MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

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Research Edition BULLETIN

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From the Desk of Rick Doblin, Ph.D.

In this summer of turmoil and transformation, with the COVID-19 pandemic far from over and global population levels of trauma, stress, and anxiety rising, MAPS' Phase 3 clinical trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) are still moving forward, though much more slowly than initially anticipated. On March 19, 2020, when the pandemic was spreading alarmingly around the world, MAPS' Data Monitoring Committee (DMC) reported excellent results of the interim analysis of MAPS' first of two Phase 3 clinical trials. The interim analysis was conducted when all 100 participants had been enrolled and 60 of these 100 participants had reached their primary outcome measure. These additional 40 participants were in various stages of treatment, including some who hadn't started treatment yet. The DMC reported that, according to the interim analysis, there is a 90% or greater probability of obtaining statistically significant results after all 100 participants had completed the study.

At a time of global crises, new approaches to heal trauma and treat mental illnesses are needed more than ever.

Shortly after the interim analysis, due to COVID-19 public health measures and shelter-in-place orders, treatments almost entirely stopped in our study, as in most studies regulated by the U.S. Food and Drug Administration (FDA). In response, the FDA reached out to the sponsors of research to offer the opportunity to discuss ending active studies early. After discussions with the FDA, we have come to agreement to end our first Phase 3 clinical trial early after 90, rather than 100, participants have been treated. However, not all of these 90 participants will have reached their primary outcome measure after three experimental sessions since some will have had treatments halted due to COVID-19 before they completed the protocol. At a minimum, all 90 participants will have had a baseline measurement of PTSD symptoms and at least one outcome measure after one or more of the experimental sessions. Statistical significance is somewhat easier to obtain for 100 participants as compared to 90 participants but our interim analysis suggests that we are in excellent shape for statistical significance, even with 90 participants.

By the time you read this edition of the MAPS *Bulletin*, all 90 participants will have completed treatments and outcome measures. We will be in the process of monitoring all the data, finalizing the data in the database lock process, then analyzing the data. We will know definitively before the end of September if our first of two Phase 3 clinical trials was statistically significant.

We're starting our second Phase 3 clinical trial on a site-by-site basis as soon as therapists and participants are safely able to be in the same place. While we can conduct virtual preparation and integration sessions, we believe the experimental sessions with MDMA or placebo must be conducted in person. We've now started screening new subjects for our second Phase 3 clinical trial at four sites with more sites starting soon, we're starting our expanded access/compassionate use treatments in

some of the sites around October 2020, then completing our second Phase 3 clinical trial in the beginning to middle of 2022 (depending on COVID-19 and the pace of enrolling new participants).

MAPS' MDMA/PTSD research for the European Medicines Agency (EMA) is also moving forward, starting to take place this summer or early fall in the Czech Republic, the Netherlands, and the United Kingdom, with Germany, Portugal, Finland, and Norway to follow. We'll be treating PTSD participants in the context of initial open-label Phase 2 studies for the purposes of training therapists by having them treat a PTSD participant under supervision of our therapist training team.

MAPS also accomplished our most ambitious fundraising campaign ever, our $30 million Capstone Campaign, in collaboration with the Psychedelic Science Funders Collaborative (PSFC). We raised the first $10 million from our Board of Directors, PSFC, and a few close allies. Then, author Tim Ferriss arranged for a $10 million, 90-day challenge grant ending September 10, 2020. Thank you to those who have donated to bring us to this historic point!

At a time of global crises, new approaches to heal trauma and treat mental illnesses are needed more than ever. Despite COVID-19, MAPS' donors, staff, therapists, participants, and even regulators are working collaboratively towards completing our research, reviewing our data, and then potentially approving MDMA-assisted psychotherapy for PTSD.

To Phase 3 and Way Beyond,

Rick Doblin

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

MAPS: Who We Are

Founded in 1986, the Multidisciplinary Association for Psychedelic Studies (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 furthers its mission by:

- Developing psychedelics and marijuana into prescription medicines.
- Training therapists and establishing a network of treatment centers.
- Supporting scientific research into spirituality, creativity, and neuroscience.
- Educating the public honestly about the risks and benefits of psychedelics and marijuana.

MAPS envisions a world where psychedelics and marijuana are safely and legally available for beneficial uses, and where research is governed by rigorous scientific evaluation of their risks and benefits.

MAPS relies on the generosity of individual donors to achieve our mission. Now that research into the beneficial potential of psychedelics is again being conducted under federal guidelines, the challenge has become one of funding. That means that the future of psychedelic and marijuana research is in the hands of individual donors. Please consider making a donation today. **maps.org/donate**

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