



Dear Supporters,

Welcome to Usona Institute's Fall newsletter! It's been a busy season for all of us here at Usona, and we're excited to share with you the progression of our work. In this issue, we'll discuss:

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Engagements with the FDA

We are pleased to announce positive progress across a variety of our ongoing interactions with the FDA. In September, the Food & Drug Administration (FDA) granted Usona a Chemistry, Manufacturing, and Controls (CMC) meeting which occurred on October 26th. This meeting was an opportunity for Usona to present its overall plans for ensuring the safety and quality of psilocybin as an investigational drug and to gather key feedback from the FDA on our processes. Each aspect of CMC—including the raw materials, vendors, and the manufacturing environment and procedures—was analyzed to ensure that the psilocybin that will be produced by Usona is high in quality and safe to administer to patients.

The results of this meeting were positive, with the FDA confirming their alignment with our cGMP (current Good Manufacturing Practices) drug synthesis and encapsulation plans. This alignment represents a significant step in the path toward Phase 3 research, and this will be the first time in the United States that psilocybin will be manufactured and formulated in this manner.

Additionally, Usona expects to receive FDA feedback on our clinical protocol, including recent refinements, in early November. Both the CMC information and clinical protocol are key components of the Investigational New Drug (IND) application, which Usona plans to submit following these critical interactions with the FDA.



Clinical Program Development

The opening of our IND will put us on track for the initiation of our first trial beginning in 2018. It will be a randomized, double-blind, and active placebo-controlled trial in Major Depressive Disorder (MDD) in the general population; this trial will be followed by additional studies, including a study in MDD in cancer patients. We've engaged with a Contract Research Organization (CRO) for critical functions such as data monitoring and pharmacovigilance.



Clinical Facilitator Program

Research participants in Usona trials will be supported by two clinical facilitators trained in the principles of therapeutic presence and in Usona-specific protocols. Based on the expertise and input of our partnering clinical teams, Usona is now in the process of building a standard set of therapeutic principles and procedures to be used as participants each prepare for, receive, and integrate their session.



Chemistry Capability

Usona is building advanced chemistry capabilities with our cGMP contractors and is currently establishing chemistry research facilities in Madison, WI and San Luis Obispo, CA, for which we are in the process of obtaining state and federal Schedule 1 licenses. Our goal is to supply the highest-quality materials to qualified institutions for basic, applied, and clinical research at the lowest possible cost for the purpose of furthering the scientific understanding of psilocybin and its therapeutic applications.



Team Expansion

As our role as the sponsor of these clinical trials has grown, so has the expertise of our team and the infrastructure supporting it. We are excited to announce the recent hire of four new team members who bring their years of experience in the fields of medicinal chemistry, regulatory affairs, and administrative management. Featured below is our Regulatory Affairs Manager, Jeremy Rybicki:



Jeremy Rybicki
Regulatory Affairs Manager

“I appreciate that Usona is taking seriously the concept of treating very common and serious disease states with previously unexplored or underdeveloped therapies. The organization and its founders are truly dedicated and focused on the patient, science, and therapeutic benefit of the investigational compound.”

As our Regulatory Affairs Manager, Jeremy provides regulatory affairs support in the development of Usona’s clinical programs and is responsible for being the liaison between Usona and health authorities. With over 15 years of experience in the pharmaceutical industry and 10 plus years of regulatory affairs experience within the areas of regulatory strategy, Chemistry Manufacturing and Controls (CMC), labeling, advertising, and promotional review, Jeremy brings a comprehensive understanding of the structure and proceedings of regulatory engagements critical to Usona’s work.



Our Appreciation

Usona Institute is able to accomplish its mission of enabling and supporting psychedelic research and FDA registration of psilocybin therapy only through collaboration with many scientists, clinicians, research centers, expert consultants, donors, and other contributors globally.

Our role as the sponsor of these studies is unique, in that our work in developing our research hypotheses, clinical programs, and study proposals for the FDA draw extensively from the research and expertise of our academic collaborators, without whom this work would not be possible. As such, Usona works to maintain a collaborative approach with our partnering academic sites, whose prior clinical and research experience have contributed to the co-development of the study protocols that Usona will manage and monitor.

We will continue to build relationships and collaborations with organizations that share our philosophy of delivering approved psilocybin therapy to those in need based on safety, high quality active drug materials, and highly-trained guides and practitioners in a not-for-profit model.

All of us at Usona Institute would like to extend our gratitude for your interest in the furtherance of our mission. If you would like any additional information, please feel free to email us at info@usonainstitute.org.

With appreciation,
The Usona team



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