There are three phases in investigating a drug as a prescription medicine. Phase I involves collecting safety data in animals and humans. Phase II involves several pilot studies administering the drug to human subjects to treat a common indication under slightly different treatment protocols. The current MAPS study in Charleston, SC, the approved studies in Switzerland and Israel, and a proposed study in Spain fall under Phase II. When these Phase II studies are completed, MAPS will submit the data to the FDA and the regulatory agencies in the other countries. We will then apply to begin Phase III, where we will expand to multi-site studies under a shared protocol to test MDMA therapy in the treatment of PTSD on a large sample of subjects. These Phase III multi-site studies, one protocol conducted throughout multiple sites in the US and one protocol conducted throughout multiple sites in Europe and Israel, will each involve about 280 total subjects, cost in the range of $2.5 million, and take two to three years.

The Israeli study differs from MAPS’ original MDMA/PTSD study conducted by Dr. Michael Michaelson in the US in that it has supplemental dosing halfway through each of the sessions. The Israeli study also uses an active placebo of low dose MDMA, rather than an inactive placebo. This will make it more difficult for the therapist and subject to be able to tell whether the subject received an active dose of MDMA or not, increasing the success of the double-blind. In this study we will also collect long-term follow-up data for one year for the second experimental session. The study in Israel also tests the efficacy of using slightly less staff time, since only one therapist is present during some of the non-drug therapy sessions, rather than both therapists. Both therapists are present during all of the experimental sessions where MDMA is administered, and at some of the non-drug therapy sessions.

MAPS Clinical Program Manager Amy Emerson has been of tremendous help in volunteering her time to implement the rigorous standards required by the US FDA and the European Medicines Agency in conducting these clinical trials with MDMA. MAPS Patron Donor Ami Shinitzky has also been very generous in donating $100,000 to this study and raising an additional $25,000 of the total of $100,000 needed to conduct this research. We are now seeking an additional $65,000 for this study. Please contact the MAPS office if you are interested in making a donation.

On January 19, 2006, we learned that the DEA had issued the necessary license for Dr. Halpern’s study of MDMA-assisted psychotherapy in advanced-stage cancer patients.