

## Capstone Fund Proposal

### **Prescription Approval & Patient Access for MDMA-Assisted Psychotherapy for PTSD in the United States, Canada, and Israel**

#### Summary

The \$30 million Capstone Fund will support the completion of the Phase 3 clinical trials required to support a New Drug Application (NDA) to the US Food and Drug Administration (FDA), with corresponding approvals from the Israeli Ministry of Health and Health Canada, along with the necessary initiatives to provide patient access including therapist training, an Expanded Access program, and other commercialization activities. MAPS and the Psychedelic Science Funders Collaborative (PSFC), an allied 501(c)3 nonprofit that supports research on and clinical trials of physician-prescribed psychedelic medicines and patient access to these treatments, have launched a \$30 million Capstone Fund to support the above-mentioned activities. \$11 million has been raised since the fund's launch in April 2020.

#### Impact Potential & Rationale

**A safe and effective treatment for PTSD is needed now, more than ever. MDMA-assisted psychotherapy is positioned to become the first-in-class FDA-approved psychedelic-assisted psychotherapy.**

MAPS, a 501(c)3 non-profit organization, has laid the groundwork for a paradigm shift in mental health care through the medicalization of psychedelic-assisted therapy. Founded in 1986 as a non-profit psychedelic pharmaceutical company, MAPS is regarded internationally as the leading organization for responsible research, psychedelic harm reduction and advocacy, and as a clearing house for the growing knowledge base in the field of psychedelic science. MAPS is positioned to set a gold-standard for accessible, ethical, legal psychedelic-assisted therapy treatment through establishing global access to MDMA-assisted psychotherapy first for PTSD, then other indications, thereby paving the way for other psychedelic-assisted therapies. To date, MAPS has raised almost \$80 million in donations for psychedelic research, advocacy and education.

In December 2014, MAPS created a regenerative hybrid non-profit/for-profit company model through the formation of the MAPS Public Benefit Corporation (MAPS PBC), a wholly owned subsidiary of MAPS 501(c)3 organization. In this model, social benefit measured by transparent metrics created with stakeholders and rooted in the nonprofit's mission and values is balanced with profit generation from potential prescription sales. Potential revenue from prescription sales will reduce reliance on philanthropy to fund further research to develop new clinical applications for MDMA-assisted psychotherapy and new psychedelic therapeutics.

## *The Cost of PTSD*

In the wake of the emergence of COVID-19, the world is collectively experiencing a traumatic event. The word “trauma” is commonly used to convey a highly stressful or shocking event, most often when one’s life or body is threatened. While every human in the world is potentially at risk, populations that are particularly affected by the current pandemic are more likely to develop acute and chronic symptoms of Posttraumatic Stress Disorder (PTSD). This risk is especially prevalent for victims of the disease and their families, health care and emergency service professionals, and front-line workers including service industry professionals who risk their own lives to continue to provide essential services.

A high proportion of people will develop acute symptoms of PTSD following a traumatic event, especially in the month following the event, with most recovering naturally. For the percentage of people who do not recover naturally, PTSD can become a disabling and life-threatening mental health condition, resulting in reduced quality of life, problematic symptoms and elevated suicide rates, particularly when unsuccessfully treated. The VA National Center for PTSD estimates there are 8 million Americans suffering from PTSD and that in a typical population, between 7-8% of the population will be diagnosed with PTSD at some point in their lives.

Over 6,000 US veterans annually commit suicide (latest estimate 17 per day), along with more than 40,000 other American suicides (another 110 per day). As of September 2018, there were more than one million US Veterans receiving disability payments for PTSD from the US Department of Veterans Affairs (VA). Using estimated financial costs to the VA for these disability payments for vets currently on disability for PTSD, the total cost to the VA is roughly \$15-20 billion annually.

## *Currently Available Treatments*

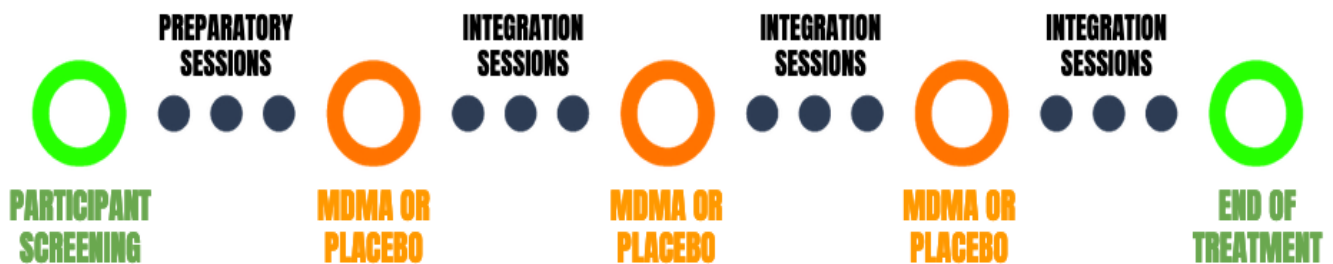
The current first-line treatment for PTSD is trauma-focused therapy including Prolonged Exposure (PE), Cognitive Processing Therapy (CPT), Cognitive Behavioral Therapy (CBT), and Eye Movement Desensitization and Reprocessing (EMDR). These therapeutic approaches are effective in symptom reduction and management for many people with PTSD. However, there is still a significant portion of patients who are treatment-resistant, and the therapies often take years for symptoms reduction to reach remission levels. The two medications approved by the US Food & Drug Administration (FDA) for the treatment of PTSD, paroxetine hydrochloride (Paxil) and sertraline hydrochloride (Zoloft), have demonstrated only small to moderate effects when compared to placebo and require ongoing daily dosing.

A comparison between current pharmacotherapies (Zoloft + Paxil) and MDMA-assisted psychotherapy for PTSD was published in *Frontiers in Psychiatry* in September 2019. The comparison demonstrated MDMA-assisted psychotherapy for PTSD, with its integrated pharmacological and psychotherapeutic approach, constitutes a substantial improvement over existing pharmacotherapies in terms of safety and effectiveness. ([Feduccia, 2019](#))

*Promise of MDMA-Assisted Psychotherapy*

**In August 2017, FDA designated MDMA-assisted psychotherapy for PTSD a Breakthrough Therapy, meaning it is among the most promising drugs being developed.**

Based on FDA trials to date, the carefully managed use of psychedelic substances, including 3,4-methylenedioxymethamphetamine (MDMA), appears to be beneficial in the treatment of several psychiatric conditions such as PTSD, social anxiety, and anxiety related to life-threatening illnesses. MDMA-assisted psychotherapy for PTSD uses MDMA to improve the effectiveness of psychotherapy. **The treatment involves 3 day-long administrations of MDMA-assisted psychotherapy scheduled 3-5 weeks apart in conjunction with twelve weekly 90-minute non-drug psychotherapy sessions:** three preparatory sessions before the first MDMA-assisted psychotherapy session and three integrative sessions after each MDMA-assisted psychotherapy session.

Phase 3 Protocol Design

Therapy is provided by teams of two investigators trained in the manualized therapeutic approach where emphasis is placed on supporting the participant's emerging experience and alternating between internal reflection and external processing. To promote safety and adherence to the therapeutic model, all therapy sessions are video recorded and randomly assessed by a team of adherence raters..

**Due to its unique pharmacological profile, MDMA is a powerful adjunct to psychotherapy which assists individuals in processing traumatic experiences in a deep and profound manner, leading to the alleviation of suffering and reduced suicides.** The therapeutic effect is not due simply to the physiological effects of the medicine; rather, it is the result of an interaction between the effects of the medicine, the therapeutic setting, and the mindsets of the participant and the therapists. Research indicates that MDMA may catalyze therapeutic processing by allowing participants to stay emotionally engaged while revisiting traumatic experiences without being overwhelmed by anxiety or other painful emotions.

MAPS-sponsored Phase 2 clinical trials in 105 subjects with chronic, treatment-resistant PTSD demonstrated that in the control group receiving psychotherapy with either inactive placebo or low-dose MDMA, 22.6% no longer met diagnostic criteria for PTSD at the primary endpoint two months after the final day-long experimental session. In the experimental group receiving psychotherapy with full-dose MDMA, 54.2% of subjects no longer met diagnostic criteria for PTSD at the primary endpoint. **At the one-year follow-up, 67% of all subjects treated with full-dose MDMA no longer met diagnostic criteria for PTSD**, demonstrating the durability of positive treatment outcomes and continued improvement over time.

## Program Detail

MAPS' top priority is to make MDMA legally available as an adjunct to psychotherapy for PTSD in the US, then Israel and Canada. Approval of the prescription use of MDMA-assisted psychotherapy for chronic PTSD is likely to result in a substantial reduction of suffering for people burdened by chronic PTSD, a reduction in suicides related to chronic PTSD, and the generation of further funding, resources, and cultural support for the global renaissance in psychedelic research.

The pivotal Phase 3 studies are randomized, blinded, placebo-controlled studies conducted under the regulatory guidance of the FDA, Copernicus IRB, and the US Drug Enforcement Administration (DEA). In the Phase 3 studies, effectiveness of MDMA-assisted psychotherapy is assessed by observing trends in the Clinician Administered PTSD Scale (CAPS-5), administered by a pool of independent, blinded raters primarily trained by the Boston VA, where the CAPS was developed.

**MAPS has reached a critical point in the progress of the MDMA/PTSD drug development program and is on the verge of successfully introducing a promising PTSD treatment to the global market.**

### Accomplished Milestones:

- 2016 - Completed an international series of six Phase 2 clinical trials and submitted the pooled data along with Phase 3 plans to the FDA for an End of Phase 2 meeting.
- 2017 - The FDA designated MDMA-assisted psychotherapy a Breakthrough Therapy and came to a legally binding agreement with MAPS regarding protocol design, primary endpoint, and statistical approach for Phase 3 trials through the Special Protocol Assessment (SPA) process.
- 2018 - Met initial fundraising goal of \$34 million in donations for the Phase 3 trials, initiated open-label lead in study (MP-16) in which new investigators were supervised while treating one PTSD patient.
- 2019 - Trained 73 investigators in the therapeutic model, conducted Phase 3 study start up and initiation, and began participant screening and treatment at 15 sites across the United States (11), Canada (2), and Israel (2) for the first Phase 3 study (MAPP-1).

**In March 2020, MAPS received a positive outcome for the most important reality-check in its 34-year history, the interim analysis for the first ever Phase 3 clinical trial of a psychedelic compound.**

An interim analysis represents a make-or-break moment for a clinical trial, as the outcome provides a sponsor with the first clear signal of the likelihood of success. After a pre-specified percentage of participants have been enrolled and treated in a study, an interim analysis for possible sample-size re-estimation provides an indication of whether or not the study is likely to succeed in obtaining statistically significant results demonstrating efficacy. Conducted by an Independent Data Monitoring Committee (DMC), an interim analysis reviews preliminary Phase 3 data and assesses how many subjects (if any) need to be added to the sample size in order to increase the probability of obtaining statistical significance, or whether continuing the study is altogether futile.

Many drug products fail in Phase 3. An example of this is Tonmya, the only other proposed treatment for PTSD that has received Breakthrough Therapy designation from the FDA. In Feb 2020, the interim analysis for Tonmya's Phase 3 study resulted in a recommendation to stop the study for futility after more than \$100 million was invested into development.

The goal of MAPS' interim analysis for its first Phase 3 MDMA-assisted psychotherapy for PTSD study (MAPP1) was to verify whether or not the sample size (N=100) for the study would achieve statistical significance. **The DMC found that zero subjects needed to be added to the study to have a 90% or greater probability of obtaining statistically significant results.** With sufficient funding, MAPS is on track to have MDMA-assisted psychotherapy for chronic PTSD receive regulatory approval for prescription use, a landmark accomplishment for the promising field of psychedelic medicine as the first psychedelic-assisted psychotherapy treatment approved for prescription use by any regulatory agency anywhere in the world.

#### **Major Activities for the MDMA/PTSD Phase 3 Drug Development Program:**

- SPA agreement - COMPLETE
- Investigator training and MP-16 lead-in study – COMPLETE
- MAPP-1 initiated, enrollment ongoing, and interim analysis – COMPLETE
- MDMA Therapy Training Program development - ONGOING
- Breakthrough Therapy meetings with FDA – ONGOING (Q2 2020)
- MAPP-1 enrollment completion and initiation of MAPP-2 – UPCOMING (Q2 2020)
- MAPP-1 database lock and close out – UPCOMING (Q3 2020)
- MAPP-2 enrollment completion and interim analysis – UPCOMING (2021)
- MAPP-2 database lock and close out – UPCOMING (2021)
- Statistical analysis and NDA submission – UPCOMING (2022)

*Please note that project milestones are subject to delays caused by the physical distancing policies being put into place in response to COVID-19.*

## Program Milestones & Deliverables

### Primary Deliverables:

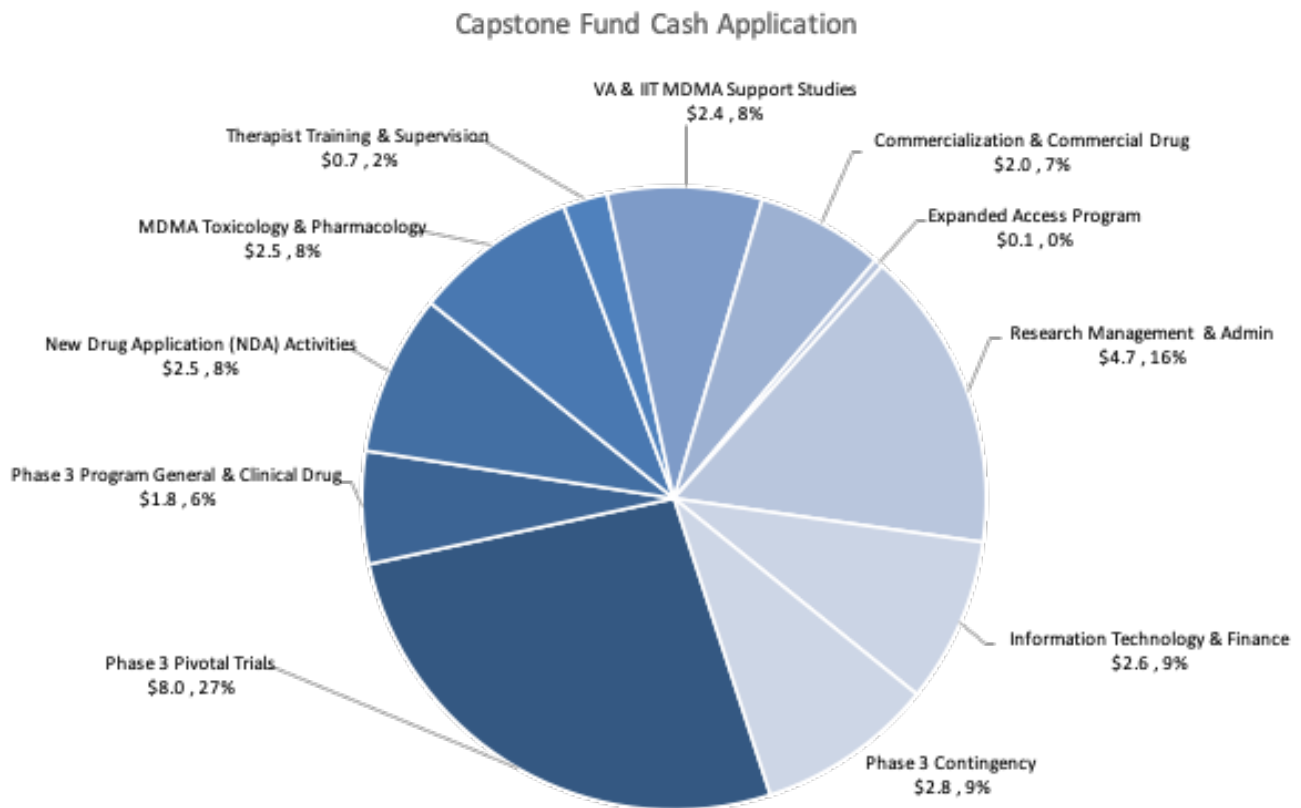
1. Complete pivotal Phase 3 Clinical Trials MAPP-1 & MAPP-2
3. New Drug Application submission to FDA
4. Successful FDA Advisory Committee Meeting
5. Expand MDMA Therapy Training Program with Certification

### Phase 3 Milestones

2020	
Q1	<ul style="list-style-type: none"> <li>● MAPP-1 complete enrollment and interim analysis</li> </ul>
Q3	<ul style="list-style-type: none"> <li>● MAPP-2 initiate enrollment</li> <li>● Select vendor for commercial drug campaign and complete API (active pharmaceutical ingredient) campaign</li> <li>● Hire Director of Commercialization</li> <li>● MP-16 Clinical Study Report submitted</li> <li>● MAPP-1 database lock</li> <li>● Complete Nonclinical Toxicology studies</li> <li>● FDA Breakthrough Therapy check-in meeting</li> </ul>
Q4	<ul style="list-style-type: none"> <li>● Initiate NDA API stability protocols</li> <li>● MAPP-1 analysis and Clinical Study Report complete</li> <li>● Study start-up of Food Effects study</li> <li>● Start enrollment for MAPPUSX cross over study</li> <li>● Complete qualification and training of 10 Expanded Access sites</li> </ul>
2021	
Q1 & Q2	<ul style="list-style-type: none"> <li>● Complete Hepatic Impairment study</li> <li>● Begin enrollment in Expanded Access (N=50)</li> <li>● FDA Breakthrough Therapy check-in meeting</li> <li>● Launch MDMA Therapy Training Program</li> <li>● Complete NDA API stability protocols</li> </ul>
Q3 & Q4	<ul style="list-style-type: none"> <li>● MAPP-2 complete enrollment and interim analysis</li> <li>● Complete Food Effects study</li> <li>● Conduct NDA stability protocol</li> </ul>
2022	
Q1-Q4	<ul style="list-style-type: none"> <li>● MAPP-2 database lock</li> <li>● MAPP-2 analysis and Clinical Study Report complete</li> <li>● Complete 80% initial enrollment, request additional subjects for Expanded Access</li> <li>● Complete NDA submission to FDA</li> </ul>

## Fund Budget

Below is a detailed budget showing a funding summary broken out by cost categories for the Capstone Fund at the end of this proposal. The Capstone Fund budget represents the direct costs to make MDMA a medicine in the US, Israel and Canada and additional funds to put MAPS PBC in a position to bring MDMA-assisted psychotherapy to market. Expenses for Phase 3 in Europe, non-MDMA studies and MAPS 501c3 operating budget are not included in this proposal. MAPS will be administering the funds for the project. Contributions made as part of the Capstone Project will be directed to “MAPS Capstone Fund” and deposited into the Capstone Fund account.



### MDMA US Capstone Fund Cash Application

Remaining FY 2020 (Feb-May) through Partial Year FY 2023	Expense	Less: Pledges & Cash	Remain Expense	Capstone Fund	%
Phase 3 Pivotal Trials	14,045,434	(6,055,621)	7,989,813	7,984,051	27%
Phase 3 Program General & Clinical Drug	4,166,739	(2,415,192)	1,751,547	1,750,283	6%
New Drug Application (NDA) Activities	3,534,962	(1,034,680)	2,500,282	2,498,479	8%
MDMA Toxicology & Pharmacology	3,600,035	(1,053,726)	2,546,308	2,544,472	8%
Research Management & Admin	6,632,595	(1,941,354)	4,691,241	4,687,858	16%
Information Technology & Finance	3,633,440	(1,063,504)	2,569,936	2,568,082	9%
Therapist Training & Supervision	5,353,380	(4,659,734)	693,646	693,146	2%
VA & IIT MDMA Support Studies	4,145,070	(1,740,353)	2,404,717	2,402,982	8%
Commercialization & Commercial Drug	4,583,083	(2,605,224)	1,977,858	1,976,432	7%
Expanded Access Program	1,211,087	(1,073,929)	137,158	137,059	0%
Phase 3 Contingency	2,759,145	-	2,759,145	2,757,156	9%
<b>Total</b>	<b>53,664,967</b>	<b>(23,643,317)</b>	<b>30,021,651</b>	<b>30,000,000</b>	

## Risks

To succeed scientifically, MAPS' drug development efforts must produce rigorous and highly monitored evidence proving that MDMA-assisted psychotherapy for chronic PTSD is safe and efficacious. The biggest risks associated with this proposal are (1) the Phase 3 studies not generating statistically significant results, thereby failing to prove efficacy, and (2) increased participant suicides in the MDMA-assisted psychotherapy group compared to the therapy with placebo control group, reducing safety.

To succeed culturally, MAPS needs political and popular support for the psychedelic research renaissance currently underway. Additional risks include (3) failure to meet the \$30 million funding need, and (4) popular and politically motivated suppression of psychedelic research (like what occurred fifty years ago).

MAPS is in a unique position where it is leading psychedelic research globally and is the only sponsor of a Phase 3 trial with psychedelic-assisted psychotherapy. If MAPS is successful in its work to medicalize MDMA-assisted psychotherapy for PTSD, the landscape will be opened to future research both by MAPS and other groups. Should MAPS fail in medicalizing MDMA-assisted psychotherapy for PTSD, it will likely have a negative effect on other ongoing and planned psychedelic research.

### *Reducing Lack of Efficacy Risk*

To reduce the risk that the study would not produce statistically significant results, MAPS has reviewed its statistical analysis plan with the FDA through the Special Protocol Assessment (SPA) process and agreed to conduct an interim analysis once 60 subjects completed their primary outcome measures and the initial subject enrollment target was met (N=100). The results of the interim analysis were that 0 subjects needed to be added to the study to have a 90% or greater probability of obtaining statistically significant results from the first Phase 3 study, MAPP-1.

### *Reducing Suicide Risk*

The patient population that MAPS is working with, individuals with severe PTSD, have a high rate of suicidal ideation and behavior related to their traumatic experiences. This high background rate is paired with the emergence of trauma during the psychotherapy process, and the requirement to taper off of psychiatric medications as a prerequisite for study enrollment. In order to reduce the potential of suicide attempts, MAPS has implemented extensive measures designed for patient safety including medical monitoring and psychological support for participants before and following their experimental sessions.

In accord with FDA regulations, our clinical teams administer the Columbia Suicide Severity Rating Scale (CSSRS) to subjects after every in-person visit, and after all three phone visits during the week after each experimental session in Phase 3. Additionally, the Data Monitoring Committee (DMC) reviews the data quarterly with the option to unblind. Historically, MAPS has observed a 2.1% rate of suicidal ideation and behavior in its studies (N=337), however due to



ongoing blinding we are unable to determine the number receiving placebo vs MDMA who are experiencing suicidal ideation.

### *Reducing Financial & Operational Risk*

MAPS is expanding its Development team to meet the challenge of raising \$30 million for the Capstone Fund and is hiring additional senior leadership staff to allow the Founder and Executive Director, Rick Doblin, to focus even more of his time on strategy and fundraising instead of day-to-day operations.

MAPS' collaboration with PSFC, with their network of high net worth individuals, is our key strategy to reducing financial risk. MAPS will draw on our network of existing donors to help raise the first \$10 million tranche, and then PSFC will request major gifts from new donors from their network. PSFC also brings outside expertise and diligence to vetting the MAPS program, giving new donors further confidence in the drug development plans. Atul Pande, former head of psychiatric drug development at GSK and Pfizer, has conducted a review of the MAPS clinical plans and revised budget, providing expert validation that will reassure prospective new donors. With Atul's expert report in hand, and the promising interim analysis results, PSFC and MAPS are convening a series of meetings, requesting seven-figure donations to support the Capstone Fund.

In 2019, MAPS conducted a re-evaluation of the MDMA/PTSD clinical development plan with the support of expert consultants and determined to shift the approach to hiring practices. Historically, MAPS has relied on passionate mission-driven staff, who often work more than a standard work week at below market rates, and has relied on the support of volunteers. This resulted in remarkable progress but led to staff stress and burnout. The de-risked approach includes hiring additional staff to manage the increasing workload demanded by the clinical development plan, as well as engaging additional expert consultants, and incentivizing raises for key staff who are critical to the success of the program.

With the promising interim analysis results, the new budget, and approach to staffing and consultants, there is a high degree of confidence that MAPS will be ready in 2022 to submit its FDA New Drug Application (NDA) and in 2022/23 receive FDA-approval for MDMA-assisted psychotherapy for PTSD, along with approval from the Israeli Ministry of Health and Health Canada. The Capstone Fund will support activities through the regulatory submissions for FDA, the Israeli Ministry of Health, and Health Canada.

### *Reducing Cultural Backlash Risk*

MAPS has intentionally obtained funding from donors across the political spectrum, most notably Rebekah Mercer (whose \$1 million donation over 4 years was restricted to treatment of veterans), Elizabeth Koch (whose \$2.7 million donation over three years was restricted to manufacturing medical grade MDMA), members of the Rockefeller and Pritzker families, and George Soros' Open Society Foundations. As a result of this broad spectrum of support, the healing we have provided to veterans and other people suffering from PTSD, and the skill of MAPS' media and communications teams, MAPS has been featured in over 370 unique media mentions so far this fiscal year (start June 1) with positive media coverage from major outlets

including CNN, 60 Minutes, Fox News, numerous military newspapers and websites, NYTimes, and Washington Post.

In efforts to reduce cultural backlash, MAPS has cultivated connections with law enforcement professionals and agencies to build support for MDMA-assisted psychotherapy for PTSD. These efforts include enrolling several police officers with PTSD in our Phase 2 and Phase 3 studies, speaking at industry conferences including the annual meeting for the International Association of Chiefs of Police, working with a police psychotherapist and his department to receive approval for him to participate in the MDMA Therapy Training Program, and consulting with a senior retired DEA official whose son fought in Iraq, came back with PTSD, and found help from cannabis.

MAPS has also built strong connections with leading PTSD researchers who work at the VA and DoD, including with the leadership of the VA's National Center for PTSD. For 30 years, MAPS has pursued sponsoring research into MDMA-assisted psychotherapy for PTSD inside the VA. MAPS is close to achieving this goal as a result of a collaboration with the Bronx VA through Dr. Rachel Yehuda, Ph.D., Professor of Psychiatry and Neuroscience and the Director of the Traumatic Stress Studies Division at the Mount Sinai School of Medicine.

Based on MAPS' multi-decade strategy to build broad spectrum political support for MDMA-assisted psychotherapy for PTSD as well as the conscious choice to actively enroll veterans and law enforcement professional in our studies and build alliances with VA/DoD therapists, researchers and senior staff, the risk of a cultural backlash against our research has been mitigated to the extent possible. MAPS will continue to expand these efforts to an ever-wider circle of supporters as Phase 3 research progresses.

## Implementation

MAPS and MAPS PBC are committed to open science, open praxis principles. In service to this commitment, MAPS publishes its research protocols, treatment manual for MDMA-assisted psychotherapy for PTSD, published articles, and investigator's brochure on its website available for free download, and actively collaborates with third-party researchers and institutions. Already, dozens of researchers and institutions are building on the body of research that MAPS has produced.

At the end of its MDMA Drug Development program, MAPS aims to have two commercial products; the MDMA drug product for sale by prescription and the MDMA-assisted psychotherapy certification. Eligible therapy providers will be able to enroll in the MDMA Therapy Training Program in order to obtain certification to administer MDMA-assisted psychotherapy as part of their clinical practice once it's approved by FDA. Once certified, providers may purchase the MDMA drug product from MAPS PBC for use in their practice. The MDMA will only be administered under clinical supervision and will not be available as a take-home medication.

To maximize public benefit, MAPS intends to run the MDMA Therapy Training Program to bring in only slightly more income than expenses to reduce the possibility of tuition cost as a barrier to

uptake. MAPS projects a reasonable income primarily from the sale of MDMA during the roughly 6 year period of data exclusivity granted by the FDA. Data exclusivity is a protected period offered to sponsors developing off-patent therapeutics where only the sponsor can use the data submitted for regulatory approval, delaying generic competitors. Should MAPS raise additional funds and conduct successful Phase 3 research for European Medicines Agency (EMA), the EMA data exclusivity period is 10 years. Any profit generated by MAPS PBC will be reinvested in additional research and educational activities consistent with MAPS' mission to mainstream the beneficial uses of psychedelics and cannabis.

The approval of MDMA-assisted psychotherapy as a legally available treatment will open untold doorways for researchers and entrepreneurs to further innovate on the applications of psychedelic-assisted therapies. MAPS aims to set a precedent for the field by establishing an ethical standard of care and clinics as centers of excellence. In service of this aim, MAPS includes supervision as an element of the training program and has created a Code of Ethics for all therapists receiving certification. MAPS has been refining the therapeutic approach and clinic design for MDMA-assisted psychotherapy since 2000 when MAPS' Phase 2 MDMA/PTSD research was first initiated.

Most critically, MAPS will be able to facilitate access to a robustly effective trauma treatment, which does not require interminable daily dosing, to patients in desperate need. The treatment will be available first through the Expanded Access program, an FDA-regulated program where a limited number of patients (N=50) will be able to receive MDMA-assisted psychotherapy outside of the clinical trial, and ahead of approval. Once FDA-approval has been granted, certified providers will be able to administer the treatment in private clinics. In preparation for FDA-approval, MAPS is developing a commercial supply of MDMA drug product, preparing its existing MDMA Therapy Training Program for public launch, consulting with commercialization and business development experts on patient access and scaling, and developing the strategy for obtaining insurance reimbursement for MDMA-assisted psychotherapy.

In the last two years in particular, MAPS has engaged in initiatives centered around ensuring inclusive patient access, with a particular focus on underserved communities (low-income, housing insecure, people of color, LGBTQ+ identified people, the elderly, etc). MAPS formed an Advisory Council with experts to advise on initiatives including a community workshop as well as a therapy training intensive designed specifically for people of color. This initiative was funded by generous donations from the Open Society Foundations, Riverstyx Foundation, the Libra Foundation, the Psychedelic Science Funders Collaborative, and Dr. Bronner's. As patient access approaches, MAPS is establishing formal programs to focus justice, equity, diversity, and impact initiatives, and integrating these initiatives across all existing programs within the MAPS Group.