

**Statement of Michael Mullette, Chief Operations Officer, MAPS-PBC  
to the  
U.S. House of Representatives  
Committee on Veterans' Affairs Subcommittee on Health**

**Re: *Emerging Therapies: Breakthroughs in the Battle Against Suicide?***

**October 19, 2023**

Chairwoman Miller-Meeks, Ranking Member Brownley, and Members of the subcommittee, thank you for the opportunity to offer this statement for the record. As the Chief Operating Officer of MAPS PBC, I sincerely appreciate your leadership in holding this first of its kind hearing on emerging therapies and their potential for treating Veterans suffering from PTSD and other mental health conditions.

MAPS Public Benefit Corporation (“MAPS PBC”) is a clinical-stage company focused on developing prescription psychedelics to bring new options to those living with mental health conditions. Based in San Jose, California, MAPS PBC has completed two phase 3 clinical trials evaluating investigational 3,4-methylenedioxymethamphetamine-assisted therapy (MDMA-assisted therapy) as a potential treatment for post-traumatic stress disorder (PTSD), both of which met their pre-specified primary and secondary endpoints.<sup>1</sup> Founded in 2014, MAPS PBC is a subsidiary of the Multidisciplinary Association for Psychedelic Studies, a 501(c)(3) non-profit organization changing the way mental health conditions are treated.

**Background on MDMA-AT**

MDMA (3,4-methylenedioxy-methamphetamine) is an entactogen – a class of psychoactive drugs that produce experiences of emotional communion, oneness, relatedness, emotional openness and are thought to have use for various medical conditions.<sup>2</sup> In the 1960’s and 1970’s, MDMA was used in conjunction with psychological therapy by mental health providers to enhance patients’ access,

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<sup>1</sup> Mitchell JM, Ot’alora MG. et al. MDMA-assisted therapy for moderate to severe PTSD: a randomized, placebo-controlled phase 3 trial. Nat Med. 2023 Sept 14 doi: 10.1038/s41591-023-02565-4. Mitchell JM, Bogenschutz M, Lilienstein A, et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med 609 2021;27:1025–33.

<sup>2</sup> O’Neil, M.J., The Merck Index: An Encyclopedia of chemicals, drugs and biologicals. Merck Research Laboratories, Merck and Co. Inc, Whitehouse station, New Jersey, 2006. 319

processing, and communication of difficult emotions and experiences.<sup>3</sup> In 1985, the U.S. Drug Enforcement Agency (“DEA”) made MDMA a Schedule I drug under the Controlled Substances Act preventing it from being used for recreational or medical use.<sup>4</sup> Since then, research has shown the unique properties of MDMA allow it to act as a catalyst to support psychotherapy by helping attenuate the brain’s fear response allowing patients to access and process painful memories without being overwhelmed.<sup>5</sup> With a growing body of evidence supporting the potential medical use of MDMA, in 2017 the U.S. Food and Drug Administration (“FDA”) granted MDMA-assisted therapy Breakthrough Therapy designation, a process designed to expedite the development and review of drugs intended to treat serious conditions and that preliminary clinical evidence indicates that it may demonstrate substantial improvement over available therapies. MAPS PBC expects to submit a new drug application including data from two Phase 3 studies (MAPP1 and MAPP2) that showed clinically significant improvements in PTSD symptoms following acute treatment with MDMA-assisted therapy to the FDA in 2023. If approved by the FDA, the DEA would reschedule MDMA from a Schedule I drug, making it available for prescription medical use. MDMA-assisted therapy is also being studied in other indications.<sup>6,7,8,9</sup>

## Background on PTSD

PTSD is a mental health condition affecting approximately 13 million Americans each year<sup>10</sup>, yet currently available treatments only provide moderate efficacy.<sup>11</sup> People with PTSD can experience debilitating symptoms that impact nearly all areas of a person’s life.<sup>12</sup> They also frequently experience comorbidities including anxiety, depression, and substance use disorder.<sup>13</sup> PTSD has an enormous economic impact resulting in an

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<sup>3</sup> Wagner MT, Mithoefer MC, Mithoefer AT, MacAulay RK, Jerome L, Yazar-Klosinski B, Doblin R. Therapeutic effect of increased openness: Investigating mechanism of action in MDMA-assisted psychotherapy. *J Psychopharmacol.* 2017 Aug;31(8):967-974. doi: 10.1177/0269881117711712. Epub 2017 Jun 21. PMID: 28635375; PMCID: PMC5544120.

<sup>4</sup> National Institute on Drug Abuse What is the history of MDMA? | National Institute on Drug Abuse (NIDA) (nih.gov). Accessed, September 8, 2023. [What is the history of MDMA? | National Institute on Drug Abuse \(NIDA\) \(nih.gov\)](https://www.drugabuse.gov/about-us/news-events/2023/09/08/what-is-the-history-of-mdma)

<sup>5</sup> Yazar-Klosinski B, Mithoefer MC. Potential Psychiatric Uses for MDMA. *Clinical Pharmacology & Therapeutics*, 2016 Nov 9. <https://doi.org/10.1002/cpt.565>

<sup>6</sup> Danforth AL, et al. *Psychopharmacology (Berl)*. 2018;235:3137-3148.

<sup>7</sup> Wolfson PE, et al. *Sci Rep*.2020;10:20442.

<sup>8</sup> Sessa B, et al. *J Psychopharmacol.* 2021;35(4):375-383.

<sup>9</sup> ClinicalTrials.gov Identifier: NCT05584826

<sup>10</sup> A National Center for PTSD. US Department of Veterans Affairs. Accessed February 14, 2023. [https://www.ptsd.va.gov/understand/common/common\\_adults.asp](https://www.ptsd.va.gov/understand/common/common_adults.asp)

<sup>11</sup> Morina N. Remission from post-traumatic stress disorder in adults: a systematic review and meta-analysis of long term outcome studies. *Clin Psychol Rev.* (2014) Apr;34(3):249-55. doi: 10.1016/j.cpr.2014.03.002

<sup>12</sup> The Mayo Clinic, PTSD, Symptoms and Causes [www.mayoclinic.org/diseases-conditions/post-traumatic-stress-disorder/symptoms-causes/syc-20355967c](https://www.mayoclinic.org/diseases-conditions/post-traumatic-stress-disorder/symptoms-causes/syc-20355967c)

<sup>13</sup> Grinage B.D. Diagnosis and Management of Post-traumatic Stress Disorder. *Am Fam Physician.* (2003);68(12):2401-2409

annual burden of over \$200 billion.<sup>14</sup> Currently available treatments for PTSD are inadequate to address the full spectrum of patients who need treatment and may not provide adequate relief from debilitating symptoms.<sup>15</sup> These limitations combined with high treatment discontinuation rates in psychotherapy underscore the urgent need for novel and effective therapies.<sup>16</sup> Moreover, PTSD disproportionately impacts Veterans. According to the U.S. Department of Veterans Affairs' National Center for PTSD, 7 out of every 100 Veterans (7%) will have PTSD at some point in their life.<sup>17</sup>

### Critical Mission Ahead

MAPS PBC's mission to alter the way mental health conditions are treated is personal for me. For the past two decades I have seen my wife, who is a therapist, struggle to find effective solutions for her patients with PTSD. I joined this company with a goal to help healthcare providers like her and their patients have access to new treatment options. As you are aware, there has not been significant innovation in the treatment of PTSD in decades. Despite growing mental health needs, development of new treatments has been slow, and the complexities of treating PTSD have grown. People with PTSD frequently experience comorbidities including anxiety, depression, and substance use disorder.

At MAPS PBC we have made significant progress researching a new investigational treatment for PTSD known as MDMA-assisted therapy. This investigational acute treatment entails a unique combination of medicine and talk therapy. While MDMA-assisted therapy is novel, the components are not new. Both prescription treatments and talk therapy are currently used to treat mental health conditions. What is unique is using them together. In our clinical studies, the participants received either MDMA and therapy or placebo and therapy three times over a twelve-week period, with three therapy sessions prior to commencing the medication sessions and three therapy sessions after concluding the medication sessions (for a total of nine therapy sessions).

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<sup>14</sup> Davis LL. The economic burden of posttraumatic stress disorder in the United States from a societal perspective. *J Clin Psychiatry.* (2022) Apr 25;83(3):21m14116. doi: 10.4088/JCP.21m14116.

<sup>15</sup> Morina N. Remission from post-traumatic stress disorder in adults: a systematic review and meta-analysis of long term outcome studies. *Clin Psychol Rev.* (2014) Apr;34(3):249-55. doi: 10.1016/j.cpr.2014.03.002.

<sup>16</sup> Varker T. Dropout from guideline-recommended psychological treatments for posttraumatic stress disorder: A systematic review and meta-analysis. *Journal of Affective Disorders Reports* (2021) Apr 2021, 100093. doi: 10.1016/j.jadr.2021.100093

<sup>17</sup> VA National Center for PTSD. US Department of Veterans Affairs. Accessed October 17, 2023.

[https://www.ptsd.va.gov/understand/common/common\\_veterans.asp](https://www.ptsd.va.gov/understand/common/common_veterans.asp) [https://www.ptsd.va.gov/understand/c](https://www.ptsd.va.gov/understand/common/common_veterans.asp)

Both of our phase 3 clinical trials evaluating investigational MDMA-assisted therapy as a potential treatment for PTSD, met their pre-specified primary and secondary endpoints. The results of the most recent Phase 3 study, MAPP2, were published in the September issue of *Nature Medicine*.<sup>18</sup> In that study, participants in the MDMA-assisted therapy group experienced a significant reduction in PTSD symptoms versus participants receiving placebo with therapy. This was measured by a change from baseline at 18 weeks in Clinician-Administered PTSD Scale for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (CAPS-5) score—the gold standard in PTSD measurement.<sup>19</sup> MDMA-assisted therapy also significantly reduced clinician-rated functional impairment which was measured by a change from baseline in the modified Sheehan Disability Scale (SDS). This scale measures impairment in functioning in three areas: work, social life, and family life. No serious adverse events were reported in either the MDMA group or the placebo control group.

Just last week I had the honor of spending time with a trial participant who is a former Naval Academy graduate. When asked why he had been interested in participating in our study he shared that despite exceptional success in the military he had struggled with suicidal thoughts and what eventually was diagnosed as PTSD for many years, not just due to combat trauma but because of many factors throughout his life. He said he tried many other things, but he felt despondent and hopeless and was desperate for some relief. While the safety and efficacy of MDMA-assisted therapy has not been demonstrated and it has not been approved by the FDA, this participant shared that he hopes other veterans have access to potential treatment options if they are approved. He hears from many of them on a regular basis and knows they feel desperate for new options to be available in the VA medical system rather than having a growing number of Veterans feel forced to seek treatment for their PTSD outside the United States.

At present MAPS-PBC is aggregating all data and preparing our new drug application for submission to the FDA by year end. If successful, we anticipate MDMA-assisted therapy for the treatment of PTSD could be approved by the FDA next year, making it the first emerging therapy of its kind available to patients suffering from PTSD.

The Veterans Administration has the opportunity to create innovative care models to ensure treatments for PTSD are scalable, accessible and, importantly, covered in a timely manner for veterans in need.

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<sup>18</sup> Mitchell JM, Ot'alora MG. et al. MDMA-assisted therapy for moderate to severe PTSD: a randomized, placebo-controlled phase 3 trial. *Nat Med*. 2023 Sept 14 doi: 10.1038/s41591-023-02565-4

<sup>19</sup> See more information from the VA's National Center for PTSD at <https://www.ptsd.va.gov/professional/assessment/adult-int/caps.asp>.

Thank you again for your leadership on this issue, and your continued commitment to the health and safety of Veterans. I am happy to respond to any questions the Committee may have.

Mike Mullette