Welcome to Usona Institute’s Spring 2019 Newsletter! With the emergence of the new season comes a flourish of activity for all of us at Usona - we’d like to share with the you the following updates:

**Usona Program Updates**

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- [cGMP Psilocybin Manufacture Complete](#)

**Usona Events**

- [Usona at the Integrative Mental Health Conference](#)
- [International Forum on Consciousness 2019](#)

**Usona in the News**

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**Organizational Announcements**

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**Proceeding to Phase 2 Clinical Study**

In January, Usona received FDA clearance to proceed on our Phase 2 study in psilocybin for major depressive disorder (MDD). This approval serves as a green light for Usona to move forward with initiating our clinical trials once site-specific regulatory approvals have been received.

In recent months, the Usona clinical team has been working diligently with our CRO and study sites on the myriad details required to operationalize the protocol. We anticipate that the first subjects will be enrolled in the third quarter of this year. Information on our study and research sites are continually updated—please visit the study profile page on our clinical trials website [here](http://usonainstitute.org) to learn more.

**Usona Clinical Trials**

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**cGMP Psilocybin Manufacture Complete**

In collaboration with our pharmaceutical contract manufacturing organization, we've successfully completed the manufacture of a large-scale psilocybin batch under current Good Manufacturing Practices (cGMPs) meeting rigorously defined release specifications. This cGMP psilocybin is now available for use in Usona’s clinical trials and will be made available to qualified researchers at no cost—for more information, please contact us at [info@usonainstitute.org](mailto:info@usonainstitute.org).

Usona’s Chemistry Research Labs continue to investigate novel compounds, optimize synthetic manufacturing processes, and collaborate on interdisciplinary research supporting psychedelic science across the globe.
In mid-April, Usona attended the Integrative Mental Health Conference in San Francisco, CA, where **Dr. Charles Raison**—Usona's Director of Clinical and Translational Research—spoke on a panel entitled *Psychedelic Stories – What the New Science of Psychedelics Means for Mental Health Care* with **Dr. Andrew Weil**, **Michael Pollan**, and moderator **Christine Whelan, PhD**. Dr. Raison also presented on an additional Psychedelics Research Panel with Dr. Scott Shannon.

Organized by The University of Arizona Center for Integrative Medicine, the aim of the conference was to "help prepare mental health professionals to advise their patients about integrative methods to enhance mental well-being." Usona Institute had a nonprofit exhibitor's booth at this conference, where interested attendees visited with Usona staff to learn more about our work. A warm thanks to all of the organizers and attendees who made this special event possible!

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**International Forum on Consciousness 2019**

**Robin Carhart-Harris PhD** speaking on the therapeutic mechanisms of psychedelics.
"This conference may come to be viewed as the tipping point on the path to FDA approval of psilocybin. It brought together a powerhouse of scientists, and experts in medicine and healthcare delivery, all of whom viewed the challenges to approval and acceptance into mainstream medicine as readily surmountable."

- Jack Henningfield PhD

From the time Usona was founded in 2014, it has assisted in sponsoring the International Forum on Consciousness held annually at the BioPharmaceutical Technology Center Institute (BTCI) in Madison, Wisconsin.

This year's forum, Psychedelic Therapy in Society: Exploring the Mechanisms of Action and Delivery of Care, took place on May 16-17 and included speakers from around the globe such as Robin Carhart-Harris PhD, Head of Psychedelic Research at Imperial College London; Jack Henningfield PhD, Adjunct Professor in the Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine & Vice President, Research, Health Policy and Abuse Liability, Pinney Associates; and many more. Recordings of the presentations are now available on the BTCI website.

Usona cGMP Drug Product for Australia's First Psilocybin Study

Australia’s first approved psilocybin clinical trial exploring psilocybin as a treatment for anxiety in the terminally ill initiated in April of 2019. Sponsored by the Australian nonprofit Psychedelic Research in Science and Medicine (PRISM) and to be conducted at Melbourne’s St. Vincent’s Hospital, the cGMP psilocybin used for this trial will be donated by Usona Institute. For more information, please refer to this article published by The Saturday Paper.

Through our commitment to Open Science, Usona is providing GMP psilocybin to qualified researchers at no cost. To inquire about potential research collaborations with Usona, contact us at info@usonainstute.org.

Usona in Spring 2019 MAPS Bulletin

Usona Institute has been featured in this season's issue of the MAPS Bulletin, a tri-annual publication that serves as "an educational tool for scientists, researchers, government officials, drug war prisoners, and educators".

Usona’s piece in the Bulletin provides highlights on our psilocybin research and other programs - to view the article, please follow the link: Usona Institute: The Path Toward Psilocybin and Depression Clinical Trials. A big thank you to the MAPS team for their work, dedication, and collaboration!
Growth - Team Expertise Expands

As the depth and breadth of our work continues to grow, so too does our team of dedicated staff and consultants. It is our pleasure to introduce the following new members of the Usona team:

**Rob Barrow**

Director of Drug Discovery & Development

As Usona’s Director of Drug Discovery and Development, Rob’s role spans the full spectrum of planning, execution, and delivery of Usona’s research programs.

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**Barb Mathison**

Senior Director, Strategic Initiatives

As the Senior Director of Strategic Initiatives, Barb is involved with identifying, planning, and implementing new projects that build on and enhance existing Usona initiatives while supporting long-term sustainability that enables the Institute to carry out its mission.

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**Nicole Smialek**

Compliance Program Manager

In her role as Quality Controls Manager, Nicole assists in developing and maintaining Usona's quality systems while ensuring compliance with Usona's regulatory obligations as a sponsor of FDA-approved studies and a holder of DEA licenses.
Usona Hiring Clinical Operations Manager

Usona Institute is currently seeking qualified applicants for the position of Clinical Operations Manager.

Please see the position objective provided below:

The Clinical Operations Manager (COM) will provide multifaceted, hands-on clinical trials operations management. With supervision from the Program Lead and support from other clinical operations team members, the COM will play a key role in the execution of Usona-sponsored trials from protocol concept through final clinical study report stage.

For additional details and to apply, please follow the link provided: Clinical Operations Manager, Usona Institute.

All of us at Usona would like to express our gratitude for Michele Gassman, Usona's current Clinical Operations Manager, for her incredible support of our organization and clinical research programs.

Support Psychedelic Research

With the generous help of our supporters, Usona has convened five regional information-sharing events in the US that have included Usona Institute experts, clinicians, knowledge leaders in the field, major donors and supporters, and others interested in our research since the publication of our last newsletter. The connections made between attendees have been one of the most valuable outcomes of these events.

We are inspired by and grateful for the support from those who share a common vision to make a positive impact on so many lives. If you are interested in hosting a future event or would like to become involved in our efforts, please reach out directly to Tura Patterson, Sr. Director Strategic Partnerships at tura.patterson@usonainstitute.org.

As a non-profit organization, Usona relies on the support of our donors to fund our medicinal chemistry research and clinical trials. If you would like to offer your support through a donation, please follow the link below or contact us.

Support Usona

Thank You

We're grateful for your interest and support of our mission, and look forward to sharing more with you in the near future!

The Usona Team