



MJP2 Quarterly Progress Report – Q1 2025

April 15, 2025

**1. % of completion and work done during project period:**

MAPS has performed approximately 10-15% of the work initially proposed in the statement of work.

**2. Program Progress Updates:**

Following the successful removal of the long-standing clinical hold on this trial last reporting period, during this reporting period MAPS moved to reinitiate the steps for study start-up after this long and unanticipated delay.

**Regulatory:** The November 7, 2024, notice from FDA indicated that MAPS “may proceed with the protocol [MJP2] using smoking as the delivery method only.” Therefore, in order to have a clear “active” protocol for study sites, MAPS prepared an updated protocol (Amendment 3, Version 1) and ICF with the removal of vaporization as a delivery method so that the active protocol will reflect only the cleared method of administration, smoking. MAPS also prepared the 2024 Data Safety Update Report (DSUR) for the FDA. At the start of Q1 2025, MAPS submitted the revised protocol and ICF with the 2024 DSUR.

While the FDA communication also indicated that the vaporization method is accepted by the Department of Psychiatry, the Center for Devices and Radiological Health still requires additional information to be provided on the technical features and safety of the vaporization device before MJP2 will be allowed to proceed with vaporization as a delivery method, and this portion of the protocol remains on clinical hold. MAPS has been in communication with the vaporization device manufacturer to work toward compiling the FDA requested data necessary to remove the clinical hold on the use of the proposed vaporization device. During Q1 2025, we gathered additional information from the device manufacturer, including significant technical and safety-related information, and plan to submit these data to the FDA with a request to remove this hold issue and reinstate vaporization as a delivery method. This submission is scheduled for early Q2 2025. We hope to reinstate vaporization as a delivery method prior to beginning study enrollment but have simultaneously continued to vigorously pursue other study start up activities with the currently cleared study protocol.

**Study Start Up:** In Q4 2024, MAPS also began study start-up activities with the CRO. As previously described, many of the overall project and program management responsibilities were delegated to Lykos Therapeutics (formerly MAPS Public Benefit Corporation); therefore, many of these responsibilities will need to be reassigned to a CRO in a new contract.

In Q1 2025, MAPS had budget planning meetings with the previously selected CRO to review and update the budget to be in line with the current scope of the study. Additionally, in order to ensure that the CRO was the most qualified and cost effective vendor to proceed with the study given the updated Sponsor structure and timelines, MAPS also sought additional bids to oversee the study from a number of different CROs, and is in the process of reviewing proposals and budgets from three other qualified applicants, with the goal of finalizing the CRO contract by the end of April.

MAPS has also renewed engagement with the two vendors providing the Investigational Products (IP) for this study. MAPS has gathered and shared important technical information (ie. grind size, moisture levels, product storage and stability, etc.) on the placebo cannabis, as well as on the process and expected timelines to access this source of placebo cannabis. MAPS has also confirmed the active IP vendors' ongoing commitment and capabilities to provide the study drug, and to prepare both the active drug and placebo into pre-rolled cigarettes for eventual supply to the potential study sites.

During this reporting period, MAPS further engaged with the three study sites that were previously vetted by the current CRO to assess their ongoing willingness and ability to proceed with the study, as well as gather additional details regarding expected site start up and per-participant costs and anticipated recruitment timelines. Despite the extended delays in achieving FDA clearance, all three sites remain engaged in the study and are eager to begin study start-up. Additionally, the sites were able to provide useful site-specific cost estimates, which have now been included in the CRO budget proposals and in the overall cost analysis for the study.

### **3. Description of Problems and Delays:**

During this reporting period, start-up activities have been initiated, including broadening the scope of potential CRO candidates to coordinate the study, and associated budget considerations. Additionally, MAPS will continue to assess the required personnel needed to ensure appropriate oversight as study development plans continue with external vendors.

Further, as the study is now cleared by FDA for smoked cannabis this is no longer a delay to study startup. However MAPS believes that providing participants the option of inhalation methods (smoking or vaporization) is important to reflect and assess "real world" patterns of use; therefore, MAPS continued to work with the associated vaporizer vendor to provide additional data to the FDA in an effort to resolve the partial clinical hold on the vaporization device. If this effort is successful, vaporization will be re-added as an option in the protocol. As this addition can take place at any time within the current study design, this effort will not otherwise impede the study start-up efforts.

### **4. Statement regarding any deviation from SOW:**

#### **A) Personnel Modifications:**

During this reporting period, McKenna Leighton departed MAPS and program responsibilities have been reallocated to Matt Clark and Dr. Philippe Lucas, PhD. Dr. Lucas was hired by MAPS to fill the role of Clinical Program Manager. Dr. Lucas resides in Canada and the mechanisms for payment of a non-US employee are still being finalized. As such, Dr. Lucas' compensation will not be reflected in the financial report until the Q2 2025 report to ensure accuracy in our billing and reporting. In Addition, MAPS' Executive Director, Kris Lotlikar, resigned and his program responsibilities have been reallocated to Ismail Ali and Betty Aldworth who have been promoted to Interim Co-Executive Directors.

B) Other Deviations:

There are no additional deviations to report during this reporting period.

**5. Quarterly Financial Expenditures:**

In Q1 2025, MAPS billed \$31,647.67 for direct administrative supplies and personnel of the VMR program, and \$54,079.38 for indirect administrative expenses. MAPS billed \$23,132.71 in program personnel expenses and \$3,541.25 for VMR contracted services. Total expenditure to date equals 15% of the total contract value.