NEWS RELEASE

Compass Pathways Announces FDA Acceptance of IND Application for PTSD and Hosts Webinar on PTSD and TRD

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- FDA Accepts Investigational New Drug (IND) Application for COMP360 for the treatment of post-traumatic stress disorder (PTSD), enabling initiation of late-stage trial
- Compass continues to advance commercial preparations to be launch-ready by the end of the year for COMP360 for treatment-resistant depression (TRD)
- Management will host webinar with KOL and industry leaders to discuss PTSD clinical trial and commercial preparations for TRD from 10:00-11:30 am ET on January 7th

LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to accelerating patient access to evidence-based innovation, today announced that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for COMP360, enabling the initiation of a late-stage clinical trial in patients with PTSD. Compass management, along with KOL and industry leaders, will host a webinar today to discuss the company's clinical trial plans for PTSD, as well as commercial preparations for treatment-resistant depression (TRD) from 10:00-11:30 am ET on January 7th.

"PTSD is one of the most challenging mental health conditions, with approximately 13 million adults in the U.S. living with persistent symptoms and limited treatment options," said Dr. Guy Goodwin, Chief Medical Officer at Compass Pathways. "We are pleased to advance our clinical development - the unmet need is profound, and it demands bold innovation. We believe COMP360 has the potential to transform the treatment landscape for PTSD and bring hope to those who need it most."

"We enter 2026 with excitement and strong momentum, driving innovation to address critical needs in both PTSD

and TRD," said Kabir Nath, Chief Executive Officer at Compass Pathways. "As our commercialization plans advance, our focus is on ensuring seamless access to COMP360 for patients living with TRD, if approved. We look forward to continuing our close collaboration with the FDA and remain committed to generating robust clinical evidence with scientific rigor as we move into this next chapter."

Late-Stage Clinical Trial for PTSD

- U.S FDA has accepted IND application for COMP360 in PTSD, enabling the initiation of a Phase 2b/3 (COMP202) clinical trial in patients living with PTSD.
- The phase 2b/3 multicenter, randomized, double-blind, controlled study, with an open label extension, aims to investigate the efficacy, safety, and tolerability of COMP360 in participants with PTSD.
- The study is comprised of 2 parts:
    - Part A (blinded) is a 12-week fixed repeat-dose, double-blinded, controlled part to confirm the efficacy of two administrations of COMP360 25 mg versus two administrations of COMP360 1 mg. The second COMP360 administration session will occur approximately 4 weeks later. The primary efficacy endpoint is the change from baseline in CAPS-5 total severity score at Week 8.
    - Part B (open-label) is a 40-week open-label follow-up to evaluate the long-term safety and efficacy of treatment in Part A. Eligible participants will receive a single open label retreatment with COMP360 25 mg. In both Part A and Part B, COMP360 may be administered adjunctively to a single permitted oral antidepressant.
- Previous Phase 2 open-label, safety and tolerability study in PTSD showed COMP360 was generally safe and well-tolerated and demonstrated both rapid and durable improvement in symptoms from baseline observed following a single administration out to 12 weeks. The results of this study were published in the September 2025 issue of the **Journal of Psychopharmacology**.

Commercialization Readiness in TRD

- Compass' strategic collaborations continue to yield valuable learnings about how COMP360 psilocybin treatment will seamlessly integrate into various healthcare settings. Compass recently added Radial, a national network of clinics delivering interventional, evidence-based treatments for mental health conditions, as its seventh collaboration
- Positive Type B meeting with the FDA in September 2025 to discuss the Company's NDA submission strategy for COMP360 in TRD and potential acceleration scenarios, including rolling submission. To facilitate rolling submission and review, Compass is disclosing second phase 3 trial (COMP006) 9-week (Part A) data together with 6-week (Part A) and 26-week (Part B) of COMP005 in the second half of Q1 2026
- 26-week (Part B) data from COMP006 is expected in early Q3 2026

Financial Updates

- Compass amended its existing term loan facility with Hercules Capital, Inc. (NYSE: HTGC), increasing the overall size to up to $150 million, of which $50 million have been drawn down under the amended loan facility as of closing. The remainder is available subject to meeting certain conditions specified in the Loan Agreement. The amendment extends the interest-only period from January 2, 2026 until at least January 5, 2029, with further extensions subject to the achievement of specified milestones, and extends the maturity date from July 1, 2027 to January 5, 2031
- This transaction provides further flexibility to the balance sheet and continues to maintain cash into 2027

January 7th PTSD & TRD Webinar - 10:00 am – 11:30 am ET

Webinar Overview:

- The discussion will feature perspectives from KOLs, industry leaders, and Compass management on the treatment landscape and unmet needs in TRD and PTSD, patient care pathways, growing interventional psychiatry infrastructure, and evolving treatment models
- Compass management team will also cover commercial readiness activities, the emerging profile of COMP360 in TRD, and plans for the late-stage PTSD program

Speakers include:

- Gary Small, MD, Director of Behavioral Health Therapies, Hackensack Meridian Health
- Geoffery Grammer, MD, CMO at Greenbrook Mental Wellness Centers
- Myriam Barthes, co-founder and CEO at Journey Clinical
- Dimitri Cavathas, CEO at HealthPort

Access:

- A live audio webcast of this event will be accessible at this link: **https://lifescievents.com/event/q0v8tp3/**. A replay of the webcast will be accessible for 30 days following the event.

About Post-Traumatic Stress Disorder (PTSD)

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 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 TRD[1]. **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 Compass Pathways

Compass Pathways plc (Nasdaq: CMPS) is a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. We are motivated by the need to find better ways to help and empower people with serious mental health conditions who are not helped by existing treatments. We are pioneering a new paradigm for treating mental health conditions focused on rapid and durable responses through the development of our investigational COMP360 synthetic psilocybin treatment, potentially a first in class treatment. COMP360 has Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) and has received Innovative Licensing and Access Pathway (ILAP) designation in the UK for treatment-resistant depression (TRD).

Compass is headquartered in London, UK, with offices in New York in the U.S. We envision a world where mental health means not just the absence of illness but the ability to thrive.

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 expectations regarding our financial guidance; our expectations regarding the anticipated benefits of the amended term loan facility, our ability to achieve specified milestones under the amended term loan facility, the availability of unfunded tranches in the future, our business strategy and goals; our expectations and projections about the company’s future cash needs and financial results; our plans and expectations regarding our clinical trials, including our phase 3 trials in TRD and our planned phase 2b/3 trial in PTSD, our expectations regarding the time periods for the release of data from the COMP005 and COMP006 Phase 3 trials for TRD; our expectations regarding discussions with the FDA, including discussions regarding potential NDA acceleration strategies, including potential for rolling NDA submission for COMP360 psilocybin treatment in TRD; our expectations regarding potential commercial launch timelines; the potential for the pivotal phase 3 program in TRD to support regulatory filings and approvals on an accelerated basis or at all; our expectations regarding the safety or efficacy of our investigational COMP360 psilocybin treatment, including as a treatment for treatment of TRD or PTSD; 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, on an accelerated timeline or at all; 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 results of early-stage clinical trials of our investigational COMP360 psilocybin treatment may not be predictive of the results of later stage clinical trials; 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; we may be unable to borrow any future tranches under the amended term loan facility as the availability of future tranches is dependent, in part, on achievement of certain milestones, the approval of the lender, and other factors;

we may be unable to comply with the covenants and other obligations under the amended term loan facility; our acceleration strategies for our NDA submission may not be successful; FDA may ultimately disagree with our proposal for a rolling NDA submission and may not permit us to utilize the rolling review process; our efforts to obtain marketing approval from FDA or regulatory authorities in any other jurisdiction for our investigational COMP360 psilocybin treatment may be unsuccessful; our efforts to commercialize and obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment, if approved, may be unsuccessful; the risk that our strategic collaborations will not continue or will not be successful; and our ability 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, the prospectus supplement related to the proposed public offering we plan to file 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. Data on file

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