



# JLS Fund Report

A Psytech Venture Fund

August 2021



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## **A North American Psychedelics Juggernaut is Underway**

It was almost a year ago when Compass Pathways debuted on the NASDAQ, under the symbol “CMPS.”

This was the first psychedelics company to IPO on a major U.S. exchange.

To be honest, it came as a surprise to many of us who have been in the psychedelics game for years. Who would’ve thought that a company running clinical trials on psilocybin therapy for the treatment of depression would be trading on the same exchange as Tesla, Amazon, and Apple?

Yet that’s exactly what happened.

Now fast-forward to August, 2021, and there are now five psychedelics companies trading on major U.S. exchanges. In addition to Compass, there’s ...

- MindMed – Trading on the NASDAQ under the symbol “MNMD.”
- Field Trip Health – Trading on the NASDAQ under the symbol “FTRP.”
- Cybin, Inc. – Trading on the NYSE under the symbol “CYBN.”
- atai Life Sciences – Trading on the NASDAQ under the symbol “ATAI.”

And more are coming, too. In fact, we expect to see as many as five currently public psychedelics companies uplisting to the NASDAQ and NYSE within the next twelve months.

Certainly the research coming out of prestigious universities, such as Johns Hopkins and Columbia, is further legitimizing the industry, but from an investment perspective, these NASDAQ and NYSE listings are offering the legitimacy and confidence required by the big institutions to take large positions in the psychedelics companies that maintain a first-mover advantage. And while we’re not chasing public companies, some of the private companies in which we invested have gone public, with some likely to uplist to senior exchanges in the U.S.

Meanwhile, as we watch public markets in the U.S. becoming more accommodating to the psychedelics industry, in Canada, we're starting to see some positive developments that are quite reminiscent of what we saw prior to the launch of the Canadian cannabis market juggernaut.

You see, back in July, the media began covering a story about how Canadian healthcare workers were taking psilocybin mushrooms for training purposes. TheraPsil, the non-profit focused on helping Canadians in medical need access legal, psilocybin-assisted psychotherapy, was highlighted several times as the organization that's administering a training program that teaches healthcare practitioners how to safely facilitate psilocybin therapy.

This idea that we're now starting to see healthcare practitioners being trained to work with psychedelics is actually a pretty big deal when you think about it.

Ten years ago, something like this couldn't have existed. But now, with billions of dollars of fresh capital pouring into the space, such a thing should not come as a surprise. This is particularly true in Canada, where four terminally ill Canadians were granted the legal right to use psilocybin mushrooms last year. This was certainly a crack in the dam of prohibition.

You see, the Canadian government was able to provide an exemption from the prohibition of psilocybin for these patients thanks to Subsection 56 of the Controlled Drugs and Substances Act, which allows the minister of health to exempt any person or any controlled substance when "necessary for a medical or scientific purpose or is otherwise in the public interest."

If this exemption sounds familiar, it's because Section 56 exemptions allowed Canadians to first use cannabis for medical purposes in 1999. This then resulted in an overflow of exemption requests, which ended up being one of the driving forces behind the decision to legalize cannabis for medical purposes in 2001. And as you know, that led to the full legalization of adult-use cannabis in 2018.

Of course, bureaucracy moves at a snail's pace when not given a proper nudge, which is why TheraPsil recently submitted a 165-page proposal to the director of Health Canada that essentially provides a regulatory platform for psychedelics.

TheraPsil notes that its proposal creates a framework for patients to access medical psilocybin in consultation with a healthcare provider, and access-regulated psilocybin products.

This framework is based upon the 2016 regulations for medical cannabis in Canada, the Access to Cannabis for Medical Purposes Regulations (ACMPR), and is similarly proposed to be called the 'APMPR', or the Access to Psilocybin for Medical Purposes Regulations. TheraPsil invites public consultation and dialogue regarding the first draft of proposed regulations and will soon make available a form to gather and systematically analyze feedback, and put forward further recommendations to Health Canada. We hope you will join us in this collaborative process to help Health Canada enact regulations that will make medical psilocybin and psilocybin therapy a safe, effective, equitable, and accessible treatment option in Canada.

Meanwhile, as TheraPsil does the heavy regulatory lifting, the Canadian Psychedelic Industry and Nanos Research recently published the results of a new poll that indicates a large majority of Canadians overwhelmingly support controlled legal access to psilocybin-assisted therapy.

Here's the press release that was released last month:

A Nanos Research Survey released today by the Canadian Psychedelic Association (CPA) shows 82 percent of Canadians approve the use of psilocybin-assisted therapy for people suffering from an end-of-life illness, and 78 percent would support a government that legalized psilocybin-assisted therapy to improve the quality of life for palliative and end-of-life patients. Commissioned between June 30 – July 5, 2021, the survey results mark an historic time for Canada's leading voice on psychedelic therapy as the Association prepares to introduce a collaborative effort to bring regulatory change to Health Canada.

With public support at an all-time high, the CPA will now focus on introducing evidence-informed regulations to officials at Health Canada.

The CPA and other experts from across Canada have been meeting with Members of Parliament, senior government officials, representatives from all parties, and national stakeholders over the past 10 months and encountered unanimous support for access to psilocybin therapy with a palliative diagnosis. After meetings in May with the Parliamentary Review

Committee on Medical Assistance in Dying (MAID), committee members moved to have Thomas Hartle, the first palliative Canadian to receive a section 56 exemption for psilocybin-assisted therapy, appear and testify before Committee when Parliament resumes this fall.

Dr. Pamela Kryskow, a medical doctor and psychedelic researcher notes, “it is encouraging that this is an issue that all political parties support and Canadians have given their endorsement for. We see this as a green light for Health Canada to proceed with the regulations.”

Although the Canadian Government, led by Minister of Health Patti Hajdu, has implemented a number of progressive steps toward increasing access to psilocybin-assisted therapies, members of both the medical and legal communities in Canada believe that such steps still leave too many Canadians with undue depression, anxiety and mental anguish, particularly Canadians in palliative care or at end-of-life.

Dr. Kryskow has witnessed firsthand what legal access to psychedelic medicine can do for Canadians in need of new treatment options.

“The proof is in the research and patient improvement. We’ve seen positive clinical evidence that shows that psilocybin-assisted therapy works tremendously well for addressing many mental health challenges where other options are ineffective. The healthcare practitioners are ready, the patients deserve this, and we’re ready to provide this medical service to Canadians.”

Cory Firth, the Executive Director of the Canadian Psychedelic Association is confident the proposed amendments will continue our collaborative effort with Health Canada.

“The MORA was prepared by some of the best researchers, industry, legal and regulatory experts in Canada,” says Firth. “As the voice of psychedelics in Canada we made sure that no stone was left unturned in our efforts to bring timely and effective regulatory change to Canadians at end-of-life and suffering from various treatment-resistant mental health conditions.”

Multiple universities across Canada are developing psychedelic medicine programs and many have already offered courses.

Private clinics across Canada are preparing for the provision of these services. Ronan Levy of Field Trip Health Ltd., a global leader in the development and delivery of psychedelic therapies and a CPA member, commented: "As a society, we've implemented processes and procedures to ensure the health and safety of Canadians, particularly as it pertains to medicines. With psychedelics, we have centuries of therapeutic use and countless clinical trials attesting to their safety and efficacy. The cost-benefit analysis strongly favours prompt access to psychedelic therapies especially if implemented via the well-considered, balanced approach set forth in the MORA."

Empowered by our strong membership base of citizens, professionals, First Nations and Indigenous advisors as well as the emerging psychedelic business community, the Canadian Psychedelic Association is united by the need for access to psychedelic medicines for patients who need it most.

#### **Nanos Research Survey snapshot:**

- **82% of Canadians polled support or somewhat support approval for allowing the use of psilocybin-assisted therapy.**
- **78% of Canadians would support or somewhat support a government that legalized mushroom-based psilocybin-assisted psychotherapy to improve the quality of life for palliative and end-of-life patients.**

Almost two thirds of Canadians (64%) believe that the Canadian government should also expand legal access to psilocybin-assisted psychotherapy for those who qualify under the Medical Assistance in Dying (MAID) rules.

While we don't know exactly how things are going to roll out in Canada, we do know that there's some real momentum building up with support from Canadian citizens, healthcare organizations, non-profits, and regulatory bodies. And certainly we're looking to capitalize on this momentum.

## JLS Fund: Investments and Advisories

### **wesana™ Wesana Begins Functional Animal Studies**

Wesana Health recently announced the commencement of functional animal studies to determine the effect of a psilocybin-based regimen on locomotor activity as well as anxiety and depression.

Here's what Mark Wingertzahn, CSO of Wesana had to say...

"The locomotor study was designed to determine whether selected combinations of doses of the test product had any effects on locomotor activity and how pronounced this effect might be. Preliminary results, just released, indicate all combination doses were well tolerated with no evidence of untoward drug-drug interactions. This data is extremely encouraging and enabled us to commence with the validated functional animal study in models of anxiety and depression with an active control earlier than planned."

Results from the anxiety and depression study are expected in early Q4.

Also worth noting is that these functional animal studies follow a pilot study that gathered quantitative data pertaining to user experiences with components of a combination therapy for treating mild to moderate traumatic brain injury (TBI), anxiety, and depression related to previous TBI and migraine headaches unrelated to TBI.



### **Psilera Announces Ground-Breaking Study using Psychedelics to Treat Alcoholism**

Psilera, Inc. announced this month that it is beginning preclinical studies with its novel drug candidates aimed at reducing alcohol consumption.

Utilizing psychedelics to treat alcoholism is not a new idea. In fact, a few years ago, researchers at Johns Hopkins University and the Erowid Center explored the effects of psychedelics on heavy alcohol users, and found "significant and long-term reductions in alcohol use following psychedelic experiences."

As reported in Psychology Today, overall, almost all study participants indicated a significant reduction in alcohol consumption after the psychedelic experience—reducing consumption from approximately 26 to four drinks per week.

In fact, 83% of participants failed to meet the clinical threshold for alcohol use disorder following the psychedelic experience. Not only did the psychedelic experience significantly curb people's drinking, but it also appeared to stave off relapse years after the psychedelic experience.

This latest study being run by Psilera, however, is ground-breaking as it will be the first in vivo screening of these psychedelic-inspired new chemical entities (NCEs).

It will be performed by Dr. Danielle Gulick's laboratory at the USF Health Neuroscience Institute at the University of South Florida. Dr. Gulick's lab specializes in addiction, especially alcoholism, and its effects on aging and neuropsychiatric disorders. Psilera will provide up to seven NCEs which will be analyzed to assess efficacy in AUD and psychedelic effects via established preclinical models.

Here's what Dr. Jackie von Salm, Co-Founder and CSO of Psilera had to say:

The growing prevalence of alcohol use disorder, especially in conjunction with the Covid-19 pandemic, needs to be addressed as the current methods of treatment are outdated and insufficient. We consider this yet another important step towards our understanding of psychedelic and psychedelic-inspired compounds, and their potential as future medicines in the field of addiction. This in vivo research will provide crucial biological feedback which will further validate our computational efforts with BRAIN to expand towards optimized, next-generation psychedelic treatments.



## **atai Seeks Shorter Psychedelic Treatments with Salvia**

atai Life Sciences recently announced the launch of Revixia Life Sciences (Revixia), a wholly owned subsidiary developing Salvinorin A (SaIA) to treat a variety of mental health disorders.



Derived from *Salvia divinorum*, SalA is a non-nitrogenous agonist of the kappa-opioid receptor (KOR) with potential use in treatment-resistant depression (TRD), substance use disorder (SUD) and pain.

Clinically, there are published reports of the potential benefits of *Salvia divinorum* in the treatment of TRD. Karl Hanes reported on 7 patients with TRD who described relief from depressive symptoms with continued oral consumption of salvia leaves three times a week. Most of these patients reported lasting benefits from their use of the herb with significantly reduced scores on quantitative measures of depression and several reported benefits such as mood enhancement, increased feelings of relaxation and increased self-awareness.

Here's what Revixia CEO, Glenn Short had to say...

Due to SalA's short psychedelic effect, it will be an attractive option for those who would like psychedelic treatment but are unwilling or unable to participate in longer sessions. The shorter experience will allow for more practical administration and monitoring, which may even make it possible to attend psychotherapy sessions on the same day.

Worth noting is that Revixia's product will be paired with a digital therapeutic being developed by atai company Introspect Digital Therapeutics, with the aim of streamlining preparation, integration, and continued patient engagement.

atai also recently announced Q2 results.

#### Here are some highlights:

- **Successfully completed Initial Public Offering on Nasdaq raising \$258.8 million in gross proceeds, including the underwriters' over-allotment.**
- **Received \$20 million upfront payment from Otsuka as part of the first major collaboration between a biopharmaceutical company developing psychedelics and large pharma.**
- **Advancement of 11 therapeutic programs, including initiation of Recogify's Phase 2 and GABA's Phase 1 trials**

- **18 significant catalysts across atai's platform anticipated over next 18 months including two clinical trials to be completed and four clinical trials to be initiated in 2021**
- **Solidified leadership position with strong cash position of \$453.6 million to advance current programs and incubate, acquire and invest in new programs.**

And here are some recent advancements and upcoming milestones related to atai's various holdings:

### **Perception Neuroscience:**

Program Details: PCN-101 is a parenteral formulation of R-ketamine, a glutamatergic modulator being developed as a rapid-acting antidepressant, with the potential to be an at-home non-dissociative alternative to S-ketamine (marketed as SPRAVATO).

#### Upcoming Milestones:

- Phase 2 randomized, double blind, placebo-controlled trial in patients with treatment-resistant depression (TRD) to be initiated in the third quarter and expected to run through late 2022.
- The trial will assess efficacy and safety, dose response and duration of action in patients with TRD.

### **Recognify Life Sciences:**

Program Details:

- RL-007, a cholinergic, glutamatergic and GABA-B receptor modulator, is an orally available compound that is thought to alter the excitatory/inhibitory balance in the brain to produce pro-cognitive effects.
- atai is developing this compound for the treatment of cognitive impairments associated with schizophrenia.

### **Q2 Advancements:**

- In April 2021, Recognify initiated a Phase 2a study for RL-007, after receiving IND clearance from the U.S. Food and Drug Administration to commence clinical trials for the treatment of Cognitive Impairment Associated with Schizophrenia (CIAS).
- The study is designed to evaluate the effects of RL-007 on safety, tolerability, electroencephalogram-based biomarkers, and cognition.

**Upcoming Milestones:**

Topline results from the Phase 2a single-arm, multiple dose trial in patients with CIAS expected in late 2021.

**GABA:**

Program Details:

- GRX-917 is an oral formulation of a deuterated version of etifoxine, a compound that has a long history of prescription use in France for treating anxiety disorders.
- GRX-917 is designed to provide rapid anxiolytic activity with improved tolerability compared to current treatments for anxiety in the United States.

Q2 Advancements:

- In June 2021, GABA initiated a randomized, double blind, placebo-controlled Phase 1 trial.
- The study will evaluate safety, tolerability, pharmacokinetics, as well as pharmacodynamics using qEEG.

**Upcoming Milestones:**

Topline results from the Phase 1 single ascending dose/multiple ascending dose program expected early in 2022.

**DemeRx:**

Program Details: DMX-1002 is an oral formulation of ibogaine, a cholinergic, glutamatergic and monoaminergic receptor modulator being developed for the treatment of opioid use disorder.

Q2 Advancements: DemeRx received approval from the UK Medicines and Healthcare products Regulatory Agency to commence subject enrollment in our proposed Phase 1/2 clinical trial.

**Upcoming Milestones:**

- Phase 1 component of Phase 1/2 trial of DMX-1002 in recreational drug users and healthy volunteers to be initiated in Q3 2021 and is expected to read out safety data in early 2022.
- The trial is designed to assess safety, tolerability, pharmacokinetics, and efficacy, and the results will inform future studies in patients with opioid use disorder.



**COMPASS Pathways:**

Program Details:

COMP360 is a proprietary formulation of synthetic psilocybin, a 5-HT<sub>2A</sub>-R agonist being developed as an oral, rapid-acting antidepressant.

Q2 Advancements”

- In June 2021, COMPASS completed dosing in the Phase 2b clinical trial of COMP360 psilocybin therapy for treatment-resistant depression.
- The randomized, double-blind, dose-ranging study investigated the safety and efficacy of psilocybin therapy in 233 patients, making it the largest clinical trial with psilocybin to date.

**Upcoming Milestones:**

Phase 2b trial results are expected in late 2021.

## Final Note

Last month was another busy one for us.

Lindsay has been appearing on a lot of panels lately, helping newcomers to the space better understand the intricacies of investing in psychedelics. While there are certainly a lot of investors very enthusiastic about getting in early in the space, successfully navigating the field of psychedelics takes a lot more than just enthusiasm.

When dealing with brain health, FDA trials and protocols, and all the complexities of regulatory hurdles and legal obligations that come with building a successful psychedelics company, you have to have decades of experience to capitalize on all this early momentum.. And that's exactly what Lindsay brings to the table for JLS. While Lindsay's proverbial dance card has been filled with conferences and interviews, Simeon has been traveling extensively throughout Europe, meeting with new investors and doing site visits of companies that we're currently reviewing. Of course, beyond what we've been looking at since last year, there continues to be a flood of new deal flow coming our way, and our team has been laser focused on rooting out and targeting the best-in-breed investments to add to our portfolio.

In fact, we'll be closing on at least two more over the next few weeks, and we'll certainly share this information with you once everything is confirmed.

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**.

If you would like to see if you qualify as an investor, take our survey here: <https://tinyurl.com/4v6j7eat>.

In gratitude,  
The JLS Team

P.S. – Earlier this month, Rick Doblin from the Multidisciplinary Association for Psychedelic Studies (M.A.P.S.) appeared on the Aubrey Marcus podcast where he discussed with Marcus' audience of 55 million listeners, the current state of clinical trials using MDMA-assisted therapy to treat PTSD.

It's always fun to watch Rick educate the masses, and he does an excellent job in this podcast. Here's a link to the interview if you'd like to check it out:  
<https://www.youtube.com/watch?v=wQE44aZXqsl>