From the desk of Rick Doblin, Ph.D.

This edition of the MAPS Bulletin provides an overview of current accomplishments and challenges in our psychedelic and medical marijuana research, with a special focus on our international series of Phase 2 MDMA-assisted psychotherapy for PTSD studies.

Replicating our impressive results from our two completed studies of MDMA-assisted psychotherapy in subjects with PTSD in additional locations with different research teams is essential for demonstrating the reliability of our data to the FDA and international regulatory agencies. Both of our completed studies—our initial U.S. Proof of Principle study (published in 2010 in the Journal of Psychopharmacology) and our Swiss study (with a paper about the results seemingly close to acceptance for publication)—have generated promising data about safety and efficacy that, if it had been from about 560 subjects rather than just 32, would justify approval for prescription use. Replicating results is also essential for showing potential donors to MAPS that the roughly $15 million more we need to raise to complete Phase 2 and Phase 3 studies over the next seven or so years is a wise investment in our mission to create legal contexts for psychedelic psychotherapy.

We now are working to obtain similarly profound and lasting results in four new studies. Two are in the United States with one ongoing in veterans in Charleston, South Carolina and one about to begin in Boulder, Colorado. One study in Israel is about to begin, and one in Canada is still struggling to obtain approval from Health Canada for the security systems required to store the roughly $1,500 worth of MDMA to be used in the study.

In addition to seeking to replicate our previous results, our new Phase 2 studies are also gathering information about how to conduct successful double-blind studies. The more uncertainty in the guesses of subjects and co-therapists about what dose was administered, the more convincing our results.

Our ongoing South Carolina study in veterans with co-therapists Michael Mitheoefer, M.D., and Annie Mitheoefer, B.S.N., divides subjects into three groups, each receiving a different dose of MDMA together with psychotherapy: one receiving 30 mg, one receiving 75 mg, and one receiving 125 mg (all subjects also receive a supplementary half dose 1½ to 2½ hours after the first dose in order to prolong the therapeutic effects). Our other Phase 2 studies in Israel, Canada, and Colorado use only two groups and various lower dosages. Preliminary results suggest that raising the lower dose