



Dear Supporters,

Welcome to Usona Institute's Winter 2018 Newsletter. The new year has seen a flurry of activity for Usona and our collaborators, and we're glad to share with you the latest updates on our work. In this edition, we'll cover the following activities:

- [FDA Investigational New Drug Submission](#)
- [Preparations for Psilocybin Clinical Trials](#)
- [Open Science Commitment](#)
- [Investigator's Brochure for Psilocybin](#)
- [Medicinal Chemistry at Usona](#)

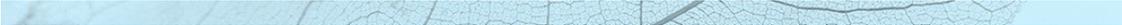
---

### **FDA Investigational New Drug Submission**

On February 20th, Usona submitted to the FDA our first Investigational New Drug (IND) application, for psilocybin as an intervention for Major Depressive Disorder (MDD) in an otherwise healthy population. The

---

IND application outlines our full research and CMC (Chemistry, Manufacturing, and Controls) plans, incorporating feedback from interactions with the FDA during the pre-IND process. This submission will be followed by a separate IND, to be filed in the coming weeks, for psilocybin as an intervention for MDD in patients with a cancer diagnosis. The opening of our INDs will pave the way for Usona to request an End-of-Phase 2 meeting with the FDA for our Phase 3 MDD in the cancer population study and will also allow Usona to apply for Breakthrough Therapy (BT) designation for our psilocybin drug product through the FDA. If BT status is granted, the FDA would provide priority review and would work with Usona to expedite the approval process.



### **Preparations for Psilocybin Clinical Trials**

In parallel with our IND submissions, our clinical operations team has been working closely with our CRO (Contract Research Organization) and other partners to coordinate and initiate all the steps necessary for conducting multi-site clinical trials. These activities include but are not limited to site contracts, budgets, data monitoring plans, recruitment website, study database development, guide program resources, standard operating procedures, and Investigator Meeting planning. We are working to get all systems up and running as quickly as possible. At this point, we anticipate contracting with four or five study sites, and our best forecast for first subject/first visit is July 2018.



### **Open Science Commitment**

As a non-profit medical research organization, Usona Institute is dedicated to working for the public good through the advancement of scientific knowledge and the alleviation of mental suffering. Guided by this purpose, Usona—along with a collection of like-minded organizations, scientists, practitioners, and philanthropists—has signed a statement to make public the scientific discoveries and processes that arise from our research. We believe that openness, transparency, and collaboration will move this field of scientific knowledge forward most efficiently and honorably, and we are pleased to commit ourselves to this approach. For more information, please see: [www.csp.org/open](http://www.csp.org/open)



### **Investigator's Brochure for Psilocybin**

As a part our IND application process, Usona recently created a comprehensive Investigator's Brochure (IB) for psilocybin. The IB is a detailed compendium of information on psilocybin's pharmacology, safety, and

---

efficacy. Consistent with our open science approach, this document will be openly shared with other researchers for use in their own regulatory submissions and clinical trials, under a Creative Commons license. To view the document, please click [here](#).

---

### **Medicinal Chemistry at Usona**

We're excited to introduce to you Usona's medicinal chemists – Alexander Sherwood PhD and Robert Kargbo PhD. Robert is based in San Luis Obispo, California and Alex is at our newly completed lab in Madison, Wisconsin. Both chemistry research labs have full synthesis and analytical capabilities. Upcoming projects will include optimizing synthetic processes for psilocybin and other compounds, natural product extraction and isolation, purity data collection in support of generating Certificates of Analysis, and bioanalyses in support of pharmacokinetic and toxicology studies of new drugs.





*Alex and Robert in 2017, along with psilocybin crystals synthesized at the San Luis Obispo research facility.*

---

### **Thank You**

All of us at Usona Institute would like to express our gratitude and appreciation for your interest in our work and mission. We wish you a wonderful winter season, and look forward to connecting with you again in the spring!

Warmly,  
*The Usona Team*

---

[Visit Our Website](#)