



## **Compass Pathways establishes research collaboration with Mindful Health Solutions to inform the development of a scalable and cost-effective delivery model for investigational COMP360 psilocybin treatment**

May 2, 2024

LONDON, May 02, 2024 (GLOBE NEWSWIRE) -- Compass Pathways plc (Nasdaq: CMPS) ("Compass"), a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health, and Mindful Health Solutions (MHS), one of the US's leading providers of innovative behavioral health care, today announced that they have entered into a research collaboration agreement to inform the development of a scalable and cost-effective delivery model for COMP360 psilocybin treatment, if approved for treatment-resistant depression (TRD). This is the latest of several collaborations for Compass, intended to better understand a range of potential approaches to deliver COMP360 to patients in different care settings.

MHS offers comprehensive mental health care services for patients living with TRD and other mental health conditions. They focus on early adoption of advanced, interventional treatment options, as part of a long-term, holistic care model that includes medication management and psychotherapy. MHS operates over 20 outpatient clinics located across California, Washington, Texas, and Georgia.

"It is crucial that we understand how different mental health service providers are positioned to deliver COMP360 psilocybin treatment to patients, should it receive FDA approval," said Kabir Nath, CEO of Compass Pathways. "By joining forces with MHS, Compass will have the opportunity to learn from a leading provider of innovative behavioral health care for people living with treatment-resistant depression and other difficult-to-treat mental health conditions."

The collaboration with MHS will include an in-depth information exchange on Compass's potential delivery model for investigational COMP360 psilocybin treatment, and how it might fit into a healthcare delivery system similar to MHS. Compass and MHS will chart the depression and TRD patient pathway and investigate challenges with the current patient care experience, including potential approaches to address these. MHS will complete training and learning sessions on Compass's psychological support model and therapist training program and conduct research to better understand therapist training needs. Compass and MHS will exchange information on model treatment rooms, site activation services, and coding and reimbursement considerations related to psychedelic treatments.

"There are millions of people in the US living with depression for whom existing treatments do not work," said John Minahan, CEO of Mindful Health Solutions. "Part of MHS's mission is to make innovative treatments accessible to everyone who may benefit from them. As such, we are proud to collaborate with Compass Pathways and to contribute to learning how COMP360 psilocybin treatment may be most effectively delivered to patients, if approved for TRD."

Compass has previously announced research collaboration agreements with Greenbrook TMS, a leading provider of interventional psychiatric treatments such as transcranial magnetic stimulation; Hackensack Meridian Health, a leading not-for-profit health care organization and the largest, most comprehensive and truly integrated network in New Jersey, addressing the full continuum of care for people living with TRD; and Journey Clinical, a leading psychedelic-assisted psychotherapy platform with the largest network of licensed therapists focused on psychedelics in the US.

### **About Compass Pathways**

Compass Pathways plc (Nasdaq: CMPS) is a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. Our focus is on improving the lives of those who are living with mental health challenges and who are not helped by current treatments. We are pioneering the development of a new model of psilocybin treatment, in which our proprietary formulation of synthetic psilocybin, COMP360, is administered in conjunction with psychological support. COMP360 has been designated a Breakthrough Therapy by 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).

We have commenced a phase 3 clinical program of COMP360 psilocybin treatment in TRD, the largest randomized, controlled, double-blind psilocybin treatment clinical program ever conducted. Previously, we completed a phase 2b study with top line data showing a statistically significant ( $p < 0.001$ ) and clinically relevant improvement in depressive symptom severity after three weeks for patients who received a single 25mg dose of COMP360 psilocybin with psychological support. We are also conducting phase 2 clinical studies of COMP360 psilocybin treatment for post-traumatic stress disorder (PTSD) and anorexia nervosa.

Compass is headquartered in London, UK, with offices in New York and San Francisco in the United States. Our vision is a world of mental wellbeing. [www.compasspathways.com](http://www.compasspathways.com).

### **About Mindful Health Solutions**

Mindful Health Solutions ([mindfulhealthsolutions.com](http://mindfulhealthsolutions.com)) is a leading provider of innovative behavioral health care in the US, with a focus on emerging psychedelic research, precision medicine, and cutting-edge treatment protocols such as transcranial magnetic stimulation, esketamine, and IV Ketamine for patients living with TRD and other serious mental illnesses. MHS operates over 20 outpatient clinics located across California, Washington, Texas, and Georgia. MHS has a team of psychiatrists, therapists and nurse practitioners focused on helping patients get the help they need. They are dedicated to improving patients' lives, especially those suffering from depression.

### **Availability of other information about Compass Pathways**

Investors and others should note that we communicate with our investors and the public using our website ([www.compasspathways.com](http://www.compasspathways.com)), our investor relations website ([ir.compasspathways.com](http://ir.compasspathways.com)), and on social media (LinkedIn), including, but not limited to, investor presentations and investor fact sheets, US Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in us to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include additional social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

### **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”, “should”, “expect”, “intend”, “plan”, “believe”, “estimate”, “predict”, “possible”, “potential” 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, the safety or efficacy of investigational COMP360 psilocybin treatment as a treatment for treatment-resistant depression, post-traumatic stress disorder or anorexia nervosa, the potential for the pivotal phase 3 program or other trials to support regulatory filings and approvals, Compass's business strategy and goals, Compass's plans, expectations and ability to achieve its goals related to this research collaboration agreement and its other research collaborations; Compass's ability to continue to advance its research, obtain regulatory approval or develop plans to bring COMP360 psilocybin treatment to patients, and Compass's expectations regarding the benefits of its 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: clinical development is lengthy and outcomes are uncertain, and therefore Compass's clinical trials may be delayed or terminated; the results early-stage clinical trials of investigational COMP360 psilocybin treatment may not be predictive of the results of later stage clinical trials; the possibility of unfavorable results from additional clinical trials of COMP360 psilocybin treatment or from subsequent analysis of existing data or new data received from additional ongoing and future studies of COMP360 psilocybin treatment; Compass's efforts to obtain marketing approval from the applicable regulatory authorities in any jurisdiction for COMP360 or any of future product candidates may be unsuccessful; Compass's efforts to obtain coverage and reimbursement for its investigational COMP360 psilocybin treatment, if approved, may be unsuccessful; the risk that this research collaboration with Mindful Health or one or more of our previously announced research collaborations will not continue or will not achieve the expected benefits; uncertainties regarding the ability to develop a scalable and cost-effective delivery model for COMP360 psilocybin treatment; the risk that market adoption and access to COMP360 psilocybin treatment, if approved, may be limited 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](http://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.

### **Enquiries**

Media: Amy Lawrence, [media@compasspathways.com](mailto:media@compasspathways.com), +44 7813 777 919

Investors: Stephen Schultz, [stephen.schultz@compasspathways.com](mailto:stephen.schultz@compasspathways.com), +1 401 290 7324