

Compass Pathways Working with U.S. Department of Veterans Affairs for Investigational Study of Psilocybin

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LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to unlocking urgently needed new treatment options in mental health care, announced today it is working with the U.S. Department of Veterans Affairs (VA) on a multi-site randomized controlled clinical trial. The study will evaluate the safety and efficacy of COMP360 psilocybin in the treatment of treatment-resistant depression (TRD) in veterans, including those with concurrent post-traumatic stress disorder (PTSD).

The trial, titled "Psilocybin Intervention for Veterans Overcoming Treatment-Resistant Depression," or PIVOT, reflects VA's commitment to pursuing innovative solutions for veterans who have not responded to existing treatments. Compass will donate the study drug - COMP360, a synthetic, proprietary pharmaceutical-grade formulation of psilocybin optimized for stability and purity. Compass will support the education and training of the investigators and their training team through the provision of training materials, guidance, and consultation on administration protocols. In turn, the investigators and their training team will train the initial cohort of health care providers and will be prepared to train additional support providers as needed.

The multi-site, double-blind, randomized controlled trial will enroll veterans diagnosed with TRD, with or without concurrent PTSD, and will compare outcomes between two different doses of COMP360 psilocybin with the option for a second open label administration four weeks after initial dose. The primary measure of efficacy will be depression severity, assessed using the Montgomery-Åsberg Depression Rating Scale (MADRS). Secondary outcomes will include assessments of PTSD symptom severity, tolerability of side effects, and overall patient-reported depression. The lead site is the Birmingham VA Health Care System in Alabama, in collaboration with four additional VA sites in Tuscaloosa, Portland, Seattle and Philadelphia.

“TRD is a critical and complex mental health challenge among veterans, often occurring alongside PTSD and underscoring the urgent need for innovative, evidence-based solutions,” said Kabir Nath, Chief Executive Officer of Compass Pathways. “We are honored to be selected as the partner of choice for this groundbreaking study and look forward to supporting Dr. Davis and the broader research team throughout its course. We’re deeply grateful for the resources provided by the VA to explore the potential of COMP360 psilocybin in addressing TRD among veterans - an effort that holds promise for transforming care and restoring hope.”

“Veterans living with TRD face immense challenges that demand more effective, transformative treatments to support their recovery and reintegration into civilian life,” said Dr. Lori Davis, Principal Investigator of the study at Birmingham VA Healthcare System. “We’re pleased to partner with Compass Pathways on this pioneering investigation, exploring psilocybin’s potential to treat not only TRD, but also comorbid PTSD—an area that remains largely unexplored. Psilocybin has the potential to mark a major breakthrough in mental health care for veterans, offering renewed hope, and improving overall quality of life for those who have exhausted available options.”

About TRD and PTSD amongst veterans

The United States is in the midst of a **mental health crisis**, with **one in five adults** experiencing mental illness each year—and military veterans experience disproportionately high levels of mental health concerns. Depression is more **prevalent** in this population, and it is estimated that **one in seven** veterans with depression may suffer from TRD, a persistent and debilitating condition defined as an inadequate response to at least two courses of approved antidepressant medications. Compounding this is PTSD, a **frequently co-occurring** condition, that complicates symptoms and recovery. Veterans living with both depression and PTSD are more than **twice as likely** to have attempted suicide compared to those with PTSD alone. These challenges underscore the urgent need for innovative, evidence-based mental health treatments.

About treatment resistant depression (TRD)

Depression, one of the most common mental health disorders, significantly impacts relationships, work performance, overall quality of life, and is associated with an increased risk of suicide. **Major depressive disorder** (MDD) has been ranked as the third cause of the burden of disease worldwide in 2008 by the World Health Organization (WHO), which has projected that this disease will rank first by 2030.

It is estimated that approximately 4 million patients in the U.S. with MDD live with TRD¹. **TRD** is broadly defined as an inadequate response to two or more appropriate courses of approved medications. 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 compared to non-treatment resistant MDD.

About Post-Traumatic Stress Disorder

Post-Traumatic Stress Disorder (PTSD) is a serious mental health condition that can develop after exposure to **traumatic events** such as personal assault, combat, natural disasters, or serious accidents. Characterized by **symptoms** such as intrusive memories, avoidance behaviors, negative shifts in mood and cognition, and heightened arousal, PTSD affects approximately **five percent** of adults in the U.S. annually. Symptoms may appear within months of the trauma or be delayed, and they must persist for **over a month** and interfere with daily functioning to meet diagnostic criteria.

PTSD can impact anyone, though **certain populations**—including veterans, first responders, and survivors of abuse—are at elevated risk. Individuals living with PTSD frequently experience **comorbid mental health conditions**, most commonly, depression, anxiety disorders, substance use disorders, as well as a significantly increased risk of suicide. These overlapping conditions can intensify distress and complicate treatment.

Affecting **13 million people** in the U.S. each year, PTSD remains an underserved condition. There are currently only two FDA-approved medications for PTSD. This limited pharmacological landscape underscores the urgent need to advance care for patients experiencing this debilitating condition.

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 York.

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, statements regarding our business strategy and goals; our plans and expectations regarding our role in this investigational study sponsored by the U.S. Department of Veterans Affairs (VA), the potential for our current or any future clinical trials to support regulatory filings and approvals for COMP360 psilocybin treatment; our expectations regarding the safety or efficacy of our investigational COMP360 psilocybin treatment, including as a treatment for treatment of TRD and PTSD; any implication that past results will be predictive of future results; our ability to obtain regulatory approval and adequate coverage and reimbursement; our ability to transition from a clinical-stage to a commercial-stage organization and effectively launch a commercial product, if regulatory approval is obtained; our expectations regarding our commercial readiness and scalability of infrastructure and training programs to deliver treatment at scale, if regulatory approval is obtained; and our expectations regarding the benefits of our investigational COMP360 psilocybin treatment. 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 clinical development which is a lengthy and expensive process with uncertain outcomes, and therefore our clinical trials may be delayed or terminated and may be more costly than expected; the clinical results from this PIVOT study conducted by U.S. Department of Veterans Affairs (VA) may not be consistent with results from our previous clinical trials of COMP360 psilocybin treatment; our need for substantial 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 delay, limit or terminate our clinical trials; our efforts to obtain marketing approval from the applicable regulatory authorities in any jurisdiction for our investigational COMP360 psilocybin treatment may be unsuccessful; and our efforts to commercialize and obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment, if approved, may be unsuccessful; 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.

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

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