MAPS One Page Study Outline * May 2, 2008

***Study Title*:** MDMA-assisted psychotherapy in twelve people with treatment-resistant Posttraumatic Stress Disorder (PTSD)-Canada [MP4]

***Study description**:* This study will consist of a randomized, double-blind, active placebo-controlled investigation of two experimental sessions of MDMA-assisted psychotherapy in twelve people with treatment-resistant PTSD, followed by an open-label segment for all subjects. The open-label segment will consist of two additional MDMA sessions for participants in the experimental group (for a total of four sessions), while subjects in the placebo group will be offered the option of undergoing four open-label MDMA sessions.

***Investigator**s*: Dr. Ingrid Pacey MD, Andrew Feldmar,MA, [independent rater]

***Subjects**:* This study will enroll twelve people, men or women, aged 18 years or older, diagnosed with PTSD with a score of at least 50 on the Clinician-Administered PTSD Scale (CAPS). Participants must have undergone at least one previous psychotherapeutic or pharmacotherapeutic treatment for PTSD. The investigators will seek to enroll some participants who are recruited from the RCMP and the Canadian military.

Primary Outcome Measure:
Clinician-Administered PTSD Scale (CAPS)

***Study Procedures**:* After giving written consent, participants will be screened to ensure they meet inclusion criteria without meeting any exclusion criteria. Eight of 12 participants will be randomly assigned to the experimental condition (125 mg MDMA followed two to 2.5 hours later by 62.5 mg), and four will be assigned to the active placebo condition (25 and 12.5 mg MDMA). MDMA will be administered during two 8-hour experimental sessions scheduled three to five weeks apart, with subjects spending the night in the treatment facility.

The randomized study segment will consist of baseline evaluation, three 60 to 90-minute preparatory sessions with the investigator-psychotherapists, two experimental sessions scheduled at three to five week intervals, a 60-90-minute integrative psychotherapy session the morning after each experimental session and at least two additional 60 to 90-minute integrative psychotherapy sessions after each experimental session scheduled a week apart. The follow-up evaluation session will take place two months after the second experimental session. Blinding will be broken for each individual during this evaluation.

Participants who received the experimental doses of MDMA will have two additional open-label MDMA sessions with the option (if approved by both therapists and participant) of increasing the dose to 150 mg., followed by 75 mg. Participants who received active placebo MDMA will have the option to enroll in four open-label experimental sessions, the first two using 125 mg followed by 62.5 mg, and the second two sessions with the option of use doses of 150 mg followed by 75 mg but otherwise following the same procedures as experimental sessions. All participants will have a final evaluation two months after their final experimental session (either second or fourth open-label session). As a separate study, we will administer a final follow-up to all subjects one year after the final experimental session.

Budget Estimate: $150,000