From the Desk of Rick Doblin, Ph.D.

On behalf of the now roughly 100 staff members at MAPS and MAPS Public Benefit Corporation (MAPS PBC), I would like to express enormous gratitude to the thousands of MAPS donors who have contributed over $100 million in support of our research and educational efforts since I founded MAPS in 1986. The inspiring news about the results of MAPP1, our first of two Phase 3 studies of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD), that I am sharing would not have been possible without the generosity and trust of MAPS donors, the dedication and expertise of MAPS and MAPS PBC staff, and the compassionate therapy provided by almost 100 therapists who have worked to treat participants with PTSD in our Phase 2 and Phase 3 clinical trials.

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In March 2020, MAPS' Data Monitoring Committee (DMC) conducted an unblinded interim analysis of the data from MAPP1 when 60% of the participants had reached their primary outcome measure, and all 100 participants had been enrolled. The DMC reported great news: we had a 90% or greater probability of obtaining statistically significant results after all 100 participants had completed the study, meaning we didn't need to add more participants to the study. Shortly after the interim analysis, the COVID-19 lockdown resulted in the halting of treatment for a period of time. The U.S. Food and Drug Administration (FDA) reached out to MAPS, as well as other sponsors of research, to offer the opportunity to end our studies early. We negotiated with the FDA so that we would end the study when 90, instead of 100, participants had one baseline measure of their PTSD symptoms, plus at least one outcome measure of their PTSD symptoms after at least one experimental session. While a study with fewer than 100 participants decreases the likelihood of statistical significance, the outstanding results of the interim analysis suggested that even with just 90 participants, we had a very good chance of obtaining statistical significance upon completion of the study.

In August 2020, we gathered the last data from the 90th participant in MAPP1, which took place at 15 study sites (two in Israel, two in Canada, and 11 in the United States). For the last several months, we have been through the process of monitoring (double-checking) all of the data and sending queries regarding the data to the researchers and study coordinators in order to reach "data lock" where the data gathering is considered complete. We need to go through such a rigorous process in order to prepare for the FDA to audit all of our data should we proceed to submit an FDA New Drug Application (NDA) seeking permission for the prescription use of MDMA-assisted psychotherapy for PTSD patients.

After we reached the point of "data lock," we then submitted the data to our statisticians for analysis. At this point, the statisticians and MAPS PBC staff were all still blind to which participants were in the control group who received therapy with an inactive placebo and which participants were in the experimental group who received therapy with MDMA. Only after the data had been analyzed were the statisticians permitted to uncover the blind and see which group was the control group and which was the experimental group.

It's now with an enormous sense of pride, satisfaction, and relief that I can share that we learned that MAPP1 was statistically significant and is therefore considered a successful Phase 3 study. MAPS is on track towards our goal of obtaining FDA approval if we can successfully complete our second Phase 3 study and other associated safety studies that the FDA has required. We now can say with certainty that the $30 million recently raised by MAPS, the Psychedelic Science Funders Collaborative

(PSFC), author Tim Ferriss, and all other donors in our Capstone Campaign will be sufficient to generate all of the research data we need prior to submitting an NDA to the FDA, and then to Health Canada and the Israeli Ministry of Health. In order to bring the therapeutic potential of MDMA-assisted psychotherapy for PTSD to the estimated 350 million people around the world who suffer from PTSD, MAPS is now launching a new $30 million campaign to raise the funds necessary to conduct Phase 3 research in Europe for approval by the European Medicines Agency (EMA) and to globalize regulatory approval in many countries of the world.

While the therapeutic use of MDMA was pioneered around 1976 by Leo Zeff, Ph.D., (a.k.a. The Secret Chief) and I have known since 1984 that MDMA-assisted psychotherapy was excellent at treating PTSD when I used this modality with someone suffering from PTSD, it's only now in 2020 that we have been able to generate evidence supporting safety and efficacy in the context of an FDA-regulated Phase 3 clinical trial. It's tragic that so much suffering could have been avoided since 1986 when the Drug Enforcement Administration (DEA) rejected the recommendation of the DEA Administrative Law Judge that the therapeutic use of MDMA-assisted psychotherapy remain legal. Our current timetable for the potential of FDA approval is the first half of 2023, 37 years after the DEA kept both the therapeutic and social use of MDMA illegal.

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We believe that potential FDA approval of MDMA-assisted psychotherapy for PTSD will be followed by regulatory approvals around the world. This will be followed by the establishment of thousands of psychedelic clinics with therapists cross-trained to provide therapy assisted by MDMA and other psychedelics, including ketamine and psilocybin, as other sponsors obtain approval from regulators. Eventually, in a post-prohibition world, there could be a licensed regulatory system for adults to legally access psychedelics to take on their own without supervision by therapists, with access to minors only with permission from their parents or guardians.

We are now in the midst of a renaissance of psychedelic research, a flourishing of non-profit and for-profit psychedelic companies, and successful psychedelic drug policy reform efforts such as the Oregon Psilocybin Program Initiative and the initiatives in Washington D.C., Ann Arbor, Santa Cruz, Oakland, and Denver that have made psilocybin mushrooms and/or plant psychedelics the lowest law enforcement priority. With the continued support of MAPS members, we have the precious and much-needed opportunity to obtain FDA approval for MDMA-assisted psychotherapy—first for PTSD and then for a wide range of other clinical indications. Our efforts are leading the way, helping other psychedelic organizations and psychedelic drug policy reform efforts toward the long-term goal of mass mental health, eventually moving toward a world with net-zero trauma and increased spirituality, tolerance, and care for the environment.

Onward to completing Phase 3 and way, way beyond!

Rick Doblin

MAPS Founder and Executive Director