From the Desk of Rick Doblin, Ph.D.

As we begin 2021, MAPS is entering a period of incredible opportunity based on accomplishments — decades in the making — realized in 2020.

We completed our first Phase 3 pivotal study of MDMA-assisted therapy for posttraumatic stress disorder (PTSD) with outstanding results, began our second Phase 3 confirmatory study, revamped our therapist training program, and successfully raised $30 million in pledges over three years in our Capstone Campaign to fund the completion of all the research necessary to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for prescription approval of MDMA-assisted therapy for PTSD.

We obtained FDA permission to conduct MDMA/PTSD research at the Bronx VA in New York with Rachel Yehuda, Ph.D., as Principal Investigator, assisted by Shannon Remick, M.D., and Allie Kaigle, Pharm.D., B.C.P., at the Loma Linda VA in California to obtain permission for their Investigator-Initiated Trial (IIT). The Bronx VA study is only waiting on Drug Enforcement Administration (DEA) registration, which we expect in the coming months, and the Loma Linda VA is only waiting on final approval from the Research Advisory Panel of California. These are the final steps before research can begin and our 30-year effort to catalyze MDMA/PTSD research inside the VA system is realized. We also worked to obtain approval for a pilot treatment development study of MDMA-assisted therapy for people suffering from eating disorders, the first of several to apply our learnings to conditions other than PTSD.

We laid the groundwork in five countries in Europe and England to complete the training of European and British therapists, necessary protocols to initiate Phase 3 research seeking approval from the European Medicines Agency (EMA). We've been in touch with therapists, researchers, and activists around the world interested in our therapist training program and bringing research into MDMA-assisted therapy for PTSD to their countries including Armenia, Bosnia, Chile, Denmark, Rwanda, South Africa, Somaliland, and elsewhere.

We filed a lawsuit against the DEA and the U.S. Attorney General (AG) on behalf of Prof. Lyle Craker, UMass Amherst, seeking to compel the DEA to respond to Prof. Craker's application, and over 30 others, for DEA licenses to grow marijuana for FDA-regulated drug development research and other federally legal purposes. We continued our work on research of cannabis for Veterans with PTSD, finalizing the soon-to-be-published scientific paper about our initial pilot study of four kinds of cannabis in 76 Veterans with PTSD and honing a protocol to study marijuana in several hundred Veterans with PTSD for submission to the FDA. The protocol and associated $10 million budget will be submitted in 2021 to the State of Michigan, which must allocate $40 million over two years for research into Veterans' mental health and reducing Veteran suicides, with funds coming from taxes from the sale of legal marijuana in Michigan and grants being awarded only to non-profits or academic researchers.

In non-research news at MAPS, we have been investing in programs and activities to better serve the psychedelic community. Our Zendo Project harm reduction program will soon reach beyond festivals and into communities. Our policy and advocacy department has grown to support increased interest in reform. Our website will soon provide easier access to the history and future of the psychedelic renaissance. You'll be invited to engage with MAPS in new ways, learn through new educational opportunities, and show off your MAPS membership with new gear. For many readers, the announcement that we've confirmed our plans for the next installment of the Psychedelic Science conference series and the new Psychedelic City event, scheduled June 18-25, 2023, will be the most exciting news yet.

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One massive new development has been the rise of for-profit psychedelic companies, with several going public. Most notable are Compass Pathways with a market cap of about $1.65 billion, Mind Medicine with a market cap over $1 billion, Field Trip Health with a market cap of about $155 million, and Numinus with a market cap of about $250 million. None of these companies have started Phase 3 studies, whereas MAPS has successfully completed our first Phase 3 study and our second is underway. MAPS has built tremendous value, but rather than letting that value be privatized, we have ensured it will be returned to the global community through our wholly-owned MAPS Public Benefit Corporation (MAPS PBC). If we obtain regulatory approval, our pharmaceutical arm will market the prescription use of MDMA-assisted therapy for PTSD with all profits being used to advance MAPS' mission.

We face several key challenges for 2021, starting with obtaining publication of the scientific paper about our Phase 3 results in a peer-reviewed journal. We will have several major meetings with FDA to address the credentialing of therapists, whether research sites and potential psychedelic clinics need a doctor on site or on call, whether our protocol to study MDMA and self-compassion will be allowed and limited to participants from the MDMA Therapy Training Program, and the prospect of filing a New Drug Application (NDA) based on the outstanding results of our first Phase 3 study. To globalize research and patient access to MDMA-assisted therapy for PTSD, we will be challenged to raise $30 million to fund research for approval by the European Medicines Agency (EMA); the research supporting FDA and EMA approval would support approval for patient access to MDMA-assisted therapy in many countries of the world. To reduce costs, improve outcomes, and meet the anticipated demand if MDMA-assisted therapy is approved, we will launch research into MDMA-assisted group therapy and roll out our new therapist training program. Compassionate use programs will serve 50 patients diagnosed with treatment-resistant PTSD in the U.S. through expanded access and 50 patients in Israel through open access.

Continuing our cannabis research, we'll be supporting Prof. Craker to obtain the DEA license he has been seeking for more than 20 years to grow marijuana for FDA drug development research. The current supply from the National Institute on Drug Abuse (NIDA) monopoly is low quality and cannot be sold commercially, limiting its usefulness to academic, not drug development, research. When Prof. Craker obtains his license, MAPS will have a viable source of cannabis for drug development research. That sea-change, alongside obtaining a $10 million grant for our marijuana/PTSD research in Veterans from the State of Michigan and final approval for publication of the results of our first marijuana/PTSD study, will uncork a decades-long backlog of research into the medical and mental health benefits of cannabis.

Our new strategy department will work with us to balance the opportunities and challenges ahead. It's crucial that we don't get overconfident with all that we have accomplished in 2020: there is still a lot of difficult work ahead, along with inevitable setbacks and unexpected challenges. I'm optimistic that with the continued and expanding support from MAPS' members and our research community, we can continue rising to the challenges.

To Phase 3 and Way Beyond,

Rick Doblin

Rick Doblin, Ph.D.
MAPS Founder and Executive Director