Clinical Development Plan:
MDMA-Assisted Psychotherapy for Posttraumatic Stress Disorder (PTSD)
The Multidisciplinary Association for Psychedelic Studies (MAPS) is a membership–based, IRS–approved 501(c)(3) non-profit research and educational organization founded in 1986.

Our mission is (1) to treat conditions for which conventional medicines provide limited relief—such as posttraumatic stress disorder (PTSD), pain, drug dependence, and anxiety and depression associated with end-of-life issues—by developing psychedelics and marijuana into prescription medicines; (2) to cure many thousands of people by building a network of clinics where treatments can be provided; and (3) to educate the public honestly about the risks and benefits of psychedelics and marijuana.
MAPS was founded in 1986, one year after the Drug Enforcement Administration (DEA) overruled a DEA Administrative Law Judge (ALJ) recommendation and made MDMA a Schedule I drug, criminalizing both its recreational and therapeutic uses. We pursue our research mission by helping and/or sponsoring scientific researchers to design, obtain governmental approval for, fund, conduct, and report on psychedelic and marijuana research in human volunteers with the goal of developing psychedelics and marijuana into legal prescription medicines.

We are actively developing and funding clinical trials with human subjects in accordance with guidelines set forth by the U.S. Food and Drug Administration, the European Medicines Agency, and the International Council on Harmonization (ICH/GCP). During this process we are training therapists to administer psychedelic drugs in therapeutic settings. We believe that psychedelics and marijuana, when used in proper settings, can be beneficial for such uses as psychotherapeutic treatment, physiological research and treatment, addiction treatment, pain relief, spiritual exploration, creativity research, brain physiology research, and related scientific inquiries.

MAPS operates as a non-profit pharmaceutical company. All of the drugs involved in MAPS’ research will be generic substances for public benefit. When these substances become prescription medicines, MAPS will not have a monopoly on their sale. For-profit pharmaceutical companies have shown no interest in developing these drugs.
Why MDMA and Why PTSD?

Q: What is MDMA?
A: MDMA is a unique medication that has the potential to enhance the psychotherapeutic process by helping people confront painful thoughts and memories with reduced fear, and helping them form a therapeutic alliance with the psychotherapists. MDMA is currently classified as a Schedule I substance, meaning that it can be legally administered to humans only in the context of a research study. MAPS’ goal is to sponsor rigorous research that proves safety and efficacy to the satisfaction of the FDA so that MDMA-assisted psychotherapy can be legally prescribed.

As increasing numbers of U.S. soldiers return home with posttraumatic stress disorder (PTSD) after serving in Iraq and Afghanistan, it’s our national priority and ethical obligation to develop more effective treatments for PTSD. MAPS is responding by conducting a series of Phase 2 pilot studies in order to demonstrate to the public and regulatory agencies that MDMA-assisted psychotherapy can be used as a remarkably effective medical treatment for chronic, treatment-resistant PTSD patients who are inadequately helped by currently available treatments. On July 19, 2010, the results of our first Phase 2 pilot study were published in the Journal of Psychopharmacology. Out of 20 subjects in the study, over 80% in the experimental group no longer met the diagnostic criteria for PTSD, compared with 25% in the placebo group.

In 2009, the U.S. Veterans Administration spent about $5.5 billion on PTSD disability payments to approximately 275,000 veterans, with costs and numbers of veterans with PTSD continuing to increase. During an appearance at a gathering of mental health professionals on October 26, 2009, U.S. Secretary of Defense Robert Gates stated, “Beyond waging the wars we are in, treatment of our wounded, their continuing care, and eventual reintegration into everyday life is my highest priority...I consider this a solemn pact between those who have suffered and the nation that owes them its eternal gratitude.”

PTSD is our top priority clinical indication in large part because MDMA possesses unique pharmacological and psychological properties that may make it especially well suited for use as an adjunct to psychotherapy with PTSD patients.

In addition, PTSD is a worldwide public health problem and is typically a chronic illness associated with high rates of psychiatric and medical co-morbidity, disability, suffering, and suicide. An array of psychotherapeutic options exist for treating PTSD and two SSRIs (sertraline and paroxetine) are approved as PTSD treatments by the FDA. However, a significant minority of PTSD patients fail to respond adequately to established PTSD psychotherapies, or respond in ways that are statistically significant but clinically inadequate. The existing evidence demonstrates that the combination of pharmacotherapy and psychotherapy is more effective in treating PTSD than either pharmacotherapy or psychotherapy alone.

Once approved, MDMA will be the first medication that works by enhancing the psychotherapeutic process, unlike other pharmacotherapy treatments that are administered on a daily basis primarily to reduce symptoms.

The primary reason for selecting MDMA as our initial drug target is that it offers patients a unique, gentle, yet profound experience of self-acceptance and an enhanced ability to feel and integrate complex, challenging emotions. Compared to other psychedelics like LSD or psilocybin, MDMA has minimal effects on perception or one’s sense of self-control. This makes MDMA a suitable drug to administer to psychedelic-naive patients as well as to therapists in training to administer MDMA-assisted psychotherapy.

Another major reason for working initially with MDMA is that over the last 25 years, the nations of the world have spent over $300 million on basic research into the risks of MDMA/Ecstasy, with all of that research in the public domain. A search on Medline for the terms MDMA or Ecstasy results in over 4,000 published papers. As a result of the enormity of the existing body of research, the funding necessary for our drug development program is drastically reduced, since we do not have to repeat these basic safety studies.

Concerns about toxicity have decreased over the past decade due to this body of research. Toxicity concerns are further minimized in our therapeutic model because MDMA is administered only a few times within a three to four month period of therapy, and only under the direct supervision of a therapist team (we require male/female co-therapist teams). This is in contrast to existing medications, which are administered daily for months, years, or often indefinitely.

“IT’s basically like years of therapy in two or three hours. You can’t understand it until you’ve experienced it.”

–former Army Ranger who participated in a MAPS-sponsored pilot study, quoted in Military.com, March 2009
“Because of MDMA’s reported ability to decrease levels of fear and defensiveness and increase the sense of trust, we hope that will be a catalyst for the therapeutic process.”

Peter Oehen, a psychiatrist in the Swiss town of Biberist, says substances such as MDMA can produce results where conventional psychotherapies fail.
“‘They help overcome the wall of denial that some patients build up,’ said Oehen.
–quoted in USA Today, April 2008

“Patients in our study had a fear of the fear.
Something about the MDMA made it possible for them to approach the feared thought, the feared ‘place’ in their mind – and when they got there, it wasn’t as terrible as they thought. A lot of these people, the light bulb went off, they had the insight, but there’s still a lot of work to do. They’ve had this for years, it’s shaped their lives, and now they have to rebuild them.”
–Mark Wagner, Ph.D., MDMA/PTSD study independent rater, quoted in The Washington Post, November 2007
Before becoming the first patient treated by Michael and Annie Mithoefer in the flagship MDMA-assisted psychotherapy study sponsored by MAPS, Donna Kilgore had suffered from posttraumatic stress disorder for over ten years. Donna had been the victim of a brutal rape in her home in 1994. For years she experienced symptoms of PTSD, including nightmares and an even more frightening sense of numbness towards her life and family. “It was what it must feel like to have no soul,” she says. It wasn’t until her symptoms escalated to flashbacks, panic attacks, fainting spells, and migraine headaches that she sought treatment and was quickly diagnosed with PTSD. She followed a regimen of various antidepressants and tried dozens of different therapists and forms of therapies, but nothing worked. “I was getting to the point where it was either go sit on a mountaintop or go dive off a cliff.” That was until she tried MDMA-assisted therapy.

“Before, I knew the path was through the battlefield, but I just could not get through it. [But during MDMA therapy] I knew I could walk through it, and I wasn’t afraid.”

–Donna
Executive Summary

After investing over $1.5 million and 25 years of dedicated effort, MAPS has completed two successful "Proof of Principle" studies of MDMA-assisted psychotherapy in subjects with chronic, treatment-resistant posttraumatic stress disorder (PTSD). Both MAPS' U.S. study (N=21) and Swiss study (N=20) were conducted without producing any Serious Adverse Events (SAE) or evidence of harmful effects. Our U.S. study produced statistically and clinically significant evidence of substantial efficacy. On July 19, 2010, a paper about the study was published in the Journal of Psychopharmacology. Our Swiss study had fewer subjects and involved statistically significant evidence of efficacy that approached statistical significance (p=0.07), with average reductions in PTSD symptoms larger than that obtained in the studies of Zoholi or Taeij that resulted in their approval by the FDA for the treatment of PTSD. MAPS' successful U.S. and Swiss studies are the foundation of the Phase 2 portion of our strategic MDMA prescription drug development plan and are essential milestones in the advancement of MDMA toward approval as a prescription medication.

In order to develop a drug into a prescription medicine, several phases of clinical trials must be conducted. In general, Phase 1 trials test the safety of a drug in healthy populations of between 10 and 100 subjects. Phase 2 trials gather preliminary information on the safety and efficacy of the drug to treat the condition under investigation in populations of 12 to 200 patients, and Phase 3 trials gather conclusive evidence regarding the safety and efficacy in larger populations of 250 to 2000 subjects. At least two Phase 3 studies are required to prove safety and efficacy before permission for prescription use can be approved. If the drug is found to be safe and efficacious in two Phase 3 studies, the sponsor of the studies submits a New Drug Application (NDA) to the FDA and/or the European Medicines Agency (EMA) for approval. If the data from these studies is supportive, MAPS will submit a New Drug Application (NDA) to the FDA and EMA for MDMA-assisted psychotherapy for PTSD. If that point is met, the decision will be made whether to move forward with these Phase 3 studies. If we do move forward, and if the data from these studies is supportive, MAPS will submit a New Drug Application (NDA) to the FDA and/or the European Medicines Agency (EMA) for approval. Should approval be granted, the addition of MDMA-assisted psychotherapy as a treatment option for PTSD could make a major contribution to improved mental health for PTSD patients around the world and would facilitate the development of MDMA and other psychedelics for a wide range of other psychotherapeutic uses.

In order to build on our successful proof-of-concept research, MAPS is seeking donations totaling $1.7 million over the next two years to make possible an international series of Phase 2 MDMA/PTSD pilot studies which will lead to the next phase of research with the U.S. FDA. We’ve developed relationships with non-profits in other countries so that donors from outside the U.S. should be able to see if they could obtain tax-deductions in their own countries. We invite you to join with us and donate, to whatever extent you are able, so that MAPS can continue to work towards developing MDMA and other psychedelics into culturally-accepted, legal prescription medicines.

MAPS International Research Strategy

MAPS has chosen, for several reasons, to conduct some of our MDMA/PTSD pilot studies outside of the U.S. In the first few years after obtaining permission in the U.S. for our initial pilot study, we were concerned about the possibility of a politically motivated backlash (due to the history and stigma surrounding research with psychedelics) causing permission to conduct this study to be withdrawn. We decided to seek approval for research from regulators in other countries, that would see its risk/benefit analysis independently affirmed elsewhere, and that would see its data in a format that could be more comfortable with its decision to let us proceed. Now that we have generated our first results in the U.S. and Swiss studies, and have obtained a “may proceed” letter from the FDA for our next U.S. MDMA/PTSD study that will enroll only veterans, we feel confident that if we meet the requirements specified by the FDA is unlikely. We have also been impressed with and grateful for the supportive manner of the staff with whom we’ve worked at the FDA. It has become clear from our meetings with the FDA that they will require us to conduct research in accordance with...
In order to build on our successful “Proof of Principle” studies, MAPS is seeking donations of $1.7 million over the next two years to make possible an international series of Phase 2 MDMA/PTSD pilot studies to make possible the next phase of research with the U.S. FDA.

By cross-submitting our U.S./Canadian Phase 3 study data to the EMEA and our European and Middle East Phase 3 study data to the FDA, we may be able to obtain prescription approval in the U.S. and Europe simultaneously. This could save many millions of dollars and several years...

With the rigorous standards of state-of-the-art scientific methodology that apply to all pharmaceutical drug development research, and will not obscure our studies because of irrational fears or drug-war-related political considerations.

The other reason for our international studies is to see if we could lay the groundwork for one of the two required Phase 3 multi-site studies to take place in the U.S. and Canada and the other in Europe and the Middle East with both the FDA and the European Medicines Agency (EMA) generally require one of the international strategy or focus on conducting our two Phase 3 studies entirely in the U.S. and Canada.

MDMA/PTSD Study in Veterans, U.S.

Our current top-priority study is our ongoing Phase 2 pilot study of MDMA-assisted psychotherapy for 16 U.S. veterans with chronic, treatment-resistant, combat-related PTSD. This study uses our most sophisticated design and was the first protocol that the FDA accepted as designed, without requesting a single change. This study has full approval from all regulatory agencies and about two hours later with 37.5 mg and four subjects receiving a threshold/low dose of 30 mg, followed about two hours later by 15 mg. These two doses were the most effective in producing an effective blind in these studies and treating subjects.

By cross-submitting our U.S./Canadian Phase 3 study data to the EMEA and our European and Middle East Phase 3 study data to the FDA, we may be able to obtain prescription approval in the U.S. and Europe simultaneously. This could save many millions of dollars and several years...

Multidisciplinary Association for Psychedelic Studies (MAPS)
Phase 2 MDMA/PTSD Studies Expenses

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<th>STUDY</th>
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ASSOCIATED PROJECTS 2008-09 2009-10 2010-11 2011-12 2012-13

End-of-Phase-2 Meeting with FDA/EMA | $0 | $0 | $0 | $50,000 |

MDMA Literature Review | $3,340 | $3,256 | $6,063 | $3,500 | $3,500 |

MDMA Treatment Manual/NIMH grant | $640 | $8,752 | $5,529 | $3,500 | $3,500 |

MDMA Therapist Training-Protocol | $9,600 | $15,038 | $17,652 | $10,000 | $25,000 |

MDMA Researcher Retreats | $7,236 | $27,067 | $2,092 | $25,000 |

Mithoefer Supervisory/PR Time | $0 | $27,951 | $33,975 | $62,500 | $64,500 |

MDMA Research General | $8,230 | $11,404 | $5,911 | $55,000 | $15,000 |

Clinical Research General | $13,360 | $32,036 | $38,885 | $45,000 | $35,000 |

Total MDMA-Related Expenses | $318,496 | $383,327 | $438,425 | $783,000 | $875,053 |

Multi-Year Projected Costs | $1,658,053 over next two years
in our flagship U.S. study, we would then be able to design our Phase 3 studies to enroll people with PTSD regardless of whether the cause of their PTSD was related to sexual assault or abuse. Should we learn that veterans require a different designed treatment program than people whose PTSD is related to sexual assault or abuse, we would need to design our Phase 3 studies to treat one group or the other.

The cost of this study is projected to be $595,000. In this three-arm design, we have more subjects than usual who could enroll in Stage 2 (open label MDMA administration) since fully half the subjects (8) would receive less than the full-dose in the randomized portion of the study. As a result, the cost is about $31,000 per subject (16) since we’re likely to repeat the entire 4-month treatment process 24 times, rather than just 16. The cost also includes over $90,000 in travel expenses that we pay for

The results at our two-month follow-up were remarkable, with over 80% of the subjects who went through the MDMA-assisted psychotherapy no longer having sufficient symptoms to be diagnosed with PTSD, as compared to 25% of the placebo group. The effect size was larger than for Zoloft or Paxil or any of the existing evidence-based psychotherapies. During the course of the study, we successfully negotiated several protocol amendments with the FDA and our IRB. We increased from two to three the number of MDMA-assisted psychotherapy sessions, which were scheduled about three to five weeks apart with weekly non-drug psychotherapy for integration and preparation. We obtained permission to administer a supplemental dose of MDMA, half the initial dose given about two hours afterwards, in order to prolong the plateau of optimal therapeutic effects. We also obtained permission to offer all subjects who received the placebo the option to enroll in the study a second time (Stage 2) with open-label, full-dose MDMA, starting after the two-month follow-up after their final experimental session. The subjects in our first U.S. study were mostly women survivors of sexual assault or childhood sexual abuse, along with two male veterans of the Iraq War. The subjects’ average duration of PTSD was over 19 years. The results at our two-month follow-up were remarkable, with over 80% of the subjects who went through the MDMA-assisted psychotherapy no longer having sufficient symptoms to be diagnosed with PTSD, as compared to 25% of the placebo group. The effect size was larger than for Zoloft or Paxil or any of the existing evidence-based psychotherapies. However, this was just a small pilot study. In addition, our treatment program is more expensive and requires more therapist time than any of the other treatments. The main limitation of this study was that we used an inactive placebo, since we needed to have a baseline of side effects that could not be attributed to MDMA. We asked the therapists and subjects to guess whether the MDMA or the placebo had been administered. The therapists always guessed correctly, and subjects almost always guessed correctly. Now that we have obtained our baseline of side effects, all other studies use active placebo, most often consisting of a low, sub-threshold dose of MDMA.

The results at our two-month follow-up were remarkable, with over 80% of the subjects who went through the MDMA-assisted psychotherapy no longer having sufficient symptoms to be diagnosed with PTSD, as compared to 25% of the placebo group.

The effect size was larger than for Zoloft or Paxil or any of the existing evidence-based psychotherapies.
study" (see below). MAPS’ clinical research team is currently preparing the manuscript for publication in a peer-reviewed scientific journal.

**These cultural differences will require us to think ever more carefully about the core elements of our therapeutic approach and how we teach them to our therapist teams. In addition, perhaps one day, our Israeli and Jordanian teams could meet together to discuss their shared research using MDMA-assisted psychotherapy to heal trauma.**

**U.S. MDMA/PTSD Relapse Study**
Our long-term follow-up to our flagship Phase 2 clinical trial of MDMA-assisted psychotherapy for PTSD revealed that although over 80% of the subjects in our previous no-longer-meets criteria for PTSD two months after treatment, for several subjects symptoms did eventually return. Benefits from MDMA-assisted psychotherapy remained during the long-term follow-up, conducted an average of 41 months after treatment. Our new ‘relapse’ study will attempt to determine whether a single additional open-label MDMA-assisted psychotherapy session along with several non-drug or drug-free psychotherapy sessions can enable these subjects to once again be free of a PTSD diagnosis. The Drug Enforcement Administration (DEA) has approved the Schedule I licenses required to transport, store, and administer the MDMA for our new “relapse study” of MDMA-assisted psychotherapy for PTSD. The study already has in place both the Food and Drug Administration (FDA) and an independent Institutional Review Board. Now that we have received all necessary clearances, we can begin enrolling subjects. The new study will take place in Charleston, S.C., and will be conducted by co-therapists Michael Michotro, M.D., and Anne Mithofer, B.S.N., and is limited to up to three subjects whose PTSD symptoms returned after participating in our flagship study of MDMA-assisted psychotherapy for PTSD.

**MDMA/PTSD Study Switzerland**
Conducting research in multiple international sites allows us to improve our research methodology by comparing results. In January 2011, the final long-term follow-up visit was completed in MAPS’ Swiss study of MDMA-assisted psychotherapy for PTSD. On June 1, the clinical research team closed and locked the database, officially concluding the data collection portion of the study. A preliminary analysis suggests that the Clinician-Administered PTSD Scale (CAPS), which is the primary measure of PTSD symptom severity, showed a trend towards improvement after treatment, with CAPS reductions somewhat larger than in comparable studies of Zoloft and Paxil. The Posttraumatic Diagnostic Scale (PDS), which is the secondary measure of PTSD symptoms completed by the subjects, also showed statistically significant improvements in symptoms after treatment.

The therapeutic results obtained in our previously completed U.S. flagship study of MDMA-assisted psychotherapy for PTSD were larger than those from our Swiss study. In order to determine how scientific journal. The quality inspection of the final data set from both studies was remarkably clean, with a 0.04% error rate (far below the 0.5% required to pass). The locked database will also be used for our final report to the U.S. Food and Drug Administration.

**MDMA/PTSD Study Canada**
The goal of our 12-person Canadian study, designed similarly to our Swiss study, is to learn if we can replicate the outstanding results of our U.S. study. Our Canadian study will be conducted in a similar cultural context as our U.S. study. Ingrid Pacey, M.D., a psychiatrist and certified Grof Holotropic Breathwork practitioner, and Andrew Feldman, M.A., a Hungarian-Canadian psychologist and disciple of R.D. Laing, are the male/female co-therapist teams conducting this study. Both of these experienced and highly-trained therapists worked with MDMA-assisted psychotherapy prior to its criminalization and share a theoretical orientation with our U.S. and Swiss teams. We’re using two senior therapists in Canada to give us the best chance to replicate the therapy. Once approved, this study will be the first psychedelic research study in Canada since the mid-1990s.

The cost of this study is projected to be $310,000, about $26,000 per subject. This cost is due in large part to the fact that the study requires two co-therapists for each PTSD treatment, in contrast to the traditional single-therapist model of many previous studies. Each of these new co-therapist teams would treat three additional subjects. With this additional funding, even though the numbers are low, we can continue our work to improve outcomes for patients with distressing differences in patients that obscure the differences in therapist teams, we will still be able to compare average efficacy when two senior therapists are working together to when each was working with a student/trainee.

Canadian regulations require that the study pharmacy be adequately secure, and that the protocol accountability procedures are in place. In order to ensure compliance, Health Canada must inspect the study pharmacy and agree that it meets all requirements. The final study protocol will be submitted to Health Canada in order to initiate the study. With the approval of the Canadian study, we will then move to our Israeli and Jordanian teams. Once the protocol is complete, it will be submitted for review by the Israeli and Jordanian regulatory bodies including the Israeli Ministry of Health and an Ethics Committee. The protocol will also be submitted to the U.S. FDA, which will only approve the study before we can start recruiting patients. The study is being conducted under a U.S. Investigational New Drug (IND) application.

In January 2011, MAPS researchers Michael Michotro, M.D., and Annie Mithofer, B.S.N., conducted a training course for therapists who will be conducting the treatment sessions. As training took place over five days, with the first three days in Tel Aviv in the basement of a house built by MAPS Founder Rick Doblin’s great-grandfather in 1923. The therapists reviewed MAPS’ treatment manual for MDMA-assisted psychotherapy for PTSD, video tapes of trial sessions from our completed U.S. MDMA/PTSD study, and were more familiarized with the study protocol.

The study will be conducted at Be’er Ya’akov Mental Health Center outside Tel Aviv, in a dedicated area in a standalone building separate from the main facility which includes a separate bathroom and kitchen. The grounds include orange groves and walking paths, making it a secure and comfortable site for conducting the sessions.

**MDMA/PTSD Study Jordan**
Building on our experience with previous studies, MAPS has determined that pairing traditionally trained psychiatrists with our team of more direct experience working with altered states of consciousness may help produce a more effective therapeutic team. For this reason, our new Israeli MDMA-assisted psychotherapy for PTSD study will require us to think ever more carefully about the core elements of our therapeutic approach and how we teach them to our therapist teams. In addition, perhaps one day, our Israeli and Jordanian teams could meet together to discuss their shared research using MDMA-assisted psychotherapy to heal trauma.

The study is currently awaiting approval from the Israeli Food and Drug Administration (FDA). The Principal Investigator will be Dr. Shuriquie, M.D., Chief of Psychiatry, Jordanian Royal Medical Services. Dr. Shuriquie is now Clinical Manager at Al-Rashid Hospital in Amman, Jordan, the largest mental health and addiction treatment
hospital in Jordan and a teaching hospital for the entire region. This is a 12-person study. The first two subjects will be enrolled in an open-label full-dose lead-in, to help us train the Jordanian co-therapists and to enable them to gain experience using our treatment method. MAPS staff will use the adherence measures to quantify therapist adherence to our treatment method as described in our treatment manual. We’ll use our standard treatment model of three experimental sessions, scheduled about three to five weeks apart, with weekly non-drug psychotherapy for purposes of preparation and integration.

The remaining ten subjects will be enrolled in the randomized, double-blind, placebo-controlled portion of the study. We’ll use the same full dose that we are using in our other studies, 125 mg followed about two hours later with 62.5 mg. We’ll use 40 mg, followed by 20 mg about two hours later, as our low-dose/placebo. This low dose of 40 mg is unique to this study and will help us gather additional information about the effectiveness in producing a double-blind with a range of doses.

The study has approval from the Ethics Committee at Al-Rashid Hospital, and has met all requirements for liability insurance. On July 30, 2011, we learned that the JFDA decided not to approve the protocol for our Jordanian study of MDMA-assisted psychotherapy for PTSD at this time, based in part on comments from an expert reviewer chosen by the JFDA. We anticipate receiving a further set of questions from JFDA, and we are hopeful this study will eventually be approved.

U.S. MDMA/PTSD Study Australia Planning for Phase 3 of our MDMA/PTSD study requires an extensive protocol to our IRB, which after extensive discussions also permitted us to proceed with the subjects in our training program. We subsequently designed a study of the psychological effects of MDMA on healthy volunteers that met the requirements of the FDA and we were given permission to proceed with the subjects in our training program. We then submitted the protocol to our IRB, which after extensive discussions also permitted us to proceed. We were profoundly encouraged by this demonstration of the FDA’s willingness to listen to us and to propose ways that their concerns could be fully addressed.

We will have trained raters to evaluate videotapes of the psychotherapy sessions using the new criteria that we’ve developed to quantify therapist adherence to the principles in our treatment manual. We’ll use this evaluation as a teaching tool to help us in more effectively training our therapist teams in order to standardize our therapeutic approach across therapist teams with different languages, cultures, and nationalities.

MAPS is now working with a group of researchers in Australia to plan a new study of MDMA-assisted psychotherapy for subjects with chronic, treatment-resistant PTSD. This study is in the protocol development process. We are hoping to have it submitted to an Institutional Review Board by the beginning of 2012 and then to the Therapeutic Goods Administration (the Australian equivalent of the U.S. FDA). The lead investigators and co-therapists will be Stuart Saker, M.D., a psychiatrist with the Australian armed forces, and clinical psychologist Fiona MacKenzie, M.Psych, another married male/female co-therapist team. Michael Mithoefer, M.D., the lead investigator for our U.S. MDMA/PTSD studies, will be the official medical monitor.

The formal sponsor for the study will be the newly formed Australian research organization Psychedelic Research in Science and Medicine (PRISM). PRISM, created by Martin Williams, Steve McDonald, Jonathan Carmichael, and others, is officially incorporated as a legal organization and has submitted its application for tax-deductible status. The study will be conducted in a non-institutional setting rather than in collaboration with an academic or military organization, just as in our U.S., Swiss, and Canadian studies. The total cost for this study is estimated at $250,000, of which MAPS has pledged $50,000.

U.S. MDMA/PTSD Therapist Training Protocol This protocol is in healthy subjects, rather than in subjects with PTSD. This protocol is a placebo-controlled, double-blind, randomized, cross-over study that allows MAPS to administer a single MDMA-assisted psychotherapy session to up to 20 therapists as part of their training to conduct MAPS’ MDMA/PTSD studies, while also conducting a series of evaluations of the psychological effects of MDMA administered to healthy volunteers in a therapeutic context. This study is now enrolling and treating subjects. Clinical Investigators Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N., are leading the study, and Julie Holland, M.D., is the medical monitor.

We initially requested permission to administer one session of MDMA-assisted psychotherapy to therapists as part of our training program. We made the case in our initial protocol submission that therapists would likely be more effective administering MDMA to their patients if they had a subjective understanding of the effects of pure MDMA from a direct, personal experience. Since MDMA is a controlled substance, the only way we could provide a legal training experience would be in the context of a clinical study. The FDA replied that there was no model for them to approve a training protocol. Instead, they recommended that we design a Phase I, randomized, double-blind, placebo-controlled cross-over study that would gather useful data in a methodologically rigorous manner. If we could accomplish that, the FDA would permit us to limit enrollment to therapists from the U.S. and around the world who had first completed our non-drug training program. We subsequently designed a study of the psychological effects of MDMA on healthy volunteers that met the requirements of the FDA and we were given permission to proceed with the subjects in our training program. We then submitted the protocol to our IRB, which after extensive discussions also permitted us to proceed. We were profoundly encouraged by this demonstration of the FDA’s willingness to listen to us and to propose ways that their concerns could be fully addressed.

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“As a member of the clinical research community, I was asked to review MAPS’ conduct of clinical trials and provide guidance. I was incredibly impressed by the clear mission to bring the high standard of clinical research and International Conference on Harmonization (ICH) guidelines to all of MAPS’ research, and to ensure that data generated would be held with the same level of integrity and respect as larger, established research institutes.”

– Felicia Lipansky, Senior Project Manager, Onyx Pharmaceuticals, MAPS volunteer
Profile of MAPS Founder and Executive Director Rick Doblin, Ph.D.

In 1972, at age 18, while attending New College of Florida, Rick decided to devote himself to becoming a psychedelic psychotherapist and researcher, at the same time that psychedelic research around the world was being shut down due to political reasons. Rick was influenced by the Holocaust and the Vietnam War to work on addressing the psychological causes of war and scapegoating, recognizing that human technological evolution has far exceeded human emotional and spiritual evolution. In 1982, Rick heard about MDMA when it was still legal. In 1984, anticipating that the DEA would soon move to criminalize MDMA, Rick co-founded a non-profit organization to organize MDMA therapists and coordinated a DEA Administrative Law Judge lawsuit to block criminalization of the therapeutic use of MDMA. The non-profit won the lawsuit but the DEA still found a way to criminalize all uses of MDMA. Rick founded MAPS in 1986 to move MDMA, psychedelics and marijuana through the FDA drug development research and approval process. In 1991, as part of Rick’s training to become a psychedelic psychotherapist, Rick was among the first people to be certified by LSD researcher Dr. Stanislav Grof as a Holotropic Breathwork practitioner. Holotropic Breathwork is a technique of deep breathing that can produce experiences similar to those produced by psychedelics. In 2001, Rick earned a Ph.D. in Public Policy from the Kennedy School of Government at Harvard University. Rick’s dissertation focused on the regulation of the medical use of psychedelics and marijuana. He has been working diligently, and successfully, putting this plan into effect ever since. Rick is married to Lynne Jones Doblin and they have three children, all teenagers: Eden (17), Lilah (15), and Eliora (13).

“MDMA opens the doorway for people to feel deep feelings of love and empathy, which is the core of being human. We should be looking at that and learning from that.”

—MAPS Executive Director Rick Doblin, Ph.D.

Quoted in The Washington Post, March 2, 2004
"It meant the world to me to be able to look at the fear, to look at the shame. I didn’t know I was ashamed. It was like I’d been wearing the scarlet letter. It was so heavy. When I got out of that session, I felt a hundred pounds lighter...

[MDMA] gave me the ability not to fear."

–Donna, a patient in a MAPS-sponsored pilot study, reflecting on her MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) brought on by childhood sexual abuse