Welcome to the Fall 2019 edition of our newsletter! After a season of exciting developments, we’re pleased to share the following updates with you:

- **Launch of PSIL201 Clinical Trial & Site Activation at NYU**
- **Conferences & Events**
- **Scientific Collaborations**
- **Collaborators in the News**
- **New Staff and Clinical Advisory Board**
- **Support Our Mission**

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**Launch of PSIL201 Clinical Trial & Site Activation at NYU**

On September 5th, 2019 Usona publicly announced the launch of our Phase 2 major depressive disorder (MDD) and psilocybin clinical trial (named PSIL201) beginning this fall, with final site initiation and
activation activities under way at all seven sites.

This is a major milestone for Usona and the advancement towards regulatory approval. We’re thankful to all of our supporters, researchers, and staff who enable this important effort to move forward. We would especially like to acknowledge the research sites and teams who have committed to carrying out the PSIL201 study to completion in the year ahead.

To view the press release, please follow the link provided here.

**PSIL201 Research Sites and Principal Investigators:**

- Johns Hopkins University - Roland Griffiths, PhD
- NYU School of Medicine - Stephen Ross, MD
- University of California San Francisco - Joshua Woolley, MD, PhD
- Yale University - Gerard Sanacora, MD, PhD
- University of Wisconsin - Madison - Randall Brown, MD
- Great Lakes Clinical Trials (Chicago, IL) - Rupal Trivedi, MD
- Segal Trials (Miami, FL) - Rishi Kakar, MD

On October 24th, Usona released news of the official activation of the first research site, NYU, led by Stephen Ross MD; this site is now cleared to actively recruit participants.

For more information please visit see our press release “Usona Institute PSIL201 Study Site Now Recruiting Patients with Depression” and visit usonaclinicaltrials.org.
Conferences & Events

INSIGHT 2019 – Berlin, Germany

The announcement of the PSIL201 study launch initiation was made at the INSIGHT 2019 conference organized by the MIND European Foundation for Psychedelic Science in Berlin, Germany from September 5-7. The conference hosted experts from around the world to engage in discussion around psychedelic research, therapy, philosophy, and public health impacts—including Usona’s Charles Raison, MD (Director of Clinical and Translational Research) and Franz Vollenweider, MD (Scientific Advisory Board member). As a primary partner of this conference, Usona extends our gratitude to the MIND Foundation for their leadership and collaborative spirit in convening and engaging thought leaders in discourse around the global advancement of psychedelic science.

To view Dr. Raison’s presentation at INSIGHT, please follow this link: “A new approach to treating depression: a non-profit’s role in approval for psilocybin”
Psych Congress – San Diego, CA

On October 3-6, Usona’s Charles Raison presented on his expertise regarding the evolutionary understandings of depression and the limitations of current antidepressants at this year’s Psych Congress in San Diego, CA. The Psych Congress is an annual conference that aims to improve patient outcomes through educating mental health practitioners on the foremost advances in psychiatric treatments.

To read a four-part Q&A series related to Dr. Raison’s presentations, please follow the links below:

1. Q&A: The Role of Antidepressants in the Treatment of Depression
2. Q&A: The Risks of Long-Term Antidepressant Treatment
3. Deciding When to Stop an Antidepressant
4. The Risks Associated With Stopping an Antidepressant

Horizons Conference - New York, NY

Dr. Malynn Utzinger, Usona’s Director of Integrative Medicine, presented at the October 11-13 Horizons: Perspectives on Psychedelics conference in NYC, NY on Usona’s clinical trials on psilocybin as a treatment for depression. Horizons is an annual forum that “examines the role of psychedelic drugs and plant medicines in science, medicine, culture, and spirituality” and is the longest running psychedelics-focused conference in world. Our thanks to the 501(c)3 nonprofit organizers Horizons, Inc., for hosting a wonderful 13th gathering.

International Society for Research on Psychedelics - New Orleans, LA
On October 18-20, Usona chemists Alexander Sherwood, Kristi Kaylo, and Robert Kargbo attended the inaugural conference of the International Society for Research on Psychedelics (ISRP) in New Orleans, LA, where Alex and Robert presented on “Synthesis and Biological Evaluation of Tryptamines Found in Hallucinogenic Mushrooms: Norbaeocystin, Baeocystin, Norpsilocybin and Aeruginascin” and “The First Direct Phosphorylation of Psilocin to Psilocybin,” respectively. The purpose of the ISRP is “to provide scientific networking and advancement of empirical science regarding classic psychedelics.”

Scientific Collaborations

In May 2019, Dirk Hoffmeister’s research group published an article in collaboration with Usona medicinal chemists Alexander Sherwood and Robert Kargbo elucidating a biosynthetic process that utilizes Psilocybe cubensis enzymes to produce novel psilocybin analogs, 6-methyl-psilocybin and 6-methyl-baeocystin. Published in Chembiochem: a European Journal of Chemical Biology, the article, “Enzymatic route toward 6-methylated baeocystin and psilocybin” represents a significant advance in understanding novel biosynthetic methods for producing new psychedelic compounds and highlights the value of engaged collaboration and shared Open Science principles among experts in the field.

We’d like to extend our congratulations to our collaborators Roland Griffiths, Matthew Johnson, Mary Cosimano, and others at Johns Hopkins University for their involvement and announcement of funding for their new research center in recent media coverage on psilocybin research—thank you for your contributions to advancing the science in this important field of medical research. Follow the links below to view their coverage on NBC’s Today Show and CBS’s 60 Minutes with Anderson Cooper:
Could psychedelic drugs be a cure for depression? – Today Show, NBC
Psilocybin Sessions: Psychedelics could help people with addiction and anxiety – 60 Minutes, CBS

In alignment with our Open Science commitment, Usona is receiving requests and providing cGMP grade psilocybin to qualified researchers at no cost. As of November 2019, we have received 40+ requests from researchers and institutions representing more than 14 countries worldwide.

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**Welcoming New Staff and Clinical Advisory Board**
In order to support the complexities inherent in the implementation of clinical trials, Usona has increased its network of expertise and support through welcoming the newest members of our team and the launch of our Clinical Advisory Board. We are excited to introduce the following staff and Clinical Advisory Board members:

**Staff**

**Marie Cuccia - Communications Associate**

In her role as a Communications Associate at Usona, Marie serves the organization’s communication needs for a full range of stakeholders including employees, donors, media, study participants, clinicians, and the general public. Marie assists in drafting and publication of various internal and external communications, manages and maintains website and social media content, and provides support in defining overall communications strategies and goals.
**Liz Vanderwerff - Associate Director, Strategic Initiatives**

As Usona's Associate Director of Strategic Initiatives, Liz focuses on the development of Usona's donor relations approach as well as the development, implementation, and management of the communications and engagement activities that enable the advancement of Usona's research programs and nonprofit mission.

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**Clinical Advisory Board**

- **Charles Raison, MD (Chair)** – Director of Clinical and Translational Research, Usona Institute; Professor, Department of Psychiatry, School of Medicine and Public Health, University of Wisconsin-Madison
- **Heidi Allen, PhD** – Associate Professor, School of Social Work, Columbia University; Co-investigator in the Oregon Health Insurance Experiment; member of NIH Health Disparities Equity Promotion Study Section
- **Robin Carhart-Harris, PhD** – Head of the Centre for Psychedelic Research, Division of Brain Sciences, Faculty of Medicine, Imperial College London
- **Tom Laughren, MD** – Director, Laughren Psychopharm Consulting; Retired Director for the Division of Psychiatry Products, FDA

For additional information on our team and advisory boards, please see the [Usona Team page of our website.](#)
Support Our Mission
As a nonprofit medical research organization, Usona Institute relies solely on the generosity of donors and supporters to make our shared vision of completing rigorous, FDA-regulated clinical trials into a medically approved treatment.

Usona is in a unique position of being the only nonprofit organization assuming the responsibility of conducting clinical trials with psilocybin under a commercial IND (Investigational New Drug), which is the only pathway towards FDA approval of a new drug. With your support, we are one step closer to a potential new treatment for people suffering with depression.

To support Usona’s work, please click on the “Support” button, or contact Barb Mathison, Sr. Director, Strategic Initiatives.

Our Appreciation
Thank you for your interest in our work and mission—we look forward to sharing more of our story with you in the near future!

The Usona Team