



A NEW INDUSTRY EMERGES

Dive into today's psychedelic technology and medicinal practices.

BY KEEGAN WILLIAMS

➔ The cannabis boom continues to rage rampantly, while another major industry, previously inaccessible because of the War on Drugs and research restrictions, is making its way to the forefront.

Psychedelics have spent decades under a Schedule I classification, deeming them to have “high abuse potential, no accepted medical use and a lack of safety even under medical supervision.” The research so far, however, conversely proves these drugs indeed hold the potential to reshape an entire market around mental health and more.

The legislative surge was swift: Denver, Colorado was the first US city in May 2019 to make the personal use and possession of small, noncommercial amounts of psychedelic drugs the lowest law enforcement priority. Oakland and Santa Cruz, California

soon followed suit, opening the doors for larger cities, like Seattle, Washington, to do the same.

New Jersey reclassified the punishments for possession of an ounce or less of psychedelic-containing mushrooms to a lesser offense, and Oregon decriminalized psilocybin, the psychedelic compound in magic mushrooms, and legalized its therapeutic use.

Canada also became one of the few countries allowing consumption of psychedelic mushrooms for people with depression and other mental conditions, expanding the exemption status beyond people with terminal illnesses. In 2021, Texas Governor Greg Abbott authorized the study of psilocybin for medical use, joining Connecticut in similar legislation.

Psychedelic reform and medical treatment present a whirlwind of new possibilities, and a number of industry pioneers are already paving the way for the road ahead. ➔



BEGINNING STAGES: A LOOK AT EMERGING CLINICAL RESEARCH

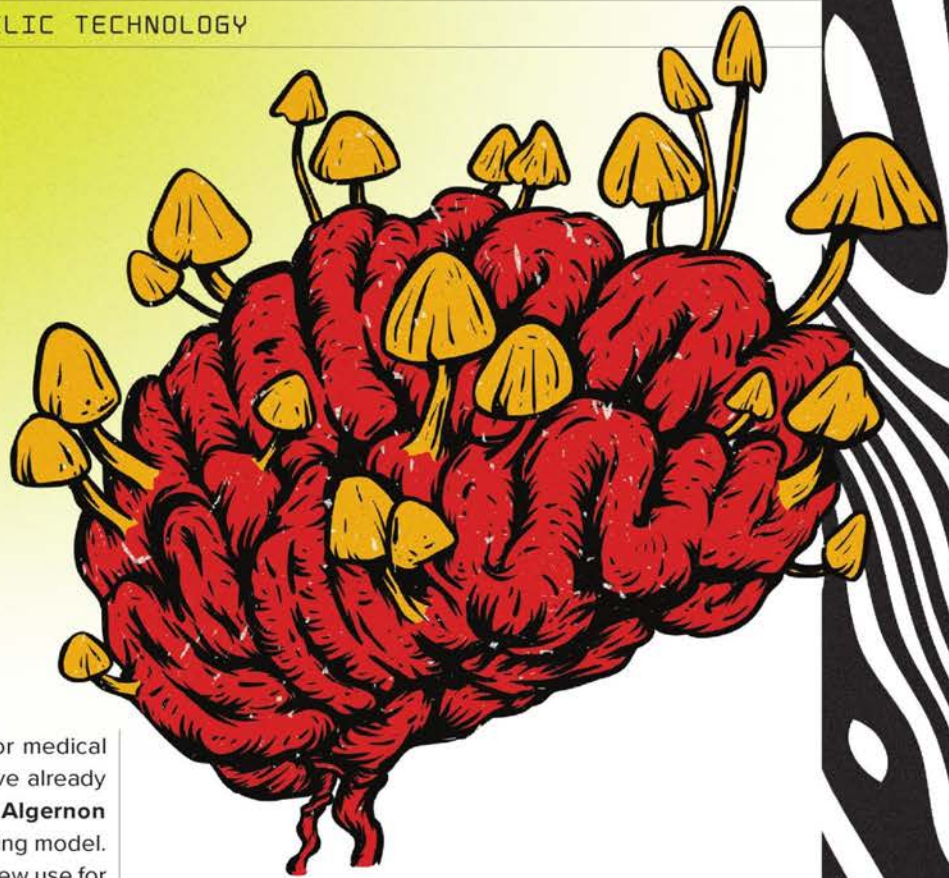
➡ The research phase of psychedelics for medical use often begins in companies that have already established a space in studying medicine. **Algernon Pharmaceuticals** works with a drug repurposing model. Drug repurposing isn't new; it looks to find a new use for drugs that have already been approved on the market.

Algernon entered the psychedelic drug world in March 2020. The company began homing in on DMT (N, N-dimethyltryptamine), a main active ingredient in ayahuasca which, when used in a psychedelic setting, often feels like an out-of-body experience, with some users reporting a feeling as if they changed into something new or traveled somewhere else entirely.

Algernon reviewed research that created a stroke in a rat brain, followed by DMT treatment. After 30 days, researchers saw a dramatic improvement in motor function compared to the control and a diminished area of infarction or tissue death.

DMT remains a Schedule I controlled substance in the United States, though it's a Schedule III controlled substance in Canada, allowing Algernon to file patents for a new form of clinical grade DMT through Health Canada approval. It deviates from the conversations in medicine surrounding psychedelics and mental health issues, uniquely focusing on DMT's potential to treat people recovering from strokes.

Algernon is planning a phase one trial at Hammersmith Medicines in the UK, with CEO Christopher Moreau citing that the regulatory agency is a "bit more open to allowing the research of psychedelic drugs." While oftentimes, a phase one study is concerned with a toxicity signal, and results have the potential to derail a program entirely, Moreau noted that DMT has already been studied dramatically, and this move forward is a "true phase one,"



"How quickly do you have to treat somebody who's had a stroke? Is DMT protective during the stroke? Is it helpful post-insult where it helps the brain rewire? This is all the exciting area that we are going to delve into."

-Christopher Moreau,
CEO of Algernon
Pharmaceuticals

or a test of dosage and safety.

Algernon focuses on a sub-psychedelic dose, pointing out that a number of stroke medicines have failed because they cause hallucinations.

"We're trying to explore the potential of DMT without making any comment about the psychedelic or any judge, right? It's strictly a practical medicine issue, and

the delivery of care to people who are already vulnerable, and they don't have a coach with them," Moreau told *High Times*.

Exploring their first human trial will allow Algernon to explore questions they have yet to answer:

"Do we treat them for an hour, three hours, 12 hours? We still don't know yet," Moreau said. "How quickly do you have to treat somebody who's had a stroke? Is DMT protective during the stroke? Is it helpful post-insult where it helps the brain rewire? This is all the exciting area that we are going to delve into."

Moreau said that solely reaching the human trial phase is a significant advancement, as some companies take years to reach the same point, if they get there at all.

"Every day, strokes are happening around the world," he added. "People that are going to suffer a stroke in the future—we can advance this medicine and find out that it is helpful, and it's going to be a tremendous benefit from people who suffer the debilitating effects of a stroke."

HMNC Brain Health similarly navigates the psychiatric industry with a focus on neuropsychiatric disorders, including treatment resistant depression (TRD) and major depressive disorder (MDD), while homing in on psychedelic drug development and technology.

The company is currently developing ketamine in a proprietary, prolonged-release format, called Ketabon, in treating TRD. Ketamine is already well-established as a fast-acting antidepressant, though, because of the side effects, regulators mandate that the medication must be taken under direct supervision of a healthcare provider.

Despite its efficacy and fast onset, this impacts the practical use of ketamine.

"Our vision is to bring this efficacy to patients, without being compromised by tolerability issues," CEO Benedikt von Braunmühl said in an email statement to *High Times*, regarding HMNC's prolonged-release formulation and their previous clinical studies.

The aim is to eventually see the responsible and safe treatment with Ketabon taking place outside of hospitals and physicians' offices, opening the doors for a wider use of this potentially life-saving treatment for the broader population in need.

Von Braunmühl said that the diagnoses within psychiatry are broad and harbor an abundance of diverse treatments, reflecting the diverse biological and psychological origins of the disturbances.

"Psychiatry has for decades applied a shotgun approach, where standard interventions, like SSRI antidepressants and atypical antipsychotics have been used broadly across these diagnoses as first-line treatments," von Braunmühl said. "Our firm belief is that if the biological disturbance can be identified, the appropriate intervention can be applied."

Von Braunmühl and the team at HMNC believe that

the future of psychiatric treatment must embrace precision psychiatry, collecting patient data—ranging from genetics and proteomics to psychological testing—to associate patient characteristics with treatments that carry a greater hope for a positive outcome.

"By doing this we may eventually overcome the trial-and-error approach that for decades, unfortunately, has been the hallmark of psychiatric drug treatment," von Braunmühl said. ➔



BENEDIKT VON
BRAUNMÜHL
CEO OF HMNC
BRAIN HEALTH

PHOTO: COURTESY BENEDIKT VON BRAUNMÜHL

"Our vision is to bring this efficacy to patients, without being compromised by tolerability issues."

THE CLINICAL PRACTICE AND KETAMINE

➡ Ketamine is already legal for medical use in the US, approved as an anesthetic in 1970. This automatically places the drug ahead of others in this conversation, and as a result, it's already grown into a substantial practice across the country.

Delic runs the largest network of ketamine wellness clinics across the country, delivering more than 60,000 treatments to date. It's FDA-approved, covered by many insurance providers and proven to be highly effective with minimal side effects.

Kevin Nicholson is the Delic COO and Ketamine Wellness Centers (KWC) CEO, which was recently acquired by Delic. He began researching ketamine therapy for mental health back in 2011 with his KWC colleagues, and he said they were initially "snake oil salesmen" to the psychiatry world. "We were... not well received. Let's just put it that way," he said.

As information spread through larger studies and institutions, the traditional psychiatry field could now see ketamine was FDA-approved for this specific use and feel more comfortable exploring other options. The blossoming of knowledge surrounding the therapeutic potential of ketamine on a broader scheme thrust KWC forward; as one of a small handful of clinics in the entire country when they started, they now sit beside more than 400, surely with more to come.

The organization has since expanded its single facility to 10 clinics in eight US states. With the merger and acquisition, it plans to grow to 20 to 25 clinics over the next 12 to 18 months, maybe even sooner.

"A big piece of that is, we want to be able to obviously bring this treatment to more people at an affordable rate but also provide the option for as other psychedelic compounds become approved that patients can get them in (a clinical) setting," Nicholson said.

While the big picture has shifted, the majority of KWC's patients seek this treatment out themselves; they are not referred to by a general practitioner or psychiatrist. Nicholson said it's "very slow" progress from the medical community, and there is still a long road ahead, asserting that mental healthcare is more crucial than ever, given the prevailing COVID-19 pandemic and its myriad, detrimental outcomes on our brains.

"Now, we have actually a good option to help them, and hopefully, it is temporary, almost like a trauma-related type exposure. We might not need long term therapy for these individuals. That might be something that we need to evaluate if



WHAT A KETAMINE-ASSISTED THERAPY SESSION LOOKS LIKE.

their symptoms occurred at the start of the pandemic," he said.

Nicholson and his colleagues are hopeful that the FDA will approve MDMA therapy before the end of 2022, and they have already started hiring and training in anticipation. Looking forward, he ultimately cited SSRIs and traditional medications as the first line of treatment for mental health and said that must change.

"Patients should be given the option to look at psychedelic-assisted therapy and psychedelic assisted-treatment, in conjunction or in exception to traditional medications," he said. "Psychedelic wellness needs to be pushed up to being a competitor of the Big Pharma that's out there, that has historically proven some benefit but also, obviously, if it had been effective as we had hoped it to be, psychedelics probably would have never come about." ➡



KEVIN NICHOLSON, COO OF DELIC AND CEO OF KETAMINE WELLNESS CENTERS

PHOTO: COURTESY KEVIN NICHOLSON

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PHOTO: COURTESY KETAMINE WELLNESS CENTERS

TELEHEALTH INNOVATIONS

PHOTO: COURTESY JOHN HUBER



The COVID-19 pandemic allowed for an exploration of our current technology and what is possible in a remote setting, notably telehealth, and a number of companies are already exploring the potential this option could offer in regard to psychedelic medicine.

TripSitter embraces virtual medicine, empowering their patients to embrace a personalized, physician directed-treatment plan for a number of conditions including anxiety, bipolar disorder, depression, obsessive compulsive disorder and PTSD. The treatment begins with an evaluation with a licensed physician, followed by the physician's determination of the prescription, which is typically delivered within three to five days.

The patient can then schedule a treatment session through the patient portal, and upon treatment day, connects with their dedicated TripSitter, who provides guidance on taking the medication, what to expect and how to create an ideal treatment environment, followed by ongoing treatment and therapy.

"I'd watch you take your medication and just be there in case you wanted something," said TripSitter CEO John Huber. "I can talk you through whatever is occurring, because I've done it with so many people already in brick-and-mortar. The psychedelic experience is very gentle. The whole thing lasts about 45 minutes once it starts."

TripSitter has a minimum three-month commitment because the ketamine is not delivered intravenously, with only 30 percent absorbed orally. While the at-home process is longer, Huber pointed to accessibility and affordability as two of the main factors that make services like TripSitter's ideal for a wide variety of patients.

"The doctors I work with in their office, they charge anywhere from \$1,200 to \$1,600 a dose. We're roughly \$400 a month for up to 12 treatments. For the price of one treatment at one of my doctors right here in Austin, \$1,500 pays for your three months. You know, that's the big advantage."

As much as TripSitter prioritizes affordability and accessibility, Huber said safety is the number one concern, and if a patient wants a speedy treatment, they will need to pay for face-to-face treatments. Though, regardless of application, he sees the



JOHN HUBER,
CEO OF TRIPSITTER

psychedelic-assisted therapy model only growing moving forward, and he also foresees that a space will remain for the telehealth option.

"So many treatments out there just kind of placate people, don't really treat the disease. Now I've got something that actually does, and I'm losing patients in my brick-and-mortar office because I'm fixing them," he said. "They might come back once or twice a year for a tune up. But that's it, you know, and that makes me happy."

Nue Life similarly uses a telehealth model for ketamine treatment, offering a personalized healing journey through prescribed doses and ongoing therapy, including virtual integration groups and health coaching sessions to optimize patient outcomes in dealing with depression, anxiety, bipolar disorder, PTSD and other conditions.

Nue Life Co-founder and CEO Juan Pablo Cappello was raised in Chile and exposed to Native American traditions early on, like the spiritual and ceremonial use of ayahuasca and, later, peyote. He carried a suspicion around the current medicinal model as he pressed forward in his life, eventually leading to the impetus behind Nue Life—building a mental wellness company that could help a million people before psilocybin becomes legal.

"When I sort of gave up a little bit of my prejudice against all things being Western medicine and really looked at the science, I realized that ketamine has some incredibly good advantages over traditional psychedelics like psilocybin," Cappello said.

"The relatively short acting nature of ketamine, and

its legality, are really the reasons why ketamine is a very attractive alternative, as well as the research," he added. "I mean, we have 60 years of research involving ketamine and unfortunately, because of the drug war, one of the victims was good research on many of the other compounds which are showing great promise today."

As the industry grows, Cappello hopes that as many thoughtful and ethical people enter as possible, rather than it becoming a purely capitalist space. Nue Life's founding team is entirely people of color and women, and Cappello said from the start, he wanted to build a different company, showing others it's possible to be a "thoughtful capitalist" highlighting the social impact of a company from day one.

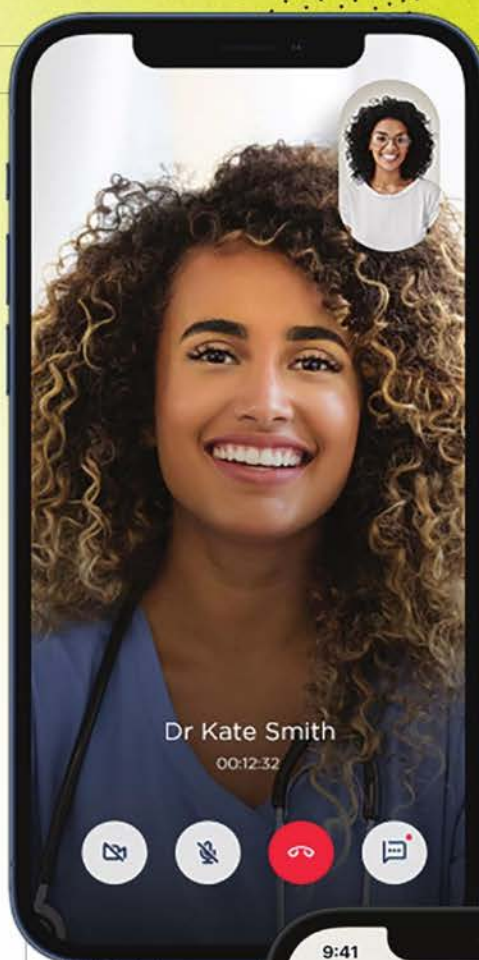
Citing the homogeneous ownership taking place in the booming cannabis industry across the US, he said, "We felt that it was very important to build a company in the psychedelic space that looked very different."

The onset of COVID-19 allowed Nue Life to explore telemedicine, citing the same affordable and accessible benefits Huber mentioned. Cappello said that telemedicine also results in a higher compliance rate (patients making their appointment times, following through with additional therapies and follow-ups, etc.) while also using digital phenotyping technology through smartphones and tech like the Apple Watch, so long as a patient gives them access.

"We're able to get a sense of how much a patient is sleeping, how much the patient is exercising, if they're interacting with their phone in a way that suggests that they're depressed or anxious, right?" Cappello said. By capturing this passive information, Nue Life offers patients a much more personalized experience.

The problem with the mental health industry today is the masking of symptoms, rather than trying to deal with the root cause of suffering, Cappello explained. In addition, he said the biggest challenge for this new industry is the idea of psychic psychedelic exceptionalism, that psychedelics will just "fix" people on their own. While psychedelics help people to reboot and reset, Nue Life sees their potential as a catalyst for change that still have their limitations.

"What's really important is what happens the day after," he said. "Is there the right integration, follow up therapy, etc., to help people not only get well but stay well? →"



2022

THE NUE LIFE
INTERFACE

SCHEDULE AN
EXPERIENCE WITH
NUE LIFE.



PHOTO: COURTESY NUE LIFE

THE PSYCHEDELIC RETREAT



In that same aim, many professionals are looking at another unique way of ensuring long-term wellness, more heavily mirroring the early medicinal practices of Indigenous cultures with a focus on setting and group guidance in the form of a psychedelic retreat.

Dimensions' approach combines insights of Western science with the ancient traditions of plant medicine to create a new approach for mental health treatment and self-betterment. Dimensions has partnered with Queens University to ensure it is collaborating with the most recent and accurate research to inform its practice, putting group therapy and ceremonies at the forefront to be led by plant elders, with respect to the original uses of these substances.

possibilities for psilocybin at the least, there is also potential for cannabis-assisted therapy sessions, or conscious cannabis sessions, in the meantime, more for people who might not have a clinical concern but who are looking to have a spiritual exploration.

"We actually blend cannabis with breath work, and when you blend cannabis with breath work, oftentimes people have experiences that are indistinguishable from DMT experiences or even ayahuasca experiences: highly visual, highly somatic," said Clinical Director Donald Currie. "Oftentimes people find that they are able to creatively problem solve in these ceremonies; they're able to come up with solutions to issues that are occurring in their life. There's not only the opportunity, as Andrew mentioned, for the psychedelic-assisted therapy side, but also for more of an exploration of consciousness."

Similar to the clinical practices currently in place, integration helps people to make meaning out of their experience. Each guest is an active participant in their own program, and the retreat additionally offers massage therapy, acupuncture, restorative yoga practices and more to align with the specific needs of each person.

PHOTO: COURTESY DIMENSIONS



ANDREW GALLOWAY, COO OF DIMENSIONS

"I don't believe that putting a blindfold on at an office building for an hour is the way plant medicines are meant to be used," said COO Andrew Galloway. "I appreciate that they're using ketamine and synthetics and stuff like that, but we believe in using the actual biomass itself, the whole plant. It will obviously depend on where our facilities are and what different plant medicines we can use." Dimensions currently has plans for three locations in the Algonquin Highlands in Ontario, Canada, as well as Jamaica and Costa Rica. Galloway noted that the future of Dimensions and the experiences it will offer depends on policy.

While Galloway believes that the future will open

PHOTO: COURTESY DIMENSIONS



DONALD CURRIE, CLINICAL DIRECTOR OF DIMENSIONS

The ceremony begins with the first phone call, Galloway said, and community is a huge aspect of the program.

"When we're in these group processes with people, and people are sharing their story, there's almost a sigh of relief when they realize that they're not the only one that has this issue," Currie said.

Moving forward, they would even love to offer a more long-term program, giving people the option to visit different locations throughout the year, each with the same feel and the same group—but potentially different medicines and a fully new setting—to continue their healing journeys.

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—Donald Currie, Clinical Director of Dimensions

"I think we're gonna have a lot of a lot of guests that don't have a lot of ailments but know there's something bigger in the world or know there's something out there, want a higher consciousness, and they look to psychedelics as a way to experience that or evolve in that area," Galloway said.

Currie additionally notes that Dimensions wants to be a resource in training psychotherapists and wellness practitioners in best practices to ensure there is a high level of integrity, ethics and safety in the community as a whole.

"Because *Nine Perfect Strangers* is not how you run a retreat," Galloway interjected, nodding to the 2021 Hulu limited series that had nine guests frantically journeying through self-actualization (with a notable lack of disclosure and consent in their treatment), methodology clearly made just for TV. "It's everything—what not to do!" Currie replied.

PSYCHEDELICS ARE HERE TO STAY

Ready or not, the psychedelic renaissance is here. Psilocybin has now been administered to more research subjects than some FDA-approved psychiatric medications, suicide rates in the US have steadily increased over two decades, while overdose rates have surged. PTSD disability claims by veterans have tripled in the last decade, and the rates of prescriptions of antidepressants has more than doubled in the last 10 years, even though they are often ineffective.

Larger states like New York and California have already introduced bills that would allow for the study of psychedelic substances and decriminalization, respectively, and more research is being done every day on the potential of psychedelic drugs in the medical field.

Experts already theorize the legalization of psychedelic drugs eventually is inevitable, though it bears the question of whether we are moving fast enough, given the substantial mental health crises society faces today and the evidence showing the efficacy of these alternative treatments.

Nue Life's Cappello resonated in the realities of our current model in mental healthcare, especially in the midst of the COVID-19 pandemic, "Unfortunately, mental health today is an industry built on failure, not an interest in industry built on success." **HT**



PHOTO: SHUTTERSTOCK

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