# From the Desk of Rick Doblin, Ph.D.

**MAPS has recently completed its** first Phase 3 study of MDMA-assisted therapy for PTSD for review and potential approval by FDA, Health Canada, and the Israeli Ministry of Health. A scientific paper about the outstanding results was published in Nature Medicine and reported on in two New York Times articles, one on the front page, and in many other media outlets. MAPS is currently in the early stages of conducting our second Phase 3 study with results from the interim analysis of that study anticipated by May 2022, with completion by August 2022 and potential approval for prescription use before the end of 2023.

MAPS has also started research to train European therapists in preparation for Phase 3 research for review and potential approval by the European Medicines Agency (EMA) around the end of 2024. No other non-profit or for-profit psychedelic company has even started Phase 3 for any psychedelic-assisted therapy for any clinical condition, yet several publicly traded for-profit psychedelic companies have market caps in excess of $1.35 billion. MAPS has raised about $110 million in philanthropic donations over the course of its 35-year history. If MAPS' wholly owned pharmaceutical arm, the MAPS Public Benefit Corporation, was publicly traded, it would probably have a market cap in the range of or exceeding these other companies. It's likely that MAPS has created public value 10X or more than total donations to date.

MAPS has earned its reputation as the global leader in psychedelic therapy research, shaping how this work is done and will be done for decades to come. MAPS has garnered a substantial amount of respect and trust in its hybrid non-profit/benefit corporation approach with open sourcing valuable information that has accelerated the growth of this field, including the gold-standard treatment protocol and ethical guidelines for therapists working with psychedelic substances. MAPS is the leading institution within this emergent field and is poised to retain its leadership position by building on decades of work that has been done for the benefit of all.

MAPS has engaged the Boston Consulting Group (BCG) to help us chart a path toward sustainability through income generated from the sale of MDMA by prescription, should we obtain approvals for marketing by FDA and other regulatory agencies around the world. While I studied the FDA drug development process for my dissertation, and we've built the MAPS Public Benefit Corporation into the world's leading team to design, conduct, and monitor psychedelic-assisted therapy research and to negotiate with regulatory agencies around the world, the commercialization of MDMA-assisted therapy for PTSD presents a new set of challenges for which we are just starting to develop the internal expertise.

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The contract with BCG has recently concluded. Our work together has been exceptionally instructive in analyzing the tasks needed to market MDMA by prescription. BCG has developed staffing and cost estimates for commercialization in the US. They also analyzed market size, and proposed estimates for US-based income based on review of the capacity of our therapist training program to produce trained therapists, on the numbers of patients that therapists can treat per year, on a range of prices for the MDMA along with cost effectiveness data that will be evaluated by insurance companies in deciding whether to offer insurance coverage for MDMA-assisted therapy for PTSD to the people they insure. BCG reviewed income during the roughly six-year period of data exclusivity that FDA provides for medicines that are off-patent (there is 10 years of data exclusivity in Europe). During the period of data exclusivity, other companies can generate their own data if they want to market MDMA-assisted therapy for PTSD but can't use MAPS' data to market a generic version. BCG also estimated income to MAPS in the US after MDMA becomes generic.

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The challenge that MAPS now faces in reaching sustainability through the sale of MDMA by prescription is primarily financial. According to the BCG report, MAPS may be able to reach sustainability sometime in 2024, assuming approval for prescription use is obtained before the end of 2023. MAPS thus will need to raise additional resources to fund commercialization expenses which are usually started two or so years prior to approval, to conduct our European research and continue our other globalization efforts for MDMA-assisted therapy for PTSD, and to support the MAPS Public Benefit Corporation staff until sustainability has been reached. We're in the process of estimating what amount of funds still needs to be raised.

Our goal is to help heal thousands, then tens and hundreds of thousands, then millions of PTSD patients. In that process, we will continue to help catalyze the mainstreaming of psychedelic-assisted therapy with hundreds of for-profit companies now part of the psychedelic corporate ecosystem, for the healing of millions more suffering from a wide range of clinical indications. The medicalization of psychedelics will also build support for drug policy reform efforts to bring about a post-Prohibition world with licensed legalization, to restore the fundamental human right to legally explore our own inner worlds.

MAPS will primarily be seeking to raise funds through philanthropy to reach a point of sustainability. We are also exploring partnerships with several for-profit companies that are interested in clinical indications for MDMA other than PTSD. MAPS has built great value in our existing data about safety of MDMA that is in large part relevant for other uses of MDMA, and we've built expertise in drug development in MAPS PBC.

The next few years will be fascinating as we build a bridge from the founding of MAPS 35 years ago in 1986 to the likelihood of sustainability in 2024. With the continued support of the MAPS community, we can build this bridge together.

Rick Doblin

Rick Doblin, Ph.D.
MAPS Founder and Executive Director