



February 2016

Letter to potential funders:

The Multidisciplinary Association for Psychedelic Studies (MAPS) Canada is currently conducting research investigating the effectiveness of MDMA-assisted psychotherapy for the treatment of post-traumatic stress disorder (PTSD). With approval and full involvement from Health Canada and the U.S. Food and Drug Administration (FDA), we are conducting the first legal research investigating the treatment potential of psychedelic-assisted therapies in Canada since 1972. In September 2015, we concluded our Phase 2 clinical trial in Vancouver, B.C. We are now preparing for the final Phase 3 clinical trials, to take place in the U.S. and Canada, which are required to make MDMA-assisted psychotherapy a legal prescription treatment. The Phase 3 trials are projected to begin in early 2017.

The Vancouver study was part of an international series of MAPS-sponsored Phase 2 clinical trials spanning five sites in four countries (USA, Canada, Israel, and Switzerland). One site in the USA enrolled primarily military veterans, and early data is very promising. This is encouraging and especially important due to the high rates of suicide in this population. In Canada, our target populations for subjects in the Phase 3 trial include military combat veterans and emergency first responders (police, fire, ambulance) who are often traumatized by their experiences.

While a contract has not yet been signed, Evan Wood, M.D., Ph.D., lead researcher at the University of British Columbia and St. Paul's Hospital, is considering being the Primary Investigator (PI) for this final stage of research. We are discussing having therapy sessions located in a facility owned and operated by St Paul's Hospital, and are involved with current renovations which would meet the needs of our study.

Our current research is based on a study by Michael Mithoefer, M.D., who demonstrated extremely positive effects for MDMA-assisted psychotherapy for those with chronic, treatment-resistant PTSD. In this study, 83% of the participants who received MDMA-assisted psychotherapy no longer qualified for PTSD after treatment, compared to only 25% of the participants receiving only psychotherapy (placebo). Many of the subjects in this study who had been unable to work due to their symptoms were able to return to work. This treatment appears to be significantly more effective than the currently best available treatments for PTSD, and will also be very cost-efficient compared to the conventional approaches. Patients will not require prolonged courses of conventional treatment, as the typical course of MDMA-assisted psychotherapy takes only a few sessions to generate significant and sustained improvements. For more information and references, see the attached description of the study.

This research is part of a larger psychedelic renaissance, as both Health Canada and the FDA in the USA have agreed to allow psychedelic research to be conducted. Researchers publishing in the USA and Europe have recently been showing promising results for psychedelic-assisted treatments for end-of-life

anxiety, cluster headaches and to reduce obsessive-compulsive symptoms. Large population data analysis indicates psychedelic use to be associated with reductions in psychological distress, suicidality, intimate partner violence and recidivism of criminal behaviour. Other researchers have found psychedelic assisted treatments to be effective for addiction treatments, specifically alcohol, heroin and tobacco use. Some of the above findings could potentially be explained by other research, which showed psychedelic treatments to be impactful on personal meaning, spirituality, openness and improved psychological well-being. A review of the current research was published in the October 2015 edition of the *Canadian Medical Association Journal*. Reference details can be found in the attached research summary document.

The goal of our current fundraising effort is to raise \$1,500,000. This is the projected cost of a full Health Canada-approved Phase 3 study in Vancouver, which would examine the effects of MDMA-assisted psychotherapy in 30-40 participants with chronic, treatment-resistant PTSD over a two-year period. With our international partners, all the data will be combined to produce sufficient statistical power for health regulatory agencies in Canada and the USA to approve MDMA for use in conjunction with psychotherapy for PTSD by licensed practitioners. Upon its successful completion, we anticipate that MDMA-assisted psychotherapy will be legally available in Canada and the USA as an affordable and effective treatment for many thousands of people suffering PTSD, who have limited modalities to alleviate their often crippling symptoms. Any assistance towards achieving this goal would be greatly appreciated.

Sincerely,

Mark Haden, M.S.W.
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Adjunct Professor UBC School of Population and Public Health