positions at the company, including Company Group Chairman, Worldwide Commercial and Operations for the CNS, Internal Medicine franchise from 2006 to 2009, Company Group Chairman for the pharmaceutical businesses in Europe, the Middle East and Africa from 2004 to 2006, and Company Group Chairman for the pharmaceutical businesses in North America from 2003 to 2004. Mr. Norton currently serves on the board of directors of Mallinckrodt, PLC and Forepoint Capital, LLC. Mr. Norton is a graduate of Control Data Institute, Australia and the College of Distributive Trades, United Kingdom. We believe that Mr. Norton is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive global pharmaceutical experience.

*Wayne J Riley, M.D., MPH, M.B.A.* has served as a member of our board of directors since March 2021. Dr. Riley serves as the President of the State University of New York (SUNY) Downstate Health Sciences University, Brooklyn, NY, USA where he holds tenured professorships in internal medicine, and health policy and management and has served since January 2017. Prior to this, Dr. Riley served as a clinical professor of medicine and adjunct professor of health policy at Vanderbilt University from July 2007 until June 2017, and as President and Chief Executive Officer of Meharry Medical College from January 2007 until July 2013. In addition, Dr. Riley currently serves as an elected member of the US National Academy of Medicine, a Commissioner of the US Medicare Payment Advisory Commission, Chair of the Board of the New York Academy of Medicine, President of the Society of Medical Administrators, an organization of leading North American physician executives, and a President Emeritus of the American College of Physicians. Dr. Riley is also a member of the Board of Directors of HCA Healthcare Inc, where he serves as Chair of the Patient Safety & Quality Committee and a member of the Audit & Compliance and Nominating & Corporate Governance Committees. He previously served as a Director of Vertex Pharmaceuticals Inc. Dr. Riley holds a BA from Yale University, Masters in Public Health from the Tulane University School of Public Health and Tropical Medicine, M.D. from the Morehouse School of Medicine, and MBA from Rice University. We believe that Dr. Riley is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive medical and health policy experience.

#### **Family Relationships**

George Goldsmith, our Chief Executive Officer and Chairman of our board of directors, is married to Ekaterina Malievskaia, our Chief Innovation Officer and a member of our board of directors. On October

5, 2020, the son of Dr. Malievskaia began work with us as Stakeholder Engagement and Operations Associate. Dr. Malievskaia's son subsequently resigned from his position, effective as of April 16, 2021. As of December 31, 2020, there were no other family relationships between our executive officers and any of our directors.

### **Corporate Governance Practices**

We are a “foreign private issuer,” as defined by the Securities and Exchange Commission, or SEC. As a result, in accordance with Nasdaq listing requirements, we may rely on home country governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards. While we voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

- Exemption from filing quarterly reports on Form 10-Q containing unaudited financial and other specified information or current reports on Form 8-K upon the occurrence of specified significant events.
- Exemption from Section 16 rules requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades in a short period of time, which will provide less data in this regard than shareholders of U.S. companies that are subject to the Exchange Act receive.
- Exemption from the Nasdaq requirement requiring disclosure of any waivers of the code of business conduct and ethics for directors and officers.
- Exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans.
- Exemption from the requirement that our audit committee have review and oversight over all “related party transactions,” as defined in Item 7.B of Form 20-F.
- Exemption from the requirement that our board of directors have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities.
- Exemption from the requirement to have independent director oversight of director nominations.

Although we may rely on certain home country corporate governance practices, we must comply with Nasdaq's Notification of Noncompliance requirement (Nasdaq Rule 5625) and the Voting Rights requirement (Nasdaq Rule 5640). Further, we must have an audit committee that satisfies Nasdaq Rule 5605(c)(3), which addresses audit committee responsibilities and authority and requires that the audit committee consist of members who meet the independence requirements of Nasdaq Rule 5605(c)(2)(A)(ii).

Because we are a foreign private issuer, our directors and senior management are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the Securities Exchange Act of 1934, or the Exchange Act. They are, however, subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules.

We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act, the rules adopted by the SEC and Nasdaq listing rules.

Accordingly, our shareholders will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq. For an overview of our corporate governance principles, see the section titled “Description of Share Capital and Articles of Association—Differences in Corporate Law.”

### Composition of Our Board of Directors

Our board of directors is currently composed of ten members. As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except that our audit and risk committee is required to consist fully of independent directors, subject to certain phase-in schedules. However, our board of directors has determined that, of our ten directors, no director other than George Goldsmith and Ekaterina Malievskaia have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of director and that each of these directors is “independent” as that term is defined under Nasdaq rules.

Our Articles provide that our board of directors be divided into three classes, designated as “Class I,” “Class II” and “Class III,” each of which consist, as nearly as possible, of one-third of the total number of directors constituting our entire board of directors and which serve staggered three-year terms. At each annual general meeting, the successors of directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Directors of the class retiring at the annual general meeting shall be eligible for re-appointment by ordinary resolution at such annual general meeting. The expiration of the current terms of the members of our board of directors and the period each member has served in that term are as follows:

Name	Class	Year Current Term Began	Year Current Term Expires
Florian Brand	I	2020	2021
Ekaterina Malievskaia	I	2020	2021
David Norton	I	2020	2021
Wayne Riley	I	2021	2021
Jason Camm	II	2020	2022
Thomas Lönngren	II	2020	2022
Robert McQuade	II	2020	2022
George Goldsmith	III	2020	2023
Annalisa Jenkins	III	2020	2023
Linda McGoldrick	III	2020	2023

There are no arrangements or understanding between us and any of the members of our board of directors providing for benefits upon termination of their service.

### Committees of Our Board of Directors

Our board of directors has three standing committees: an audit and risk committee, a compensation and leadership development committee and a nominating and corporate governance committee.

#### **Audit and Risk Committee**

Our audit and risk committee consists of Annalisa Jenkins, Linda McGoldrick and Robert McQuade and assists our board of directors in overseeing our accounting and financial reporting processes. Ms. McGoldrick serves as chair of our audit and risk committee. Our audit and risk committee consists exclusively of members of our board of directors who are financially literate, and Dr. Jenkins and Ms. McGoldrick are each considered an “audit committee financial expert” as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Our board of directors has determined that all of the members of our audit and risk committee

satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act. Our audit and risk committee will meet at least four times per year and oversee and review our internal controls, accounting policies and financial reporting, and provide a forum through which our independent registered public accounting firm reports. Our audit and risk committee will meet regularly with our independent registered public accounting firm without management present. The audit and risk committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

Our audit and risk committee's responsibilities include:

- recommending the appointment of the independent auditor to the annual general meeting of shareholders;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- evaluating the independent auditor's qualifications, performance and independence, and presenting its conclusions to our full board of directors on at least an annual basis;
- reviewing and discussing with management and our independent registered public accounting firm our financial statements and our financial reporting process; and
- reviewing, approving or ratifying any related party transactions.

#### ***Compensation and Leadership Development Committee***

Our compensation and leadership development committee consists of Jason Camm, Annalisa Jenkins, David Norton and Wayne Riley. Dr. Jenkins serves as chair of our compensation and leadership development committee. Under SEC and Nasdaq rules, there are heightened independence standards for members of our compensation and leadership development committee, including a prohibition against the receipt of any compensation from us other than standard board member fees. Although foreign private issuers are not required to meet this heightened standard, all of our compensation and leadership development committee members are expected to meet this heightened standard.

Our compensation and leadership development committee's responsibilities include:

- identifying, reviewing and proposing policies relevant to the compensation and benefits of our directors and executive officers;
- evaluating the performance of our principal executive officers in light of such corporate goals and objectives and based on such evaluation: (i) determining cash compensation of our principal executive officer; and (ii) reviewing and approving grants and awards to our principal executive officer under equity-based plans;
- overseeing and administering our employee share option scheme or equity incentive plans in operation from time to time;
- annually reviewing and recommending to our board of directors the corporate goals and objectives relevant to the compensation of our principal executive officer;
- reviewing and approving or recommending to our board of directors the cash compensation of our other executive officers;

- reviewing and establishing our overall management compensation, philosophy and policy;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable rules;
- reviewing and recommending to our board of directors the compensation of our directors;
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement; and
- reviewing and approving the retention, termination or compensation of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

Each member of our compensation and leadership development committee will be a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act.

#### ***Nominating and Corporate Governance Committee***

Our nominating committee consists of Thomas Lönngren, Jason Camm, Linda McGoldrick and Wayne Riley. Mr. Lönngren serves as chair of our nominating and corporate governance committee.

Our nominating and corporate governance committee's responsibilities include:

- drawing up selection criteria and appointment procedures for directors;
- assessing the functioning of individual members of our board of directors and executive officers and reporting the results of such assessment to our board of directors;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by shareholders;
- reviewing the composition of our board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- recommending to our board of directors the persons to be nominated for election as directors and to each of our board of directors' committees;
- developing and recommending to our board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors and management.

#### **Code of Business Conduct and Ethics**

We have adopted a Code of Business Conduct and Ethics, or Code of Ethics, applicable to our and our subsidiaries' employees, independent contractors, senior management and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the Code of Ethics is posted on our website, which is located at [www.compasspathways.com](http://www.compasspathways.com). Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein.

#### **Compensation of Executive Officers and Directors**

For the year ended December 31, 2020, the aggregate compensation accrued or paid to the members of our board of directors and our executive officers for services in all capacities was \$15,558,678 including the estimated grant date fair value of share-based compensation awarded in the



fiscal years ended December 31, 2020. This share-based compensation included options to purchase ordinary shares with the exercise price and total shares granted outlined in the “Outstanding Equity Awards, Grants and Option Exercises” section below. The total amounts accrued to provide pension, retirement or similar benefits for our directors and officers for the fiscal year ended December 31, 2020 was \$21,293.

### Non-Executive Director Cash Fees

We have entered into appointment letters with each non-executive director who is not affiliated with one of our investor shareholders. The appointment letters provide for an annual director’s fee of \$38,524 payable in equal monthly installments in arrears as compensation for services. In addition to the basic fee, committee fees may be paid for chairing or membership of a Board committee. Mr. Camm has waived his right to both cash and non-cash compensation as of February 1, 2021. The table below shows the annual fees (in U.S. dollars) currently payable to our non-executive directors.

Board member	Board Base	Lead Director	Audit		CompDev		NomGov		InnovRes		Total
			Chair	Member	Chair	Member	Chair	Member	Chair	Member	
Florian Brand	38,524										38,524
Jason Camm	38,524					5,137		3,852		5,137	52,650
Annalisa Jenkins	38,524			7,705	10,273					5,137	61,639
Thomas Lönnngren	38,524						7,705				46,229
Linda McGoldrick	38,524		15,410					3,852			57,786
Robert McQuade	38,524			7,705					10,273		56,502
David Norton	38,524	12,841				5,137					56,502
Wayne Riley	38,524					5,137		3,852			47,513
<b>Total \$</b>	<b>308,192</b>	<b>12,841</b>	<b>15,410</b>	<b>15,410</b>	<b>10,273</b>	<b>10,274</b>	<b>7,705</b>	<b>7,704</b>	<b>10,273</b>	<b>10,274</b>	<b>417,345</b>

### Directors and Executive Management Compensation

For the year ended December 31, 2020, the table below sets forth the compensation paid to our directors, and, in the case of Mr. Goldsmith and Dr. Malievskaja, reflects the compensation paid for their services as our executives.

	Base Salary	Bonus <sup>(2)</sup>	Share-based payment <sup>(3)</sup>	Other <sup>(4)</sup>	Total variable	Total fixed	Total
George Goldsmith (5)	\$ 453,936	\$ 234,743	\$ 567,911	\$ 34,113	\$ 234,743	\$ 1,055,960	\$ 1,290,703
Ekaterina Malievskaja	362,287	150,403	547,627	23,708	150,403	933,622	1,084,025
David York Norton	16,052	—	173,219	—	—	189,271	189,271
Florian Brand	10,944	—	11,119	—	—	22,063	22,063
Jason Camm(1)	14,957	—	11,119	—	—	26,076	26,076
Annalisa Jenkins	17,511	—	176,835	—	—	194,346	194,346
Thomas Lönnngren	13,133	—	248,321	—	—	261,454	261,454
Robert McQuade	16,052	—	11,119	—	—	27,171	27,171
Linda McGoldrick	16,417	—	15,609	—	—	32,026	32,026

(1) On February 1, 2021, Mr. Camm permanently waived any and all compensation which he was entitled to receive during the year ended December 31, 2020.

(2) In 2020, Mr. Goldsmith and Dr. Malievskaja’s annual bonus outcome was 100% of target for each, resulting in a total bonus pay out for the financial year ended December 31, 2020 of 55% of Mr. Goldsmith’s base salary and 45% of Dr. Malievskaja’s base salary in each case for the period following

completion of our IPO, and 50% and 40% of their respective base salaries for the period from January 1, 2020 until completion of our IPO.

(3) Share based payments represent the intrinsic value of share options that vested during the years ended December 31, 2019 and December 31, 2020 and the intrinsic value of RSUs granted in the years ended December 31, 2019 and December 31, 2020. The intrinsic value of the share options is the difference between the share price on the date of vesting and the exercise price of the option. In the case of RSUs, the share price on the day of issue. No amount of this award was attributable to share price appreciation. The face value of the awards is defined as the market value of the shares on the date of grant. This was a weighted average value of £8.38 per share in the year, meaning the total face value of the options and RSUs issued in 2020 was £4.7 million.

(4) Represents life assurance and income protection insurance. No non-employee director is currently in receipt of a pension payment. Each non-employee director is either not entitled to a pension payment or has opted out of receiving it. There are no payments made in lieu of pension entitlement.

(5) Mr. Goldsmith does not receive any additional remuneration in respect of his role as Chairman.

#### ***Executive Employment Contracts***

We engage our executive officers using standard terms as set out in our executive employment agreements. These agreements entitle the executive officers to receive an annual base salary. These agreements also entitle the executive officer to participate in an annual, discretionary bonus scheme, the amount of any such bonus to be determined at the compensation and leadership development committee's sole discretion. The amount of the annual discretionary bonus is equal to a certain percentage of each executive officer's annual base salary. Research and development, business development, financial and commercial targets are discussed with the compensation and leadership development committee and set at the start of the year by the Board. The payment of any bonus is at the absolute discretion of the compensation and leadership development committee which has the discretion to override out-turn of the bonus if appropriate to do so, including but not limited to factors such as our underlying financial and operational performance and individual performance.

This agreement also entitles the executive officer to participate in our equity incentive plans, the amount of such equity participation to be determined at the compensation and leadership development committee's sole discretion. We also contribute a certain percentage of the executive officer's basic salary to a group personal pension scheme. The executive officer is entitled to a number of additional benefits generally available to our employees.

The agreements entered into by Messrs. Morgan, Goldsmith, Poulsen and Wilde and Dr. Malievskaia may be terminated by either party by giving the other party notice (nine months' notice, in the case of Mr. Goldsmith, Dr. Malievskaia and Mr. Morgan, and the applicable statutory notice period under German law, in the case of Mr. Wilde). We reserve the right to place the executive officer on garden leave at any time after notice has been given by either party, and to pay in lieu of notice. We may terminate the agreement without notice or payment in lieu of notice in certain circumstances as a result of the executive officer's behavior or conduct, including for example, repeated breach of the service agreement after warning from us, dishonesty, gross misconduct or willful neglect in the discharge of their duties under the service agreement. If we terminate an executive officer, other than Mr. Wilde, within 12 months following a change in control, or the executive terminates employment due to a fundamental breach of the contract, such executive will be entitled to receive a lump sum payment equal to the sum of (i) 18 months' salary, in the case of Mr. Goldsmith, 12 months' salary in the case of Dr. Malievskaia, Mr. Morgan and Mr. Poulsen, (ii) a pro rata portion of his or her annual bonus (or in the case of Mr. Poulsen, an additional fixed lump sum payment) and (iii) an amount equal to the cost of us providing other benefits for 18 months (in the case of Mr. Goldsmith) or 12 months (in the case of Dr. Malievskaia, Mr. Morgan and Mr. Poulsen).

These agreements contain standard intellectual property and confidentiality provisions, which survive termination.

### ***Outstanding Equity Programs***

In 2017, we established an option pool for purposes of granting share options and allotting shares to our employee and non-employee service providers.

As of December 31, 2020, we had reserved 6,127,316 ordinary shares for the employee share option pool, of which 222,227 ordinary shares have been issued, options for 5,130,751 ordinary shares have been granted and 1,117,598 ordinary shares remain unallocated in the employee share option pool.

In connection with a sale, our board of directors may provide that such options shall be exchanged for options of the acquirer. If such exchange does not occur, such options shall be exercisable in full (and if not so exercised, shall lapse). In connection with an asset sale, such options may be exercised in full within such period of time as specified by our board of directors (and if not so exercised, shall lapse). In connection with any variation in share capital, our board of directors has discretion to take action to prevent the dilution or enlargement of intended benefits.

Any amendment may not affect an award which has already been granted without the consent of the affected grantee.

Following our IPO, we ceased making grants under this option pool.

### ***2020 Share Option and Incentive Plan***

In September 2020, we adopted the 2020 Share Option and Incentive Plan, or the 2020 Plan. The 2020 Plan allows the compensation and leadership development committee to make equity-based and cash-based incentive awards to our officers, employees, directors and other key persons (including consultants). The material terms of the 2020 Plan are summarized below. Except where the context indicates otherwise, references hereunder to our ordinary shares shall be deemed to include a number of ADS' equal to an ordinary share.

We have initially reserved 2,074,325 ordinary shares, or the Initial Limit, 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 four percent 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, or the Annual Increase. This number is subject to adjustment in the event of a sub-division, consolidation, share dividend or other change in our capitalization. Our compensation and leadership development committee did not increase the number of shares reserved and available for issuance under the plan as of January 1, 2021.

The ordinary shares underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of shares, expire or are otherwise terminated (other than by exercise) under the 2020 Plan will be added back to the ordinary shares available for issuance under the 2020 Plan.

The maximum aggregate number of shares that may be issued in the form of incentive share options shall not exceed the Initial Limit cumulatively increased on January 1, 2022 and on each January 1 thereafter by the lesser of the Annual Increase for such year or 2,074,325 ordinary shares.

The 2020 Plan is administered by our compensation and leadership development committee. Our compensation and leadership development committee has full power to select, from among the

individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2020 Plan. Persons eligible to participate in the 2020 Plan will be those full or part-time officers, employees, non-employee directors and other key persons (including consultants) as selected from time to time by our compensation and leadership development committee in its discretion.

The 2020 Plan permits the granting of both options to purchase ordinary shares intended to qualify as incentive share options under Section 422 of the Code, and options that do not so qualify. The option exercise price of each option will be determined by our compensation and leadership development committee but may not be less than 100% of the fair market value of our ordinary shares on the date of grant. The term of each option will be fixed by our compensation and leadership development committee and may not exceed 10 years from the date of grant. Our compensation and leadership development committee will determine at what time or times each option may be exercised.

Our compensation and leadership development committee may award share appreciation rights subject to such conditions and restrictions as it may determine. Share appreciation rights entitle the recipient to ordinary shares, or cash, equal to the value of the appreciation in our share price over the exercise price. The exercise price of each share appreciation right may not be less than 100% of the fair market value of the ordinary shares on the date of grant.

Our compensation and leadership development committee may award restricted shares and restricted share units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation and leadership development committee may also grant ordinary shares that are free from any restrictions under the 2020 Plan. Unrestricted shares may be granted to participants in recognition of past services or other valid consideration and may be issued in lieu of cash compensation due to such participant. Our compensation and leadership development committee may grant cash bonuses under the 2020 Plan to participants, subject to the achievement of certain performance goals.

The 2020 Plan provides that in the case of, and subject to, the consummation of a "sale event" as defined in the 2020 Plan, all outstanding awards may be assumed, substituted or otherwise continued by the successor entity. To the extent that the successor entity does not assume, substitute or otherwise continue such awards, then (i) all share options and share appreciation rights will automatically become fully exercisable and the restrictions and conditions on all other awards with time-based conditions will automatically be deemed waived, and awards with conditions and restrictions relating to the attainment of performance goals may become vested and non-forfeitable in connection with a sale event in the compensation and leadership development committee's discretion and (ii) upon the effectiveness of the sale event, the 2020 Plan and all awards will automatically terminate. In the event of such termination, (i) individuals holding options and share appreciation rights will be permitted to exercise such options and share appreciation rights (to the extent exercisable) prior to the sale event; or (ii) we may make or provide for a cash payment to participants holding options and share appreciation rights equal to the difference between the per share cash consideration payable to shareholders in the sale event and the exercise price of the options or share appreciation rights (to the extent then exercisable).

Our board of directors may amend or discontinue the 2020 Plan and our compensation and leadership development committee may amend the exercise price of options and amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2020 Plan require the approval of our shareholders. No awards may be granted under the 2020 Plan after the date that is 10 years from the date of shareholder approval.

As of December 31, 2020, options to purchase 4,908,524 ordinary shares were outstanding under the 2020 Plan.

### **2020 Employee Share Purchase Plan**

In September 2020, our board of directors adopted, and our shareholders approved, the 2020 Employee Share Purchase Plan, or ESPP, which became effective on the day prior to the listing of our ADSs on the Nasdaq Global Select Market. We may elect to implement the ESPP in the future.

The ESPP initially reserves and authorizes 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<sup>st</sup>, beginning on January 1, 2022, by the least of (i) 510,080 ordinary shares, or (ii) up to 1% of the outstanding number of ordinary shares on the immediately preceding December 31<sup>st</sup>, or such lesser number of ordinary shares as determined by the plan administrator. The share reserve is subject to adjustment in the event of a share split, share dividend or other change in our capitalization.

The ESPP is administered by our compensation and leadership development committee. The administrator has the authority to make all determinations for administration of the ESPP.

All employees employed by us or by any of our designated affiliates whose customary employment is for more than 20 hours a week (unless this exclusion is not permitted by applicable law) are eligible to participate in the ESPP. Any employee who owns 5% or more of the total combined voting power or value of all classes of our shares is not eligible to purchase ordinary shares under the ESPP.

Offerings to our employees to purchase ordinary shares under the ESPP may be made at such times as determined by the administrator. Offerings will continue for such period, referred to as offering periods, as the administrator may determine, but may not be longer than 27 months. Each eligible employee may elect to participate in any offering by submitting an enrollment form before the applicable offering date.

Each employee who is a participant in the ESPP may purchase ordinary shares by authorizing payroll deductions of up to 15% of his or her eligible compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase ordinary shares on the last business day of the applicable offering period equal to the lower of (i) the accumulated payroll deductions divided by either a per share price equal to 85% of the fair market value of a share of our ordinary shares on the first business day or the last business day of the offering period, whichever is lower, (ii) a number of ordinary shares determined by dividing the product of (A) US\$2,500 and (B) the number of months in the offering period, by the fair market value on the first day of the offering period, or (iii) such other lesser maximum number of ordinary shares as shall have been established by the administrator in advance of the offering. Under applicable tax rules, an employee may purchase no more than US\$25,000 worth of ordinary shares, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our compensation and leadership development committee or board of directors at any time. An amendment that increases the number of our Class A ordinary shares that are authorized under the ESPP and certain other amendments require the approval of our shareholders. The plan administrator may adopt subplans under the ESPP for employees of our non-U.S. subsidiaries and may permit such employees to participate in the ESPP on different terms, to the extent permitted by applicable law.

## Outstanding Equity Awards, Grants and Option Exercises

The following table summarizes the options that we granted to our executive officers and directors pursuant to the terms of our equity program established in 2017 and the 2020 Plan during the year ended December 31, 2020.

Name	Ordinary Shares Underlying Option	Exercise Price	Grant Date	Expiration Date
<b>Executive Officers</b>				
George Goldsmith	113,600	£13.13	9/18/2020	9/18/2030
Lars Christian Wilde	1,015,813	£0.01	5/19/2020	5/19/2030
Lars Christian Wilde	44,710	£0.01	6/30/2020	6/30/2030
Lars Christian Wilde	85,200	£13.13	9/18/2020	9/18/2030
Piers Morgan	167,499	£3.79	3/30/2020	3/30/2030
Piers Morgan	44,710	£0.01	6/30/2020	6/30/2030
Piers Morgan	74,408	£13.13	9/18/2020	9/18/2030
Nate Poulsen, J.D.	30,466	£1.87	3/30/2020	3/30/2030
Nate Poulsen, J.D.	39,192	£13.13	9/18/2020	9/18/2030
Ekaterina Malievskaia, M.D., MScPH.	85,200	£13.13	9/18/2020	9/18/2030
<b>Directors</b>				
Florian Brand	21,584	£25.44	11/23/2020	11/23/2030
Jason Camm	21,584	£25.44	11/23/2020	11/23/2030
Annalisa Jenkins, MBBS, FRCP	14,771	£1.87	3/30/2020	3/30/2030
Annalisa Jenkins, MBBS, FRCP	21,584	£13.13	9/18/2020	9/18/2030
Thomas Lönngren	14,771	£0.01	3/30/2020	3/30/2030
Thomas Lönngren	23,740	£0.01	6/30/2020	6/30/2030
Thomas Lönngren	21,584	£13.13	9/18/2020	9/18/2030
Linda McGoldrick	21,584	£13.13	9/18/2020	9/18/2030
Robert McQuade, Ph.D.	21,584	£25.44	11/23/2020	11/23/2030
David Norton	14,771	£1.87	3/30/2020	3/30/2030
David Norton	21,584	£13.13	9/18/2020	9/18/2030

## RELATED PARTY TRANSACTIONS

Since January 1, 2018, we have engaged in the following transactions with our directors, executive officers or holders of more than 5% of our outstanding share capital and their affiliates, which we refer to as our related parties.

### Loans and Advances by Tapestry

Before COMPASS Pathfinder Holdings Limited became our holding company in August 2017, we operated our business through COMPASS Pathways Limited, which was subsequently renamed COMPASS Pathfinder Limited as part of our corporate reorganization. In July 2017, COMPASS Pathways Limited entered into a loan agreement with Tapestry Networks Inc., or Tapestry, a U.S. S-corp incorporated in the state of Delaware, in which George Goldsmith, our Chief Executive Officer, Co-Founder and Chairman of our board of directors owns 100% of the issued and outstanding shares of capital stock. Pursuant to the loan agreement, Tapestry issued an interest-free loan in the principal amount of \$672,337 to COMPASS Pathways Limited to fund COMPASS Pathways Limited's payments to its vendors, or the Tapestry Loan. COMPASS Pathways Limited repaid \$443,102 of the Tapestry Loan on the date of the loan agreement. After such partial repayment, COMPASS Pathways Limited and Tapestry entered into a new loan agreement with respect to the remaining outstanding principal, in the amount of \$229,235 of the Tapestry Loan. In October 2018, the remaining \$229,235 of the Tapestry Loan was paid in full by COMPASS Pathways Limited.

### Accounting and Professional Services by Tapestry

Since our formation, Tapestry has provided, and continues to provide, certain accounting and professional services to us. In September 2017, we entered into an informal arrangement with Tapestry, pursuant to which we paid monthly service fees to Tapestry. In March 2020, we entered into a consulting agreement with Tapestry to govern this arrangement from that point on. We incurred accounting and professional fees totaling \$0.2 million and \$0.1 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, a balance of \$8,000.00 in the aggregate was due and payable to Tapestry.

### Preferred Share Financings

#### *2018 Convertible Loan Notes*

In each of February and March 2018, we entered into a loan note instrument pursuant to which we sold an aggregate of £6,050,000 of convertible loan notes, or the 2018 Convertible Loan Notes, to certain investors. All 2018 Convertible Loan Notes were converted into 2,128,031 shares of our Series A preferred shares at a conversion price of £2.84 per share upon the completion of our Series A financing in September 2018.

The following table summarizes the 2018 Convertible Loan Notes purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding share capital. The terms of these purchases were the same for all purchasers of our 2018 Convertible Loan Notes.

Name	Principal Amount of 2018 Convertible Loan Notes	Series A Preferred Shares Converted
Apeiron Investment Group Limited <sup>(1)</sup>	£100,000	35,083

(1) Apeiron Investment Group Limited purchased £100,000 of 2018 Convertible Loan Notes, which were converted into 308,826 Series A preferred shares. All such shares were transferred to ATAI in December 2018.

#### *Series A Preferred Financing*

In September 2018, we completed our Series A financing by issuing an aggregate of 44,044,857 Series A preferred shares, excluding the Series A preferred shares issued as a result of the conversion of

the 2018 Convertible Loan Notes, at an issue price of £0.43 per share to certain investors, pursuant to the share purchase agreements entered into with these investors.

The following table summarizes the Series A preferred shares purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding share capital. The terms of these purchases were the same for all purchasers of our Series A preferred shares.

Name	Series A Preferred Shares	Aggregate Purchase Price Paid
Apeiron Investment Group Limited <sup>(1)</sup>	2,640,430	£9,999,990

(1) Apeiron Investment Group Limited purchased 23,243,220 Series A preferred shares in our Series A financing, which shares were transferred to ATAI Life Sciences AG in December 2018.

#### *2019 Convertible Loan Notes*

In August 2019, we entered into a loan note instrument pursuant to which we sold an aggregate of £15,000,000 of convertible loan notes, or the 2019 Convertible Loan Notes, to certain investors. All 2019 Convertible Loan Notes were converted into our Series B preferred shares at a conversion price of £8.70 per share in April 2020.

The following table summarizes the 2019 Convertible Loan Notes purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding share capital. The terms of these purchases were the same for all purchasers of our 2019 Convertible Loan Notes.

Name	Principal Amount of 2019 Convertible Loan Notes	Series B Preferred Shares Converted
ATAI Life Sciences AG	£6,181,986	710,621
TT6, LLC, Series 1 <sup>(1)</sup>	£318,590	36,533

(1) Jason Camm, our director, holds a more than 10% share interest in TT6, LLC, Series 1.

#### *Series B Preferred Financing*

In April 2020, we completed the initial closings of our Series B financing by issuing an aggregate of 3,969,208 Series B preferred shares at an issue price of \$12.54 per share to certain investors, pursuant to the share purchase agreements entered into with these investors.

The following table summarizes the Series B preferred shares purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding share capital in the initial closings of our Series B financing. The terms of these purchases were the same for all purchasers of our Series B preferred shares.

Name	Series B Preferred Shares	Aggregate Purchase Price Paid
McQuade Center for Strategic Research and Development LLC <sup>(1)</sup>	1,594,677	£ 19,998,514.00

(1) McQuade Center for Strategic Research and Development LLC holds 4.3% of our issued and outstanding share capital and has appointed Robert McQuade to our board of directors. At the time of this transaction, the McQuade Center for Strategic Research and Development LLC held more than 5% of our issued and outstanding share capital.

In April 2020, ATAI signed an irrevocable undertaking in favor of us, pursuant to which ATAI undertook to purchase 425,871 Series B preferred shares at a purchase price of \$12.54 per share no later than September 17, 2020. This purchase was completed on August 10, 2020.



### **Share Transfer between Founders and ATAI**

In December 2018, Mr. Goldsmith and Dr. Malievskaia each transferred 441,830 ordinary shares (883,660 total) to ATAI as contemplated by the shareholders' agreement entered into by and among us and certain of our shareholders in connection with our Series A preferred financing. In exchange, Mr. Goldsmith and Dr. Malievskaia each received 209,666 bearer shares of capital stock, or approximately 3.7% (7.4% total), of ATAI.

### **Share Option Contract**

In May 2020, we and Lars Christian Wilde, our President, Chief Business Officer and Co-Founder, entered into a share option contract pursuant to which Mr. Wilde has an option to purchase 1,015,813 ordinary shares from us at an exercise price of less than £0.01 per share. The shares underlying the share option are subject to a vesting schedule. On August 17, 2020, all of the shares underlying the share option fully vested.

### **Call Option Agreements**

In May 2020, we and Lars Christian Wilde entered into a call option agreement with each of Mr. Goldsmith and Dr. Malievskaia. Pursuant to the call option agreements, Mr. Wilde has an option to purchase 776,565 of our ordinary shares for an exercise price of less than £0.01 per share from each of Mr. Goldsmith and Dr. Malievskaia, exercisable at any time upon the earlier of (i) May 19, 2021 and (ii) the date on which 50% or more of our ordinary shares or all our material assets are transferred, but in any case, no later than May 19, 2030. The option will terminate if Mr. Wilde ceases to be employed by us at any time prior to May 19, 2021. These call option agreements were amended and restated on July 21, 2020 in order to allow the wholly-owned holding company of Mr. Wilde to acquire the ordinary shares from Mr. Goldsmith and Dr. Malievskaia on Mr. Wilde's behalf. These call option agreements were amended and restated on September 9, 2020 in connection with our corporate reorganization.

### **Agreements with Shareholders**

In connection with our preferred, Series A preferred and Series B preferred financings, we entered into subscription and shareholders' agreements containing registration rights, information rights and rights of first refusal, among other things, with certain holders of our preferred, Series A preferred and Series B preferred shares. These shareholder agreements terminated upon the closing of our IPO, except for the registration rights granted under our shareholders' agreement, dated April 17, 2020 and amended and restated on August 7, 2020, entered into in connection with our Series B preferred financing, as more fully in our prospectus dated September 17, 2020, filed with the SEC pursuant to Rule 424(b), under the heading "Description of Share Capital and Articles of Association—Registration Rights," which information is incorporated herein by reference.

### **Participation in our Initial Public Offering**

In September 2020, we sold an aggregate of 8,625,000 ADSs in our initial public offering at a price of \$17.00 per share. Certain related persons made purchases of our ADSs in our initial public offering. Mr. Camm, a member of our board of directors, purchased 1,300 ADSs for a purchase price of \$22,100. Srinivas Rao, the chief scientific officer of ATAI Life Sciences AG, our largest shareholder, purchased 3,700 ADSs for a purchase price of \$34,000. The wife of Mr. Wilde, our President, Chief Business Officer, and Co-Founder, purchased 5,000 ADSs for a purchase price of \$85,000, and certain family members of Mr. and Mrs. Wilde purchased an aggregate of 10,000 ADSs for an aggregate purchase price of \$170,000. The son of Dr. Malievskaia, our Chief Innovation Officer and a member of our board of directors, purchased 2,000 ADSs for a purchase price of \$34,000. The wife of Mr. Brand, a member of our board of directors, purchased 1,300 ADSs for a purchase price of \$22,100.

### **Agreements with Our Executive Officers and Directors**

We have entered into employment agreements with our executive officers and service agreements with our non-executive directors, except Florian Brand. These agreements contain customary provisions

and representations, including confidentiality, non-competition, non-solicitation and inventions assignment undertakings by the executive officers. However, the enforceability of the non-competition provisions may be limited under applicable law.

#### **Family Relationships**

George Goldsmith, our Chief Executive Officer and Chairman of our board of directors, is married to Ekaterina Malievskaia, our Chief Innovation Officer and a member of our board of directors. On October 5, 2020, Dr. Malievskaia's son began work with us as Stakeholder Engagement and Operations Associate. As of December 31, 2020, there were no other family relationships between our executive officers and any of our directors.

#### **Insurance and Indemnification**

To the extent permitted by the Companies Act 2006 and in accordance with our Articles, we are empowered to indemnify our directors against any liability they incur by reason of their directorship. Prior to the completion of our IPO, we obtained and maintain directors' and officers' insurance to insure such persons against certain liabilities. We entered into a deed of indemnity with each of our directors and members of our senior management prior to the completion of our IPO. We have entered into a deed of indemnity with each of our directors and executive officers. These agreements and our Articles of Association require us to indemnify our directors and executive officers to the fullest extent permitted by law.

#### **Related Party Transaction Policy**

We have adopted a related party transaction policy. This policy became effective on September 17, 2020, the date on which our registration statement on Form F-1 in connection with our IPO was declared effective by the SEC. Pursuant to this policy, the audit and risk committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related parties in which the related party has a direct or indirect material interest. For purposes of this policy, a related party is defined as a director, executive director, nominee for director, or greater than 5% beneficial owner of any class of our voting securities, and their immediate family members.

## PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of April 26, 2021, for:

- each beneficial owner of 5% or more of our outstanding ordinary shares;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission, or SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include ordinary shares that can be acquired within 60 days of April 26, 2021. Percentage ownership calculations are based on 37,006,873 ordinary shares outstanding as of April 26, 2021.

Except as otherwise indicated, all of the shares reflected in the table are ordinary shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

As of April 26, 2021, 9,157,386 ordinary shares, representing approximately 25.0% of our issued and outstanding ordinary shares, were held by 39 U.S. shareholders of record.

Except as otherwise indicated in the table below, addresses of the directors, executive officers and named beneficial owners are in care of COMPASS Pathways plc, 3rd Floor, 1 Ashley Road, Altrincham, Cheshire WA14 2DT, United Kingdom.

NAME OF BENEFICIAL OWNER	ORDINARY SHARES BENEFICIALLY OWNED			
	NUMBER BEFORE OFFERING	PERCENT BEFORE OFFERING	NUMBER AFTER OFFERING	PERCENT AFTER OFFERING
<i>5% or greater shareholders:</i>				
ATAI Life Sciences AG <sup>(1)</sup>	7,935,663	21.4 %	7,935,663	19.4 %
George Goldsmith <sup>(2)</sup>	4,532,748	12.2 %	4,532,748	11.1 %
Ekaterina Malievskaia <sup>(3)</sup>	4,532,748	12.2 %	4,532,748	11.1 %
Entities affiliated with Peter Thiel <sup>(4)</sup>	2,352,516	6.3 %	2,352,516	5.7 %
<i>Directors and Officers:</i>				
George Goldsmith <sup>(2)</sup>	4,532,748	12.2 %	4,532,748	11.1 %
Lars Christian Wilde <sup>(5)</sup>	841,740	2.3 %	841,740	2.1 %
Piers Morgan <sup>(6)</sup>	186,128	*	186,128	*
Nate Poulsen <sup>(7)</sup>	243,895	*	243,895	*
Ekaterina Malievskaia <sup>(3)</sup>	4,532,748	12.2 %	4,532,748	11.1 %
Florian Brand <sup>(8)</sup>	1,300	*	1,300	*
Annalisa Jenkins <sup>(9)</sup>	119,755	*	119,755	*
Thomas Lönnngren <sup>(10)</sup>	123,711	*	123,711	*
David Norton <sup>(11)</sup>	119,755	*	119,755	*
Jason Camm	1,300	*	1,300	*
Robert McQuade <sup>(12)</sup>	1,594,677	4.3 %	1,594,677	3.9 %
Wayne Riley	—	—	—	—
All current directors and executive officers as a group (12 persons)	12,297,757	33.1 %	12,297,757	30.2 %

\* Represents beneficial ownership of less than one percent.

- (1) Represents 7,935,663 ordinary shares held by ATAI Life Sciences AG, or ATAI. ATAI Life Sciences AG is a German public limited company. Its address is Barer Straße 7, 80333 München, Germany.
- (2) Represents 4,521,571 ordinary shares held by Mr. Goldsmith and 11,177 restricted share units exercisable by Mr. Goldsmith within 60 days after April 26, 2021. Mr. Goldsmith and Dr. Malievskaia are married but they expressly disclaim beneficial ownership of each other's shares in the Company.
- (3) Represents 4,521,571 ordinary shares held by Dr. Malievskaia and 11,177 restricted share units exercisable by Dr. Malievskaia within 60 days after April 26, 2021. Mr. Goldsmith and Dr. Malievskaia are married but they expressly disclaim beneficial ownership of each other's shares in the Company.
- (4) Based solely on a Schedule 13G filed with the SEC on February 16, 2021 by Peter Thiel, The Founders Fund VII, LP, The Founders Fund VII Entrepreneurs Fund, LP, The Founders Fund VII Principals Fund, LP, The Founders Fund VII Management, LLC and Rivendell Investments 2017-9 LLC. Represents (i) 1,794,756 ordinary shares held by Rivendell Investments 2017-9 LLC, a limited liability company formed under the laws of the State of Delaware, (ii) 494,190 ordinary shares held by The Founders Fund VII, LP, a limited partnership formed under the laws of the State of Delaware, (iii) 59,218 ordinary shares held by The Founders Fund VII Principals Fund, LP, a limited partnership formed under the laws of the state of Delaware, and (iv) 4,352 ordinary shares held by The Founders Fund VII Entrepreneurs Fund, LP, a limited partnership formed under the laws of the State of Delaware. Mr. Thiel is the beneficial owner of Rivendell Investments 2017-9 LLC and has sole voting and investment power over the securities held by Rivendell Investments 2017-9 LLC. Mr. Thiel is one of three Managing Members of the General Partner of each of The Founders Fund VII, LP, The Founders Fund VII Principals Fund, LP and The Founders Fund VII Entrepreneurs Fund, LP and may be deemed to share voting and investment power over the securities held by The Founders Fund VII, LP, The Founders Fund VII Principals Fund, LP and The Founders Fund VII Entrepreneurs Fund, LP. The other two Managing Members are Brian Singerman and Keith Rabois. The address of Rivendell Investments 2017-9 LLC is 1209 Orange Street, Wilmington, Delaware 19801. The address of each of The Founders Fund VII, LP, The Founders Fund VII Principals Fund, LP and The Founders Fund VII Entrepreneurs Fund, LP is One Letterman Drive, Building D, 5th Floor, San Francisco, California 94129.
- (5) Represents (i) options to purchase 836,740 ordinary shares from the Company, exercisable by Mr. Wilde within 60 days after April 26, 2021 and (ii) 5,000 ADSs, each representing one ordinary share, held by Mr. Wilde's wife. The business address of Mr. Wilde is Reichswaldallee 25, 40472 Düsseldorf, Germany.

- (6) Represents options to purchase 186,128 ordinary shares from the Company, exercisable by Mr. Morgan within 60 days after April 26, 2021.
- (7) Represents options to purchase 233,839 ordinary shares from the Company, exercisable by Mr. Poulsen and 10,056 restricted share units exercisable by Mr. Poulsen within 60 days after April 26, 2021.
- (8) Represents 1,300 ADSs, each representing one ordinary share, held by Mr. Brand's wife.
- (9) Represents options to purchase 113,820 ordinary shares from the Company, exercisable by Ms. Jenkins and 5,935 restricted share units exercisable by Ms. Jenkins within 60 days after April 26, 2021. The business address of Ms. Jenkins is PO BOX 1152, Princeton, New Jersey 08542.
- (10) Represents (i) 99,049 ordinary shares, of which 5,503 are subject to forfeiture and our repurchase pursuant to a restricted share agreement between us and Mr. Lönngren dated January 31, 2020 and (ii) options to purchase 24,662 ordinary shares from the Company, exercisable by Mr. Lönngren within 60 days after April 26, 2021. The business address of Mr. Lönngren is Fröviboda 37, 755 91 Uppsala, Sweden.
- (11) Represents options to purchase 113,820 ordinary shares from the Company and 5,935 restricted share units, exercisable by Mr. Norton within 60 days after April 26, 2021.
- (12) Represents 1,594,677 ordinary shares held by McQuade Center for Strategic Research and Development LLC. Dr. McQuade, the Officer and Manager of McQuade Center for Strategic Research and Development LLC, may be deemed to have voting and investment power over the shares beneficially owned by McQuade Center for Strategic Research and Development LLC, but he disclaims beneficial ownership of such shares.

## DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

*The following describes our issued share capital, summarizes the material provisions of our articles of association, or Articles, and highlights certain differences in corporate law in the United Kingdom and the United States. Please note that this summary is not intended to be exhaustive. For further information, please refer to the full version of our articles of association, which are incorporated by reference herein.*

We were incorporated pursuant to the laws of England and Wales as COMPASS Rx Limited in June 2020 to become the holding company for COMPASS Pathfinder Holdings Limited. Pursuant to the terms of a share for share exchange agreement entered into on August 7, 2020 as part of our corporate reorganization, all shareholders of COMPASS Pathfinder Holdings Limited exchanged each of the shares held by them for 1,161 of the same class, with the same shareholder rights, of newly issued shares of COMPASS Rx Limited and, as a result, COMPASS Pathfinder Holdings Limited became a wholly owned subsidiary of COMPASS Rx Limited. Subsequently, we re-registered COMPASS Rx Limited as a public limited company and renamed it as COMPASS Pathways plc.

We are registered with the Registrar of Companies in England and Wales under number 12696098, and our registered office is at 3rd Floor, 1 Ashley Road, Altrincham, Cheshire, WA14 2DT, United Kingdom.

In connection with our initial public offering, certain resolutions were passed by our shareholders. These included resolutions for the:

- adoption of our Articles, which became effective upon the completion of our initial public offering. See “Articles of Association” below;
- general authorization of our directors for purposes of Section 551 of the Companies Act 2006 to issue our shares and grant rights to subscribe for or convert any securities into our shares up to a maximum aggregate nominal amount of £536,000 for a period of five years; and
- empowering of our directors pursuant to section 570 of the Companies Act 2006 to issue equity securities for cash pursuant to the section 551 authority referred to above as if the statutory preemption rights under section 561(1) of the Companies Act 2006 did not apply to such allotments.

### Issued Share Capital

As of December 31, 2020, our issued share capital was 35,930,331 ordinary shares with a nominal value of £0.008 per share.

### Ordinary Shares

Our ordinary shares have the rights and restrictions described in “Key Provisions of our Articles of Association” below. In accordance with our Articles, the following summarizes the rights of holders of our ordinary shares:

- each holder of our ordinary shares is entitled to one vote per ordinary share on all matters to be voted on by shareholders generally;
- the holders of our ordinary shares shall be entitled to receive notice of, attend, speak and vote at our general meetings and receive a copy of every report, accounts, circular or other documents sent out by us to our shareholders; and
- holders of our ordinary shares are entitled to receive such dividends as are recommended by our directors and declared by our shareholders.

## Deferred Shares

Our deferred shares have the rights and restrictions set out in our Articles, to be adopted with effect from the completion of this offering. In summary:

- the holders of our deferred shares are not entitled to vote on shareholder matters, or receive notice of, attend, speak or vote at our general meetings or receive copies of our reports, accounts, circulars or other documents sent to our shareholders;
- the holders of our deferred shares shall not be entitled to receive any dividends or participation in the profits of the Company;
- in the event of a winding up or liquidation of the Company, the deferred shares shall only participate in the surplus assets of the Company to the extent that each ordinary share has first received the amount paid up on that ordinary shares plus the sum of £1,000,000 in respect of each ordinary share; and
- the deferred shares shall not be transferable, save as in accordance with the limited circumstances set out in our Articles.

## Registered Shares

We are required by the Companies Act 2006 to keep a register of our shareholders. Under English law, the ordinary shares are deemed to be issued when the name of the shareholder is entered in our share register. The share register therefore is prima facie evidence of the identity of our shareholders, and the shares that they hold. The share register generally provides limited, or no, information regarding the ultimate beneficial owners of our ordinary shares. Our share register is maintained by our registrar, Neville Registrars Limited. Holders of our ADSs are not treated as our shareholders and their names are therefore not entered in our share register. The depositary, the custodian or their nominees is the holder of the shares underlying our ADSs. Holders of our ADSs have a right to receive the ordinary shares underlying their ADSs. For discussion on our ADSs and ADS holder rights, see “Description of American Depositary Shares” in this prospectus.

Under the Companies Act 2006, we must enter an allotment of shares in our share register as soon as practicable and in any event within two months of the allotment. We will perform all procedures necessary to update the share register to reflect the ordinary shares being sold in this offering, including updating the share register with the number of ordinary shares to be issued to the depositary upon the completion of this offering. We also are required by the Companies Act 2006 to register a transfer of shares (or give the transferee notice of and reasons for refusal as the transferee may reasonably request) as soon as practicable and in any event within two months of receiving notice of the transfer.

We, any of our shareholders or any other affected person may apply to the court for rectification of the share register if:

- the name of any person, without sufficient cause, is wrongly entered in or omitted from our share register; or
- there is a default or unnecessary delay in entering on the register the fact of any person having ceased to be a shareholder or on which we have a lien, provided that such delay does not prevent dealings in the shares taking place on an open and proper basis.

## Registration Rights

The holders of 5,233,628 of our ordinary shares are entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of a shareholders’ agreement between us and holders of our convertible preferred shares, which were subsequently

converted into ordinary shares in connection with our initial public offering. The shareholders' agreement includes demand registration rights, short-form registration rights and piggyback registration rights.

***Demand Registration Rights***

Under the terms of the shareholders' agreement, we will be required, upon the written request of holders of a majority of these securities to file a registration statement and use best efforts to effect the registration of all or a portion of these shares for public resale. We are required to effect only two registrations pursuant to this provision of the shareholders' agreement.

***Short-Form Registration Rights***

Pursuant to the shareholders' agreement, if we are eligible to file a registration statement on Form F-3 or Form S-3, upon the written request of holders of a majority of these securities at an aggregate offer price of at least \$5.0 million, we will be required to effect a registration of such shares. We are required to effect only two registrations in any twelve (12) month period pursuant to this provision of the shareholders' agreement. The right to have such shares registered on Form F-3 or Form S-3 is further subject to other specified conditions and limitations.

***Piggyback Registration Rights***

Pursuant to the shareholders' agreement, if we register any of our securities either for our own account or for the account of other shareholders, other than in connection with a registration for any employee benefit plan, corporate reorganization, or the offer or sale of debt securities, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the shareholders' agreement, we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

***Indemnification***

Our shareholders' agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

***Expiration of Registration Rights***

The registration rights granted under the shareholders' agreement will terminate on the earliest of (i) a deemed liquidation event, as defined in our Articles, (ii) the fifth anniversary of the completion of our IPO and (iii) such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all registrable securities held by a shareholder without limitation during a three-month period without registration.

**Key Provisions of our Articles of Association**

Our Articles were approved by our shareholders on September 11, 2020 and were adopted with effect from the completion of the IPO. A summary of certain key provisions of our Articles is set out below. The summary below is not a complete copy of the terms of our Articles. For further information, please refer to the full version of our Articles filed as an exhibit to the IPO registration statement.

Our Articles contain no specific restrictions on our purpose and therefore, by virtue of section 31(1) of the Companies Act 2006, our purpose is unrestricted.



Our Articles contain, among other things, provisions to the following effect:

***Share Capital***

Our share capital consists of ordinary shares and deferred shares. We may, in accordance with section 551 of the Companies Act 2006, be authorized by our shareholders to generally and unconditionally allot our shares or grant rights to subscribe for or to convert any security into our shares by way of an ordinary resolution. We may issue these shares with such rights and restrictions as may be determined by the ordinary resolution, or if no ordinary resolution is passed or so far as the resolution does not make specific provision, as our board of directors may determine, including shares which are to be redeemed, or are liable to be redeemed at our option or the option of the holder of such shares. However, an amendment to our Articles, which requires the passing of a special resolution, will be required to issue any shares other than ordinary shares.

***Voting***

The shareholders have the right to receive notice of, and to attend and vote at, our general meetings. Subject to any other provisions of our Articles and without prejudice to any special rights, privileges or restrictions as to voting attached to any shares forming part of our share capital, each shareholder who is present in person (or, in the case of a corporation, by representative) or by proxy at a general meeting on a show of hands has one vote and, on a poll, every such shareholder who is present in person (or, being a corporation, by representative) or by proxy has one vote in respect of every share held by him or her.

***Variation of Rights***

Whenever our share capital is divided into different classes of shares, the special rights attached to any class may be varied or abrogated either: (i) with the consent in writing of the holders of not less than three-quarters in nominal value of the issued shares of that class (excluding any shares of that class held as treasury shares), or (ii) with the authority of a special resolution passed at a general meeting of the holders of the shares of that class, and may be so varied and abrogated while we are a going concern.

***Dividends***

We may, subject to the provisions of the Companies Act 2006 and our Articles, by ordinary resolution from time to time declare dividends to be paid to shareholders according to their respective rights and interests in our profits, however no dividend shall exceed the amount recommended by our board of directors.

Subject to the provisions of the Companies Act 2006, our board of directors may declare interim dividends (including any dividend at a fixed rate) as appears our board of directors to be justified by our profits available for distribution. Except as provided otherwise by the rights attached to shares, all dividends may be declared or paid in any currency. Our board of directors may decide the rate of exchange for any currency conversions that may be required and how any costs involved in such conversions are to be met.

All dividends that remain unclaimed after a period of twelve (12) years from the date after they were first declared or became due for payment shall, if our board of directors so resolves, be forfeited and shall cease to remain owing by us.

Unless otherwise provided by the rights attached to the share, no dividend or other monies payable by us or in respect of a share shall bear interest as against us.

***Liquidation***

On a distribution of assets on a liquidation, dissolution or winding-up the surplus assets remaining after payment of our liabilities shall be distributed among the holders of our ordinary shares in proportion to the number of our ordinary shares held, irrespective of the amount paid or credited as paid on any share.

### ***Transfer of Ordinary Shares***

Each shareholder may transfer all or any of his shares which are in certificated form by means of an instrument of transfer in any usual form or in any other form which our board of directors may approve. Each shareholder may transfer all or any of his shares which are in uncertificated form by means of a “relevant system” (i.e., the CREST System) in such manner provided for, and subject as provided in, the uncertificated securities rules (as defined in our Articles) (i.e., the CREST Regulations).

Our board of directors may, in its absolute discretion, refuse to register a transfer of shares in certificated form unless:

- (i) it is for a share which is fully paid up;
- (ii) it is for a share upon which we have no lien;
- (iii) it is only for one class of share;
- (iv) it is in favor of a single transferee or no more than four joint transferees;
- (v) it is duly stamped or is duly certificated or otherwise shown to the satisfaction of our board of directors to be exempt from stamp duty; and
- (vi) it is delivered for registration to our registered office (or such other place as our board of directors may determine), accompanied (except in the case of a transfer by a person to whom we are not required by law to issue a certificate and to whom a certificate has not been issued or in the case of a renunciation) by the certificate for the shares to which it relates and such other evidence as our board of directors may reasonably require to prove the title of the transferor (or person renouncing) and the due execution of the transfer or renunciation by such transferor or, if the transfer or renunciation is executed by some other person on his behalf, the authority of that person to do so.

Our board of directors shall not refuse to register any transfer of partly paid shares in respect of which ADSs are admitted to Nasdaq on the grounds that they are partly paid shares in circumstances where such refusal would prevent dealings in such shares from taking place on an open and proper basis.

Our board of directors may refuse to register a transfer of uncertificated shares in any circumstances that are allowed or required by the uncertificated securities rules and the relevant system (in each case as defined in our Articles) (i.e., the CREST Regulations and the CREST System).

### ***Allotment of Shares and Preemption Rights***

Subject to the Companies Act 2006 and to any rights attached to existing shares, any share may be issued with or have attached to it such rights and restrictions as we may by ordinary resolution determine, or if no ordinary resolution has been passed or so far as the resolution does not make specific provision, as our board of directors may determine (including shares which are to be redeemed, or are liable to be redeemed at our option or the holder of such shares). However, an amendment to our Articles, which requires the passing of a special resolution, will be required to issue any shares other than ordinary shares.

In accordance with section 551 of the Companies Act 2006, our board of directors may be generally and unconditionally authorized to exercise all of our powers to allot shares or grant rights to subscribe for or to convert any security into our shares up to an aggregate nominal amount equal to the amount stated in the relevant ordinary resolution authorizing such allotment. The authorities referred to above were included in the ordinary resolution of our shareholders passed on September 11, 2020 and remain in force at the date of this prospectus.

Pursuant to section 561 of the Companies Act 2006, shareholders are granted preemptive rights when new shares are issued for cash. However, it is possible for our Articles, or shareholders at a general meeting representing at least 75% of our ordinary shares present (in person or by proxy) and eligible to vote at that general meeting, to disapply these preemptive rights. Such a disapplication of preemption rights may be for a maximum period of up to five years from the date of the shareholder resolution. In either case, this disapplication would need to be renewed by our shareholders upon its expiration (i.e., at least every five years).

On September 11, 2020, our shareholders approved the disapplication of preemptive rights for a period of five years from the date of approval by way of a special resolution of our shareholders. This included the disapplication of preemption rights in relation to the allotment of our ordinary shares in connection with this offering. This 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).

#### ***Alteration of Share Capital***

We may, in accordance with the Companies Act 2006, by ordinary resolution consolidate all or any of our share capital into a smaller number of shares of a larger nominal amount than our existing shares, or cancel any shares which, at the date of that ordinary resolution, have not been taken or agreed to be taken by any person and diminish the amount of our share capital by the amount of shares so cancelled, or sub-divide our shares, or any of them, into shares of a smaller nominal amount than our existing shares.

We may, in accordance with the Companies Act 2006, reduce or cancel our share capital or any capital redemption reserve or share premium account in any manner and with and subject to any conditions, authorities and consents required by law.

#### ***Board of Directors***

##### *Appointment of Directors*

Unless otherwise determined by ordinary resolution, the number of directors (other than any alternate directors) shall not be less than two, but there shall be no maximum number of directors.

Subject to our Articles and the Companies Act 2006, we may by ordinary resolution appoint a person who is willing to act as a director and our board of directors shall have power at any time to appoint any person who is willing to act as a director, in both cases either to fill a vacancy or as an addition to the existing board of directors.

Our Articles provide that, our board of directors will be divided into three classes, designated as "Class I", "Class II" and "Class III", each of which will consist, as nearly as possible, of one-third of the total number of directors constituting our entire board of directors and which will serve staggered three-year terms. At each annual general meeting, the successors of directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Directors of the class retiring at the annual general meeting shall be eligible for re-appointment by ordinary resolution at such annual general meeting.

At every subsequent annual general meeting any director who has been appointed by our board of directors since the last annual general meeting must retire from office and may offer themselves for reappointment by the shareholders by ordinary resolution.

##### *Proceedings of Directors*

Subject to the provisions of our Articles, our board of directors may regulate their proceedings as they deem appropriate. A director may, and the secretary at the request of a director shall, call a meeting of the directors.

The quorum for a meeting of our board of directors shall be fixed from time to time by decision of the board of directors, but it must never be fewer than two directors (or duly appointed alternate directors).

Questions and matters requiring resolution arising at a meeting shall be decided by a majority of votes of the participating directors, with each director having one vote. In the case of an equality of votes, the chairperson will have a second or casting vote (unless the chairperson is not entitled to vote on the resolution in question).

#### *Directors' Compensation*

Directors shall be entitled to receive such fees as our board of directors shall determine for their services as our directors, and for any other service which they undertake on our behalf provided that the aggregate fees payable to the directors must not exceed £750,000 per annum or such higher amount as may from time to time be decided by ordinary resolution. Directors shall be entitled to reasonable additional remuneration (whether by way of salary, commission, participation in profits or otherwise) for any special duties or services performed or rendered to us, as determined by our board of directors, and in respect of any employment or executive office. The directors shall also be entitled to be paid reasonable travel, hotel and other expenses properly incurred by them in connection with their attendance at meetings of shareholders or class meetings, board of director or committee meetings or otherwise in connection with the performance of their duties as directors.

#### *Conflicts of Interest*

Our board of directors may, in accordance with the requirements in our Articles, authorize any matter proposed to them by any director which would, if not authorized, involve a director breaching his duty under the Companies Act 2006, to avoid conflicts of interests.

A director seeking authorization in respect of such conflict shall declare to our board of directors the nature and extent of his interest in a conflict as soon as is reasonably practicable. The director shall provide our board of directors with such details of the matter as are necessary for our board of directors to decide how to address the conflict together with such additional information as may be requested by our board of directors.

Any authorization by our board of directors will be effective only if:

- (i) to the extent permitted by the Companies Act 2006, the matter in question shall have been proposed by any director for consideration in the same way that any other matter may be proposed to the directors under the provisions of our Articles;
- (ii) any requirement as to the quorum for consideration of the relevant matter is met without counting the conflicted director and any other conflicted director; and
- (iii) the matter is agreed to without the conflicted director voting or would be agreed to if the conflicted director's and any other interested director's vote is not counted.

#### *Permitted Interests*

Under our Articles, certain transactions which would otherwise give rise to a conflict are considered to be permitted interests of our directors. In the event that these permitted interests arise, the director in question will still count towards the quorum requirements of the relevant meeting and be entitled to vote on resolutions relating to such permitted interests, including but not limited to the following matters:

- (i) the giving by such director of any security, guarantee or indemnity for any money or any liability which such director, or any other person, has lent or obligations such director or any other person has undertaken at the request, or for the benefit, of us or any of our subsidiary undertakings;

- (ii) the giving of any security, guarantee or indemnity to any other person for a debt or obligation which is owed by us or any of our subsidiary undertakings, to that other person if such director has taken responsibility for some or all of that debt or obligation. Such director can take this responsibility by giving a guarantee, indemnity or security;
- (iii) a proposal or contract relating to an offer of any shares or debentures or other securities for subscription or purchase by us or any of our subsidiary undertakings, if such director takes part because such director is a holder of shares, debentures or other securities, or if such director takes part in the underwriting or subunderwriting of the offer;
- (iv) any arrangement for the benefit of our employees or the employees of any of our subsidiary undertakings which only gives such director benefits which are also generally given to employees to whom the arrangement relates;
- (v) any arrangement involving any other company if such director (together with any person connected with such director) has an interest of any kind in that company (including an interest by holding any position in that company or by being a shareholder of that company). This does not apply if such director knows that that such director has a relevant interest in a company. A company shall be deemed to be one in which such director has a relevant interest if and so long as (but only if and so long as) such director is to their knowledge (either directly or indirectly) the holder of or beneficially interested in one percent or more of any class of the equity share capital of that company (calculated exclusive of any shares of that class in that company held as treasury shares) or of the voting rights available to shareholders of that company;
- (vi) a contract relating to insurance which we can buy or renew for the benefit of our directors or a group of people which includes our directors; and
- (vii) a contract relating to a pension, superannuation or similar scheme or a retirement, death, disability benefits scheme or employees' share scheme which gives such director benefits which are also generally given to the employees to whom the scheme relates.

A director is not permitted to vote (or count towards the quorum) on a resolution relating to their own appointment or the settlement or variation of the terms of their appointment to an office or place of profit with us, or any other company in which we have an interest.

#### *Directors' Indemnity*

Subject to the provisions of the Companies Act 2006, all of our directors, secretaries or other officers (other than an auditor) shall be indemnified against any loss or liability incurred by them in connection with their duties or powers in relation to us or any of our subsidiaries or any pension fund or employees' share scheme of us or any of our subsidiaries or in relation to our activities as trustee of any occupational pension scheme which is operated by us from time to time. This indemnity includes any liability incurred by a director in defending any civil or criminal proceedings in which judgment is given in that director's favor or the director is acquitted or the proceedings are otherwise disposed of without any finding or admission of any material breach of duty on his part and we may provide the director with funds to meet expenditure incurred in connection with the proceedings set out above.

#### **General Meetings**

We must convene and hold annual general meetings once a year in accordance with the Companies Act 2006. Under the Companies Act 2006, an annual general meeting must be called by notice of at least 21 clear days and a general meeting must be called by notice of at least 14 clear days.

No business shall be transacted at any general meeting unless a quorum is present when the meeting proceeds to business, but the absence of a quorum shall not preclude the choice or appointment

of a chairperson of the meeting which shall not be treated as part of the business of the meeting. Save as otherwise provided by our Articles, shareholders holding thirty-three and one-third percent (33 ⅓%) of our issued shares (excluding any shares held as treasury shares) present in person or by proxy (or in the case of a corporation, by a representative) and entitled to vote shall be a quorum for all purposes.

#### ***Choice of Forum/Governing Law***

Our Articles provide that the courts of England and Wales is the exclusive forum for resolving all shareholder complaints other than shareholder complaints asserting a cause of action arising under the Securities Act and the Exchange Act, for which, 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 will be the exclusive forum. As a company incorporated in England and Wales, the choice of the courts of England and Wales as our exclusive forum for resolving all shareholder complaints, other than complaints arising under the Securities Act and the Exchange Act, allows us to more efficiently and affordably respond to such actions, and provides consistency in the application of the laws of England and Wales to such actions. Similarly, we have selected the United States District Court for the Southern District of New York as our exclusive forum for resolving shareholder complaints arising under the Securities Act and the Exchange Act in order to more efficiently and affordably respond to such claims. This choice of forum also provides both us and our shareholders with a forum that is familiar with and regularly reviews cases involving U.S. securities law. Although we believe this choice of forum benefits us by providing increased consistency in the application of U.S. securities law for the specified types of action, it may have the effect of discouraging lawsuits against our directors and officers. Any person or entity purchasing or otherwise acquiring any interest in our ordinary shares will be deemed to have notice of and consented to the provisions of our Articles, including the exclusive forum provision. However, it is possible that a court could find our forum selection provision to be inapplicable or unenforceable. The enforceability of similar exclusive forum provisions (including exclusive federal forum provisions for actions, suits or proceedings asserting a cause of action arising under the Securities Act) in other companies' organizational documents has been challenged in legal proceedings, and there is uncertainty as to whether courts would enforce the exclusive forum provisions in our Articles. Additionally, our shareholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. See "Risk Factors—Risks Related to this Offering and Ownership of Our ADSs— 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."

#### **Borrowing Powers**

Subject to our Articles and the Companies Act 2006, our board of directors may exercise all of our powers to:

- (a) borrow money;
- (b) indemnify and guarantee;
- (c) mortgage or charge;
- (d) create and issue debentures and other securities; and
- (e) give security either outright or as collateral security for any of our debt, liability or obligation or any of a third party.

### **Capitalization of Profits**

The directors may, if they are so authorized by an ordinary resolution of the shareholders, decide to capitalize any of our undivided profits not required for paying any preferential dividend (whether or not they are available for distribution), or any sum standing to the credit of any reserve or fund which is available for distribution or standing to the credit of our share premium account, capital redemption reserve or other undistributable reserve. The directors may also, subject to the aforementioned ordinary resolution, appropriate any sum which they so decide to capitalize to the persons who would have been entitled to it if it were distributed by way of dividend and in the same proportions.

### **Limitation on Owning Securities**

Neither English law nor our Articles restrict in any way the ownership or voting of our shares by non-residents.

### **Uncertificated Shares**

Subject to the Companies Act 2006 and any applicable uncertificated securities rules (as defined in our Articles), our board of directors may permit title to shares of any class to be issued or held otherwise than by a certificate and to be transferred by means of a "relevant system" (i.e., the CREST System) without a certificate and may make arrangements for a class of shares to be transferred to that relevant system.

Our board of directors may, subject to compliance with the uncertificated securities rules (as defined in our Articles), determine at any time that title to any class of shares must be in certificated form and that such class of shares will cease to be transferred to a relevant system from a date specified by our board of directors. Our board of directors may take such steps as it sees fit in relation to the evidencing of and transfer of title to uncertificated shares, any records relating to the holding of uncertificated shares and the conversion of uncertificated shares to certificated shares, or vice-versa. Ordinary shares may be changed from uncertificated to certified form (and vice versa) in accordance with and subject to the uncertificated securities rules (as defined in our Articles).

We may, by notice to the holder of an uncertificated share, require that share to be converted into certificated form.

If, and subject to under our Articles or pursuant to the Companies Act 2006, we are entitled to sell, transfer or otherwise dispose of, forfeit, re-allot, accept the surrender of or otherwise enforce a lien over an uncertificated share, such entitlement shall include the right of our board of directors to:

- (i) require the holder of the uncertified share by notice in writing to change that share from uncertified to certificated form;
- (ii) appoint any person to act on behalf of the holder of the uncertified share to take such steps as may be required in order to effect the transfer of that share; and
- (iii) take such other action that our board of directors considers appropriate to achieve the sale, transfer, disposal, forfeiture, re-allotment or surrender of that share or otherwise to enforce a lien in respect of that share.

Unless our board of directors determines otherwise, shares which a shareholder holds in uncertificated form shall be treated as separate holdings from any shares which that shareholder holds in certificated form and any shares issued or created out of or in respect of any uncertificated shares shall be uncertificated shares and any shares issued or created out of or in respect of any certificated shares shall be certificated shares.

Our board of directors may take such other action that our board of directors considers appropriate to achieve the sale, transfer, disposal, forfeiture, re-allotment or surrender of an uncertified share or otherwise to enforce a lien in respect of it.

## **Other Relevant UK Laws and Regulations**

### ***Mandatory Bid***

We believe that, as of the date of this prospectus, our place of central management and control is not 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 (a summary of which is set out below). In the event that this changes, or if the interpretation and application of the Takeover Code by the 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 subject to it are conducted. In particular, the Takeover Code contains certain rules in respect of mandatory offers. Under the Takeover Code:

- (a) any person who acquires, whether by a series of transactions over a period of time or not, an interest in shares which (taken together with shares in which he is already interested, and in which persons acting in concert with him or her are interested) carry 30% or more of the voting rights of a company; or
- (b) any person who, together with persons acting in concert with him or her, is interested in shares which in the aggregate carry not less than 30% of the voting rights of a company but does not hold shares carrying more than 50% of such voting rights and such person, or any person acting in concert with him or her, acquires an interest in any other shares which increases the percentage of shares carrying voting rights in which he is interested,

such person shall, except in limited circumstances, be obliged to extend offers, on the basis set out in Rules 9.3, 9.4 and 9.5 of the Takeover Code, to the holders of any class of equity share capital, whether voting or non-voting, and also to the holders of any other class of transferable securities carrying voting rights. Offers for different classes of equity share capital must be comparable; the Takeover Panel should be consulted in advance in such cases.

- (i) An offer under Rule 9 of the Takeover Code must be in cash and at the highest price paid for any interest in the shares by the person required to make an offer or any person acting in concert with him or her during the 12 months prior to the announcement of the offer.
- (ii) Under the Takeover Code, a “concert party” arises where persons acting together pursuant to an agreement or understanding (whether formal or informal and whether or not in writing) actively cooperate, through the acquisition by them of an interest in shares in a company, to obtain or consolidate control of the company. “Control” means holding, or aggregate holdings, of an interest in shares carrying 30% or more of the voting rights of the company, irrespective of whether the holding or holdings give de facto control.

### ***Squeeze-out***

- (i) Under Sections 979 to 982 of the Companies Act 2006, where a takeover offer has been made for us and the offeror has acquired, or unconditionally contracted to acquire, not less than 90% in value of the shares to which the offer relates and not less than 90% of the voting rights carried by those shares, it could then compulsorily acquire the remaining 10%. It would do so by sending a



notice to the outstanding shareholders telling them that it will compulsorily acquire their shares, provided that no such notice may be served after the end of: (a) the period of three months beginning with the day after the last day on which the offer can be accepted; or (b) if earlier, and the offer is not one to which section 943(1) of the Companies Act 2006 applies, the period of six months beginning with the date of the offer.

- (ii) Six weeks following service of the notice, the offeror must send a copy of it to the company together with the consideration for the ordinary shares to which the notice relates, and an instrument of transfer executed on behalf of the outstanding shareholder(s) by a person appointed by the offeror.
- (iii) The company will hold the consideration on trust for the outstanding shareholders.

#### ***Sell-out***

- (i) Sections 983 to 985 of the Companies Act 2006 also give minority shareholders in the company a right to be bought out in certain circumstances by an offeror who has made a takeover offer. If a takeover offer relating to all the ordinary shares of the company is made and the offeror has acquired or unconditionally agreed to acquire not less than 90% in value of the voting shares and not less than 90% of the voting rights carried by those shares, at any time before the end of the period within which the offer could be accepted, any holder of shares to which the offer related who had not accepted the offer could by a written communication to the offeror require it to acquire those shares. The offeror is required to give any shareholder notice of his right to be bought out within one month of that right arising. The offeror may impose a time limit on the rights of minority shareholders to be bought out, but that period cannot end less than three months after the end of the acceptance period, or, if longer a period of three months from the date of the notice.
- (ii) If a shareholder exercises his rights, the offeror is bound to acquire those shares on the terms of the offer or on such other terms as may be agreed.

#### ***Disclosure of Interest in Shares***

Pursuant to Part 22 of the Companies Act 2006, a company incorporated in England and Wales is empowered by notice in writing to require any person whom the company knows to be, or has reasonable cause to believe to be, interested in the company's shares or at any time during the three years immediately preceding the date on which the notice is issued to have been so interested, within a reasonable time to disclose to the company details of that person's interest and (so far as is within such person's knowledge) details of any other interest that subsists or subsisted in those shares.

Under our Articles, if a shareholder defaults in supplying us with the required details in relation to the shares in question, or the Default Shares, within the prescribed period of 14 days, the shareholder shall not be entitled to vote or exercise any other right conferred by membership in relation to general meetings. Where the Default Shares represent 0.25% or more in nominal value of the issued shares of the class in question (calculated exclusive of any shares held as treasury shares), the directors may direct that:

- any dividend or other money payable in respect of the Default Shares shall be retained by us without any liability to pay interest on it when such dividend or other money is finally paid to the shareholder; and/or
- no transfer by the relevant shareholder of shares (other than a transfer permitted in accordance with the provisions of our Articles) may be registered (unless such shareholder is not in default and the transfer does not relate to Default Shares).

### ***Purchase of Own Shares***

English law permits a public limited company to purchase its own shares out of the distributable profits of the company or the proceeds of a fresh issue of shares made for the purpose of financing the purchase, subject to complying with procedural requirements under the Companies Act 2006 and provided that its articles of association do not prohibit it from doing so. Our Articles, a summary of which is provided above, do not prohibit us from purchasing our own shares. A public limited company must not purchase its own shares if, as a result of the purchase, there would no longer be any issued shares of the company other than redeemable shares or shares held as treasury shares. Shares must be fully paid in order to be repurchased.

Any such purchase will be either a “market purchase” or “off-market purchase,” each as defined in the Companies Act 2006. A “market purchase” is a purchase made on a “recognized investment exchange” (other than an overseas exchange) as defined in the UK Financial Services and Markets Act 2000, as amended, or FSMA. An “off-market purchase” is a purchase that is not made on a “recognized investment exchange.” Both “market purchases” and “off-market purchases” require prior shareholder approval by way of an ordinary resolution. In the case of an “off-market purchase,” a company’s shareholders, other than the shareholders from whom the company is purchasing shares, must approve the terms of the contract to purchase shares and in the case of a “market purchase,” the shareholders must approve the maximum number of shares that can be purchased and the maximum and minimum prices to be paid by the company. Both resolutions authorizing “market purchases” and “off-market purchases” must specify a date, not later than five years after the passing of the resolution, on which the authority to purchase is to expire.

Nasdaq is an “overseas exchange” for the purposes of the Companies Act 2006 and does not fall within the definition of a “recognized investment exchange” for the purposes of FSMA and any purchase made by us would need to comply with the procedural requirements under the Companies Act 2006 that regulate “off-market purchases.”

A share buy-back by a company of its shares could give rise to UK stamp duty reserve tax and stamp duty at the rate of 0.5% of the amount or value of the consideration payable by the company (rounded up to the next £5.00). The charge to UK stamp duty reserve tax would be cancelled or, if already paid, repaid (generally with interest), where a transfer instrument for UK stamp duty purposes has been duly stamped within six years of the charge arising (either by paying the UK stamp duty or by claiming an appropriate relief) or if the instrument is otherwise exempt from UK stamp duty.

Our Articles do not have conditions governing changes to our capital which are more stringent than those required by law.

### ***Distributions and Dividends***

Under the Companies Act 2006, before a company can lawfully make a distribution or dividend, it must ensure that it has sufficient distributable reserves, as determined on a non-consolidated basis. The basic rule is that a company’s profits available for the purpose of making a distribution are its accumulated, realized profits, so far as not previously utilized by distribution or capitalization, less its accumulated, realized losses, so far as not previously written off in a reduction or reorganization of capital duly made. The requirement to have sufficient distributable reserves before a distribution or dividend can be paid applies to us and to each of our subsidiaries that has been incorporated under English law.

As a public company, it is also not sufficient that we have made a distributable profit for the purpose of making a distribution. An additional capital maintenance requirement is imposed on us to ensure that our net worth is at least equal to the amount of our capital. A public company can only make a distribution:

- if, at the time that the distribution is made, the amount of its net assets (that is, the total excess of assets over liabilities) is not less than the total of its called up share capital and undistributable reserves; and
- if, and to the extent that, the distribution itself, at the time that it is made, does not reduce the amount of the net assets to less than that total.

**Shareholder Rights**

Certain rights granted under the Companies Act 2006, including the right to requisition a general meeting or require a resolution to be put to shareholders at the annual general meeting, are only available to our members. For English law purposes, our members are the persons who are registered as the owners of the legal title to the shares and whose names are recorded in our share register. If a person who holds their ADSs in DTC wishes to exercise certain of the rights granted under the Companies Act 2006, they may be required to first take steps to withdraw their ADSs from the settlement system operated by DTC and become the registered holder of the shares in our share register. A withdrawal of shares from DTC may have tax implications.

**Exchange Controls**

There are no governmental laws, decrees, regulations or other legislation in the UK that may affect the import or export of capital, including the availability of cash and cash equivalents for use by us, or that may affect the remittance of dividends, interest, or other payments by us to non-resident holders of our ordinary shares or ADSs, other than, on current law, withholding tax requirements that may apply in respect of interest and royalties. There is no limitation imposed by English law or in our Articles on the right of non-residents to hold or vote shares.

**Differences in Corporate Law**

The applicable provisions of the Companies Act 2006 differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the Companies Act 2006 applicable to us and the General Corporation Law of the State of Delaware relating to shareholders' rights and protections.

	ENGLAND AND WALES	DELAWARE
Number of Directors	Under the Companies Act 2006, a public limited company must have at least two directors and the number of directors may be fixed by or in the manner provided for in a company's articles of association.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.

Removal of Directors	Under the Companies Act 2006, shareholders may remove a director without cause by an ordinary resolution (which is passed by a simple majority of those voting in person or by proxy at a general meeting) irrespective of any provisions of any service contract the director has with the company, provided 28 clear days' notice of the resolution has been given to the company and its shareholders. On receipt of notice of an intended resolution to remove a director, the company must forthwith send a copy of the notice to the director concerned. Certain other procedural requirements under the Companies Act 2006 must also be followed, such as allowing the director to make representations against his or her removal either at the meeting or in writing.	Under Delaware law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, shareholders may effect such removal only for cause, or (ii) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his or her removal would be sufficient to elect him or her if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.
Vacancies on the Board of Directors	Under English law, the procedure by which directors, other than a company's initial directors, are appointed is generally set out in a company's articles of association, provided that where two or more persons are appointed as directors of a public limited company by resolution of the shareholders, resolutions appointing each director must be voted on individually.	Under Delaware law, vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) or by a sole remaining director unless (i) otherwise provided in the certificate of incorporation or bylaws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.
Annual General Meeting	Under the Companies Act 2006, a public limited company must hold an annual general meeting within the six-month period beginning with the day following the company's annual accounting reference date.	Under Delaware law, the annual meeting of shareholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.
General Meeting	Under the Companies Act 2006, a general meeting of the shareholders of a public limited company may be called by the directors.	Under Delaware law, special meetings of the shareholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.
	Shareholders holding at least 5% of the paid-up capital of the company carrying voting rights at general meetings (excluding any paid up capital held as treasury shares) can require the directors to call a general meeting and, if the directors fail to do so within a certain period, may themselves (or any of them representing more than one half of the total voting rights of all of them) convene a general meeting.	

Notice of General Meetings	Under the Companies Act 2006, at least 21 clear days' notice must be given for an annual general meeting and any resolutions to be proposed at the meeting, subject to a company's articles of association providing for a longer period. Subject to a company's articles of association providing for a longer period, at least 14 clear days' notice is required for any other general meeting of a public limited company. In addition, certain matters, such as the removal of directors or auditors, require special notice, which is 28 clear days' notice. The shareholders of a company may in all cases consent to a shorter notice period, the proportion of shareholders' consent required being 100% of those entitled to attend and vote in the case of an annual general meeting and, in the case of any other general meeting, a majority in number of the members having a right to attend and vote at the meeting, being a majority who together hold not less than 95% in nominal value of the shares giving a right to attend and vote at the meeting.	Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the shareholders must be given to each shareholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour and purpose or purposes of the meeting.
Quorum	Subject to the provisions of a company's articles of association, the Companies Act 2006 provides that two shareholders present at a meeting (in person, by proxy or authorized representative under the Companies Act 2006) shall constitute a quorum for companies with more than one shareholder.	The certificate of incorporation or bylaws may specify the number of shares, the holders of which shall be present or represented by proxy at any meeting in order to constitute a quorum, but in no event shall a quorum consist of less than one third of the shares entitled to vote at the meeting. In the absence of such specification in the certificate of incorporation or bylaws, a majority of the shares entitled to vote, present in person or represented by proxy, shall constitute a quorum at a meeting of stockholders.
Proxy	Under the Companies Act 2006, at any meeting of shareholders, a shareholder may designate another person to attend, speak and vote at the meeting on their behalf by proxy.	Under Delaware law, at any meeting of shareholders, a shareholder may designate another person to act for such shareholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Preemptive Rights	<p>Under the Companies Act 2006, “equity securities,” being (i) shares in the company other than shares that, with respect to dividends and capital, carry a right to participate only up to a specified amount in a distribution, referred to as “ordinary shares,” or (ii) rights to subscribe for, or to convert securities into, ordinary shares, proposed to be allotted for cash must be offered first to the existing equity shareholders in the company in proportion to the respective nominal value of their holdings, unless an exception applies or a special resolution to the contrary has been passed by shareholders in a general meeting or the articles of association provide otherwise in each case in accordance with the provisions of the Companies Act 2006.</p>	<p>Under Delaware law, shareholders have no preemptive rights to subscribe to additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.</p>
Authority to Allot	<p>Under the Companies Act 2006, the directors of a company must not allot shares or grant rights to subscribe for or convert any security into shares unless an exception applies or an ordinary resolution has been passed by shareholders in a general meeting authorizing such allotment or the articles of association provide for such authorization, in each case in accordance with the provisions of the Companies Act 2006.</p>	<p>Under Delaware law, if the corporation’s charter or certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. The board of directors may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.</p>

Liability of  
Directors and  
Officers

Under the Companies Act 2006, any provision, whether contained in a company's articles of association or any contract or otherwise, that purports to exempt a director of a company, to any extent, from any liability that would otherwise attach to him or her in connection with any negligence, default, breach of duty or breach of trust in relation to the company, is void. Any provision by which a company directly or indirectly provides an indemnity, to any extent, for a director of the company or of an associated company against any liability attaching to him or her in connection with any negligence, default, breach of duty or breach of trust in relation to the company of which he or she is a director is also void except as permitted by the Companies Act 2006, which provides exceptions for the company to (i) purchase and maintain insurance against such liability; (ii) provide a "qualifying third party indemnity," or an indemnity against liability incurred by the director to a person other than the company or an associated company as long as he or she is successful in defending the claim or criminal proceedings; and (iii) provide a "qualifying pension scheme indemnity," or an indemnity against liability incurred in connection with the company's activities as trustee of an occupational pension plan.

Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its shareholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for:

- any breach of the director's duty of loyalty to the corporation or its shareholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or
- any transaction from which the director derives an improper personal benefit.

Voting Rights	<p>For an English company it is usual for the articles of association to provide that, unless a poll is demanded by the shareholders of a company or is required by the chairperson of the meeting or the company's articles of association, shareholders shall vote on all resolutions on a show of hands. Under the Companies Act 2006, a poll may be demanded by (i) not fewer than five shareholders having the right to vote on the resolution; (ii) any shareholder(s) representing not less than 10% of the total voting rights of all the shareholders having the right to vote on the resolution (excluding any voting rights attaching to treasury shares); or (iii) any shareholder(s) holding shares in the company conferring a right to vote on the resolution (excluding any voting rights attaching to treasury shares) being shares on which an aggregate sum has been paid up equal to not less than 10% of the total sum paid up on all the shares conferring that right. A company's articles of association may provide more extensive rights for shareholders to call a poll. Under English law, an ordinary resolution is passed on a show of hands if it is approved by a simple majority (more than 50%) of the votes cast by shareholders present (in person or by proxy) and entitled to vote. If a poll is demanded, an ordinary resolution is passed if it is approved by holders representing a simple majority of the total voting rights of shareholders present, in person or by proxy, who, being entitled to vote on the resolution. Special resolutions require the affirmative vote of not less than 75% of the votes cast by shareholders present, in person or by proxy, at the meeting.</p>	<p>Delaware law provides that, unless otherwise provided in the certificate of incorporation, each shareholder is entitled to one vote for each share of capital stock held by such shareholder.</p>
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Shareholder Vote  
on Certain  
Transactions

The Companies Act 2006 provides for schemes of arrangement, which are arrangements or compromises between a company and any class of shareholders or creditors and used in certain types of reconstructions, amalgamations, capital reorganizations or takeovers. These arrangements require:

- the approval at a shareholders' or creditors' meeting convened by order of the court, of a majority in number of shareholders or creditors or a class thereof representing 75% in value of the capital held by, or debt owed to, the class of shareholders or creditors, or class thereof present and voting, either in person or by proxy; and
- the approval of the court.

Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires:

- the approval of the board of directors; and
- the approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of the corporation entitled to vote on the matter.

Standard of Conduct for Directors	<p>Under English law, a director owes various statutory and fiduciary duties to the company, including:</p> <ul style="list-style-type: none"> <li>• to act in the way he considers, in good faith, would be most likely to promote the success of the company for the benefit of its members as a whole, and in doing so have regard (amongst other matters) to: (i) the likely consequences of any decision in the long-term, (ii) the interests of the company's employees, (iii) the need to foster the company's business relationships with suppliers, customers and others, (iv) the impact of the company's operations on the community and the environment, (v) the desirability to maintain a reputation for high standards of business conduct, and (vi) the need to act fairly as between members of the company;</li> <li>• to avoid a situation in which he has, or can have, a direct or indirect interest that conflicts, or possibly conflicts, with the interests of the company;</li> <li>• to act in accordance with the company's constitution and only exercise his powers for the purposes for which they are conferred;</li> <li>• to exercise independent judgment;</li> <li>• to exercise reasonable care, skill and diligence;</li> <li>• not to accept benefits from a third party conferred by reason of his being a director or doing, or not doing, anything as a director; and</li> <li>• a duty to declare any interest that he has, whether directly or indirectly, in a proposed or existing transaction or arrangement with the company.</li> </ul>	<p>Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the shareholders.</p> <p>Directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its shareholders. The duty of care generally requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself or herself of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he or she reasonably believes to be in the best interests of the corporation. He or she must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation.</p> <p>In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the shareholders.</p>
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Shareholder Suits	<p>Under English law, generally, the company, rather than its shareholders, is the proper claimant in an action in respect of a wrong done to the company or where there is an irregularity in the company's internal management. Notwithstanding this general position, the Companies Act 2006 provides that (i) a court may allow a shareholder to bring a derivative claim (that is, an action in respect of and on behalf of the company) in respect of a cause of action arising from a director's negligence, default, breach of duty or breach of trust and (ii) a shareholder may bring a claim for a court order where the company's affairs have been or are being conducted in a manner that is unfairly prejudicial to some of its shareholders.</p>	<p>Under Delaware law, a shareholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:</p> <ul style="list-style-type: none"><li>• state that the plaintiff was a shareholder at the time of the transaction of which the plaintiff complains or that the plaintiffs shares thereafter devolved on the plaintiff by operation of law; and</li><li>• allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action; or</li><li>• state the reasons for not making the effort.</li></ul> <p>Additionally, the plaintiff must remain a shareholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.</p>
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## Stock Exchange Listing

Our ADSs are listed on the Nasdaq Global Select Market under the symbol "CMPS."

## Transfer Agent and Registrar of Shares

Our share register is maintained by Neville Registrars Limited. The share register reflects only record owners of our ordinary shares. Holders of our ADSs are not treated as our shareholders and their names are therefore not be entered in our share register. The depositary, the custodian or their nominee(s) is the holder of the ordinary shares underlying our ADSs. Holders of our ADSs have a right to receive the ordinary shares underlying their ADSs. For discussion on our ADSs and ADS holder rights, see "Description of American Depositary Shares" in this prospectus.

## DESCRIPTION OF AMERICAN DEPOSITARY SHARES

### American Depositary Shares

Citibank, N.A. is the depositary bank for the American Depositary Shares. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. American Depositary Shares are frequently referred to as "ADSs" and represent ownership interests in securities that are on deposit with the depositary bank. ADSs may be represented by certificates that are commonly known as "American Depositary Receipts," or "ADRs." The depositary bank typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank, N.A. (London), located at Citigroup Centre, Canary Wharf, London, E14 5LB, United Kingdom.

We have appointed Citibank, N.A. as depositary pursuant to a deposit agreement. A copy of the deposit agreement is on file with the SEC under cover of a registration statement on Form F-6. You may obtain a copy of the deposit agreement from the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 and from the SEC's website ([www.sec.gov](http://www.sec.gov)). Please refer to registration number 333-248514 when retrieving such copy.

We are providing you with a summary description of the material terms of our ADSs and of your material rights as an owner of ADSs. Please remember that summaries by their nature lack the precision of the information summarized and that the rights and obligations of an owner of ADSs will be determined by reference to the terms of the deposit agreement and not by this summary. We urge you to review the deposit agreement in its entirety. The portions of this summary description that are italicized describe matters that may be relevant to the ownership of ADSs but that may not be contained in the deposit agreement.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in one ordinary share that is on deposit with the depositary and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary or the custodian on behalf of the owner of our ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary may agree to change our ADS-to-ordinary share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners. The custodian, the depositary and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of our ADSs. The depositary, the custodian and their respective nominees will be the record holders of the deposited property represented by our ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of our ADSs, the registered holders of our ADSs (on behalf of the applicable ADS owners) only through the depositary, and the depositary (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of our ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as owner of ADSs and those of the depositary. As an ADS holder you appoint the depositary to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares are governed by the laws of England and Wales, which may be different from the laws of the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

The manner in which you own the ADSs (i.e., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect your rights and obligations, and the manner in which, and extent to which, the depositary bank's services are made available to you. As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary will hold on your behalf the shareholder rights attached to the ordinary shares underlying your ADSs. As an owner of ADSs you will be able to exercise the shareholders rights for the ordinary shares represented by your ADSs through the depositary only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.

As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary in your name reflecting the registration of uncertificated ADSs directly on the books of the depositary (commonly referred to as the direct registration system or DRS). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary to the holders of our ADSs. The direct registration system includes automated transfers between the depositary and The Depository Trust Company, or DTC, the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as ADS owner. Banks and brokers typically hold securities such as our ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes you have opted to own our ADSs directly by means of an ADS registered in your name and, as such, we will refer to you as the "holder." When we refer to "you," we assume the reader owns ADSs and will own ADSs at the relevant time.

The registration of the ordinary shares in the name of the depositary or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of our ADSs representing the ordinary shares. The depositary or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of our ADSs representing the deposited property.

## **Dividends and Other Distributions**

As a holder of ADSs, you generally have the right to receive the distributions we make on the securities deposited with the custodian. Your receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction the applicable fees, taxes and expenses.

### ***Distributions of Cash***

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the

depository will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of England and Wales.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depository will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depository will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depository holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

#### ***Distributions of Shares***

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depository will either distribute to holders new ADSs representing the ordinary shares deposited or modify our ADS-to-ordinary shares ratio, in which case each ADS you hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of our ADS-to-ordinary share ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depository may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (i.e., the U.S. securities laws) or if it is not operationally practicable. If the depository does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

#### ***Distributions of Rights***

Whenever we intend to distribute rights to purchase additional ordinary shares, we will give prior notice to the depository and we will assist the depository in determining whether it is lawful and reasonably practicable to distribute rights to purchase additional ADSs to holders.

The depository will establish procedures to distribute rights to purchase additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). You may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of your rights. The depository is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to purchase new ordinary shares other than in the form of ADSs.

The depository will *not* distribute the rights to you if:

- we do not timely request that the rights be distributed to you or we request that the rights not be distributed to you; or

- we fail to deliver satisfactory documents to the depositary; or
- it is not reasonably practicable to distribute the rights.

The depositary will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary is unable to sell the rights, it will allow the rights to lapse.

#### ***Elective Distributions***

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to you. In such case, we will assist the depositary in determining whether such distribution is lawful and reasonably practicable.

The depositary will make the election available to you only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary will establish procedures to enable you to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to you, you will receive either cash or additional ADSs, depending on what a shareholder in England and Wales would receive upon failing to make an election, as more fully described in the deposit agreement.

#### ***Other Distributions***

Whenever we intend to distribute property other than cash, ordinary shares or rights to purchase additional ordinary shares, we will notify the depositary in advance and will indicate whether we wish such distribution to be made to you. If so, we will assist the depositary in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to you and if we provide all of the documentation contemplated in the deposit agreement, the depositary will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary may sell all or a portion of the property received.

The depositary will *not* distribute the property to you and will sell the property if:

- we do not request that the property be distributed to you or if we ask that the property not be distributed to you; or
- we do not deliver satisfactory documents to the depositary; or
- the depositary determines that all or a portion of the distribution to you is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

#### ***Redemption***

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary will convert the redemption funds received into U.S. dollars upon the terms of the deposit agreement and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary. You may have to pay fees, expenses, taxes and other governmental charges upon the redemption of your ADSs. If less than all ADSs are being redeemed, our ADSs to be retired will be selected by lot or on a pro rata basis, as the depositary may determine.

### **Changes Affecting Ordinary Shares**

The ordinary shares held on deposit for your ADSs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of our assets.

If any such change were to occur, your ADSs would, to the extent permitted by law, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary may in such circumstances deliver new ADSs to you, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of your existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to our ADSs the change affecting the ordinary shares. If the depositary may not lawfully distribute such property to you, the depositary may sell such property and distribute the net proceeds to you as in the case of a cash distribution.

### **Issuance of ADSs upon Deposit of Ordinary Shares**

Upon completion of this offering, the ordinary shares being offered pursuant to this prospectus will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depositary will issue ADSs to the underwriters named in this prospectus. After the completion of this offering, the ordinary shares that are being offered for sale pursuant to this prospectus will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depositary will issue ADSs to the underwriters named in this prospectus.

After the completion of this offering, the depositary may create ADSs on your behalf if you or your broker deposit ordinary shares with the custodian. The depositary will deliver these ADSs to the person you indicate only after you pay any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. Your ability to deposit ordinary shares and receive ADSs may be limited by United States and England and Wales legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary will only issue ADSs in whole numbers.

When you make a deposit of ordinary shares, you will be responsible for transferring good and valid title to the depositary. As such, you will be deemed to represent and warrant that:

- the ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained;
- all preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised;
- you are duly authorized to deposit the ordinary shares;



- the ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and our ADSs issuable upon such deposit will not be, “restricted securities” (as defined in the deposit agreement); and
- the ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary may, at your cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

### **Transfer, Combination and Split Up of ADRs**

As an ADR holder, you will be entitled to transfer, combine or split up your ADRs and our ADSs evidenced thereby. For transfers of ADRs, you will have to surrender the ADRs to be transferred to the depositary and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the depositary deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have your ADRs either combined or split up, you must surrender the ADRs in question to the depositary with your request to have them combined or split up, and you must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

### **Withdrawal of Ordinary Shares Upon Cancellation of ADSs**

As a holder, you will be entitled to present your ADSs to the depositary for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. Your ability to withdraw the ordinary shares held in respect of our ADSs may be limited by United States and England and Wales considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by your ADSs, you will be required to pay to the depositary the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. You assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, our ADSs will not have any rights under the deposit agreement.

If you hold ADSs registered in your name, the depositary may ask you to provide proof of identity and genuineness of any signature and such other documents as the depositary may deem appropriate before it will cancel your ADSs. The withdrawal of the ordinary shares represented by your ADSs may be delayed until the depositary receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary will only accept ADSs for cancellation that represent a whole number of securities on deposit.

You will have the right to withdraw the securities represented by your ADSs at any time except as a result of:

- temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends;

- obligations to pay fees, taxes and similar charges; and/or
- restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair your right to withdraw the securities represented by your ADSs except to comply with mandatory provisions of law.

### **Voting Rights**

As a holder, you generally have the right under the deposit agreement to instruct the depositary to exercise the voting rights for the ordinary shares represented by your ADSs. The voting rights of holders of ordinary shares are described in “Description of Share Capital and Articles of Association—Articles of Association” in this prospectus.

At our request, the depositary will distribute to you any notice of shareholders’ meeting received from us together with information explaining how to instruct the depositary to exercise the voting rights of the ordinary shares represented by ADSs.

If the depositary timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder’s ADSs as follows:

- In the event of voting by show of hands, the depositary will vote (or cause the custodian to vote) all ordinary shares held on deposit at that time in accordance with the voting instructions received from a majority of holders of ADSs who provide timely voting instructions.
- In the event of voting by poll, the depositary will vote (or cause the custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders of ADSs.

Securities for which no voting instructions have been received will not be voted (except as otherwise contemplated by the deposit agreement). Please note that the ability of the depositary to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure you that you will receive voting materials in time to enable you to return voting instructions to the depositary in a timely manner.

## Fees and Charges

As an ADS holder, you will be required to pay the following fees under the terms of the deposit agreement:

SERVICE	FEE
Issuance of ADSs (i.e., an issuance of ADS upon a deposit of ordinary shares or upon a change in our ADS(s)-to-ordinary shares ratio), excluding ADS issuances as a result of distributions of ordinary shares	Up to U.S. 5¢ per ADS issued
Cancellation of ADSs (i.e., a cancellation of ADSs for delivery of deposited property, upon a change in our ADS(s)-to-ordinary shares ratio, or for any other reason)	Up to U.S. 5¢ per ADS cancelled
Distribution of cash dividends or other cash distributions (i.e., upon a sale of rights and other entitlements)	Up to U.S. 5¢ per ADS held
Distribution of ADSs pursuant to (i) share dividends or other free share distributions, or (ii) exercise of rights to purchase additional ADSs	Up to U.S. 5¢ per ADS held
Distribution of securities other than ADSs or rights to purchase additional ADSs (i.e., upon a spin-off)	Up to U.S. 5¢ per ADS held
ADS Services	Up to U.S. 5¢ per ADS held on the applicable record date(s) established by the depositary bank
Registration of ADS transfers (i.e., upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and vice versa, or for any other reason)	Up to U.S. 5¢ per ADS (or fraction thereof) transferred
Conversion of ADSs of one series for ADSs of another series (i.e., upon conversion of Partial Entitlement ADSs for Full Entitlement ADSs, or upon conversion of Restricted ADSs (each as defined in the Deposit Agreement) into freely transferable ADSs, and vice versa)	Up to U.S. 5¢ per ADS (or fraction thereof) transferred

As an ADS holder you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the fees, expenses, spreads, taxes and other charges of the depositary and/or service providers (which may be a division, branch or affiliate of the depositary) in the conversion of foreign currency;
- the reasonable and customary out of pocket expenses incurred by the depositary in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees, charges, costs and expenses incurred by the depositary, the custodian or any nominee in connection with the ADR program.

ADS fees and charges for (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person for whom our ADSs are issued (in the case of ADS issuances) and to the person for whom ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary into DTC, our ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving our ADSs being issued or the DTC participant(s) holding our ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and our ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) our ADS service fee, holders as of our ADS record date will be invoiced for the amount of our ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, our ADS fees and charges for distributions other than cash and our ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs. In the case of (i) registration of ADS transfers, the ADS transfer fee will be payable by the ADS Holder whose ADSs are being transferred or by the person to whom the ADSs are transferred, and (ii) conversion of ADSs of one series for ADSs of another series, the ADS conversion fee will be payable by the Holder whose ADSs are converted or by the person to whom the converted ADSs are delivered.

In the event of refusal to pay the depositary fees, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to our ADS holder. Certain of the depositary fees and charges (such as our ADS services fee) may become payable shortly after the closing of our ADS offering. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary. You will receive prior notice of such changes. The depositary may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of our ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary agree from time to time.

### **Amendments and Termination**

We may agree with the depositary to modify the deposit agreement at any time without your consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to your substantial rights any modifications or supplements that are reasonably necessary for our ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges you are required to pay. In addition, we may not be able to provide you with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

You will be bound by the modifications to the deposit agreement if you continue to hold your ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent you from withdrawing the ordinary shares represented by your ADSs (except as permitted by law).

We have the right to direct the depositary to terminate the deposit agreement. Similarly, the depositary may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary must give notice to the holders at least 30 days before termination. Until termination, your rights under the deposit agreement will be unaffected.

## **Termination**

After termination, the depositary will continue to collect distributions received (but will not distribute any such property until you request the cancellation of your ADSs) and may sell the securities held on deposit. After the sale, the depositary will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

In connection with any termination of the deposit agreement, the depositary may make available to owners of ADSs a means to withdraw the ordinary shares represented by ADSs and to direct the depositary of such ordinary shares into an unsponsored American depositary share program established by the depositary. The ability to receive unsponsored American depositary shares upon termination of the deposit agreement would be subject to satisfaction of certain U.S. regulatory requirements applicable to the creation of unsponsored American depositary shares and the payment of applicable depositary fees.

## **Books of Depositary**

The depositary will maintain ADS holder records at its depositary office. You may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to our ADSs and the deposit agreement.

The depositary will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

## **Limitations on Obligations and Liabilities**

The deposit agreement limits our obligations and the depositary's obligations to you. Please note the following:

- We and the depositary are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depositary disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- The depositary disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to you on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- We and the depositary will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- We and the depositary disclaim any liability if we or the depositary are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our Articles, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.

- We and the depositary disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our Articles or in any provisions of or governing the securities on deposit.
- We and the depositary further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting ordinary shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the depositary also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to you.
- We and the depositary may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- We and the depositary also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.
- Nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary bank and you as ADS holder.
- Nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to us or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those transactions, to us or to the ADS owners, or to account for any payment received as part of those transactions.

*As the above limitations relate to our obligations and the depositary's obligations to you under the deposit agreement, we believe that, as a matter of construction of the clause, such limitations would likely to continue to apply to ADS holders who withdraw the ordinary shares from the ADS facility with respect to obligations or liabilities incurred under the deposit agreement before the cancellation of the ADSs and the withdrawal of the ordinary shares, and such limitations would most likely not apply to ADS holders who withdraw the ordinary shares from the ADS facility with respect to obligations or liabilities incurred after the cancellation of the ADSs and the withdrawal of the ordinary shares and not under the deposit agreement.*

*In any event, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder. In fact, you cannot waive our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.*

## **Taxes**

You will be responsible for the taxes and other governmental charges payable on our ADSs and the securities represented by our ADSs. We, the depositary and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary and the

custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary and to the custodian proof of taxpayer status and residence and such other information as the depositary and the custodian may require to fulfill their legal obligations. You are required to indemnify us, the depositary and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

### **Foreign Currency Conversion**

The depositary will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable holders.

### **Governing Law/Waiver of Jury Trial**

The deposit agreement, the ADRs and the ADSs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) are governed by the laws of England and Wales.

As an owner of ADSs, you irrevocably agree that any legal action arising out of the Deposit Agreement, the ADSs or the ADRs, involving the Company or the Depositary, may only be instituted in as state or federal court in the City of New York.

AS A PARTY TO THE DEPOSIT AGREEMENT, YOU IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT OR THE ADRs AGAINST US AND/OR THE DEPOSITARY.

*The deposit agreement provides that, to the extent permitted by law, ADS holders 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 ordinary shares, the ADSs or the deposit agreement, including any claim under U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law. However, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.*

## ORDINARY SHARES AND ADSs ELIGIBLE FOR FUTURE SALE

Based on the number of shares outstanding as of April 26, 2021, upon completion of this offering, and assuming no exercise of the underwriters' option to purchase additional ADSs, 41,006,873 of our ordinary shares, including ordinary shares underlying ADSs, will be outstanding, assuming the issuance of 4,000,000 ADSs offered by us in this offering. Future sales of ADSs in the public market after this offering, and the availability of ADSs for future sale, could adversely affect the market price of our ADSs prevailing from time to time. Some of the ADSs underlying our ordinary shares are subject to contractual and legal restrictions on resale as described below. There may be sales of substantial amounts of our ADSs or ordinary shares in the public market after such restrictions lapse, which could adversely affect prevailing market prices of our ADSs.

We expect 20,773,453 ADSs, or 21,373,453 ADSs if the underwriters exercise in full their option to purchase additional ADSs, sold in this offering will be freely transferable without restriction, except for any shares purchased by one or more of our existing "affiliates," as that term is defined in Rule 144 under the Securities Act of 1933, or the Securities Act. We expect the remaining 20,233,420 of our ordinary shares, including ordinary shares underlying ADSs, will be subject to the contractual 90-day lock-up period described below. This may adversely affect the prevailing market price of our ADSs and our ability to raise equity capital in the future.

### Rule 144

In general, persons who have beneficially owned restricted ordinary shares for at least six months, and any of our affiliates who own either restricted or unrestricted securities, are entitled to sell their securities without registration with the Securities and Exchange Commission, or SEC, under an exemption from registration provided by Rule 144 under the Securities Act.

#### ***Non-Affiliates***

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of restricted securities under Rule 144 if:

- the restricted securities have been held for at least six months, including the holding period of a prior owner other than one of our affiliates;
- we have been subject to the Securities Exchange Act of 1934, or the Exchange Act, periodic reporting requirements for at least 90 days before the sale; and
- we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the restricted securities for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of restricted securities without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting.

#### ***Affiliates***

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above. They are also subject to additional restrictions, by which such person would be required to comply with the manner of



sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

- 1% of the number of ordinary shares then outstanding, which will equal approximately 359,303 shares immediately after the completion of this offering based on the number of ordinary shares outstanding as of December 31, 2020; or
- the average weekly trading volume of our ADSs on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six-month holding period of Rule 144, which does not apply to sales of unrestricted securities.

#### **Rule 701**

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and in the section of this prospectus titled "Underwriting" and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

#### **Regulation S**

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus delivery requirements of the Securities Act, provided that no directed selling efforts (as that term is defined in Regulation S) are made in the United States, subject to certain other conditions. In general, this means that our ordinary shares may be sold in some manner outside the United States without requiring registration in the United States.

#### **Lock-up Agreements**

All of our directors, executive officers and substantially all of our shareholders have agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our ADSs, ordinary shares or such other securities for a period of 90 days after the date of this prospectus, without the prior written consent of Cowen and Company, LLC, Evercore Group L.L.C. and Berenberg Capital Markets LLC may waive the provisions of these agreements, in full or in part, at any time in their sole discretion. See "Underwriting."

## MATERIAL INCOME TAX CONSIDERATIONS

*The following summary contains a description of material UK and U.S. federal income tax consequences of the acquisition, ownership and disposition of our ordinary shares or ADSs. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to the decision to acquire ordinary shares or ADSs in this offering.*

### **Material U.S. Federal Income Tax Considerations for U.S. Holders**

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of our ordinary shares or ADSs. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire securities. This discussion applies only to a U.S. Holder that is an initial purchaser of the ordinary shares or ADSs pursuant to the offering and that holds our ordinary shares or ADSs as a capital asset for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including state and local tax consequences, estate tax consequences, alternative minimum tax consequences, the potential application of the Medicare contribution tax, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ordinary shares or ADSs as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to ordinary shares or ADSs;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt entities or government organizations;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes;
- regulated investment companies or real estate investment trusts;
- persons that own or are deemed to own 10% or more of the voting power or value of our ordinary shares or ADSs;
- persons who acquired our ordinary shares or ADSs pursuant to the exercise of any employee share option or otherwise as compensation;
- persons holding our ordinary shares or ADSs in connection with a trade or business, permanent establishment, or fixed base outside the United States; and
- persons who own (directly or through attribution) 10% or more (by vote or value) of our outstanding ordinary shares.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ordinary shares or ADSs, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ordinary shares or ADSs and partners in such partnerships are encouraged to consult their tax advisers as to the particular U.S. federal income tax consequences of holding and disposing of ordinary shares or ADSs.

The discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the income tax treaty between the UK and the United States, all as of the date hereof, changes to any of which may affect the tax consequences described herein—possibly with retroactive effect.

A “U.S. Holder” is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares or ADSs and is:

- (i) An individual who is a citizen or individual resident of the United States;
- (ii) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;
- (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- (iv) a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Generally, a U.S. Holder of an ADS should be treated for U.S. federal income tax purposes as holding the ordinary shares represented by our ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares. The U.S. Treasury has expressed concerns that intermediaries in the chain of ownership between the holder of an ADS and the issuer of the security underlying our ADS may be taking actions that are inconsistent with the beneficial ownership of the underlying security. Accordingly the creditability of foreign taxes, if any, as described below, could be affected by actions taken by intermediaries in the chain of ownership between the holders of ADSs and our company if as a result of such actions the holders of ADSs are not properly treated as beneficial owners of the underlying ordinary shares. These actions would also be inconsistent with the claiming of the reduced tax rate, described below, applicable to dividends received by certain non-corporate holders.

PERSONS CONSIDERING AN INVESTMENT IN ORDINARY SHARES OR ADSs SHOULD CONSULT THEIR OWN TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEM RELATING TO THE ACQUISITION, OWNERSHIP AND DISPOSITION OF THE ORDINARY SHARES OR ADSs, INCLUDING THE APPLICABILITY OF U.S. FEDERAL, STATE AND LOCAL TAX LAWS.

#### ***Passive Foreign Investment Company Rules***

If we are classified as a passive foreign investment company, or PFIC, in any taxable year, a U.S. Holder will be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income is passive income (such as interest income); or
- at least 50% of its gross assets (determined on the basis of a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income.

Based on the current and expected composition of our income and assets and the value of our assets, we do not expect to be a PFIC for our current taxable year. However, 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. If we are treated as a non-publicly traded CFC for the year being tested for purposes of the PFIC rules, the value of our assets will be measured by the adjusted tax basis of our assets. If we are a publicly traded CFC or not a CFC for such year, the value of our assets generally will be determined by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by the spending of the cash we raise in any offering, including this offering.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns the ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the tests described above unless (i) we cease to be a PFIC and the U.S. Holder has made a "deemed sale" election under the PFIC rules, or (ii) the U.S. Holder makes a Qualified Electing Fund Election, or QEF Election, with respect to all taxable years during such U.S. Holders holding period in which we are a PFIC. If the "deemed sale" election is made, a U.S. Holder will be deemed to have sold the ordinary shares or ADSs the U.S. Holder holds at their fair market value and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. Holder's ordinary shares or ADSs with respect to which such election was made will not be treated as shares in a PFIC and the U.S. Holder will not be subject to the rules described below with respect to any "excess distribution" the U.S. Holder receives from us or any gain from an actual sale or other disposition of the ordinary shares or ADSs. U.S. Holders should consult their tax advisors as to the possibility and consequences of making a deemed sale election if we cease to be a PFIC and such election becomes available.

For each taxable year we are treated as a PFIC with respect to U.S. Holders, U.S. Holders will be subject to special tax rules with respect to any "excess distribution" such U.S. Holder receives and any gain such U.S. Holder recognizes from a sale or other disposition (including, under certain circumstances, a pledge) of ordinary shares or ADSs, unless (i) such U.S. Holder makes a QEF Election or (ii) our ordinary shares or ADSs constitute "marketable" securities, and such U.S. Holder makes a mark-to-market election as discussed below. Distributions a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions a U.S. Holder received during the shorter of the three preceding taxable years or the U.S. Holder's holding period for the ordinary shares or ADSs will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over a U.S. Holder's holding period for the ordinary shares or ADSs;
- the amount allocated to the taxable year of disposition or distribution, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and

- the amount allocated to each other year will be subject to the highest tax rate in effect for that year for individuals or corporations, as appropriate, and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or “excess distribution” cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ordinary shares or ADSs cannot be treated as capital, even if a U.S. Holder holds the ordinary shares or ADSs as capital assets.

If we are a PFIC, a U.S. Holder will generally be subject to similar rules with respect to distributions we receive from, and our dispositions of the stock of, any of our direct or indirect subsidiaries that also are PFICs, as if such distributions were indirectly received by, and/or dispositions were indirectly carried out by, such U.S. Holder. U.S. Holders should consult their tax advisors regarding the application of the PFIC rules to our subsidiaries.

U.S. Holders can avoid the interest charge on excess distributions or gain relating to the ordinary shares or ADSs by making a mark-to-market election with respect to the ordinary shares or ADSs, provided that the ordinary shares or ADSs are “marketable.” Ordinary shares or ADSs will be marketable if they are “regularly traded” on certain U.S. stock exchanges or on a foreign stock exchange that meets certain conditions. For these purposes, the ordinary shares or ADSs will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs are listed on Nasdaq, which is a qualified exchange for these purposes. Consequently, if our ADSs remain listed on Nasdaq and are regularly traded, and you are a holder of ADSs, we expect the mark-to-market election would be available to you if we are a PFIC. Each U.S. Holder should consult its tax advisor as to the whether a mark-to-market election is available or advisable with respect to the ordinary shares or ADSs.

A U.S. Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of the ordinary shares or ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in the ordinary shares or ADSs. An electing holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted basis in the ordinary shares or ADSs over the fair market value of the ordinary shares or ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of the ordinary shares or ADSs will be treated as ordinary income, and any losses incurred on a sale or other disposition of the shares will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the Internal Revenue Service, or the IRS, unless the ordinary shares or ADSs cease to be marketable.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves “marketable.” As a result, even if a U.S. Holder validly makes a mark-to-market election with respect to our ordinary shares or ADSs, the U.S. Holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

We do not intend to provide information necessary for U.S. holders to make QEF elections which, if available, would result in tax treatment different from the general tax treatment for PFICs described above.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

WE STRONGLY URGE YOU TO CONSULT YOUR TAX ADVISOR REGARDING THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs.

#### ***Taxation of Distributions***

Subject to the discussion above under "Passive Foreign Investment Company Rules," distributions paid on ordinary shares or ADSs, other than certain pro rata distributions of ordinary shares or ADSs, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we may not calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations and the discussions above regarding concerns expressed by the U.S. Treasury, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to "qualified dividend income" if we are a "qualified foreign corporation" and certain other requirements are met. However, the qualified dividend income treatment will not apply if we are treated as a PFIC with respect to the U.S. Holder. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss. The amount of any distribution of property other than cash (and other than certain pro rata distributions of ordinary shares or ADSs or rights to acquire ordinary shares or ADSs) will be the fair market value of such property on the date of distribution.

For foreign tax credit limitation purposes, our dividends will generally be treated as passive category income. Because no UK income taxes will be withheld from dividends on ordinary shares or ADSs, there will be no creditable foreign taxes associated with any dividends that a U.S. Holder will receive. The rules governing foreign tax credits are complex and U.S. Holders should therefore consult their tax advisers regarding the effect of the receipt of dividends for foreign tax credit limitation purposes.

#### ***Sale or Other Taxable Disposition of Ordinary Shares and ADSs***

Subject to the discussion above under "Passive Foreign Investment Company Rules," gain or loss realized on the sale or other taxable disposition of ordinary shares or ADSs will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the ordinary shares or ADSs for more than one year at the time of sale or other taxable disposition. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ordinary shares or ADSs disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. Subject to the PFIC rules described above, long-term capital gains recognized by certain non-corporate U.S. Holders (including individuals) will generally be subject to reduced rates of U.S. federal income tax. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the ordinary shares or ADSs are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

#### ***Information Reporting and Backup Withholding***

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding on a duly executed IRS Form W-9 or otherwise establishes an exemption.

The amount of any backup withholding from a payment to a U.S. Holder may be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle the U.S. Holder to a refund, provided that the required information is timely furnished to the IRS.

#### ***Information with Respect to Foreign Financial Assets***

Certain U.S. Holders who are individuals (and, under regulations, certain entities) may be required to report information relating to the ordinary shares or ADSs, subject to certain exceptions (including an exception for ordinary shares or ADSs held in accounts maintained by certain U.S. financial institutions), by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. Such U.S. Holders who fail to timely furnish the required information may be subject to a penalty. Additionally, if a U.S. Holder does not file the required information, the statute of limitations with respect to tax returns of the U.S. Holder to which the information relates may not close until three years after such information is filed. U.S. Holders should consult their tax advisers regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares or ADSs.

#### ***UK Taxation***

The following is intended as a general guide to current UK tax law and HM Revenue & Customs, or HMRC, published practice (which is not binding) applying as at the date of this prospectus (both of which are subject to change at any time, possibly with retrospective effect) relating to the holding and disposing of ADSs. It does not constitute legal or tax advice and does not purport to be a complete analysis of all UK tax considerations relating to the holding of ADSs, or all of the circumstances in which holders of ADSs may benefit from an exemption or relief from UK taxation. It is written on the basis that we do not (and will not) directly or indirectly derive 75% or more of its qualifying asset value from UK land, and that we are and will remain solely resident in the UK for tax purposes and will therefore be subject to the UK tax regime and not the U.S. tax regime save as set out above under "Material U.S. Federal Income Tax Considerations for U.S. Holders."

Except to the extent that the position of non-UK resident persons is expressly referred to, this guide relates only to persons who are resident (and in the case of individuals, domiciled or deemed domiciled) for tax purposes solely in the UK and do not have a permanent establishment, branch or agency (or equivalent) in any other jurisdiction with which the holding of our ADSs is connected, or UK Holders, who are absolute beneficial owners of our ADSs (and do not hold our ADSs through an Individual Savings

Account or a Self-Invested Personal Pension) and any dividends paid in respect of our ADSs or underlying ordinary shares (where the dividends are regarded for U.K. tax purposes as that person's own income).

This guide may not relate to certain classes of UK Holders, such as (but not limited to):

- persons who are connected with us;
- financial institutions;
- insurance companies;
- charities or tax-exempt organizations;
- collective investment schemes;
- pension schemes;
- market makers, intermediaries, brokers or dealers in securities or persons who hold ADSs otherwise than as an investment;
- persons who have (or are deemed to have) acquired their ADSs by virtue of an office or employment or who are or have been our officers or employees or any of our affiliates; and
- individuals who are subject to UK taxation on a remittance basis or to whom split-year treatment applies.

It is assumed for the purposes of this guide that a holder of ADSs is the beneficial owner of the underlying ordinary shares and any dividends paid in respect of the underlying ordinary shares (where the dividends are regarded for UK tax purposes as that person's own income) for UK direct tax purposes.

THESE PARAGRAPHS ARE A SUMMARY OF CERTAIN UK TAX CONSIDERATIONS AND ARE INTENDED AS A GENERAL GUIDE ONLY. IT IS RECOMMENDED THAT ALL HOLDERS OF ADSs OBTAIN ADVICE AS TO THE CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSAL OF OUR ADSs IN THEIR OWN PARTICULAR CIRCUMSTANCES FROM THEIR OWN TAX ADVISORS. IN PARTICULAR, NON-UK RESIDENT OR DOMICILED PERSONS OR PERSONS SUBJECT TO TAXATION IN ANY JURISDICTION OTHER THAN THE UK ARE ADVISED TO CONSIDER THE POTENTIAL IMPACT OF ANY RELEVANT DOUBLE TAXATION AGREEMENTS.

### ***Dividends***

#### *Withholding Tax*

Dividends that we pay will not be subject to any withholding or deduction for or on account of UK tax.

#### *Income Tax*

An individual UK Holder may, depending on his or her particular circumstances, be subject to UK tax on dividends received from us. An individual holder of ADSs who is not resident for tax purposes in the UK should not be chargeable to UK income tax on dividends received from us unless he or she carries on (whether solely or in partnership) a trade, profession or vocation in the UK through a permanent establishment, branch or agency to which our ADSs are attributable. There are certain exceptions for trading in the UK through independent agents, such as some brokers and investment managers.

Dividend income is treated as the top slice of the total income chargeable to UK income tax for an individual UK Holder. An individual UK Holder who receives a dividend in the 2021/2022 tax year will be



entitled to a tax-free allowance of £2,000. Income within the dividend allowance counts towards an individual's basic or higher rate limits and may, therefore, affect the level of personal allowance to which they are entitled. Dividend income in excess of this tax-free allowance will (subject to the availability of any income tax personal allowance) be taxed at 7.5% (for the tax year 2021/2022) to the extent the excess amount falls within the basic rate band, 32.5% (for the tax year 2021/2022) to the extent the excess amount falls within the higher rate band, and 38.1% (for the tax year 2021/2022) to the extent the excess amount falls within the additional rate band.

#### *Corporation Tax*

A corporate holder of ADSs who is not resident for tax purposes in the UK should not be chargeable to UK corporation tax on dividends received from us unless it carries on (whether solely or in partnership) a trade in the UK through a permanent establishment to which our ADSs are attributable.

Corporate UK Holders should not be subject to UK corporation tax on any dividend received from us so long as the dividends qualify for exemption, which should be the case, although certain conditions must be met. It should be noted that the exemptions, whilst of wide application, are not comprehensive and are subject to anti-avoidance rules in relation to a dividend. If the conditions for the exemption are not satisfied or such anti-avoidance provisions apply, or such UK Holder elects for an otherwise exempt dividend to be taxable, UK corporation tax will be chargeable on the amount of any dividends (at the current rate of 19% for the tax year 2021/2022 rising to 25% in the tax year 2023/2024 for companies with profits of more than £50,000 whilst the rate of 19% will apply to companies with profits not exceeding £50,000 with a tapered rate applying to profits between £50,000 and £250,000).

#### **Chargeable Gains**

A disposal or deemed disposal of ADSs by a UK Holder may, depending on the UK Holder's circumstances and subject to any available exemptions or reliefs (such as the annual exemption), give rise to a chargeable gain or an allowable loss for the purposes of UK capital gains tax and corporation tax on chargeable gains.

If an individual UK Holder who is subject to UK income tax at either the higher or the additional rate is liable to UK capital gains tax on the disposal of ADSs, the applicable rate will be 20% (for the tax year 2021/2022). For an individual UK Holder who is subject to UK income tax at the basic rate and liable to UK capital gains tax on such disposal, the applicable rate would be 10% (for the tax year 2021/2022), save to the extent that any capital gains when aggregated with the UK Holder's other taxable income and gains in the relevant tax year exceed the unused basic rate tax band. In that case, the rate applicable to the excess would be 20% (for the tax year 2021/2022).

If a corporate UK Holder becomes liable to UK corporation tax on the disposal (or deemed disposal) of ADSs, the main rate of UK corporation tax would apply (currently 19% for the tax year 2021/2022 rising to 25% in the tax year 2023/2024 for companies with profits of more than £50,000 whilst the rate of 19% will apply to companies with profits not exceeding £50,000 with a tapered rate applying to profits between £50,000 and £250,000).

A holder of ADSs that is not resident for tax purposes in the UK should not normally be liable to UK capital gains tax or corporation tax on chargeable gains on a disposal (or deemed disposal) of ADSs, unless the person is carrying on (whether solely or in partnership) a trade, profession or vocation in the UK through a branch or agency (or, in the case of a corporate holder of ADSs, through a permanent establishment) to which our ADSs are attributable. However, an individual holder of ADSs who has ceased to be resident for tax purposes in the UK or is treated as resident outside the UK for the purposes of a double taxation treaty for a period of five years or less and who disposes of ADSs during that period of temporary non-residence may be liable on his or her return to the UK (or upon ceasing to be regarded as resident outside the U.K. for the purposes of double taxation treaty) to UK tax on any capital gain realized (subject to any available exemption or relief).

### **Stamp Duty and Stamp Duty Reserve Tax**

*The discussion below relates to the holders of our ordinary shares or ADSs wherever resident, however it should be noted that special rules may apply to certain persons such as market makers, brokers, dealers or intermediaries.*

#### *Issue of Ordinary Shares*

No UK stamp duty or stamp duty reserve tax, or SDRT, is generally payable on the issue of the ordinary shares underlying our ADSs.

#### *Transfers of Ordinary Shares*

An unconditional agreement to transfer ordinary shares will normally give rise to a charge to SDRT at the rate of 0.5% of the amount or value of the consideration payable for the transfer. The purchaser of the shares is liable for the SDRT. Transfers of ordinary shares in certificated form are generally also subject to stamp duty at the rate of 0.5% of the amount or value of the consideration given for the transfer (rounded up to the next £5.00). Stamp duty is normally paid by the purchaser. The charge to SDRT will be cancelled or, if already paid, repaid (generally with interest), where a transfer instrument has been duly stamped within six years of the charge arising, (either by paying the stamp duty or by claiming an appropriate relief) or if the instrument is otherwise exempt from stamp duty.

#### *Clearance Services and Depositary Receipts*

Under current UK tax law and published HMRC practice, no SDRT (and, where the transfer is effected by a written instrument, stamp duty) is generally payable where an issue or transfer of ordinary shares (including an unconditional agreement to transfer ordinary shares) to a clearance service or a depositary receipt system (including to a nominee or agent for, a person whose business is or includes the issue of depositary receipts or the provision of clearance services) is an integral part of an issue of share capital. It is understood that HMRC regards the facilities of DTC as a clearance service for these purposes.

#### *Issue or Transfers of ADSs*

No UK SDRT or stamp duty is required to be paid in respect of the issue of or an agreement to transfer ADSs (including by way of a paperless transfer of ADSs through the facilities of DTC).

## UNDERWRITING

We and Cowen and Company, LLC, Evercore Group L.L.C. and Berenberg Capital Markets LLC, as the representatives of the several underwriters for the offering named below have entered into an underwriting agreement with respect to the ADSs being offered. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase from us the number of ADSs set forth opposite its name below. Cowen and Company, LLC, Evercore Group L.L.C. and Berenberg Capital Markets LLC are the representatives of the underwriters.

<u>Underwriters</u>	<u>Number of ADSs</u>
Cowen and Company, LLC	1,320,000
Evercore Group L.L.C.	1,120,000
Berenberg Capital Markets LLC	680,000
Cantor Fitzgerald & Co.	480,000
BTIG, LLC	400,000
Total	4,000,000

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent and that the underwriters have agreed, severally and not jointly, to purchase all of the ADSs sold under the underwriting agreement if any of these ADSs are purchased, other than those ADSs covered by the option to purchase additional ADSs described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the ADSs, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

*Option to Purchase Additional ADSs.* We have granted to the underwriters an option to purchase up to 600,000 additional ADSs at the public offering price, less the underwriting discounts and commissions. This option is exercisable for a period of 30 days from the date of this prospectus. To the extent that the underwriters exercise this option, the underwriters will purchase additional ADSs from us in approximately the same proportion as shown in the table above.

*Discounts and Commissions.* The following table shows the public offering price, underwriting discounts and commissions and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional ADSs.

We estimate that the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$0.96 million and are payable by us. We also have agreed to reimburse the underwriters for up to \$20,000 for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

	Per ADS	Without Over-Allotment	With Over- Allotment
Public offering price	\$36.00	\$144,000,000	\$165,600,000
Underwriting discount	\$2.16	\$8,640,000	\$9,936,000
Proceeds, before expenses, to us	\$33.84	\$135,360,000	\$155,664,000

The underwriters propose to offer the ADSs to the public at the public offering price set forth on the cover of this prospectus. The underwriters may offer the ADSs to securities dealers at the public offering price less a concession not in excess of \$1.296 per ADS. If all of the ADSs are not sold at the public offering price, the underwriters may change the offering price and other selling terms. Sales of ADSs made outside of the United States may be made by affiliates of certain of the underwriters. Certain of the underwriters may sell ADSs through one or more of their affiliates as selling agents.

Our ADSs are listed on the Nasdaq Global Market under the symbol "CMPS."

*Stabilization.* In connection with this offering, the underwriters may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase ADSs so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the ADSs while the offering is in progress.
- Overallotment transactions involve sales by the underwriters of ADSs in excess of the number of ADSs the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of ADSs over-allotted by the underwriters is not greater than the number of ADSs that they may purchase pursuant to the option to purchase additional ADSs. In a naked short position, the number of ADSs involved is greater than the number of ADSs that the underwriters have the option to purchase. The underwriters may close out any short position by exercising their option to purchase additional ADSs and/or purchasing ADSs in the open market.
- Syndicate covering transactions involve purchases of ADSs in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of ADSs to close out the short position, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market as compared with the price at which they may purchase ADSs through exercise of the option to purchase additional ADSs. If the underwriters sell more ADSs than could be covered by exercise of the option to purchase additional ADSs and, therefore, have a naked short position, the position can be closed out only by buying ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the ADSs in the open market that could adversely affect investors who purchase in the offering.
- Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the ADSs originally sold by that syndicate member is purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our ADSs or preventing or retarding a decline in the market price of our ADSs. As a result, the price of our ADSs in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price

of our ADSs. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

*Passive Market Making.* In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our ADSs on the Nasdaq Global Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended, during a period before the commencement of offers or sales of ADSs and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, such bid must then be lowered when specified purchase limits are exceeded.

*Lock-Up Agreements.* Pursuant to certain "lock-up" agreements, we and our executive officers, directors and certain of our affiliated shareholders, have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic consequence of ownership of, directly or indirectly, or make any demand or request or exercise any right with respect to the registration of, or file with the SEC a registration statement under the Securities Act relating to, any ADSs or securities convertible into or exchangeable or exercisable for any ADSs without the prior written consent of Cowen and Company, LLC, Evercore Group L.L.C. and Berenberg Capital Markets LLC for a period of 90 days after the date of the pricing of the offering. Cowen and Company, LLC, Evercore Group L.L.C. and Berenberg Capital Markets LLC may waive the provisions of these agreements, in full or in part, at any time in their sole discretion.

This lock-up provision applies to ADSs and to securities convertible into or exchangeable or exercisable for ADSs. It also applies to ADSs owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The exceptions permit our executive officers, directors and certain of our affiliated shareholders, among other things and subject to restrictions, to: (a) issue ADSs or options pursuant to employee benefit plans, (b) issue ADSs upon exercise of outstanding options or warrants or (c) issue securities in connection with acquisitions or similar transactions. The exception permit parties to the "lock-up" agreements, among other things and subject to restrictions, to: (a) make certain gifts, (b) if the party is a corporation, partnership, limited liability company or other business entity, make transfers to transfers to any securityholder, partner or member of, or owner of a similar equity interest in, the party, as the case may be, if, in any such case, such transfer is not for value, (c) if the party is a trust, make certain distributions to beneficiaries if such transfer is not for value, (d) if the party is a corporation, partnership, limited liability company or other business, corporate or similar legal entity in its place of incorporation, any transfer made by the party (i) in connection with the sale or other bona fide transfer in a single transaction of all or substantially all of the party's share capital, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the party's assets, in any such case not undertaken for the purpose of avoiding the restrictions imposed by the lock-up or (ii) to another corporation, partnership, limited liability company or other business entity so long as the transferee is an affiliate of the party and such transfer is not for value, (e) transfers made solely by operation of law, such as pursuant to a qualified domestic order or in connection with a divorce settlement, (f) transfers to us pursuant to agreements in effect on the date of the final prospectus relating to this offering under which we has the option to repurchase such shares upon termination of the party's service to us, (g) make transfers to us to satisfy tax withholding obligations pursuant to our equity incentive plans disclosed in this prospectus, (h) transfers pursuant to third-party tender offer, merger, consolidation or other similar transaction, (i) enter into transactions relating to ordinary shares represented by ADSs acquired in open market transactions after completion of the offering, provided that no public announcement or filing is required to be made regarding such transaction during the 90-day lockup period, (j) enter into a 10b5-1 trading plan, provided that such plan does not permit the sale of any ordinary shares (including ordinary shares represented by ADSs) during the 90-day lock-up period and no public announcement or filing is made regarding such plan during the 90-day lock-up period, and (k) makes sales under a 10b5-1 trading plan in existence as of the date of the lockup.

Cowen and Company, LLC, Evercore Group L.L.C. and Berenberg Capital Markets LLC in their sole discretion, may release our ADSs and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release our ADSs and other securities from lock-up agreements, Cowen and Company, LLC, Evercore Group L.L.C. and Berenberg Capital Markets LLC will consider, among other factors, the holder's reasons for requesting the release, the number of ADSs for which the release is being requested and market conditions at the time of the request.

In connection with our initial public offering, we and all of our directors and executive officers and substantially all of our stockholders agreed to 180 day lock-up agreements on substantially the same terms as the 90 day lock-up agreements for this offering. The Representatives have waived the lock-up agreement from our initial public offering to the extent necessary to permit us to sell shares of our common stock in this offering.

#### *Selling Restrictions*

*Canada.* The ADSs may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the ADSs must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

*Switzerland.* The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

*European Economic Area.* In relation to each Member State of the European Economic Area (each a Relevant State), no ADSs have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the ADSs which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the ADSs may be offered to the public in that Relevant State at any time:

- (a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of ADSs shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any ADSs or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with us and each of the underwriters and that it is a “qualified investor” within the meaning of Article 2(e) of the Prospectus Regulation.

In the case of any ADSs being offered to a financial intermediary as that term is used in Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the ADSs acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any ADSs to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an “offer to the public” in relation to the ADSs in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any ADSs to be offered so as to enable an investor to decide to purchase or subscribe for any ADSs, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

*United Kingdom* No ADSs have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the ADSs which has been approved by the Financial Conduct Authority, except that the ADSs may be offered to the public in the United Kingdom at any time:

- (a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the ADSs shall require us or any of the underwriters to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to the ADSs in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any ADSs to be offered so as to enable an investor to decide to purchase or subscribe for any ADSs and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the UK Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the “Order,” and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2) (a) to (d) of the Order (all such persons together being referred to as “relevant persons”). In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons. Any person in the UK who is not a relevant person must not act on or rely upon this document or any of its contents.

*Hong Kong.* The ADSs have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the ADSs has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to ADSs which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made thereunder.

*Singapore.* Each underwriter has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each underwriter has represented and agreed that it has not offered or sold any ADSs or caused the ADSs to be made the subject of an invitation for subscription or purchase and will not offer or sell any ADSs or cause the ADSs to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs, whether directly or indirectly, to any person in Singapore other than:

- (a) (to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA)) pursuant to Section 274 of the SFA;
- (b) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or
- (c) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA. Where the ADSs are purchased under Section 275 of the SFA by a relevant person which is:
  - (A) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
  - (B) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (however described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the ADSs pursuant to an offer made under Section 275 of the SFA except:

- (i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (ii) where no consideration is or will be given for the transfer;
- (iii) where the transfer is by operation of law;
- (iv) as specified in Section 276(7) of the SFA; or



- (v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Singapore SFA Product Classification - In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of ADSs, we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the ADSs are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

*Israel.* In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase ADSs under the Israeli Securities Law, 5728 - 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728-1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 - 1968, subject to certain conditions, collectively, the Qualified Investors. The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. We have not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 - 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our ADSs to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728 - 1968. In particular, we may request, as a condition to be offered ADSs, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 - 1968 and the regulations promulgated thereunder in connection with the offer to be issued ADSs; (iv) that the ADSs that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 - 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 - 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriters and their respective affiliates, with a view to the final placement of the securities as contemplated in this document. Accordingly, no purchaser of the ADSs, other than the underwriters, is authorized to make any further offer of ADSs on our behalf or on behalf of the underwriters.

*Other Relationships.* Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees. Certain of our underwriters also served as underwriters in our initial public offering in September 2020.

*Electronic Offer, Sale and Distribution of ADSs.* A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute

prospectuses electronically Cowen and Company, LLC, Evercore Group L.L.C. and Berenberg Capital Markets LLC may agree to allocate a number of ADSs to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

## EXPENSES OF THIS OFFERING

Set forth below is an itemization of the total expenses, excluding the underwriting discounts and commissions, which are expected to be incurred in connection with the sale of ADSs in this offering. With the exception of the registration fee payable to the SEC and the filing fee payable to FINRA, all amounts are estimates.

EXPENSE	AMOUNT	
SEC registration fee	\$	18,031
FINRA filing fee		25,340
Printing expenses		100,000
Legal fees and expenses		325,000
Accounting fees and expenses		276,000
Transfer agent and registrar fees and expenses		200,000
Miscellaneous fees and expenses		15,629
<b>Total</b>	\$	960,000

## **LEGAL MATTERS**

The validity of our ADSs and our ordinary shares and certain other matters of U.S. federal law and English law will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts and Goodwin Procter (UK) LLP, London, United Kingdom, respectively. Legal counsel to the underwriters in connection with this offering are Cooley LLP, New York, New York with respect to U.S. federal law and Cooley (UK) LLP, London, United Kingdom with respect to English law.

## **EXPERTS**

The financial statements as of December 31, 2020 and December 31, 2019 and for the years then ended included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The registered business address of PricewaterhouseCoopers LLP is 1 Embankment Place, London, WC2N 6RH, United Kingdom.

## **SERVICE OF PROCESS AND ENFORCEMENT OF LIABILITIES**

We are incorporated and currently existing under the laws of England and Wales. In addition, certain of our directors and officers reside outside of the United States and most of the assets of our non-U.S. subsidiaries are located outside of the United States. As a result, it may be difficult for investors to effect service of process on us or those persons in the United States or to enforce in the United States judgments obtained in United States courts against us or those persons based on the civil liability or other provisions of the United States securities laws or other laws.

In addition, uncertainty exists as to whether the courts of England and Wales would:

- recognize or enforce judgments of United States courts obtained against us or our directors or officers predicated upon the civil liabilities provisions of the securities laws of the United States or any state in the United States; or
- entertain original actions brought in England and Wales against us or our directors or officers predicated upon the securities laws of the United States or any state in the United States.

We have been advised by Goodwin Procter LLP that there is currently no treaty between (i) the United States and (ii) England and Wales providing for reciprocal recognition and enforcement of judgments of United States courts in civil and commercial matters (although the United States and the UK are both parties to the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards) and that a final judgment for the payment of money rendered by any general or state court in the United States based on civil liability, whether or not predicated solely upon the United States securities laws, would not be automatically enforceable in England and Wales. We have also been advised by Goodwin Procter LLP that any final and conclusive monetary judgment for a definite sum obtained against us in United States 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:

- the relevant U.S. court had jurisdiction over the original proceedings according to English conflicts of laws principles at the time when proceedings were initiated;

- the courts of England and Wales had jurisdiction over the matter on enforcement and we either submitted to such jurisdiction or were resident or carrying on business within such jurisdiction and were duly served with process;
- the U.S. judgment was final and conclusive on the merits in the sense of being final and unalterable in the court that pronounced it and being for a definite sum of money;
- the judgment given by the courts was not in respect of penalties, taxes, fines or similar fiscal or revenue obligations (or otherwise based on a U.S. law that the courts of England and Wales consider to relate to a penal, revenue or other public law);
- the judgment was not procured by fraud;
- recognition or enforcement of the judgment in England and Wales would not be contrary to public policy or the Human Rights Act 1998;
- the proceedings pursuant to which judgment was obtained were not contrary to natural justice;
- the U.S. judgment was not arrived at by doubling, trebling or otherwise multiplying a sum assessed as compensation for the loss or damages sustained and not being otherwise in breach of Section 5 of the UK Protection of Trading Interests Act 1980, or is a judgment based on measures designated by the Secretary of State under Section 1 of that Act;
- there is not a prior decision of the courts of England and Wales or the court of another jurisdiction on the issues in question between the same parties; and
- the English enforcement proceedings were commenced within the limitation period.

Whether these requirements are met in respect of a judgment based upon the civil liability provisions of the United States 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.

Subject to the foregoing, investors may be able to enforce in England and Wales judgments in civil and commercial matters that have been obtained from U.S. federal or state courts. Nevertheless, we cannot assure you that those judgments will be recognized or enforceable in England and Wales.

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. In addition, it may not be possible to obtain an English judgment or to enforce that judgment if the judgment debtor is or becomes subject to any insolvency or similar proceedings, or if the judgment debtor has any set-off or counterclaim against the judgment creditor. Also note that, in any enforcement proceedings, the judgment debtor may raise any counterclaim that could have been brought if the action had been originally brought in England unless the subject of the counterclaim was in issue and denied in the U.S. proceedings. It should also be noted that in the courts of England and Wales system the usual rule is that the losing party is ordered to pay the legal costs of the litigation that were incurred by the successful party. These costs are assessed by the courts of England and Wales at the conclusion of the litigation.

## **WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the Securities and Exchange Commission, or SEC, a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act of 1933, or the Securities Act. We have also filed a related registration statement on Form F-6 (File No. 333-248514) with the SEC to register the ADSs. This prospectus, which forms a part of the registration statement, does not contain all of the information included in the registration statement and the exhibits and schedules to the registration statement. Certain information is omitted and you should refer to the registration statement and its exhibits and schedules for that information. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

The SEC maintains an Internet website (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding issuers, like us, that file electronically with the SEC. We maintain a corporate website at [www.compasspathways.com](http://www.compasspathways.com). Information contained in, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

We are subject to the information reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, applicable to foreign private issuers. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and current reports on Form 6-K. Those reports may be inspected without charge at the locations described above. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

As a foreign private issuer, we are also exempt from the requirements of Regulation FD (Fair Disclosure) which, generally, are meant to ensure that select groups of investors are not privy to specific information about an issuer before other investors. We are, however, still subject to the anti-fraud and anti-manipulation rules of the SEC, such as Rule 10b-5. Since many of the disclosure obligations required of us as a foreign private issuer are different than those required of U.S. domestic reporting companies, our shareholders, potential shareholders and the investing public in general should not expect to receive information about us in the same amount, or at the same time, as information is received from, or provided by, other U.S. domestic reporting companies. We are only liable for violations of the rules and regulations of the SEC that apply to us as a foreign private issuer.

We will send the depositary a copy of all notices of shareholders meetings and other reports, communications and information that are made generally available to shareholders. The depositary has agreed to mail to all holders of ADSs a notice containing the information (or a summary of the information) contained in any notice of a meeting of our shareholders received by the depositary and will make available to all holders of ADSs such notices and all such other reports and communications received by the depositary.

## **INCORPORATION BY REFERENCE OF CERTAIN DOCUMENTS**

The SEC allows us to “incorporate by reference” information from other documents that we file with it, which means that we can disclose information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. We incorporate by

reference into this prospectus and the registration statement of which this prospectus is a part our Annual Report on Form 20-F for the year ended December 31, 2020, filed with the SEC on March 9, 2021.

We will provide to each person at their request, including any beneficial owner, to whom a prospectus is delivered, a copy of the document that has been incorporated by reference into this prospectus but not delivered with this prospectus, upon written or oral request at no cost to the requester. Please direct your request, either in writing or by telephone, to COMPASS Pathways plc, Attention: Investor Relations, 1 Ashley Road, 3rd Floor, Altrincham, Cheshire WA14 2DT, United Kingdom, and our telephone number is +1-646-905-3974. In addition, a copy of the document incorporated herein by reference may be accessed at our website at [www.compasspathways.com](http://www.compasspathways.com). The reference to our website address does not constitute incorporation by reference of the information contained on or accessible through our website, and you should not consider the contents of our website in making an investment decision with respect to our ADSs.

**INDEX TO THE FINANCIAL STATEMENTS**  
**Consolidated Financial Statements of COMPASS Pathways Plc**

**INDEX TO ANNUAL CONSOLIDATED FINANCIAL STATEMENTS**

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## **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of COMPASS Pathways Plc

### ***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of COMPASS Pathways Plc and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, of convertible preferred shares and shareholders' equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

### ***Basis for Opinion***

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

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

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

/s/PricewaterhouseCoopers LLP  
Reading, United Kingdom  
March 9, 2021

We have served as the Company's auditor since 2018.

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

	December 31,	
	2020	2019
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash	\$ 190,327	\$ 24,966
Restricted cash	29	18
Prepaid expenses and other current assets	12,048	7,187
Total current assets	202,404	32,171
Investment	529	—
Property and equipment, net	245	218
Deferred tax assets	221	—
Other assets	57	—
Total assets	\$ 203,456	\$ 32,389
<b>LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' DEFICIT</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 2,739	\$ 1,262
Accounts payable - due to a related party	8	63
Accrued expenses and other liabilities	4,148	1,457
Convertible notes payable	—	12,397
Convertible notes payable - due to a related party	—	8,692
Total current liabilities	6,895	23,871
Total liabilities	6,895	23,871
Commitments and contingencies (Note 14)		
Convertible preferred shares, £0.008 par value; no shares authorized, issued and outstanding at December 31, 2020; 9,782,505 shares authorized, issued and outstanding at December 31, 2019; aggregate liquidation preference of \$39,279 at December 31, 2019	—	38,908
<b>SHAREHOLDERS' EQUITY (DEFICIT):</b>		
Ordinary shares, £0.008 par value; 35,930,331 and 10,752,429 shares authorized, issued and outstanding at December 31, 2020 and 2019, respectively	367	111
Deferred shares, £21,921.504 par value; one share authorized, issued and outstanding at December 31, 2020; no shares authorized, issued and outstanding at December 31, 2019	28	—
Additional paid-in capital	279,480	7,162
Accumulated other comprehensive income (loss)	14,585	(98)
Accumulated deficit	(97,899)	(37,565)
Total shareholders' equity (deficit)	196,561	(30,390)
Total liabilities, convertible preferred shares and shareholders' deficit	\$ 203,456	\$ 32,389

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

**COMPASS PATHWAYS PLC**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2020	2019
<b>OPERATING EXPENSES:</b>		
Research and development	\$ 23,366	\$ 12,563
General and administrative	27,862	8,390
General and administrative - fees due to a related party	165	226
Total operating expenses	51,393	21,179
<b>LOSS FROM OPERATIONS:</b>	(51,393)	(21,179)
<b>OTHER INCOME (EXPENSE), NET:</b>		
Other income, net	319	73
Foreign exchange losses	(11,702)	(81)
Fair value change of convertible notes	(1,041)	(670)
Fair value change of convertible notes - due to a related party	(730)	(469)
Benefit from R&D tax credit	4,245	2,729
Total other income (expense), net	(8,909)	1,582
Loss before income taxes	(60,302)	(19,597)
Income tax expense	(32)	(15)
Net loss	(60,334)	(19,612)
<b>Other comprehensive income:</b>		
Foreign exchange translation adjustment	14,683	337
<b>Comprehensive loss</b>	<b>\$ (45,651)</b>	<b>\$ (19,275)</b>
Net loss per share attributable to ordinary shareholders—basic and diluted	<b>\$ (3.55)</b>	<b>\$ (2.62)</b>
Weighted average ordinary shares outstanding—basic and diluted	<b>16,991,664</b>	<b>7,476,422</b>

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

**COMPASS PATHWAYS PLC**  
**Consolidated Statements of Convertible Preferred Shares and Shareholders' Equity (Deficit)**  
(in thousands, except share and per share amounts)

	CONVERTIBLE PREFERRED SHARES		A CONVERTIBLE PREFERRED SHARES		B CONVERTIBLE PREFERRED SHARES		ORDINARY £0.008 PAR VALUE		DEFERRED £0.0008 PAR VALUE		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL SHAREHOLDERS' EQUITY (DEFICIT)
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	AMOUNT	AMOUNT	AMOUNT	AMOUNT
<b>Balance at December 31, 2018</b>	<b>2,650,980</b>	<b>\$ 3,761</b>	<b>7,131,525</b>	<b>\$ 35,147</b>	<b>—</b>	<b>\$ —</b>	<b>10,551,166</b>	<b>\$ 111</b>	<b>—</b>	<b>\$ —</b>	<b>\$ 3,909</b>	<b>\$ (435)</b>	<b>\$ (17,953)</b>	<b>\$ (14,368)</b>
Issuance of ordinary shares, net of issuance costs	—	\$ —	—	\$ —	—	\$ —	201,263	—	—	—	—	—	—	\$ —
Share-based compensation expense	—	\$ —	—	\$ —	—	\$ —	—	—	—	—	3,253	—	—	\$ 3,253
Unrealized gain (loss) on foreign currency translation	—	\$ —	—	\$ —	—	\$ —	—	—	—	—	—	337	—	\$ 337
Net loss	—	\$ —	—	\$ —	—	\$ —	—	—	—	—	—	—	(19,612)	\$ (19,612)
<b>Balance at December 31, 2019</b>	<b>2,650,980</b>	<b>\$ 3,761</b>	<b>7,131,525</b>	<b>\$ 35,147</b>	<b>—</b>	<b>\$ —</b>	<b>10,752,429</b>	<b>\$ 111</b>	<b>—</b>	<b>\$ —</b>	<b>\$ 7,162</b>	<b>\$ (98)</b>	<b>\$ (37,565)</b>	<b>\$ (30,390)</b>
Issuance of B convertible preferred shares, net of issuance costs	—	\$ —	—	\$ —	4,913,404	\$ 61,316	—	—	—	—	—	—	—	\$ —
Conversion of notes into B convertible preferred shares	—	\$ —	—	\$ —	1,723,263	\$ 21,614	—	—	—	—	—	—	—	\$ —
Exercise of share options	—	\$ —	—	\$ —	—	\$ —	197,702	2	—	—	(2)	—	—	\$ —
Exercise of share options but shares not issued	—	\$ —	—	\$ —	—	\$ —	—	—	—	—	16	—	—	\$ 16
Forfeiture of ordinary shares	—	\$ —	—	\$ —	—	\$ —	(63,972)	(1)	—	—	1	—	—	\$ —
Effect of corporate reorganization including conversion of preferred shares to ordinary shares	(2,650,980)	\$ (3,761)	(7,131,525)	\$ (35,147)	(6,636,667)	\$ (82,930)	16,419,172	167	1	28	121,643	—	—	\$ 121,838
Issuance of ordinary shares, net of issuance costs	—	\$ —	—	\$ —	—	\$ —	8,625,000	88	—	—	132,677	—	—	\$ 132,765
Share-based compensation expense	—	\$ —	—	\$ —	—	\$ —	—	—	—	—	17,983	—	—	\$ 17,983
Unrealized gain on foreign currency translation	—	\$ —	—	\$ —	—	\$ —	—	—	—	—	—	14,683	—	\$ 14,683
Net loss	—	\$ —	—	\$ —	—	\$ —	—	—	—	—	—	—	(60,334)	\$ (60,334)
<b>Balance at December 31, 2020</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>35,930,331</b>	<b>\$ 367</b>	<b>1</b>	<b>\$ 28</b>	<b>\$ 279,480</b>	<b>\$ 14,585</b>	<b>\$ (97,899)</b>	<b>\$ 196,561</b>

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

**COMPASS PATHWAYS PLC**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	Year Ended December 31,	
	2020	2019
<b>CASH FLOWS OPERATING ACTIVITIES:</b>		
Net loss	\$ (60,334)	\$ (19,612)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	112	63
Change in fair value of convertible notes	1,771	1,139
Non-cash share-based compensation	17,983	3,253
Deferred tax assets	(221)	—
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(4,490)	(3,430)
Other assets	(57)	—
Accounts payable	1,303	580
Accrued expenses and other liabilities	2,553	194
Net cash used in operating activities	(41,380)	(17,813)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(131)	(165)
Purchase of investments	(497)	—
Net cash used in investing activities	(628)	(165)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds of issuance of convertible preferred shares, net of issuance costs	61,316	—
Issuance of ADRs in initial public offering, net of issuance costs	132,823	—
Proceeds from exercise of share options	16	—
Proceeds from issuance of convertible notes	—	18,434
Payments of initial public offering costs	—	(55)
Net cash provided by financing activities	194,155	18,379
Effect of exchange rate changes on cash, cash equivalents and restricted cash	13,225	1,676
Net increase in cash	165,372	2,077
Cash, cash equivalents and restricted cash, beginning of year	24,984	22,907
Cash, cash equivalents and restricted cash, end of year	\$ 190,356	\$ 24,984
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:</b>		
Deferred offering costs included in accrued expenses	\$ —	\$ 58
Conversion of convertible notes into convertible preferred shares	\$ 21,614	\$ —

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

	Year Ended December 31,	
	2020	2019
Cash and cash equivalents	\$ 190,327	\$ 24,966
Short-term restricted cash	\$ 29	\$ 18
Total cash, cash equivalents and restricted cash	\$ 190,356	\$ 24,984

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

**COMPASS PATHFINDER HOLDINGS LIMITED**  
**Notes to Condensed Consolidated Financial Statements**

**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 a public limited company incorporated in England and Wales and was originally incorporated under the name COMPASS Rx Limited before being renamed COMPASS Pathways plc as part of our corporate reorganization as more particularly described below. Prior to and in contemplation of the consummation of the Company's initial public offering, or IPO, of American Depositary Shares, or ADSs, the Company undertook a corporate reorganization. The corporate reorganization took place in several steps, all of which have been completed. The Company refers to the following steps, which are discussed in more detail below, as the "corporate reorganization".

- Prior to the corporate reorganization, the holding company of the COMPASS group was COMPASS Pathfinder Holdings Limited.

- Pursuant to the terms of a share for share exchange completed on August 7, 2020, all of the shareholders of COMPASS Pathfinder Holdings Limited, which, until the corporate reorganization was the holding company of the Compass group, exchanged each of the shares held by them for 1,161 of the same class, with the same shareholder rights, of newly issued shares of COMPASS Rx Limited and, as a result, COMPASS Pathfinder Holdings Limited became a wholly owned subsidiary of COMPASS Rx Limited. This share exchange had the effect of a 1:1,161 share split. No shareholder rights or preferences changed as a result of the share for share exchange. COMPASS Pathfinder Holdings Limited is a private limited liability company incorporated under the laws of England and Wales and its primary offices are in London, United Kingdom. COMPASS Pathfinder Holdings Limited has one wholly-owned subsidiary, COMPASS Pathfinder Limited, whose primary office is in London, United Kingdom. COMPASS Pathfinder Limited has one wholly-owned subsidiary, COMPASS Pathways Inc. whose primary office is located in New York, United States of America.

- Pursuant to Part 17 of the Companies Act 2006, on August 19, 2020, COMPASS Rx Limited reduced its share capital by way of a reduction of the nominal value of each share in the capital of COMPASS Rx Limited from £1.00 to £0.001 in order to satisfy the net asset test requirement in section 92 of the Companies Act 2006 for the re-registration of COMPASS Rx Limited as a public limited company and to create distributable reserves in order to support future distributions activity by the Company (although we note that none are currently planned).

- COMPASS Rx Limited was re-registered as a public limited company and renamed COMPASS Pathways plc, effective on August 21, 2020. COMPASS Pathways plc is a holding company with nominal activity.

- On September 22, 2020, immediately prior to the completion of the Company's IPO, the different classes of issued share capital of COMPASS Pathways plc were reorganized on a one-for-0.1136 basis into a single class of 27,305,331 ordinary shares by way of a reverse share split, which has been retroactively restated in our consolidated financial statements. As part of this reverse share split, the nominal value of COMPASS Pathways plc's ordinary shares changed from £0.001 per share to £0.008 per share and a single, non-voting deferred share with a nominal value of £21,921.504 in the capital of the Company was created and transferred to the Company.

- On September 22, 2020, the Company completed the IPO. In the IPO, the Company sold an aggregate of 8,625,000 ADSs representing the same number of ordinary shares, including 1,125,000 ADSs pursuant to the underwriters' over-allotment right option to purchase additional ADSs, at a public offering price of \$17.00 per ADS. Net proceeds were approximately \$132.8 million, after deducting underwriting discounts and commissions and other offering expenses.

COMPASS Pathways plc is a continuation of COMPASS Pathfinder Holdings Limited and its subsidiaries, and the corporate reorganization has been accounted for as a combination of entities under common control. The corporate reorganization associated with the IPO has been given retrospective effect in these financial statements and such financial statements represent the financial statements of COMPASS Pathways plc. In connection with the corporate reorganization, outstanding restricted share awards and option grants of COMPASS Pathfinder Holdings Limited were exchanged for share awards and option grants of COMPASS Pathways plc with identical restrictions.

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 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 ordinary shares in connection with the IPO. The Company has incurred recurring losses since its inception, including net losses of \$60.3 million and \$19.6 million for the years ended December 31, 2020 and 2019, respectively. In addition, as of December 31, 2020, the Company had an accumulated deficit of \$97.9 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 December 31, 2020 of \$190.3 million will be sufficient to fund its operating expenses and capital expenditure requirements through to 2023.

The Company continues to assess its business plans and the impact which the 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. No assurances can be given that this analysis will enable the Company to avoid part or all of any future impact from the COVID-19 pandemic, including downturns in business sentiment generally or in its sector in particular. 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 shutdowns or other business disruptions, its ability to conduct our 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 consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or U.S. GAAP.

### ***Principles of Consolidation***

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

### ***Use of Estimates***

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for research and development expenses, the fair value of ordinary shares, share-based compensation, measurement of the fair value of the Company's convertible notes 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 December 31, 2020 and 2019 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 Financial Instruments***

Certain 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 Company's convertible notes issued prior to IPO were classified within Level 3 of the fair value hierarchy because their fair values are estimated by utilizing valuation models and significant unobservable inputs. The convertible notes were valued using a scenario-based discounted cash flow analysis. Two primary scenarios were considered and probability weighted to arrive at the valuation conclusion for each convertible note. The first scenario considers the value impact of conversion at the stated discount to the issue price if the Company raises over £25.0 million in an equity financing before the first anniversary of the issuance date, the Qualified Financing, otherwise Non-Qualified Financing, while the second scenario assumes the convertible notes are held to maturity. As of the issuance date of the convertible notes, an implied yield was calculated such that the probability weighted value of the convertible note was equal to the principal investment amount. The implied yield of previously issued convertible notes is carried forward and used as the primary discount rate for subsequent valuation dates. The Company estimates the fair value of the convertible notes based on a future value on projected conversion dates which have been i) discounted back to the valuation date at an appropriate discount rate and ii) probability weighted to arrive at an indication of value for the convertible notes.

#### ***Fair Value Option***

As permitted under Accounting Standards Codification 825, Financial Instruments, or ASC 825, the Company has elected the fair value option to account for its convertible notes. In accordance with ASC 825, the Company records these convertible notes at fair value with changes in fair value recorded as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. As a result of applying the fair value option, direct costs and fees related to the convertible notes were expensed as incurred and were not deferred. The Company concluded that it was appropriate to apply the fair value option to the convertible notes because there are no non-contingent beneficial conversion options related to the convertible notes.

#### ***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 consolidated statement 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 years ended December 31, 2020 and 2019.

**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 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 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 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 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 accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical 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 consolidated statement 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.

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 11 for the Company's assumptions used in connection with option grants made during the periods covered by these consolidated financial statements. Assumptions used in the option pricing model include the following:

Expected volatility. The Company lacks 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, 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 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 date of grant.

The OPM method 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.

#### ***Foreign Currency Translation***

The Company maintains its 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 consolidated statement of operations and comprehensive loss. The Company recorded foreign exchange losses of approximately \$11.7 million and \$0.1million for the years ended December 31, 2020 and 2019, respectively.

For financial reporting purposes, the 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' deficit 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 (loss) income, a component of shareholders' equity (deficit).

## **Income Taxes**

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in its tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the 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 consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed as the amount of benefit to recognize in the consolidated financial statements. The amount of benefits that may be used is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate, as well as the related net interest and penalties. As of December 31, 2020 and 2019, 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 consolidated statement of operations and comprehensive loss. As of December 31, 2020 and 2019 no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheets.

### ***Benefit from Research and Development Tax Credit***

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, or R&D, tax credits is recognized in the consolidated statements of operations and comprehensive loss as a component of other income, net, and represents the sum of the 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. Further, changes to the EU State Aid cap to limit the total aid claimable in respect of a given project to €7.5 million may impact the Company's ability to claim R&D tax credits in future.

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' deficit that result from transactions and economic events other than those with shareholders. For the years ended December 31, 2020 and 2019, 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 ordinary shares, share options, convertible preferred and Series A convertible preferred shares, outstanding during the period determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive. 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 August 2018, the FASB issued ASU 2018-13, Changes to the Disclosure Requirements for Fair Value Measurement, or ASU 2018-13, which amends changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty which should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. ASU 2018-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those periods. Early application is permitted. The Company adopted this ASU as of January 1, 2020 and it has no material impact on the consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The new standard will align the requirements for capitalizing implementation costs for hosting arrangements (services) with costs for internal-use software (assets). As a result, certain implementation costs incurred in hosting arrangements will be deferred and amortized. The new standard will be effective for the Company on January 1, 2020. The Company adopted this ASU as of January 1, 2020 and an immaterial amount of implementation costs were capitalized within other assets as of December 31, 2020.

***Recently Issued Accounting Pronouncements Not Yet Adopted***

In February 2016, the Financial Accounting Standards Board, or the FASB, issued Accounting Standard Update, or ASU, No. 2016-02, (Topic 842) Leases, or ASU 2016-02. ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. For public entities, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU 2016-02 is effective for the Company for the year ended December 31, 2021, and all interim periods thereafter. Early adoption is permitted. In July 2018, the FASB issued ASU 2018-11 Leases – Targeted Improvements, or ASU 2018-11, intended to ease the implementation of the new lease standard for financial statement preparers by, among other things, allowing for an additional transition method. In lieu of presenting transition requirements to comparative periods, as previously required, an entity may now elect to show a cumulative effect adjustment on the date of adoption without the requirement to recast prior period financial statements or disclosures presented in accordance with ASU 2016-02.

The Company is continuing to evaluate developments within the new lease guidance and is finalizing its evaluation of its existing population of contracts to ensure all contracts that meet the definition of a lease contract under the new standard are identified. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated financial statements and footnote disclosures. The Company is currently evaluating the impact of adopting this guidance on the Company's consolidated financial statements and expects that its operating lease commitments will be subject to the new standard and recognized as right-of-use assets and operating lease liabilities upon adoption of this standard, which will increase the total assets and total liabilities that it reports relative to such amounts presented prior to adoption.

In December 2019, the FASB issued ASU 2019-12, "Income Taxes - Simplifying the Accounting for Income Taxes (Topic 740)," or ASU 2019-12, 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.

**3. Fair Value Measurements**

There are no financial instruments measured at fair value on a recurring basis as of December 31, 2020. The following table presents information about the Company's financial instruments measured at fair

value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2019:

Description	Fair Value Measurement as of December 31, 2019 Using:		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Observable Inputs (Level 3)
<b>Liabilities</b>	\$ —	\$ —	\$ 21,089
Convertible Notes	\$ —	\$ —	\$ 21,089

Management believes that the carrying amounts of the Company's consolidated financial instruments, including accounts payable and accrued expenses approximate fair value due to the short-term nature of those instruments.

The Company elected the fair value option to account for its convertible notes issued during 2019 (See Note 8). The fair value of the convertible notes was determined based on significant inputs not observable in the market, which represents a level 3 measurement within the fair value hierarchy.

The Company recorded a loss of \$1.8 million and \$1.1 million for changes in the fair value of the convertible notes in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2020 and 2019, respectively.

The following table provides a roll forward of the aggregate fair value of the Company's convertible notes, for which fair value was determined using level 3 inputs (in thousands):

	Convertible notes
Balance as of December 31, 2018	\$ —
Issuance of convertible notes	\$ 18,434
Change in fair value	\$ 1,139
Exchange difference	\$ 1,516
Balance as of December 31, 2019	\$ 21,089
Change in fair value	\$ 1,771
Settlement of convertible notes	\$ (21,614)
Exchange difference	\$ (1,246)
Balance as of December 31, 2020	\$ —

#### 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 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 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 December 31, 2020, no impairment loss was recognized.



## 5. Prepaid Expenses and Other Current Assets

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

	December 31,	
	2020	2019
UK R&D tax credit	\$ 4,610	\$ 4,791
Prepaid insurance premium	3,154	212
Prepaid research and development	2,317	903
VAT recoverable	1,171	426
Deferred IPO costs	—	115
Other current assets	796	740
	<u>\$ 12,048</u>	<u>\$ 7,187</u>

## 6. Property and Equipment, Net

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

	December 31,	
	2020	2019
Lab equipment	\$ 130	\$ 114
Office equipment	260	133
Furniture and fixtures	37	38
Leasehold improvements	6	—
	<u>433</u>	<u>285</u>
Less: accumulated depreciation	<u>(188)</u>	<u>(67)</u>
	<u>\$ 245</u>	<u>\$ 218</u>

Depreciation and amortization expense were \$0.1 million for the years ended December 31, 2020 and 2019.

## 7. Accrued Expenses and Other Liabilities

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

	December 31,	
	2020	2019
Accrued research and development expense	\$ 720	\$ 491
Accrued professional expenses	701	232
Accrued compensation and benefit costs	1,687	682
Payroll tax payable	384	—
Income taxes payable	243	15
Other liabilities	413	37
	<u>\$ 4,148</u>	<u>\$ 1,457</u>

## 8. Convertible Notes

On August 28, 2019, the Company entered into convertible note agreements for a total additional principal amount of \$18.4 million (£15.0 million). The convertible notes issued in 2019 are collectively referred to as the “2019 Convertible Notes”. The 2019 Convertible Notes bore interest at 3% per annum and were payable concurrently with repayment of the principal amount. No repayment of principal or interest was due until maturity, which occurred 12 months after issuance of the 2019 Convertible Notes.

Under the agreement, the 2019 Convertible Notes automatically converted upon a Qualified Financing and Non-Qualified Financing securities upon (i) the completion of a Qualified Financing; or (ii) noteholder majority had approved a Non-Qualified Financing constituting a conversion event, at 15% discount of the per share price of the securities sold in either a Qualified Financing or Non-Qualified Financing.

On April 17, 2020, upon the Series B convertible preferred share financing, which constituted a Qualified Financing, the outstanding principal of the convertible notes of \$18.4 million (£15.0 million) automatically converted into 1,723,263 Series B convertible preferred shares, and there was no outstanding balance as of December 31, 2020.

The Company elected the fair value option to account for the 2019 Convertible Notes. The Company recorded the 2019 Convertible Notes at fair value and subsequently remeasured them to fair value at each reporting date. Changes in fair value were recognized as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. The Company recognized losses in the consolidated statements of operations and comprehensive loss of \$1.8 million and \$1.1 million as change in fair value of the convertible notes during the years ended December 31, 2020 and 2019.

As of December 31, 2019, the outstanding 2019 Convertible Notes are shown on the accompanying consolidated balance sheets at the fair value of \$21.1 million.

## 9. Convertible Preferred Shares

Prior to the IPO, the Company had issued convertible preferred shares, Series A convertible preferred shares and Series B convertible preferred shares.

In August 2017, the Company entered into a subscription and shareholders agreement, or the 2017 Agreements, pursuant to which the Company issued an aggregate of 2,650,980 convertible preferred shares for total proceeds of approximately \$3.9 million and incurred issuance costs of \$0.1 million, recorded as a reduction to convertible preferred shares.

The 2017 Agreements were amended and restated in September 2018, as so amended, the Amended 2018 Agreements. Pursuant to the Amended 2018 Agreements, the Company issued 7,131,525 Series A convertible preferred shares for an aggregate purchase price of \$35.4 million and incurred issuance costs of \$0.3 million, recorded as a reduction to convertible preferred shares.

On April 17, 2020, the Company closed a Series B funding round to secure an additional \$80.0 million of funding, including the conversion of the 2019 Convertible Notes (see Note 8), through the issuance of Series B convertible preferred shares. The Company received \$61.6 million in cash proceeds upon the issuance of 4,913,404 Series B convertible preferred shares and incurred issuance costs of \$0.3 million, recorded as a reduction to the convertible preferred shares. The 2019 Convertible Notes were converted into 1,723,263 Series B convertible preferred shares. The issuance price of the Series B convertible preferred shares was \$1.42 per share.

Convertible preferred shares and Series A convertible preferred shares consisted of the following as of December 31, 2019 (in thousands, except for share amounts):

	Shares		Liquidation Preference	Carrying Value
	Authorized	Outstanding		
Convertible preferred shares	2,650,980	2,650,980	\$ 3,865	\$ 3,761
Series A convertible preferred shares	7,131,525	7,131,525	35,414	35,147
	9,782,505	9,782,505	\$ 39,279	\$ 38,908

Upon closing of the IPO, the convertible preferred shares and Series A convertible preferred shares as of December 31, 2019, together with the Series B convertible preferred shares issued during the year ended December 31, 2020, were converted to 16,419,172 ordinary shares. The holders of the Company's convertible preferred shares, Series A convertible preferred shares and Series B convertible preferred shares had certain voting, dividend, and redemption rights, as well as liquidation preferences and conversion privileges. All rights, preferences, and privileges associated with the convertible preferred shares, Series A convertible preferred shares and Series B convertible preferred shares were terminated at the time of the Company's IPO in conjunction with the conversion of all outstanding shares of convertible preferred shares, Series A convertible preferred shares and Series B convertible preferred shares into ordinary shares.

## **10. Ordinary Shares**

In August 2017, the Company issued 10,551,166 ordinary shares for services rendered to the Company at a nominal value of £0.008 per share. In connection with the issuance of convertible preferred shares in August 2017, vesting conditions were placed on the 10,551,166 shares. These shares vested as follows: 25% of the shares held by certain of the founders vested on August 17, 2017; 25% of the shares vested on August 17, 2018; and 50% of shares vested in twenty-four equal monthly installments from August 17, 2018 through August 17, 2020. The fair value of the ordinary shares issued to certain of the founders in excess of the consideration initially paid was recognized as share-based compensation over the vesting period.

In October 2019, the Company issued 102,214 and 99,049 ordinary shares to a non-employee and an employee, with the vesting period of three and four years, respectively. The employee left the Company in July 2020 and 63,972 ordinary shares were forfeited and repurchased by the Company.

On September 22, 2020, the Company closed its IPO of ADSs representing its ordinary shares and issued and sold 8,625,000 ADSs at a public offering price of \$17.00 per ADS, resulting in net proceeds of approximately \$132.8 million after deducting underwriting fees and offering costs. Upon the closing of the IPO, the convertible preferred shares and Series A convertible preferred shares and Series B convertible preferred shares were converted to 16,419,172 ordinary shares.

Each ordinary share entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Ordinary shareholders are entitled to receive dividends, if any, as may be declared by the board of directors. Through December 31, 2020, no cash dividends had been declared or paid by the Company.

## **11. 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 December 31, 2020, 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 December 31, 2020, there were 440,207 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 December 31, 2020 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 by the Company prior to April 17, 2020 contain provisions that to the extent then outstanding, they will be subject to accelerated vesting upon the occurrence of a Sale, Asset Sale or listing of the Company's ordinary shares on any stock exchange, and any such unvested options accordingly became fully vested upon a Listing (as such term is defined in the 2017 Plan). 1,015,813 options granted to the President and Chief Business officer of the Company on May 19, 2020 became fully vested on August 17, 2020, resulting in the recognition of \$9.5 million in share-based compensation expense, including \$2.4 million in research and development expenses and \$7.1 million in general and administrative expenses.

The options granted before June 30, 2020 are 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 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. 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 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 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).

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 2,074,325 shares as of December 31, 2020, of which 1,178,547 shares remained available for future grant.

During the years ended December 31, 2020 and 2019, the Company granted options to purchase 3,405,490 and 1,539,411 ordinary shares to employees and non-employees, respectively.

### Ordinary Shares

A summary of the changes in the Company's unvested ordinary shares during the year ended December 31, 2020 are as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested and Outstanding as of December 31, 2019	1,907,515	\$ 0.74
Granted	—	—
Vested	(1,829,786)	0.69
Forfeited	(63,972)	0.05
Unvested and Outstanding as of December 31, 2020	13,757	\$ 2.36

As of December 31, 2020, there was less than \$0.1 million of unrecognized compensation cost related to unvested restricted shares, which is expected to be recognized over a weighted-average period of 0.4 years. The total fair value of vested shares was \$1.3 million and \$1.7 million for the years ended December 31, 2020 and 2019, respectively.

### Restricted Share Units

A summary of the changes in the Company's unvested restricted share units during the year ended December 31, 2020 are as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested and Outstanding as of December 31, 2019	—	\$ —
Granted	257,708	10.19
Vested	—	—
Forfeited	(40,226)	10.19
Unvested and Outstanding as of December 31, 2020	217,482	\$ 10.19

As of December 31, 2020, there was \$2.0 million of unrecognized compensation cost related to unvested restricted share units, which is expected to be recognized over a weighted-average period of 3.20 years. The exercise price of restricted share units is at a nominal value less than £0.01 per share.

### Share Options

The following table summarizes the Company's share options activity for the year ended December 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2019	1,539,411	\$ 0.82	9.58	\$ 2,284
Granted	3,405,490	\$ 7.17		
Exercised	(429,929)	\$ 0.05		
Forfeited	(84,632)	\$ 9.87		
Outstanding as of December 31, 2020	4,430,340	\$ 5.61	9.22	\$ 186,426
Exercisable as of December 31, 2020	3,020,137	\$ 0.88	9.00	\$ 141,213
Unvested as of December 31, 2020	1,410,203	\$ 15.75	9.67	\$ 45,215

During the year ended December 31, 2020, 429,929 share options were exercised. Of which 232,227 share options were exercised by certain optionees with a total exercise price of less than \$0.1 million. These ordinary shares were not issued to those optionees by December 31, 2020 and the amount received by the Company was recorded in the additional paid-in capital as at that date.

The weighted average exercise price of options granted to UK employees during the year ended December 31, 2020 was \$4.04 per share. The weighted average exercise price of options granted to United States employees during the year ended December 31, 2020 was \$4.77 per share.

The weighted average exercise price of options granted to UK employees during the year ended December 31, 2019 was less than \$0.01 per share. The weighted average exercise price of options granted to United States employees during the year ended December 31, 2019 was \$1.39 per share.

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 \$9.83 and \$1.88 per share during the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, there was \$18.1 million of unrecognized compensation cost related to unvested share options, which is expected to be recognized over a weighted-average period of 3.5 years.

### **Share Option Valuation**

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the share options granted to employees and directors during the years ended December 31, 2020 and 2019 were as follows:

	Year Ended December 31,	
	2020	2019
Expected term (in years)	5.95 years	5.90 years
Expected volatility	66.10 %	63.40 %
Risk-free interest rate	0.43 %	1.88 %
Expected dividend yield	— %	— %
Fair value of underlying ordinary shares	\$ 12.58	\$ 2.16

### **Share-based Compensation Expense**

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

	Years Ended December 31,	
	2020	2019
Research and development	\$ 6,336	\$ 1,817
General and administrative	\$ 11,647	\$ 1,436
	<u>\$ 17,983</u>	<u>\$ 3,253</u>

## 12. Income Taxes

The provision for income taxes for the years ended December 31, 2020 and 2019 was computed at the UK statutory income tax rate. The income tax provision for the years then ended comprised (in thousands):

	Year Ended December 31,	
	2020	2019
Current income tax provision		
United Kingdom	\$ —	\$ —
Foreign	253	15
Total current expense:	\$ 253	\$ 15
Deferred income tax benefit:		
United Kingdom	—	—
Foreign	(221)	—
Total deferred income tax benefit:	(221)	—
Total provision for income taxes	\$ 32	\$ 15

A reconciliation of income tax expense computed at the statutory UK income tax rate to income taxes as reflected in the consolidated financial statements is as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Income taxes at UK statutory rate	\$ (11,458)	\$ (3,724)
Permanent differences	340	238
UK R&D tax credit	1,664	1,036
Change in valuation allowance	8,683	2,205
State income taxes	(5)	5
Deferred tax asset true-up	919	—
Other	(111)	255
	\$ 32	\$ 15

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2020 and 2019 consist of the following (in thousands):

	Year Ended December 31,	
	2020	2019
Net operating loss carryforward	\$ 10,075	\$ 2,936
Charitable contributions	—	2
Share-based compensation	3,128	757
Reserves and accruals	62	—
Total deferred tax assets	13,265	3,695
Valuation allowance	\$ (13,000)	\$ (3,665)
Depreciation	(44)	(30)
Total deferred tax liabilities	(44)	(30)
Net deferred tax assets	\$ 221	\$ —

As of December 31, 2020 and 2019, the Company had UK net operating loss carryforwards of approximately \$53.0 million and \$17.7 million, respectively, that can be carried forward indefinitely.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2020 and 2019 related primarily to the increases in net operating loss and were as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Valuation allowance at beginning of year	\$ 3,665	\$ 1,321
Increases recorded to income tax provision	8,683	2,344
Increases recorded to CTA	652	
Decreases recorded to income tax provision	—	—
Valuation allowance at end of year	<u>\$ 13,000</u>	<u>\$ 3,665</u>

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2020 and 2019, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all of the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance against its net UK deferred tax assets as of December 31, 2020 and 2019. The deferred tax asset recognized relates entirely to the US entity.

The Company applies the authoritative guidance on accounting for and disclosure of uncertainty in tax positions, which requires the Company to determine whether a tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. For tax positions meeting the more likely than not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than fifty percent likelihood of being realized upon the ultimate settlement with the relevant taxing authority. There were no material uncertain tax positions as of December 31, 2020 and 2019.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense when in a taxable income position. As of December 31, 2020 and 2019, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statement of operations and comprehensive loss.

The Company and its subsidiaries file income tax returns in the UK and U.S. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the federal, state, or foreign tax authorities, if such tax attributes are utilized in a future period.



### 13. 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):

	Year Ended December 31,	
	2020	2019
<b>Numerator</b>		
Net loss	\$ (60,334)	\$ (19,612)
Net loss attributable to ordinary shareholders - basic and diluted	<u>\$ (60,334)</u>	<u>\$ (19,612)</u>
<b>Denominator</b>		
Weighted-average number of ordinary shares used in net loss per share - basic and diluted	16,991,664	7,476,422
Net loss per share - basic and diluted	<u>\$ (3.55)</u>	<u>\$ (2.62)</u>

The Company's potentially dilutive securities, which include unvested ordinary shares, unvested restricted share units, convertible preferred shares, Series A convertible preferred shares 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 years ended December 31, 2019 and 2020 because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2020	2019
Unvested ordinary shares	13,757	—
Unvested restricted share units	217,482	—
Convertible preferred shares	—	2,650,980
Series A convertible preferred shares	—	7,131,525
Share options	4,430,340	1,539,411
	<u>4,661,579</u>	<u>11,321,916</u>

### 14. Commitments and Contingencies

#### **Legal Proceedings**

From time to time, the Company may be a party to litigation or subject to claims incident to the ordinary course of business. The Company was not a party to any material litigation and did not have material contingency reserves established for any liabilities as of December 31, 2020 and 2019.

#### **Leases**

The Company's corporate headquarters is located in London, United Kingdom, for which, as of December 31, 2020 and 2019, the Company leases a series of office space at 19 Eastbourne Terrace, London, United Kingdom from The Office Group under a non-cancelable lease. The lease related to this facility is classified as an operating lease over a two year term. The Company recognizes rent expense on a straight-line basis over the respective lease period.

The Company leased office space at 180 Varick Street NY, NY from BioInnovations Labs, LLC under a cancelable lease that can be terminated by either party with one-month advanced notice. The lease related to this facility is classified as an operating lease.

The following table summarizes the future minimum lease payments due under operating leases as of December 31, 2020 (in thousands):

Year Ended December 31,	Amount	
2021	\$	1,020
	\$	1,020

The Company recorded rent expense totaling \$1.0 million and \$0.4 million for the years ended December 31, 2020 and 2019, respectively.

#### **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.

#### **15. Related Party Transactions**

On August 28, 2019, as part of the Company's 2019 Convertible Notes issuance an amount of \$7.6 million (£6.2 million) was issued to a shareholder and it was converted to 710,621 shares of Series B convertible preferred shares on April 17, 2020. As of December 31, 2019, the shareholder's convertible loan note remained outstanding. Refer to Note 8 for additional information on the 2019 Convertible Notes.

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 totaling \$0.1 million and \$0.2 million for the years ended December 31, 2020 and 2019. As of December 31, 2020 and 2019, the Company had less than \$0.1 million and \$0.1 million outstanding to Tapestry, respectively.

#### **16. Employee Benefit Plans**

In the UK, the Company makes contributions to private defined benefit pension schemes on behalf of its employees. The Company paid less than \$0.1 million and \$0.1 million in contributions for the years ended December 31, 2020 and 2019, respectively.

#### **17. Subsequent Events**

On January 04, 2021, the Company entered into a clinical research agreement with Sheppard Pratt Health System, Inc. in Baltimore, Maryland, or Sheppard Pratt, pursuant to which the Company will, upon receipt of a mutually agreed budget, fund Sheppard Pratt to construct a Center of Excellence, through which certain investigator-initiated studies may be conducted.

**4,000,000 American Depositary Shares  
Representing 4,000,000 Ordinary Shares**



**PROSPECTUS**

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April 29, 2021

**Cowen  
Evercore ISI  
Berenberg  
Cantor  
BTIG**

Through and including May 24, 2021 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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