NEWS RELEASE

Compass Pathways Announces Six-Month Data from Second Phase 3 Trial Confirming Rapid and Durable Profile

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- New 6-month data supports COMP360's potential to establish a new standard of care in TRD
- Data from positive COMP006 Phase 3 trial demonstrates durable benefit through at least 6 months further validating COMP360's differentiated profile in highly chronic TRD
- Across two highly statistically significant positive Phase 3 trials, COMP360 is the first classic psychedelic[1] to consistently demonstrate rapid onset, significant durability and reproducibility of effect in TRD, one of psychiatry's most difficult conditions in which to demonstrate efficacy
- COMP360 continues to demonstrate a generally well-tolerated and safe profile with no new safety findings
- Rolling NDA submission and initial review underway and final submission expected to be completed in Q4
- Commercial launch-readiness on track for end of 2026, with launch expected in first half of 2027
- Compass continues to progress late-stage PTSD program, where millions of patients are urgently in need of new, effective options
- Compass to host a webinar on July 7th at 8:00 am ET

LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to accelerating patient access to evidence-based innovation, announced today the 26-week results (Part B) from its second ongoing Phase 3 COMP006 trial of COMP360, a synthetic, proprietary formulation of psilocybin, for treatment-resistant depression (TRD) which confirm COMP360's rapid onset and durable profile. The 26-week findings in nearly 600 patients build on previously reported results from the first Phase 3 trial, COMP005, which demonstrated rapid onset and durable response to at least 6 months, with a generally well-tolerated and safe profile in people living with TRD.

The COMP360 Phase 3 program participants represent a highly chronic TRD population. In COMP006, participants had current depressive episodes lasting on average over three years and an average of more than six lifetime depressive episodes. Within the context of this severe population, 39% of participants in the 25 mg arm achieved a clinically meaningful reduction in MADRS[2] (≥ 25%) by week 6, following two fixed doses of COMP360, and maintained durable response at least through Week 26. This compares favorably to the 25% in COMP005 following a single dose, supporting the potential value of a second dose in enhancing clinical benefit for some patients. COMP360 continues to demonstrate a generally well-tolerated and safe profile, with the vast majority of treatment-emergent adverse events (TEAEs) being transient and predominantly occurring on day of dosing.

A rolling New Drug Application (NDA) submission and initial review with the U.S. Food and Drug Administration (FDA) is underway and final submission remains on track to be completed in Q4, 2026. Compass anticipates the launch of COMP360 in the first half of 2027 subject to FDA approval and following Drug Enforcement Administration (DEA) rescheduling.

“The COMP006 data further strengthens our robust clinical package for COMP360 and represents an important step toward completing our NDA submission,” said Kabir Nath, Chief Executive Officer of Compass Pathways. “COMP360 has demonstrated consistent results, with rapid onset and durable benefit for people living with chronic, treatment-resistant depression. We are convinced this profile will lead to a profound shift in mental health care — moving beyond daily or frequent administration towards an option potentially involving just a few treatments in a year that could be life changing for patients. As we advance launch preparations for TRD, we continue to have active interactions with the FDA with our rolling NDA submission underway and on track for final submission in Q4, and launch anticipated in the first half of 2027. We are excited by the data we have generated for COMP360 and thrilled for the millions of patients with TRD who could potentially benefit from our achievements.”

“We are grateful to the hundreds of participants across our Phase 3 program along with the sites, providers and caregivers who have made it possible for us to generate data supporting the safety and efficacy of COMP360. The participants in our Phase 3 program reflect the clinical reality of TRD: people with a chronic, treatment-resistant condition who had already been failed by multiple antidepressant regimens and, in many cases, were in their current depressive episode for nearly four years,” said Dr. Guy Goodwin, Chief Medical Officer of Compass Pathways. “COMP360 has demonstrated rapid, durable and reproducible clinical effects through at least six months — with a consistent safety profile — across two large, well-controlled Phase 3 studies in TRD. Against a high level of chronicity and treatment resistance, this achievement at scale is remarkable in one of psychiatry’s most underserved patient populations. For a condition that places profound burden on patients, families and the healthcare system, COMP360 has the potential to establish a new standard of care and fundamentally change what patients and clinicians can expect from treatment.”

“At Mindful Health Solutions we work with many patients struggling with chronic, severe depression who have failed to respond to standard antidepressants. The latest results from Compass’ COMP006 Part B mark an important step towards bringing a novel class of therapeutics to the many patients in need,” said Tobias Marton MD PhD, CMO of Mindful Health Solutions. “The patients enrolled in Compass’ trial had a high degree of treatment resistance reflected by a current episode length of more than 3 years on average and a history of over 6 lifetime episodes. With 39% of patients achieving a clinically meaningful response after two doses of psilocybin – an effect maintained for an average of six months – and almost 30% of those responders going into remission in the treatment interval, these results are exciting. For us, this represents a significant advancement for psychiatry that will strengthen our ability to reduce the suffering and improve the lives of some of our sickest patients.”

Key findings from COMP006 Part B

Efficacy profile

- COMP006 Part A (previously disclosed in February 2026) successfully met its primary endpoint at Week 6, delivering highly statistically significant and clinically meaningful results
- Rapid onset of effect was observed, with consistent separation between the 25 mg and the 1 mg arm maintained through the randomized, blinded Part B period to Week 26
- 39% of participants in the 25 mg arm achieved a clinically meaningful reduction in MADRS (≥ 25%) at Week 6, maintaining benefit, on average, through at least Week 26
    - Retreatment in Part B further enhanced benefit: nearly 30% of participants who achieved a clinically meaningful response at Week 6 later went into remission [3] following retreatment in Part B
- Together with COMP005, the COMP006 26-week data confirm a consistent, differentiated profile for COMP360, with rapid onset and durable benefit observed across two large, well-controlled Phase 3 studies in TRD

Safety profile

In a highly chronic TRD population with long-lasting depressive episodes, and consistent with previous studies, COMP360 continues to demonstrate a generally well-tolerated and safe profile with no new safety findings.

- Majority of TEAEs were transient and predominantly occurring on day of dosing
    - Most common adverse events were nausea, headache, anxiety and visual hallucination
- Serious adverse events (SAEs) were similar across arms (6.3% in the 1 mg arm and 5.7% in the 25 mg arm) over 26 weeks but low overall across the trial

Live Webcast

Compass management will host a live audio webcast on July 7th at 8:00 am ET. The webcast will be accessible at this link: **https://lifescievents.com/event/iwt2n58/**

A replay of the webcast will be accessible for 30 days following the event.

About the COMP360 Phase 3 Program

The COMP360 program aims to evaluate the safety and efficacy of COMP360 psilocybin, a synthetic, proprietary formulation of psilocybin under investigation for difficult-to-treat mental health conditions. There are two pivotal Phase 3 trials, COMP005 and COMP006, evaluating the efficacy of COMP360 for treatment-resistant depression (TRD).

The ongoing COMP006 trial, running in parallel to the COMP005 trial, is a randomized, double-blind study with 581 dosed participants across North America and Europe and is comparing the efficacy and safety of two fixed doses, taken three weeks apart, of 25 mg COMP360 to 10 mg COMP360 and 1 mg COMP360 (25 mg: n=296; 10 mg: n=142; 1 mg: n=143). There is a potential for a total of 4 doses of COMP360 across a 52-week period. The trial is comprised of three parts: Part A, which was blinded through 9 weeks, Part B which recently concluded and remained blinded through week 26, and Part C, which contains an open-label treatment part from week 26 to 52.

The COMP005 trial is a randomized, double-blind, placebo-controlled study, with 258 dosed participants across the United States and is assessing the efficacy and safety of a single dose of 25 mg COMP360 versus placebo for reducing symptom severity in TRD (COMP360 25 mg: n=171; placebo: n=87). There is a potential for a total of 3 doses of COMP360 across a 52-week period. The trial is comprised of three parts: Part A, which was blinded through 6 weeks; Part B, which was blinded through week 26; and Part C, which contains an open-label treatment part from week 26 to 52.

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[4]. **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 business strategy and goals; our expectations regarding the safety or efficacy of our investigational COMP360 psilocybin treatment, including as a treatment for TRD or PTSD; our plans and expectations regarding our clinical trials, including our phase 3 trials in TRD and our phase 2b/3 trial in PTSD; 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 our rolling submission of a new drug application, or NDA, for COMP360 psilocybin treatment in TRD and 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 expectations regarding potential commercial launch timelines and our commercial readiness; our efforts and 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 our expected, accelerated timeline or at all; and our expectations regarding the benefits of our investigational COMP360 psilocybin treatment, including as a treatment of TRD or

PTSD. 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 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 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; 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, or approval from regulatory authorities in other jurisdictions, for our investigational COMP360 psilocybin treatment on an accelerated basis, or at all, may be unsuccessful; the timing and substance of decisions by the Drug Enforcement Administration 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 to commercialize and obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment, if approved, may be unsuccessful; and our ability to manage growth and 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.

References

1. For the definition of classic psychedelic, see Vollenweider, F.X. and Smallridge, J.W., 2022. Classic psychedelic drugs: update on biological mechanisms. Pharmacopsychiatry, 55(03), pp.121-138
2. Montgomery-Åsberg Depression Rating Scale
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4. 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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