

Optimi Health, ATMA Journey Centers To Proceed With Phase I Natural Psilocybin and MDMA Clinical Trial Application to Health Canada

Optimi aiming to become the first vertically integrated psychedelics firm to formulate and trial MDMA for healthy subjects

VANCOUVER, BC — [Optimi Health Corp.](#) (CSE: OPTI) (OTCQX: OPTHF) (FRA: 8BN) (“Optimi” or the “Company”), a Canadian-based company licensed by Health Canada to produce and supply natural, EU-GMP grade psilocybin and other psychedelic substances, most notably MDMA, is pleased to announce that in conjunction with ATMA Journey Centers (“ATMA”), the companies have confirmed their intent to proceed with a Phase I clinical trial application (CTA) that will document the safety of the Optimi’s natural psilocybin biomass and 3,4-methylenedioxy-methamphetamine (MDMA) in healthy patients.

Upon Health Canada approval, it would be the first trial to assess both safety and additional markers, such as the mystical experience questionnaire in healthy subjects that have consumed MDMA.

Optimi CEO, Bill Ciprick, says the goal of the clinical trial is to acquire data, including blood pressure, temperature, heart rate, and ECG readings, for Optimi’s proprietary formulation using natural EU-GMP psilocybin and MDMA. These products are being produced and tested in-house at Optimi’s 20,000 square foot facilities in Princeton, British Columbia.

“The clinical validation of our products on healthy subjects brings us one-step closer to commercialization,” said Ciprick. “Coming off the success of ATMA’s recently completed Phase I psilocybin trial and a No Objection Letter to conduct its N-500 Phase II psilocybin clinical trial on frontline healthcare professionals, we’re excited to officially begin the process,” he added. “For the thousands of trained professionals waiting to experience natural, EU-GMP psilocybin and MDMA, we share their enthusiasm and believe we have an ethical responsibility to supply them with a life-changing product that is receiving considerable attention from regulatory bodies across the world.”

ATMA is currently the only Canadian organization that has received approval from Health Canada to conduct a Phase I safety trial with psilocybin in healthy therapists, which it completed last month. Health Canada recently provided ATMA with a No Objection Letter to conduct an N-500 psilocybin Phase II clinical trial aimed at studying the potential relief of COVID-19-associated mental health concerns in frontline healthcare providers, in addition to documenting the healthcare providers’ firsthand evaluation of the potential effectiveness of psilocybin psychotherapy in the application.

ATMA CEO, David Harder, recognizes the historical context of the CTA and says his team is committed to building on the success of his company’s leadership in therapist-centred and therapist-driven support and training.

“Securing a clinical trial using natural EU-GMP psilocybin and MDMA is key to the growth of training and providing for experiential learning with both of these molecules, and others, as they are developed by Optimi,” said Harder. “This is critical in providing a solid training program for therapists to prepare for the need that is already at our doorstep,” he added.

In August, psychedelic pioneer and industry stalwart, Rick Doblin, outlined his organization’s (the Multidisciplinary Association for Psychedelic Studies – MAPS) goal to train 25,000 therapists in MDMA-assisted therapy for PTSD before 2030.

He added that a further 100,000 therapists could be “kept busy” through potential clinical indications for MDMA and psilocybin such as alcohol and substance abuse, social anxiety, and phobias.

In 2017, the Food and Drug Administration (FDA) granted Breakthrough Therapy designation to MDMA-assisted psychotherapy for the treatment of PTSD.

Optimi’s plan for commercialization involves the Company being an active leader in meeting therapist demand for natural EU-GMP psilocybin and MDMA.

Both Ciprick and Harder have confirmed that Optimi will serve as the official clinical trial sponsor while ATMA delivers clinical research expertise through its medical advisory team led by Dr. Michael Blough. Details of the CTA protocol will be released upon receipt of a No Objection Letter from Health Canada.

The Optimi-ATMA partnership is intended as an expansion of the scope of the relationship which began with the signing of an initial psilocybin supply agreement in June 2022 and will serve as the basis for the further development of the Company’s commercial pipeline.

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ABOUT OPTIMI (CSE: OPTI) (OTCQX: OPTHF) (FRA: 8BN)

Optimi Health Corp. is a Canadian-based company licensed by Health Canada to produce and supply natural, EU-GMP grade psilocybin and synthetic psychedelic substances, as well as functional mushrooms that focus on the health and wellness markets. Built with the purpose of producing scalable psychedelic formulations for transformational human experiences, the Company’s goal is to be the number one trusted, compassionate supplier of safe drug products throughout the world. Optimi’s products are grown at its two facilities comprising a total of 20,000 square feet in Princeton, British Columbia, making it the largest psilocybin and MDMA cultivator in North America.

ABOUT ATMA JOURNEY CENTERS

ATMA is pioneering a therapist-centered and therapist-driven business model for the psychedelic industry, by building the largest online community platform for psychedelic practitioners. Education, training, and business support services will all be accessible on one user friendly technology platform. ATMA’s philosophy of inclusivity will encourage more participation from healthcare professionals, which will in turn yield more data and experiences. Overall, this will lead to increased effectiveness and accessibility of psychedelic-assisted therapy. Beginning with a clear focus on psilocybin-assisted therapy, ATMA will be able to expand to other psychedelics as the regulatory environment also expands. ATMA provides a clear, guided path for healthcare professionals and clinics to build psychedelic-assisted therapies into their current practices.

FORWARD-LOOKING STATEMENTS

This news release contains forward-looking statements and forward-looking information within the meaning of Canadian securities legislation (collectively, “forward-looking statements”) that relate to

Optimi's current expectations and views of future events. Any statements that express, or involve discussions as to, expectations, beliefs, plans, objectives, assumptions or future events or performance (often, but not always, through the use of words or phrases such as "will likely result," "are expected to," "expects," "will continue," "is anticipated," "anticipates," "believes," "estimated," "intends," "plans," "forecast," "projection," "strategy," "objective," and "outlook") are not historical facts and may be forward-looking statements and may involve estimates, assumptions and uncertainties which could cause actual results or outcomes to differ materially from those expressed in such forward-looking statements. No assurance can be given that these expectations will prove to be correct and such forward-looking statements included in this news release should not be unduly relied upon. These statements speak only as of the date of this news release. In particular and without limitation, this news release contains forward- looking statements pertaining to activities proposed to be conducted under the Company's approved Health Canada dealer's licence and associated business related to Psilocybin, Psilocin, other psychedelic substances, some being synthetically formulated, and Optimi's plans, focus and objectives.

Forward-looking statements are based on a number of assumptions and are subject to a number of risks and uncertainties, many of which are beyond Optimi's control, which could cause actual results and events to differ materially from those that are disclosed in or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, the impact and progression of the COVID-19 pandemic and other factors set forth under "Forward-Looking Statements" and "Risk Factors" in the Company's Annual information Form dated January 12, 2022, and other continuous disclosure filings available under Optimi's profile at www.sedar.com. Optimi undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. New factors emerge from time to time, and it is not possible for Optimi to predict all of them or assess the impact of each such factor or the extent to which any factor, or combination of factors, may cause results to differ materially from those contained in any forward-looking statement.

Any forward-looking statements contained in this news release are expressly qualified in their entirety by this cautionary statement.