NEWS RELEASE

Compass Pathways Completes COMP360 Psilocybin New Drug Application to U.S. FDA for Treatment-Resistant Depression

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- Robust NDA submission supported by data from two highly statistically significant Phase 3 trials and a Phase 2b study that each met its primary endpoint and involved a total of more than 1,000 participants living with highly chronic TRD
- Deep commercial capabilities in place to enable successful launch execution and broad patient access with launch readiness on track for expected launch in H12027, subject to FDA approval

LONDON & JERSEY CITY, N.J.--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to unlocking urgently needed new treatment options in mental health care, today announced the Company completed its submission of a New Drug Application (NDA) to the U.S. FDA for COMP360 psilocybin, its investigational synthetic, proprietary formulation of psilocybin, for treatment-resistant depression (TRD).

"People living with treatment-resistant depression have gone too long experiencing disproportionate suffering, despite years of trying available treatment options without meaningful relief. The completion of our NDA submission reflects years of perseverance and commitment by patients, families, advocates, researchers and healthcare providers who have worked alongside us toward the shared goal of bringing new treatment options to this community," said Kabir Nath, Chief Executive Officer of Compass Pathways. "Compass is leading the development of this new class of medicines with rigor and discipline, successfully completing the largest late-stage clinical program in psychedelic treatments. We are deeply grateful to the entire Compass team for the achievement of this extraordinary milestone. We look forward to continuing the review process, and we are focused on delivering COMP360 to patients as quickly as possible, subject to FDA approval. We have a world-class and fully scaled commercial organization, and the infrastructure and capabilities in place to support broad patient access

upon approval."

About treatment-resistant depression (TRD)

TRD is a form of **depression**, distinguished from **major depressive disorder** (MDD), by its definition requiring an inadequate response to two or more courses of antidepressants of adequate dose and duration. An estimated 4 million people in the U.S. live with TRD, of whom fewer than 5% are currently on a TRD-indicated treatment.[1,2,3] TRD has a significantly greater impact on individuals compared to MDD, leading to residual symptoms, poorer quality of life, increased comorbidities, higher mortality, and an increased risk of suicide.[5] Research suggests this may be attributed to the role of altered brain network functioning in TRD, with biological changes becoming more entrenched with recurrent or prolonged depressive episodes.[4,5,6,7,8]

Many people living with TRD experience years of cycling through treatments that aren't providing meaningful relief, with an impact extending across work, school, relationships and daily life. A **national survey** of people with TRD and their caregivers revealed the cumulative burden of the treatment cycle, with 95% of surveyed patients describing themselves as either functioning but struggling, surviving day-to-day or barely getting by. Furthermore, the impact extends well beyond the individual, with approximately 70% of caregivers reporting that TRD negatively affects the whole family's social, physical and/or mental health, reinforcing the urgent need for new treatment approaches that can meaningfully improve the lives of those affected by TRD.

About Compass Pathways

We believe mental health patients deserve the possibility of a better future. Compass Pathways plc (Nasdaq: CMPS) is a biotechnology company dedicated to unlocking urgently needed new treatment options in mental health care. Our initial focus is developing COMP360 psilocybin, a proprietary, investigational, synthetic psilocybin treatment under evaluation for treatment-resistant depression (TRD) and post-traumatic stress disorder (PTSD). COMP360 is a potentially first-in-class treatment and has Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA), as well as Innovative Licensing and Access Pathway (ILAP) designation in the UK for TRD. We are leading the world's largest classic psychedelic clinical program in TRD, and building upon that robust foundation, we are executing a late-stage trial evaluating COMP360 for PTSD, another condition with high unmet need. Our goal is to advance treatments that move the field of psychiatry towards treatment options that offer rapid onset and sustained durability with infrequent dosing.

Compass is headquartered in London, UK, with a U.S. office in New Jersey.

We are driven by our purpose of unlocking pathways to be – opening futures filled with possibility. Together, we are on an ambitious journey toward enabling people living with mental health conditions to find clarity through self-

discovery, because every journey needs a Compass.

Forward-looking statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. In some cases, forward-looking statements can be identified by terminology such as “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, although not all forward-looking statements contain these words. Forward-looking statements include express or implied statements relating to, among other things, our business strategy and goals; our expectations regarding the safety or efficacy of our investigational COMP360 psilocybin treatment; any implication that preliminary results will be predictive of full safety and efficacy data from our phase 3 program; our expectations regarding the timing of the review by the Food and Drug Administration, or FDA, of such NDA, including potential acceleration due to the grant of rolling review and award of a National Priority Voucher for COMP360 psilocybin treatment in TRD; the potential for the pivotal phase 3 program in TRD to support regulatory filings and approvals on an accelerated basis or at all; our expected timing of our commercial launch for COMP360 psilocybin treatment in TRD, if approved by the FDA, including the timing and substance of decisions by the U.S. Drug Enforcement Administration, or the DEA, and states to reschedule COMP360 psilocybin treatment, if approved by FDA, which contains Schedule I controlled substances and must be rescheduled before commercializing COMP360 psilocybin in the U.S.; our efforts and our ability to obtain regulatory approval and adequate coverage and reimbursement; our ability to grow our organization and transition from a clinical-stage to a commercial-stage organization and effectively launch a commercial product, if regulatory approval is obtained; our expectations regarding market adoption and commercial potential for COMP360; and our expectations regarding the benefits of our investigational COMP360 psilocybin treatment as a treatment for TRD. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Compass’s control and which could cause actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements.

These risks, uncertainties, and other factors include, among others: uncertainties associated with risks related to the full results and safety data from our Phase 3 clinical trials in TRD may not be consistent with the preliminary results to date; our need for additional funding to achieve our business goals and if we are unable to obtain this funding when needed and on acceptable terms, we could be forced to reduce spending and delay or limit business plans; that the rolling review process and/or the National Priority Voucher pilot program may not actually lead to a faster FDA review or approval process; our efforts to obtain FDA approval for our investigational COMP360 psilocybin treatment on an accelerated basis, or at all, may be unsuccessful; the DEA and the states may not

reschedule COMP360 psilocybin treatment, if approved by FDA, on a timely basis, or at all; our efforts to commercialize and obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment, if approved and rescheduled, may be unsuccessful, including failure to achieve an adequate level of acceptance and adoption by payors, health technology assessment bodies, healthcare professionals, patients and the medical community at large; we may not be able to retain key personnel; and those risks and uncertainties described under the heading "Risk Factors" in Compass's most recent annual report on Form 10-K or quarterly report on Form 10-Q and in other reports we have filed with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at **www.sec.gov**. Except as required by law, Compass disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Compass's current expectations and speak only as of the date hereof.

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1. Wing V, et al. Poster S97 Contemporary Estimate of the National Prevalence of Treatment-Resistant Depression in the United States. Presented at ADAA 2026.
2. IQVIA.
3. Data on file.

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