

Safer psychedelic medicines for better mental health treatments



psycheceutical.com Fort Lauderdale FL     

Notable Investors

Kevin Harrington

'Shark Tank' Investor and Famed Entrepreneur

Bruce Cassidy

Investor and Executive Leader

Trent Dilfer

UAB Head Football Coach and Former NFL Quarterback

Highlights

- 1 Developing two patented delivery technologies to increase the safety and efficacy of psychedelics
- 2 Phase I trial first dosing results of ketamine topical for PTSD shown to be safe and well-tolerated
- 3 Observational data of ketamine topical for PTSD showed 80% of patients experienced symptom relief
- 4 Kevin Harrington, celebrity Shark Tank star, has invested and joined as Strategic Advisor

- 5 Dr. Julian E. Bailes, famed neurosurgeon and brain injury expert, joined as Chief Medical Officer
- 6 Featured in Forbes, Benzinga, U.S. News, Business Insider, BioSpace, Pharmacy Times, and more
- 7 Named a "2023 Top 10 Biotech Startup" by Life Sciences Review
- 8 Agreement with Vici Health Sciences, a DEA Schedule 1 lab, to develop novel compounds & formulations

Our Team



Chad Harman Chief Executive Officer

Mr. Harman is a 25-year cannabis and health insurance executive possessing unique leadership experience across operations, manufacturing, finance, product development, etc.

We all know a friend or family member affected by depression, anxiety, PTSD, or addiction. Mental health disorders are the true global pandemic. Current treatments are largely ineffective, often with needless side effects. Psychedelic compounds show great promise, but need to be delivered like current pharmaceuticals with dosing control.



Kevin Harrington Strategic Advisor

Kevin Harrington is a famed entrepreneur, investor, business executive, and best-selling author. An original "Shark" on the Emmy-winning TV show "Shark Tank", he's been involved in more than 1,000 products and produced over \$6 billion in global sales.



Dr. Julian Bailes Chief Medical Officer

Dr. Bailes is a leader in the field of neurosurgery, the impact of brain injury on brain function, and the understanding of Chronic Traumatic Encephalopathy (CTE). He was portrayed by the actor Alec Baldwin in the movie "Concussion".



Anish Tuteja Chief Science Officer

Dr. Tuteja is a Professor of Materials Science and Engineering, Chemical Engineering, and Macromolecular Science and Engineering at the University of Michigan. His work has also led to over 20 patents and patent disclosures.



Aric Logsdon Scientific Director

Dr. Aric Logsdon is a biomedical researcher with expertise in preclinical drug discovery for human neurological diseases. Aric completed Postdoctoral training at the University of Washington and has written more than 50 peer-reviewed publications.



Dr. Ronald Aung-Din Clinical Advisor

Dr. Aung-Din practices General Neurology and Neuro-Psychiatry and is certified by the American Board of Psychiatry and Neurology. He developed and holds 13 patents related to NeuroDirect therapy.



Zappy Zapolin Co-Founder

Zappy Zapolin is a futurist, psychedelic concierge to the stars, and award-winning filmmaker



Zappy Zapom is a futurist, psychedelic conierge to the stars, and award-winning filmmaker who is dedicated to the expansion of human consciousness. Playboy Magazine called him "The Man Who Wants to Change the World with Psychedelics."



Michael Hlavsa Chief Financial Officer

Mr. Hlavsa has 44 years of executive and financial experience as a CPA, certified internal auditor and global management accountant. Michael has been an officer and director of several publicly traded companies on the NYSE, NASDAQ and OTCBB exchanges.

Safer psychedelic medicines for better mental health treatments



It seems like everyone these days knows a friend or family member who is struggling with their mental health, or is personally facing such issues themselves—whether it's depression, anxiety, PTSD, or addiction. **90% of adults** say the U.S. is experiencing a mental health crisis, and the problem continues to worsen since the COVID-19 pandemic. **These serious disorders need a better approach to treatment.**



Current treatments for mental health are still based on 1980s technology, using SSRIs and SNRIs to change levels of serotonin in the brain. However, new research has shown ***no evidence*** linking serotonin levels to depression or anxiety. Additionally, these medicines are not designed for long-term use, come with numerous side effects, and have shown severe withdrawal symptoms. Neuroscientists are now calling for a fundamental reassessment of how mental illness is treated.



OUR MISSION

To make psychedelic medicines
safer and more effective

Decades of research have shown that psychedelic medicines have **powerful potential for lifesaving mental health treatment** by promoting **neuroplasticity in the brain**. However, for widespread adoption, psychedelics need to be delivered in the same way that pharmaceuticals are – with safe and controlled dosing.

Psycheceutical Inc. is a bioscience company bringing this much-needed innovation for precision psychedelic dosing to the mental health industry. Our mission is to develop cutting-edge delivery technologies to provide the safe and effective delivery of psychedelic medicines. We're combining the brain-enhancing aspects of *psychedelics* with the controlled dosing of *pharmaceuticals* – creating “*psycheceuticals*” that can be used across the mental health treatment spectrum.

\$400 BILLION Global mental health market size and growing

The therapeutic use of psychedelics for depression, anxiety, PTSD and more is a booming industry, with billions of dollars being poured into psychedelic drug research and development. **Many neuroscientists and physicians believe that psychedelic medicine will become the next major breakthrough in mental health treatment**, representing an approximate \$400 billion global market size that is expected to reach \$540 billion by 2030 (Yahoo Finance, Feb. 2022).

THE PROBLEM

***Unsafe dosing* prevents the widespread use of lifesaving psychedelic medicines**

Until now, there have been significant medical and technological limitations keeping psychedelic medicines from being safe, effective, and widely accessible:

- Most psychedelic compounds don't easily reach the targeted receptors in the brain because they are blocked by the blood-brain barrier.
- High doses are usually required to achieve the desired effect, but can cause toxicity to the liver and kidneys and often lead to unpleasant “trippy” effects like hallucinations, dizziness, nausea, and vomiting.

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- Psychedelics taken orally can take hours to have an effect.
- Psychedelic drugs usually require administration in a clinical setting, which can be very expensive and is usually not covered by insurance.



Psycheceutical is seeking to remove these barriers by developing two next-generation patented delivery technologies designed to increase the safety and efficacy of psychedelic compounds. Our goal is to provide direct and profound benefits to those suffering from mental health disorders.

This novel precision dosing technology is being developed to:

- Deliver psychedelic compounds directly to targeted receptor sites in the brain within minutes, bypassing the blood-brain barrier
- Bypass the stomach and liver to reduce exposure to drug toxicities
- Eliminate the “trippy” hallucinogenic side effects
- Be administered at home instead of a clinical setting, greatly lowering the cost of care for both insurance companies and patients



We believe that our two patented delivery technologies are poised to become the foundation for how psychedelic medicines will be delivered to treat mental health disorders.



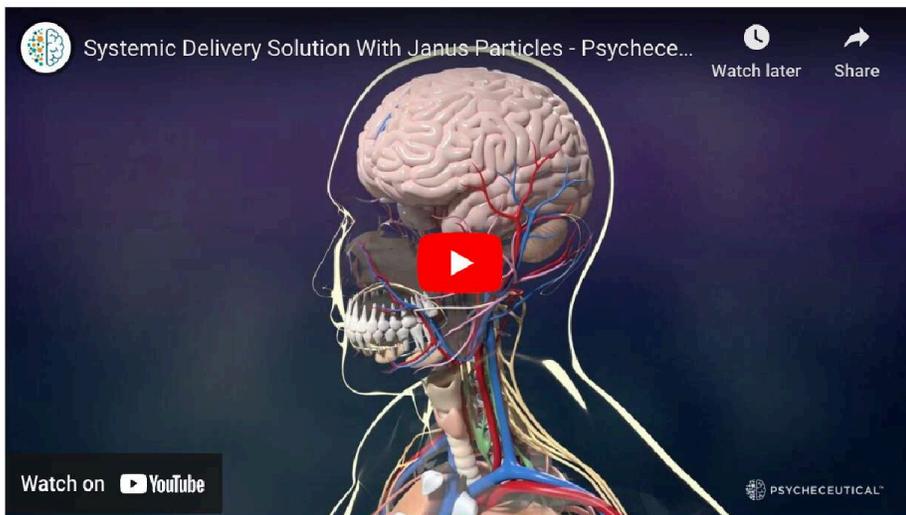


NeuroDirect™ Non-Systemic Delivery Technology

(Currently in Phase 1 Clinical Trials)

Psycheceutical's patented NeuroDirect™ non-systemic delivery technology is being developed to deliver neuroaffective compounds directly into the nervous system through topical application at the back of the neck. This delivery method is expected to act within minutes to enable immediate and sustained delivery, safe dosage control, and consistent results—while avoiding the systemic side effects of psychedelic compounds such as hallucinations, nausea, dizziness, as well as toxicity to the liver and kidneys.

NeuroDirect is intended to be administered at home or on-the-go instead of a clinical setting, which could greatly lower the cost of care for both insurance companies and patients. By making psychedelic medicines safer and cheaper, those suffering from mental health disorders or central nervous system diseases would potentially have greater access to these life-saving treatments.



Janus Particle Systemic Delivery Technology

(Currently in the Pre-clinical Phase)

Psycheceutical's patented Janus particle systemic delivery system is designed to use nano-sized multi-layered compounds (called Janus particles) to deliver targeted doses of any psychedelic compound directly through the blood-brain barrier.

Our patented manufacturing process can make Janus particles in virtually any size or shape, as some shapes have shown better absorption by certain types of cells. Our Janus particles are intended for lower dosages, which would minimize unwelcome side effects and toxicity by avoiding the stomach, digestive tract, and liver. This delivery method is designed to improve the effectiveness of the active components, target specific cells, and deliver multiple medicines at the same time or in time-release.

Drug Pipeline



Our initial focus for our drug pipeline is using the FDA 505(b)(2) regulatory pathway for new drug applications (NDAs), which have full safety and effectiveness reports but can reference some of the information required for approval from other data and study results. Our 505(b)(2) drugs use established, unmodified psychedelic molecules with decades of supporting clinical data, which can result in a *much less expensive and much faster route to approval* while creating new products with tremendous commercial value.

Other psychedelic companies in the industry are typically following the traditional 505(b)(1) development pathway by attempting to modify the molecular structure of psychedelic compounds to remove the psychedelic effects. This requires extensive FDA approvals and preclinical studies, leading to higher expenses and longer timelines.

Treatment of PTSD

The first drug in our development pipeline is our NeuroDirect ketamine topical cream for the treatment of PTSD. We've selected ketamine because it's currently the only legal psychedelic compound. The market size for PTSD treatment is over \$16 billion per year, and there are no known effective therapeutic solutions currently available.

Our novel NeuroDirect ketamine topical has already shown positive preclinical results in a recently published study in *Drug Development & Delivery*. In 100 patients with intractable depression, anxiety, and other symptoms commonly associated with PTSD who had failed numerous other treatments, more than 80% experienced symptom relief from the NeuroDirect ketamine cream.

“Discernible improvement[s] in anxiety, depression, paranoia and unrealistic fear, focusing issues, cloudy thinking, neuropathic pain, and other such symptoms were noted within 8-10 minutes of topical drug application. No psychogenic effects, such as hallucinations or dissociative phenomena, were experienced by any patient. To the contrary, patients indicated their thought processes were clearer, more focused,

and that they were more keenly aware of surroundings.”

We recently announced the completion of dosing of the first cohort of subjects in a Phase I clinical trial of our NeuroDirect topical ketamine formulation for the treatment of PTSD. *Key results from the cohort confirmed the topical administration of NeuroDirect ketamine to be successful, safe and well-tolerated.* Psycheceutical’s clinical trial program is the *first ever* to test the topical application of ketamine for use in treating a mental health disorder (source: [ClinicalTrials.gov](https://www.clinicaltrials.gov)). Phase II clinical trials for NeuroDirect ketamine topical are planned for the beginning of 2024.

Treatment of Addiction



EVERY 5 MINUTES
That's how often someone dies
of a drug overdose in the U.S.

The next compound in our development pipeline will focus on the treatment of substance abuse disorders. The current market for treatment of substance abuse in the U.S. is more than **\$35 billion annually**, with patient relapse rates estimated at **40-60%**. There are currently no therapeutics on the market that have shown the ability to consistently and effectively treat cravings, withdrawal, and other symptoms that are experienced by those battling with substance abuse.

We have received positive initial feedback from the National Institute of Drug Abuse and the FDA about our development strategy to seek fast-track approval of our substance abuse product to combat the current addiction crisis.



During the next few years, a higher frequency of mental health illnesses combined with a greater awareness of mental health is expected to fuel a global market expansion for psychedelic medications. Mental health disorders result in large economic costs to those afflicted, their families, and society as a whole. The United States alone already spends nearly over **\$280 billion on mental health**

treatments annually, with current therapies only showing marginal efficacy.

Psychedelic medicines have the potential to capture a huge share of this market, while having greater effectiveness, reduced risk, and the potential for a dramatic improvement in quality of life for up to one billion people.

Leadership



Members of the Psycheceutical team

We've assembled an incredibly talented and diverse team, consisting of medical doctors and specialists, biotechnology scientists, FDA regulatory advisors, psychedelic industry insiders, and business development experts.

We're honored to have famed entrepreneur and "Original Shark" from *Shark Tank*, Kevin Harrington, as an investor and Strategic Advisor to provide expertise on the company's growth and development. Kevin is an advocate of mental health, and sees psychedelic medicines as the future of mental health treatment. He believes the psychedelic medicine industry will be worth over \$1 trillion dollars in the next few decades, and chose to invest in Psycheceutical because our patented delivery technologies could benefit the entire industry.

Medical Team

Our Medical Advisory Board is led by our Chief Medical Officer, Dr. Julian Bailes, a world-renowned leader in the field of neurosurgery. Bailes was played by Alec Baldwin in the movie *Concussion* with Will Smith, detailing his discovery of CTE brain injury in athletes. His leadership and expertise have been invaluable, particularly for our strategy to deliver drugs to specific receptor sites in the brain. The Board also includes cardiologist Dr. Thomas Cabell and neuropsychologist Dr. Tony Strickland, who work in tandem with the company's scientific team in identifying and reviewing outstanding molecules to bring through the drug discovery and development process to clinical application.

Science Team

Our science team includes the inventors of our two patents: our Chief Science Officer Dr. Anish Tuteja, and our Clinical Advisor Dr. Ronald Aung-Din. The work of Dr. Tuteja at the University of Michigan has led to over 20 patents and

patent disclosures including our Janus Particle manufacturing technology, while Dr. Aung-Din has been granted 13 patents related to his NeuroDirect technology. Our regulatory and research advisors are guiding our clinical trial processes as we continue to add new intellectual property to our portfolio to further shareholder value.

BRAND AWARENESS

FEATURED PRESS

- USNews**
Psycheceutical Listed as One of The Top 7 Psychedelic Stocks to Watch
- Forbes**
Shark Tank's Kevin Harrington Invests In Psychedelics Company Psycheceutical
- BENZINGA**
Psycheceutical Licenses New Delivery Technologies For Psychedelic Medicines
- Pharmacy Times**
Novel Psychedelic Treatment Approach Bypasses Hallucinogenic Effects to Allow Widespread Adoption

FEATURED SPEAKERS

- PSYTECH**
- Microdose**
- MEET DELIC**
- PSYCHEDELIC INSIGHTS**
PSYCHOLOGICAL GUIDANCE OF PSYCHEDELICS
- angels+ entrepreneurs**

Psycheceutical has been honored to be featured extensively in the media, as excitement builds about our breakthrough biotechnology. Check out our [Press Room](#) to see press features, our press releases, and podcasts our team members have been featured on.

Here are some notable articles written about us:

- [**Forbes: Armed With Two Patents, Psycheceutical Plans To Transform Psychedelic Drug Delivery**](#)
- [**Pharmacy Times: Novel Psychedelic Treatment Approach Bypasses Hallucinogenic Effects to Allow Widespread Adoption**](#)
- [**Freethink: New clinical trial is testing a ketamine skin cream for PTSD**](#)
- [**Benzinga: Psycheceutical Developing The First Ever Topical Psychedelic Cream To Treat PTSD**](#)
- [**Forbes: Shark Tank's Kevin Harrington Invests In Psychedelics Company Psycheceutical**](#)

BUSINESS MODEL

DUAL REVENUE STREAMS

Our growth strategy is to continue development efforts for our delivery technologies and our planned drug development programs. We then plan to focus on revenue opportunities through the licensing of our proprietary assets and the commercialization of the drugs that come out of our drug development efforts.

Licensing

It is our expectation to be able to generate revenues through the licensing of our drug delivery technologies to pharmaceutical and psychedelic drug development companies in exchange for customary upfront cash payments, milestone payments, and royalty payments.

In-house IP and Drug Development

We intend to develop and then commercialize our own unique drugs as well as intellectual property surrounding drug delivery technologies and formulations in the psychedelic and neurological spaces.

Psycheceutical finds itself in a mode of “cooperation,” since we believe existing companies who are developing pharmaceutical approaches will require our novel delivery systems to more effectively deliver their products.

Strategic Partnership with Vici Health Sciences



Members of the Psycheceutical team meeting with the founders of Vici Health Sciences at their formulation lab in Maryland

Psycheceutical has entered into an exclusive option to acquire a majority equity ownership stake in Vici Health Sciences, a state-of-the-art formulation and testing lab in Maryland. Vici is a DEA Schedule 1-5 licensed facility, meaning they can legally synthesize and formulate all psychedelic compounds. This opportunity would allow us to establish vertical integration, allowing our drug development pipeline to move quickly and without interruption.



Summary

Unfortunately, mental health conditions are on the rise worldwide. In the U.S. alone, **more than 50%** of Americans will be diagnosed with a mental illness or disorder at some point in their life. Effective mental health treatments have been sorely lacking for decades, and millions of people continue to suffer. While psychedelic medicines have shown incredible promise, they need to be safe, effective, and delivered in controlled dosages to be approved for use by the general public.

Psycheceutical has the team and the technology to take on the mental illness crisis. Our patented delivery technologies can potentially benefit the entire emerging psychedelic medicine industry, projected to be worth more than \$1 trillion dollars in the coming decades. By becoming a shareholder today, you can join us in our mission to be part of the solution for mental health care and to truly make a difference in the world.