

JLS Fund Report

A Psytech Venture Fund

August 2023

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Prohibition Relents Down Under with the Legalization of MDMA and Mushrooms

On July 1st, a crack appeared in the dam of prohibition and not only re-invigorated psychedelics legalization advocates, but caught the attention of mainstream media outlets across the globe.

Australia, home to the 13th largest economy in the world, became the first continent to legalize the use of MDMA and psychedelic mushrooms for mental health treatments. This, after Australia's Therapeutic Goods Administration announced that it found the substances to be "relatively safe" when used in a "medically-controlled environment."

Of course, there are other countries that have legalized, decriminalized or just looked the other way on certain psychedelic substances in a less-structured manner.

Take the Netherlands, for instance, where psilocybin mushrooms are illegal, but psilocybin truffles, which are the fruiting body of the mushroom, are legal. So today, not only can you buy psilocybin truffles at what are called "smart shops," but there's even a publicly-traded company called Red Light Holland (CSE: TRIP) (OTCBB: TRUFF) that produces and distributes psilocybin truffles throughout the Netherlands. While this isn't necessarily our focus, this is not trivial when it comes to the transition away from prohibition.

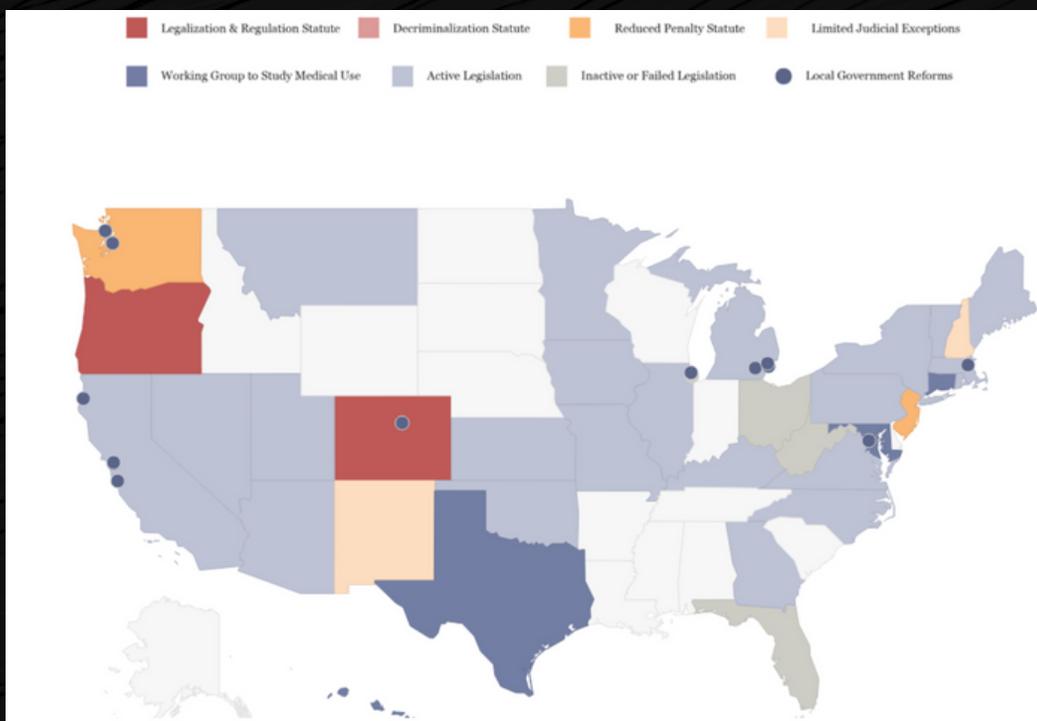
There's also a retail market for psilocybin mushrooms in Jamaica, which simply never prohibited these substances, and saw its first legal psychedelic mushroom retail store open in 2021 by Silo Wellness. Today, Silo runs psychedelic wellness retreats in Jamaica, and was featured on Anderson Cooper's CNN special on psychedelics.

And just 478 miles from Jamaica are the Bahamas, where psilocybin mushrooms are legal to grow and sell, despite it being considered a controlled substance. The Bahamas are also home to a growing psilocybin retreat industry, but unlike Jamaica, the country is home to treatment centers that also offer ibogaine and DMT-assisted treatments.

Other countries that have legal or “semi-legal” markets, include Nepal (mushrooms), Mexico (ibogaine), Brazil (mushrooms and ayahuasca), and Peru (ayahuasca).

And of course, in the U.S., progress has been made with individual states legalizing, decriminalizing, and actively seeking to legislate the production, consumption and sale of various psychedelic substances.

The good folks over at Psychedelic Alpha put together an interactive map that details the various psychedelic drug policy reforms happening all across the country, which you can [check out here](#).



Also worth noting: The American Medical Association (AMA) recently approved a Current Procedural Terminology (CPT) III code for psychedelic therapies. CPT codes are essential for physicians and health care professionals when assigning treatment and seeking reimbursements from insurance companies.

This is a very big deal.

The codes are expected to go into effect when they are published on January 1, 2024. Once effective, the CPT codes will provide physicians and other qualified healthcare professionals a means to seek coverage and reimbursement for delivering psychedelic-assisted therapy approved by the U.S. Food and Drug Administration.

The exciting thing about Australia, however, is that the country is officially treating psychedelic-assisted therapy as a legitimate form of treatment for mental health conditions, fully backed by the government and with significant support from the medical community.

Not only is this a game-changer for those who will benefit from this therapy, but the data that researchers will now be able to collect with this new legal structure will prove to be invaluable for the industry on a global scale. We'll continue to provide you with any new developments on this data collection in our weekly updates.

JLS Fund: Investment Updates

Fluence

Fluence is a psychotherapy training services provider that offers a suite of interactive programs to educate licensed professionals and advanced graduate students in psychedelic integration and psychedelic-assisted therapy.

Over the course of the first half of 2023, we've seen more and more mainstream media sources not only covering the psychedelics industry as a whole, but also investigating potential shortfalls in the rollout of psychedelic-assisted therapies.

Certainty this has been the case in regards to having enough properly trained therapists to administer these medicines in the most efficacious ways possible.

In a May, 2023 piece in National Geographic, journalist Meryl Davids Landau wrote: "The U.S. may approve therapies using MDMA and psilocybin. The medical community is preparing for the deluge of demand."

A "deluge of demand" almost seems like an understatement, and some have classified this as a potential crisis for the psychedelics industry. But crisis breeds opportunity. And this is definitely the case for Fluence. Since its inception, Fluence has trained therapists at roughly 50 different clinical trial sites in the U.S., Australia, the UK, Canada, and across the EU in the use of psilocybin and 5-MEO-DMT. Additionally, the company has created eight psychedelic therapy manuals for eight different drug-indication combinations.

Fluence is also producing scalable on-demand video and audio content for various projects, in addition to a series of on-demand continuing education programs for community-based clinicians to advance their knowledge of psychedelic therapies.

In Q1, the company grew sales by 41% YoY, doubled its total number of paying customers vs Q1, 2022, and signed a drug developer agreement with Cybin (NYSE: CYBN), where Fluence will be partnering with the company to modify its therapy manual and protocols with the goal of designing and implementing a therapist training program in Q3/Q4, ahead of the phase 3 clinical trial of its psilocybin-based treatment of major depressive disorder.

Psilera

Psilera is a biotech research company developing next-generation, non-hallucinogenic psychedelic therapies.

In the first half of 2023, Psilera announced its lead clinical candidate PSIL-006, which is a non-hallucinogenic form of psilocybin that, in preclinical studies, has shown promise for treating depression, anxiety, PTSD, addiction, and cognitive disorders. Patent issuance is now expected before the end of the year.

We also got an update on the company's DMT transdermal patch, which is a design that could allow for a non-invasive and dose-controlled method for treating substance use disorders, PTSD and depression.

In preclinical animal studies, the DMT transdermal patch has shown 80% bioavailability through the skin. Psilera was issued a patent on this product last year. What's particularly interesting about this transdermal approach is not just patient comfort, as a transdermal application is far less invasive and inconvenient than episodic oral dosing and intravenous needles, but that it can offer a cost benefit for insurance companies that are now considering direct reimbursements for these kinds of treatments. Providing cost-effective solutions to psychedelic-assisted therapies is paramount to health insurance approval, which is one of the reasons we remain so bullish on Psilera and its transdermal patch. Seeing an 80% bioavailability through the skin further confirms Psilera is progressing well.

Ceretype Neuromedicine

Ceretype Neuromedicine is a biotech company developing and deploying advanced brain imaging and AI to de-risk and accelerate the development of psychiatric and neurological therapies.

Ceretype has continued to move forward at a rapid pace since we last updated you on the company a few months back, when the major news was that the company locked in a partnership with Calyx Medical Imaging to provide its fMRI platform.

This was a big deal, as Calyx is owned by GLO Healthcare, a healthcare platform created by private equity investor CapVest Partners, which has about \$8 billion of assets under management.

Since then, Ceretype has continued to deliver on moving forward with new contracts and partnerships, as well as seeking out new ones. Here's a brief rundown...

The company's PD drug development contract with a major academic hospital has started to bear fruit, with its first healthy subject scan (performed on 5/23), which confirmed the efficacy of the system and of the neuropsychological activation program. Pre-treatment scans have been completed on three patients as of June 23, 2023.

(To clarify, PD, or pharmacodynamics, is the body's biological response to drugs.)

Ceretype has also partnered with a Calyx clinical research channel partner, looking at CNS mechanisms of physiological responses, which includes fMRI as a secondary endpoint.

The first part of the project (developing appropriate stimulus set for task-based fMRI) has been agreed upon with contracting currently in progress, and the first patient is scheduled for trial in November.

The company is also looking at a potential channel partnership with a neurological multiomics biomarker platform company that is working on neurological disorders with a first use case in a high interest/synergistic indication (multiple sclerosis).

That company is exploring the addition of functional neuroimaging to its platform, which currently includes blood and structural imaging biomarkers.

If this moves forward, the first applications would be in the clinical trial space and synergistic with Ceretype's current go-to-market strategy.

In addition to that partnership, the company has reviewed a Phase 2 study with a biotech company running trials for anxiety disorders. This is in preparation for an upcoming multisite Phase 2 randomized, double-blind, placebo-controlled follow-up study, which has tentatively been scheduled to begin Q4 2023.

Parow Entheobiosciences

Parow Entheobiosciences is a pre-clinical biotechnology company developing targeted entheogen therapeutics to treat various psychiatric diseases. It has also developed the world's first cell-based 5-MeO-DMT.

Parow reached a major milestone in the first half of 2023, as it now has a robust body of pre-clinical data showing superior efficacy of its first drug candidate, P601, a "full spectrum" psilocybin, over chemically synthesized psilocybin. This data includes:

- Pre-clinical behavioral, translational and metabolomic evidence recently presented and prepared for publication.
- Parow's studies on the effects of P601 as compared to synthetic psilocybin show significant differences, especially on neuroplasticity-related synaptic proteins.
- Early results indicating that P601 may be more efficacious than synthetic psilocybin in non-human disease models of major psychiatric conditions.
- Completion of the CMC (chemistry, manufacturing and controls) dossier for P601, containing full manufacturing information, for pre-IND and related meetings with local and international authorities for the first-in-human trial, which is being led by Professor Dan J. Steyn, a leading OCD researcher in obsessive-compulsive disorder and recipient of the World Congress of Biological Psychiatry lifetime achievement award.

Parow has also continued to present its results at top-tier neuropharmacology forums and was active at CINP (The International College of Neuropsychopharmacology) in Montreal in May, where founder and CFO, Professor Bernard Lerer led a session on psychedelic therapeutics (Mechanism of action of psychedelics – a translational perspective), with top researchers in the field.

And here are some recent scientific publications that provide a deeper dive into what Parow is doing...

[Effect of psilocybin on marble burying in ICR mice: role of 5-HT1A receptors and implications for the treatment of obsessive-compulsive disorder](#)

[Incilius alvarius Cell-Based Synthesis of 5-Methoxy-N,N-Dimethyltryptamine](#)

[Could psychedelic drugs have a role in the treatment of schizophrenia? Rationale and strategy for safe implementation?](#)

Research Highlights

The development of psilocybin therapy for treatment-resistant depression: <https://www.cambridge.org/core/journals/bjpsych-bulletin/article/development-of-psilocybin-therapy-for-treatment-resistant-depression-an-update/7391E43A9FBF4AC31EFAF01C27DF73F0>

Psychedelics in the treatment of eating disorders: Rationale and potential mechanisms:

https://www.sciencedirect.com/science/article/pii/S0924977X23001098?utm_source=hs_email&utm_medium=email&_hsenc=p2ANqtz-9leFlkXCQOP4m9tqzDt9Hdxec0HqjniaDhDCrxW9zF22K74FZ4eQftTqGzQg_oC5Jitgb9

A Phenomenological Investigation of Psilocybin Use Among the Bereaved:

<https://www.proquest.com/openview/b854ddd010974973bf9562d00fd7058a/1?pq-origsite=gscholar&cbl=18750&diss=y>

Comparative acute effects of mescaline, lysergic acid diethylamide, and psilocybin in a randomized, double-blind, placebo-controlled cross-over study in healthy participants:

https://www.nature.com/articles/s41386-023-01607-2?utm_source=hs_email&utm_medium=email&_hsenc=p2ANqtz-9zzdWJQ6sGImWUhKGSiBcan1oU6FzsFH02d6-eJIV0p7o5YUyQbWJvGmLlchUEYnf66mxo

Final Note

Without a doubt, the first half of 2023 has been a busy one, and we've been making a lot of progress.

In fact, in a few weeks, we'll be sending you a special update with some really exciting news about a number of our portfolio companies, as well as how we're using our first-mover advantage and vast network of investors, academics, business leaders, and policymakers to capitalize on some new developments that will add even more value to JLS Fund. We can't wait to share this with you!

Who is JLS?

JLS was formed to invest in the exciting intersection of science, technology and neurology, leveraging the enormous potential of plant-based and psychedelic medicines to heal illness and enhance wellness. We focus on the development of drugs for intractable mental and physical conditions and enabling technology and tools that accelerate and enhance the delivery of those therapies.



Who is JLS?

CONTACT US

If you have any questions or would like to set up a call to discuss our progress, learn more about any of these companies or increase your investment into the fund, feel free to contact us at info@jls.fund.

For those of you who have not invested with us yet, you can reach us by filling out our [inquiry form](#).

