

# From the Desk of Rick Doblin, Ph.D.

THIS ISSUE OF THE Multidisciplinary Association for Psychedelic Studies (MAPS) Bulletin contains our annual financial report for Fiscal Year 2019 (FY19: June 1, 2018 – May 31, 2019). Our report provides details on income and expenses for all of MAPS' research and educational activities, and explains how MAPS is funding with charitable donations these activities and a staff that now exceeds 60 people. We also list and thank the many donors who are providing MAPS' essential funding. This financial report continues MAPS' policy of transparency and is an invitation for review, comments, and questions. This issue also contains articles about a range of MAPS' activities.

We're approaching the most important transition in MAPS' over 33-year MDMA-assisted psychotherapy drug development effort, beginning with MAPS' founding in April 1986. This transition is anticipated to take place in April 2020, and will be catalyzed by the interim analysis of MAPS' first of two Phase 3 studies of MDMA-assisted psychotherapy for people with severe, chronic, posttraumatic stress disorder (PTSD). The interim analysis is to be conducted by our Data Monitoring Committee (DMC) for the purpose of re-estimating sample size, and will look at unblinded data from the first 60 of the 100 subjects in our first Phase 3 study. The DMC will tell us whether or not we will need to add more subjects to our Phase 3 study in order to obtain statistically significant results. Once we know the results of the interim analysis, we'll have crucial information about the likelihood of obtaining U.S. Food and Drug Administration (FDA) approval for MDMA-assisted psychotherapy for PTSD—and if so, approximately how long it will take and how much it will cost.

If the results of the first Phase 3 study are promising, we'll initiate our second Phase 3 study, start more comprehensive planning for commercialization of prescription use, and work to raise the remaining funds we need—about \$8 million—to expand our Phase 3 MDMA-assisted psychotherapy for PTSD research to Europe. If the results are not promising, and are substantially different from our Phase 2 results which led FDA to designate MDMA-assisted psychotherapy for PTSD as a Breakthrough Therapy, we'll need to reevaluate all of our research procedures and therapist training program to figure out what went wrong.

As we move steadily and hopefully closer to our interim analysis, we're also in the midst of challenging negotiations with FDA. MAPS and FDA are in the process of addressing issues regarding our therapist training program, specifically whether we can retain and expand our research protocol in which therapists have the option to receive MDMA-assisted psychotherapy as a subject in a therapeutic context so they can better understand and support their patients with PTSD. We're also in discussions with FDA about whether we can initiate Expanded Access for compassionate purposes in order to provide MDMA-assisted

psychotherapy to treatment-resistant PTSD patients who aren't able to volunteer for our Phase 3 studies, whether because they live too far away from our Phase 3 sites or because our Phase 3 sites are full, or for other reasons. In addition, we're working with FDA to come to an agreement on the credentials that will be required of our two-person co-therapy teams. We have excellent advisers and lawyers assisting MAPS in these negotiations, and there is a very good chance that FDA will eventually come to appreciate and approve our proposals. I'm optimistic because our proposals are strongly data-driven and make clinical sense. We are willing to make compromises when necessary in our negotiations with FDA, in order to ensure our continued measured progress toward the prescription use of MDMA-assisted psychotherapy for PTSD. Neither the FDA, nor MAPS, nor anybody else has ever done this before, so it's worth taking the time to do it right.

With the continued support of MAPS donors, together with the outstanding work of our staff at MAPS, the MAPS Public Benefit Corporation (MAPS PBC), and MAPS Europe BV, and the dedication of our therapists and courageous patients, we'll bring psychedelic psychotherapy into the mainstream of legally accessible technologies of healing that are accessible to all who can benefit from them.



To Phase 3 and beyond,

*Rick Doblin*

Rick Doblin, Ph.D.

**MAPS Founder & Executive Director**