



JLS Fund Report

A Psytech Venture Fund

May 2023

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The Inevitable Demise of Psychedelics Prohibition

Last month marked the 127th anniversary of when the first Olympics of the modern era was held after a 1,500-year absence following the banning of the games by Roman Emperor Theodosius I.

It's hard to imagine revitalizing something so historically significant after a 1,500-year hiatus. But that's exactly what happened. And with much success.

At the re-opening of the games in 1896, athletes from 13 different countries competed in front of a crowd of 60,000 people. 100 years later, at the Atlanta winter Olympic games in 1996, 8.3 million tickets were sold!

This is absolutely amazing when you think about the fact that Theodosius I saw the Olympic games as an exercise in paganism and a threat to peace. So he stepped in and outlawed them. Yet the truth is, the early Olympic games actually promoted peace, as it was the one time when the constantly warring Greeks declared a truce so as to ensure their athletes could compete in a safe environment.

So when the Olympics returned in 1896, they were seen, and even celebrated, as a symbol of hope and peace.

Looking back at the history of the Olympics, particularly the prohibition of the Olympic games, one could draw an interesting parallel to the prohibition of psychedelics, which, for the most part, has essentially been prohibited for less than 60 years; merely a blip in time compared to the prohibition of the Olympics.

At one time, psychedelics were as ubiquitous as food and water, and much like the Olympics, promoted wellness, peace, and goodwill. They were also outlawed by powerful world leaders.

Today, however, as we see the beginnings of the dismantling of prohibition, the world is seeing just how important psychedelics are to the health and well-being of our global society. This is particularly true when you look at all the data indicating that psychedelics could serve as a powerful tool in addressing the global mental health crisis. This, by the way, is the primary catalyst for the psychedelics renaissance and has resulted in a wealth of fodder for new decriminalization and legalization efforts.

There's little doubt that there will be dozens of new legislative efforts in 2023 that will serve to strengthen the psychedelics market... capitalizing early on the best-in-breed psychedelics companies the way we have puts us at a significant advantage going forward.

Here are a few of the more notable efforts we've seen in Q1 ...

- A trio of New York state lawmakers introduced a bill to legalize natural psychedelics. If passed, the bill would amend New York state law to legalize the “possession, use, cultivation, production, creation, analysis, gifting, exchange, or sharing by or between natural persons of twenty-one years of age or older of a natural plant or fungus-based hallucinogen.” The bill would apply to natural psychedelics including DMT, ibogaine, mescaline, psilocybin, and psilocin, and would also legalize the use of natural psychedelics for religious purposes and allows people to provide psychedelic services “with or without remuneration.”
- Eight new psychedelics decriminalization efforts are now moving forward in Massachusetts.
- The Missouri House officially backed a bill requiring state research on psychedelics to treat depression and PTSD.
- A bipartisan pair of federal lawmakers rebranded and relaunched a congressional caucus to educate lawmakers on the growing evidence from leading research institutions that therapy involving substances like psilocybin and MDMA can help effectively treat PTSD, depression, and substance use disorder.
- Sen. Ron Kouchi of Hawaii filed a bill to create a “therapeutic psilocybin working group” that would be tasked with studying the “medicinal and therapeutic effects of psilocybin or psilocybin-based products” for conditions such as anxiety, depression, and post-traumatic stress disorder.
- New Hampshire Rep. Matthew Santonastaso filed a bill to remove the DMT from the list of controlled substances under state statute.

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- Utah Senate Minority Leader Luz Escamilla announced plans to file legislation to legalize psilocybin for people with serious mental health conditions.
- West Virginia, Rep. Kayla Young filed a bill that would remove psilocybin from the state's list of controlled substances.
- Texas Lawmakers filed three bills to expand state-sponsored psychedelics research.
- Bipartisan congressional lawmakers filed an updated version of a bill to streamline the federal rescheduling of "breakthrough therapies" like psilocybin and MDMA in order to promote research and drug development.
- Arizona lawmakers approved a bill in committee to promote research into the medical potential of psilocybin mushrooms for a variety of conditions, including depression, anxiety, long COVID symptoms, and substance abuse disorder.
- Oregon Rep. Earl Blumenauer introduced a bill that would allow some end-of-life patients to use psilocybin and other investigational treatments.
- The country of Australia announced that, with a prescription, it will allow access to MDMA and psilocybin for the treatment of mental illness.

There's little doubt that there will be dozens of new legislative efforts in 2023 that will serve to strengthen the psychedelics market. And certainly, capitalizing early on the best-in-breed psychedelics companies the way we have puts us at a significant advantage going forward.

If Q1 is any indication of how the rest of the year will pan out regarding decriminalization and legalization efforts, this is going to be an amazingly profitable year for all of us.

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.

Fluence had a solid year in 2022, generating \$1.6 million in total sales and enrolling nearly 2,000 mental health professionals in its workshops and training programs. And 2023 started off with a bang as the company's psilocybin-assisted therapy program was featured in the New York Times, as well as a number of other more prominent media platforms that are covering the roll-out of Oregon's Psilocybin Services initiative.

If you're unfamiliar, voters in the state of Oregon approved a measure to allow the use of psilocybin in supervised facilities. At the start of this year, the Oregon Health Authority, which oversees the Oregon Psilocybin Services program, began accepting applications for licensure. Only therapists that are accepted can legally screen and treat patients with psilocybin. And those therapists must be trained by educators that have also been licensed by Oregon's Higher Education Coordinating Commission.

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In October 2022 Fluence received that license and is now in an exceptional position to fully capitalize on Oregon's Psilocybin Services program.

While there is any number of ways to benefit from the rapid development of the psychedelics market, we knew that supporting qualified clinicians that provide this much-needed training would bear fruit early. And we were right.

Fluence has become one of the foremost experts in professional training for the psychedelics market, and in fact, was chosen to lead a training at Massachusetts General Hospital as part of a clinical trial to study psilocybin as a treatment for IBS.

Gilgamesh

Gilgamesh is a clinical-stage biotech whose vision is to reshape how mental illnesses are treated by shifting away from symptom management to a focus on rapid-acting and durable therapies targeting the fundamental drivers of disease.

Closing out 2022, Gilgamesh became a clinical-stage company with the successful initiation of a Phase I trial of its treatments for depression, anxiety, and opioid use disorder. These specific treatments are particularly attractive as they allow for home use, thereby reducing the burden of treatment and increasing compliance. These are incredibly unique molecules that give Gilgamesh some very valuable IP.

By the end of Q2, Gilgamesh expects to complete its SAD (Single Ascending Dose) and MAD (Multiple Ascending Dose) studies and Phase 1b for Major Depressive Disorder. It will also open an Investigational New Drug Application to enable the expansion of its clinical development.

Gilgamesh remains well funded with a cash position of about \$40 million and enough runway for the next 22 months.

FireflyVR

FireflyVR is a developer of virtual reality software and products that use VR as an integral tool of psychedelic therapies.

FireflyVR is coming off a very successful 2022, and continuing that success in the first quarter of 2023.

Back in December, Firefly VR signed a Cooperative Research and Development Agreement (CRADA) to utilize its Sanctuary program for the San Francisco VA for substance abuse testing.

If you're unfamiliar, the Sanctuary is a Virtual Reality experience built to prepare a patient for transformational ketamine treatment. It incorporates established techniques used by mental health experts to provide a safe, engaging, and comfortable experience to prepare for meaningful therapy.

The Sanctuary is a clinically designed solution that combines cognitive behavioral therapy to help reduce pre-procedure anxiety and develop positive intentions when the medicine is administered, ultimately improving outcomes.

Now the CRADA is already progressing ahead of schedule and is expected to be completed in Q2. And here's the interesting part...

The leader of the study, Dr. David Pennington, shared with management that he is envisioning the FireflyVR platform as a "component of standard care". There is a significant budget opportunity to progress this completed CRADA into a VA task order, thereby accessing \$650 million that has been budgeted to bring VR tools into the VA over the 5-yr period from September 2022 to September 2027.

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Firefly VR is well-positioned to capitalize on this opportunity. Moreover, the company is currently in discussions for a broad statement of work related to VR for various treatment modalities for the VA.

Worth noting: on January 8th, FireflyVR signed a commercial agreement with DemeRX (an ATAI Life Sciences company), to customize the Sanctuary for a proprietary Ibogaine molecule. If this pans out, the company foresees commercialization with a royalty structure for Firefly. This project is likely to gain some high visibility through atai and COMPASS Pathways, in which atai holds a significant position.

The company's Sanctuary experience is also being considered by Meta (formerly known as Facebook). Firefly is currently in discussions for a commercial pilot of a non-Ketamine version of the Sanctuary with internal Meta employees. The company is looking to close this deal in Q3.

Although it's still relatively early in the year, Firefly is already finalizing a pilot that includes co-publishing rights on a clinical study with Reliance Medical Group, which is a UnitedHealth Group (UHG) company and has a behavioral health network of more than 325,000 annual patient visits. Phase two of the pilot is also expected, and will likely include another UHG company, Atrius Health, which boasts around 650,000 patients. FireflyVR has actually had a Master Service Agreement in place with UHG since 2019 and has seven Statements of Work completed to date.

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 picked up a lot of press in early April after it was announced that the company had partnered up with Calyx Medical Imaging to provide its fMRI platform.

In an effort to provide the most up-to-date and best-in-class technology, Calyx will now be able to leverage Ceretype's advanced fMRI technology to bring new and more effective psychiatric treatments to market.

Worth noting: 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. This is not bad company to be in.

Of course, Ceretype didn't get here overnight, and there's a lot more happening than just its recent partnership with Calyx.

Since December 2022, Ceretype has developed and implemented a web-based stimulus delivery system for task-based fMRI that has deployed with its first biotech client.

The company has also developed standardized training and SOPs for a clinical trial product, continued to develop its first-of-kind biomarker report to provide clear analysis for drug development and clinical care, and is currently building disease-specific report panels.

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What Ceretype has accomplished just in the past five months is truly remarkable.

We should also point out that a pilot project for Ceretype's SaMD (Software as a Medical Device) with a leading academic center/hospital began in Q1, and patient data collection is currently underway.

Data collection for the company's clinical trial on neurodegenerative disease intervention is also currently underway with FPI (First person enrolled) planned for late April and into early May.

Research Highlights

Psychedelics may improve mental health by getting inside nerve cells: <https://www.sciencenews.org/article/psychedelics-improve-mental-health-nerve-cells>

A single administration of Psilocybin persistently rescues cognitive deficits caused by adolescent chronic restraint stress without long-term changes in synaptic protein gene expression: <https://www.liebertpub.com/doi/abs/10.1089/psymed.2022.0012>

The effectiveness of microdose psilocybin in the treatment of neuropsychiatric Lyme disease: <https://www.tandfonline.com/doi/full/10.2147/IMCRJ.S395342>

Human brain effects of DMT assessed via EEG-fMRI: <https://www.pnas.org/doi/full/10.1073/pnas.2218949120>

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 can accelerate and enhance the delivery of those therapies.

Final Note

For the past year or so, we've been sending you weekly emails to keep you updated on everything that's happening in the world of psychedelics.

From new deals and new research to policy moves and even celebrity endorsements, we want to make sure that as we continue to capitalize on the early development of this amazingly impactful and disruptive industry, you are kept in the loop regarding all the important developments that are happening in the space.

We hope you've been enjoying these weekly updates and find them both educational and, in some ways, entertaining. That being said, if there's anything else you'd like to see in our weekly updates, please let us know. Because not only are we excited about capitalizing on the rapid growth of the psychedelics market, we're equally excited about sharing our knowledge and research with you.

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 news@jls.fund.

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

