

Numinus Announces Key Milestones in MAPS-Sponsored MDMA-Assisted Therapy for PTSD Clinical Trial

NEWS PROVIDED BY
Numinus Wellness Inc. →
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Numinus has received approvals from Health Canada and the Institutional Ethics Review Board

VANCOUVER, BC, Jan. 19, 2022 /CNW/ - Numinus Wellness Inc. ("Numinus" or the "Company") (TSX: NUMI), a leader in psychedelics-focused mental healthcare, is pleased to announce that it has completed key steps to prepare to enroll participants at its clinics participating in "A multi-site open-label extension study of MDMA-assisted psychotherapy for PTSD (MAPPUSX)", sponsored by the Multidisciplinary Association for Psychedelic Studies (MAPS).

The Canadian study sites, which will continue to study the safety of MDMA-assisted therapy in treating severe PTSD, under the leadership of MAPS Public Benefit Corporation (MAPS PBC) as study sponsor, have recently received regulatory authorization from Health Canada, ethical approval from an Institutional Review Board (IRB) and a Section 56 exemption from the Controlled Drug and Substance Act (Canada), which will allow the use of MDMA throughout the duration of the clinical trial.

"We are thrilled that our talented team of doctors and researchers at Numinus are helping pave the path forward to greater access to safe psychedelic-assisted psychotherapy with this study further evaluating the safety of MDMA-assisted therapy in treating severe PTSD," says Payton Nyquest, Founder and CEO, Numinus. "This is an exciting next step in the MAPPUSX study, happening at our clinics in both British Columbia and Quebec, and we look forward to how this work supports expanded collaboration with MAPS in the future."

Numinus will host the Canadian sites for MAPPUSX, managed through Numinus' two recently acquired, purpose-designed clinics, allowing for quick completion of the Canadian segment of the MAPS-sponsored trial.

"The recent approvals from Health Canada and the IRB, coupled with our clinics in Montreal and Vancouver already being regulatorily compliant, allow us to quickly conduct this phase of the research at these sites," said Dr. Joe Flanders, VP, Psychology, Numinus and therapist for the Montreal site of the trial. "I'm proud to be a part of this study alongside our clinical and research teams as we work towards examining the important findings around MDMA-assisted therapy for PTSD and, ultimately, translating research findings into mainstream clinical practice."

The trial will be open to eligible participants who were previously enrolled in the placebo arm of the parent study (MAPP1) or who were not able to receive treatment due to COVID-19 restrictions.

NOTE

The safety of MDMA-assisted therapy is currently under investigation. It has not yet been approved by Health Canada or the U.S. Food and Drug Administration (FDA), does not work for everyone, and carries risks even in therapeutic settings. These statements are no guarantee of future Health Canada or FDA approval or availability of MDMA-assisted therapy. These statements necessarily involve known and unknown risks and uncertainties, which may cause actual outcomes to differ materially from projections.

About Numinus

Numinus Wellness (TSX: NUMI) helps people to heal and be well through the development and delivery of innovative mental health care and access to safe, evidence-based psychedelic-assisted therapies. The Numinus model - including psychedelic production, research and clinic care - is at the forefront of a transformation aimed at healing rather than managing symptoms for depression, anxiety, trauma, pain and substance use. At Numinus, we are leading the integration of psychedelic-assisted therapies into mainstream clinical practice and building the foundation for a healthier society.

Learn more at www.numinus.com and follow us on [LinkedIn](#), [Facebook](#), [Twitter](#), and [Instagram](#).

About MAPS

Founded in 1986, MAPS is a 501(c)(3) non-profit research and educational organization that develops medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana. MAPS is sponsoring the most advanced psychedelic therapy research in the world: Phase 3 clinical trials of MDMA-assisted therapy for PTSD. Since its founding, MAPS has raised over \$130 million for psychedelic and marijuana research and education and has earned both the [Guidestar Platinum Seal of Transparency](#) and a [4-Star Rating from Charity Navigator](#). Learn more at maps.org

ABOUT MAPS PUBLIC BENEFIT CORPORATION (MAPS PBC)

MAPS Public Benefit Corporation (MAPS PBC) catalyzes healing and well-being through psychedelic drug development, therapist training programs, and sales of prescription psychedelics while prioritizing public benefit above profit. Founded in 2014, MAPS PBC is a wholly owned subsidiary of the Multidisciplinary Association for Psychedelic Studies (MAPS), a 501(c)(3) non-profit organization. Learn more at www.mapspublicbenefit.org

Forward-looking statements

This press release contains forward-looking statements within the meaning of applicable securities laws. All statements that are not historical facts, including without limitation, statements regarding future estimates, plans, programs, forecasts, projections, objectives, assumptions, expectations or beliefs regarding future performance are "forward-looking statements". Forward-looking statements can be identified by the use of words such as "expects", "does not expect", "is expected", , "intends", "anticipates", "does not anticipate", "believes" or variations of these words, expressions or statements, that certain actions, events or results "may", "could", "would", "might" or "will be" taken, will occur or will be realized. Such forward-looking statements involve risks, uncertainties and other known and unknown factors that could cause actual results, events or developments to differ materially from the results, events or developments expected and expressed or implied in such forward-looking statements. These risks and uncertainties include, but are not limited to, dependence on obtaining and maintaining regulatory approvals, including the acquisition and renewal of federal, provincial, municipal, local or other licenses, and any inability to obtain all necessary government authorizations, licenses and permits to operate and expand the Company's facilities; regulatory or policy changes such as changes in applicable laws and regulations, including federal and provincial legalization, due to fluctuations in public opinion, industry perception of integrative mental health, including the use of psychedelic-assisted therapy, delays or inefficiencies or any other reason; any other factor or development likely to hamper the growth of the market; the Company's limited operating and profitability track record; dependence on management; the Company's need for additional financing and the effects of financial market conditions and other factors on the availability of capital; competition, including that of more established and better funded competitors; the continued impact of the COVID-19 pandemic; and the need to build and maintain alliances and partnerships, including with research and development companies, customers and suppliers. These factors should be carefully considered, and readers are cautioned not to place undue reliance on forward-looking statements. Despite the Company's efforts to identify the main risk factors that could cause actual measures, events or results to differ materially from those described in forward-looking statements, other risk factors may cause measures, events or developments to materially differ from those anticipated, estimated or intended. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in forward-looking statements. The Company does not undertake to revise forward-looking statements, even if new information becomes available as a result of future events, new facts or any other reason, except as required by applicable laws.

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