



BIOMEDICAL BREAKTHROUGH:



DMT-TREATMENT FIRST-MOVER ALERT!



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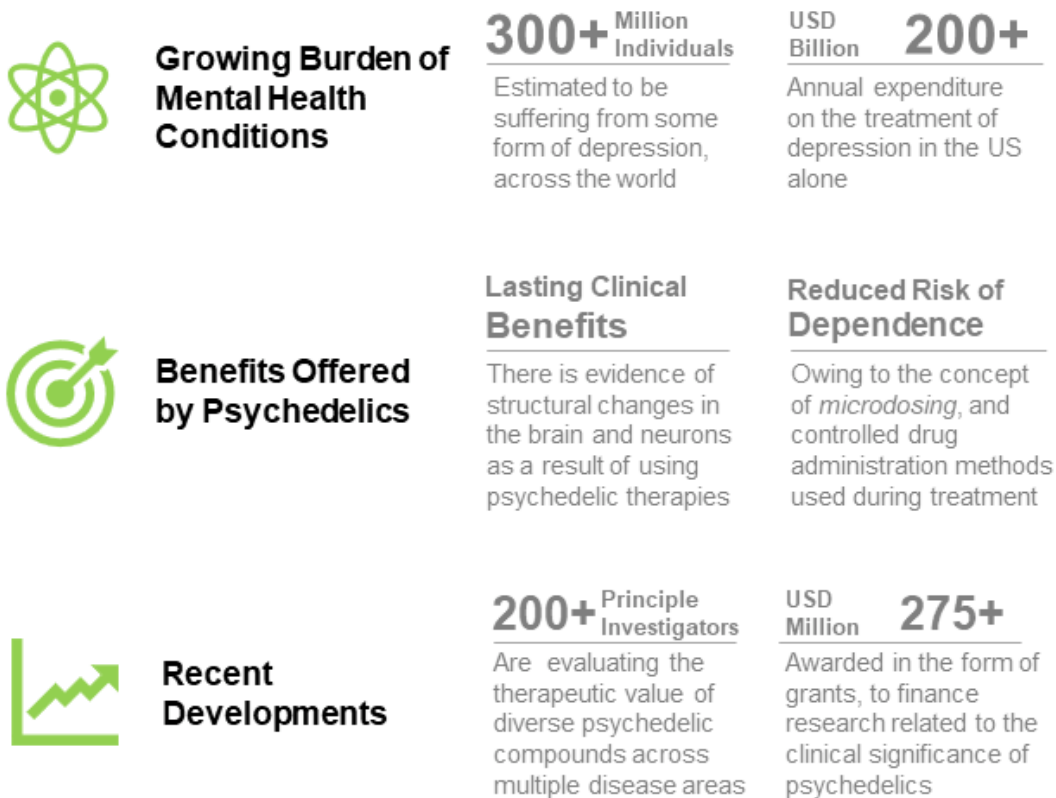
2020 brought numerous often-ignored issues to the forefront, including the need to address untreated physical and behavioral health problems. 2020 forced us to take a serious look at our well-being – and to question the efficacy of conventional treatments.

Among the most promising treatment avenues in recent years is psychedelic medicine. The progress in psychedelics often mirrors what we saw in the cannabis niche: a profound change in sentiment; once-demonized drugs are now viewed as legitimate medical solutions for high-need disorders.

Unlike in past decades, today's experts are looking closely at an array of medical solutions derived from psychedelics. These are real and viable treatments for the mood disorders that millions of individuals struggle with every day: addiction, anxiety, depression, post-traumatic stress disorder (PTSD), and more.

For many years, psychedelics have been known to produce a heightened state of consciousness and have been used for personal development or to facilitate the healing of emotional disturbances and “diseases of despair”.

Generally, psychedelics were classified in the 1960's and 1970's as Schedule I drugs under the United States Controlled Substances Act – and they're still federally branded as illicit even today. Significant progress is made in advancing psychedelic medicine and reforming the laws and regulations surrounding these promising treatments.



Abbreviations: LSD: Lysergic acid diethylamide, MDMA: 3,4-methylenedioxyamphetamine

Courtesy: rootsanalysis.com

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The seeds of reform were planted many years ago; instances of addictive behavior reduction through the use of entheogens (plant-based medicines that provide a spiritual experience) have been [studied](#) and observed since the 1950's.

In North America and around the world, recent changes in policy are resulting in what MAPS (Multidisciplinary Association for Psychedelic Studies) executive director Rick Doblin [describes](#) as “a global renaissance in public and scientific interest, regulatory approvals and funding for psychedelic research.”

Over time, there's been a global domino effect; research repeatedly demonstrated the therapeutic value of psychedelics – and regulators eased restrictions and even overturned outdated laws surrounding these promising medical therapies:

- **2001:** Portugal effectively [decriminalizes the possession of all drugs](#).
- **2005:** The New Mexico Court of Appeals [decides](#) that growing hallucinogenic mushrooms isn't illegal.
- A [2006 study](#) conducted by Johns Hopkins University found that psychedelic mushrooms can provide [substantial and sustained personal meaning and spiritual significance](#) 14 months after ingestion.
- **December 2008:** The Netherlands [establishes](#) specific limits for the possession of fresh and dry psychoactive mushrooms.
- **2009:** Possession of up to 40 psilocybin mushrooms is [decriminalized](#) in the Czech Republic.
- **May 2011:** The FDA [approves](#) a study of MDMA-assisted psychotherapy to treat PTSD that found that after two months, over 80% of subjects no longer met the diagnostic criteria for PTSD and after 41 months, PTSD scale scores declined even further.
- **2015:** A significant long-term study of 19,000 people, who reported using psychedelics, [concludes](#) that the use of psychedelic drugs could not be found to cause psychological distress, anxiety, depression, or suicidal thoughts.
- **January 2016:** Possession of psilocybin mushrooms is [decriminalized](#) in Austria.
- **2016:** A [double-blind study](#) at Johns Hopkins University determines that 80% of participants showed clinically [significant decreases in depressed mood and anxiety](#) after six months of magic mushroom usage.
- **2017:** A large-scale U.K. research study [concludes](#) that psilocybin shows promise as a potential treatment for obsessive-compulsive disorder, alcohol and tobacco addiction, and anxiety.
- **October 2018:** The U.S. Food and Drug Administration (FDA) [grants breakthrough therapy designation](#) to a company for its use of psilocybin in addressing treatment-resistant depression. Granting breakthrough therapy status can [greatly accelerate](#) the process of drug development and review.

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- **March 2019:** The FDA [approves](#) a ketamine-like spray for people suffering from treatment-resistant depression.
- **November 2019:** The FDA once again [grants](#) breakthrough therapy status to the use of psilocybin in addressing treatment-resistant depression.
- **Early 2019:** Israel [becomes](#) the first government to approve a “Compassionate Use” program for MDMA-assisted psychotherapy for PTSD.
- **May 8, 2019:** Voters in Denver, Colorado, [approve](#) the United States’ first referendum on decriminalizing hallucinogenic mushrooms.
- **December 2019:** the FDA [approves](#) limited MDMA therapy.
- **August 2020:** The Canadian government [pledges](#) to respond to a petition calling for the decriminalization of psychedelics after it garners nearly 15,000 signatures. Canada [classifies](#) psilocybin mushrooms, for example, as a Schedule III drug, which is defined as posing some risks to public health in some situations.
- **2020:** A Johns Hopkins study [finds](#) that 80% of smokers quit after “one dose of psilocybin and research on 51 cancer patients showed the drug decreased anxiety and depression in 80% of those tested.”
- **November 3, 2020:** A meaningful day in the U.S. - voters in Oregon and Washington, D.C. dramatically change their respective states’ laws pertaining to psychedelics:
 - **In Oregon, the voters overwhelmingly passed Measure 109:** Legalize Psilocybin by a 56% majority; this measure will mandate that state health authority create a program for administering psilocybin products to people 21 and older.
 - Oregon’s Measure 110: Addiction Recovery Centers took it a step further by not only decriminalizing the personal possession for adults of a variety of drugs, but also allocating state funds towards health assessments, addiction treatment, harm-reduction efforts, and other services for people with addiction disorders.
 - Washington, D.C.’s Initiative 81: The Entheogenic Plants and Fungus Measure – which passed by a 76% “yes” vote – declare that police must now treat the non-commercial cultivation, distribution, possession, and use of entheogenic plants and fungi (including DMT and psilocybin) among the lowest law enforcement priorities.

| Updated Dec. 4, 2020 | | |
|----------------------|-----------|--------------|
| Answer | Votes | Pct. |
| ✓ Yes | 1,333,268 | 58.5% |
| No | 947,313 | 41.5 |
| Total reported | 2,280,581 | |

Oregon’s Vote Count for Measure 110. Courtesy: New York Times

The movement in support of decriminalization for psychedelic medicine is gaining momentum and is influencing the scientific and regulatory regimes of multiple geographies.

In our opinion, additional U.S. states will continue to grant millions of untreated and under-treated patients with access to these life-changing medicines, by way of reforming regulations in the coming years.

Access to psychedelics-based treatments, particularly in the area of addiction treatment, is important because the currently prevalent, conventional methodologies are woefully inadequate, judging by their results.

The go-to treatment of prescribing pills has numerous problems. They're only partially effective or even entirely ineffective in solving the problem. The pills that are prescribed are themselves highly addictive and can have unwanted side effects.

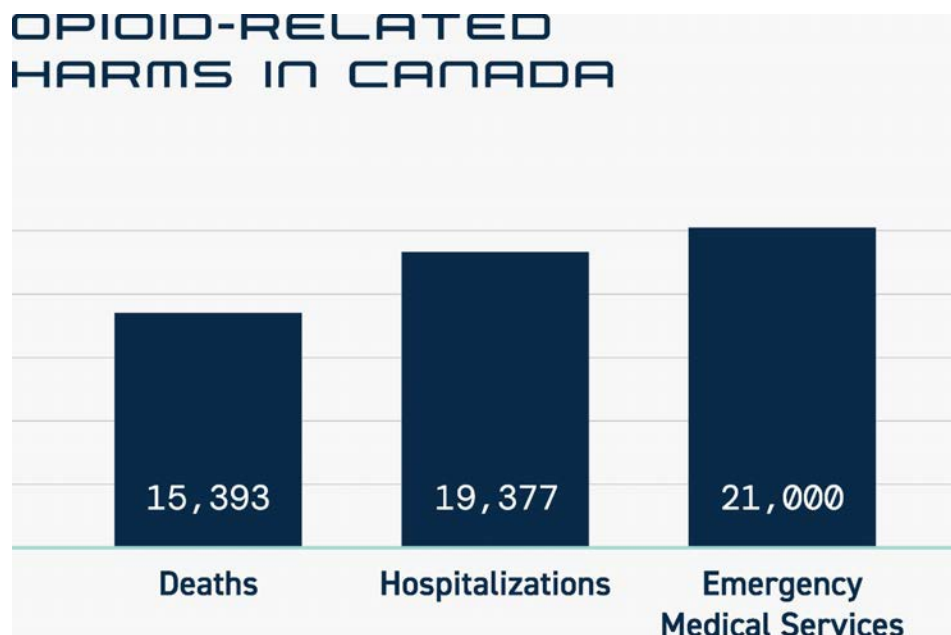
Addiction treatment centers that utilize the 12-step model might only offer limited help to people who struggle with addiction. On top of that, these programs can cost up to \$650/day and may require the patient to stay at a clinic for 60 to 90 days of detox, followed by recovery work.

Traditional approaches have mostly failed to properly address an issue that has torn apart families, cost taxpayers billions, and taken far too many lives. Addiction is a deep problem and conventional methods simply aren't getting the job done:

- The U.S. Surgeon General's Report on Alcohol, Drugs and Health [confirmed](#) that only a small fraction of those in need of treatment – around 10% of people with a substance use disorder – receive any type of specialty treatment at all.
- The INCB produced a report estimating that only one in six problem drug-users worldwide (roughly 4.5 million people) receive the required treatment, at a global cost of about \$35 billion annually.
- From 2015 to 2017, hospitalizations for opioid overdoses or complications increased to about 17 admissions each day, and between 2016 and 2019, Canada lost 15,393 lives to the opioid crisis.
- As [reported](#) in the 2018 National report of the First Nations Regional Health Survey, 24.9% of adults and 10.4% of youths between the ages of 12 and 17 reported opioid use.
- Nearly 21 million Americans have at least one addiction, and approximately 2.1 million Americans have an opioid use disorder.
- Since 1999, the sale of opioid painkillers has increased by 300% – and about 20% to 30% of people, who take prescription opioids, misuse them.
- More than 90% of people, who have an addiction, started to drink alcohol or use drugs before they were 18 years old.
- About 20% of Americans, who have depression or an anxiety disorder, also have a substance use disorder

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- Drug overdose deaths have more than tripled since 1990, and about 130 Americans die every day from an opioid overdose.
- Alcohol and drug addiction cost the U.S. economy more than \$600 billion every year.



Courtesy: Entheon Biomedical

The realm of psychedelic medicine offers the hope of safer and more effective treatments where conventional approaches have failed. Among the most promising treatment possibilities is dimethyltryptamine, commonly known as DMT. Unlike many of the compounds found in medications that people take nowadays, DMT is naturally occurring and is not generally known to be addictive.

- DMT is widely found in many plant and animal species, and even in the human brain, and is well tolerated and metabolized in humans.
- It's been determined that the human body's naturally occurring DMT may be involved in various physiological processes including stress reduction and protection, anti-inflammation, immune responses, neuroplasticity, or dream consciousness.
- Moreover, it has been proposed in the scientific community that DMT can actually increase the brain's neuro-plasticity and even promote the formation of new neural connections, or synapses.
- Animal studies have shown that DMT promotes neuro-plasticity, neuronal growth and increased synaptic connections – processes correlated with improvements in depressive symptoms. Electroencephalogram (EEG) observations of DMT's effects on brain waves have also shown changes hypothesized to be beneficial for depression.
- A survey study done in conjunction with Ohio State University found that around 80% of people using the psychedelic substance 5-MeO-DMT in a ceremonial setting said that their depression or anxiety improved following its use.

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- In line with that study, Ohio State University researcher Alan Davis actually suggested that the symptomatic improvement occurred in an hour or less: “One of the interesting things about 5-Meo-DMT is that the duration of effect is anywhere from 20 to 60 minutes.”
- Dr. Malin Vedøy Uthaug’s dissertation work suggests that both ayahuasca (which contains DMT as the psychoactive ingredient) and 5-MeO-DMT used in a naturalistic setting are associated with persisting betterment (up to four weeks) in mental health-related variables.
- While other drugs in the psychedelics class can produce intense effects that last up to 12 hours, the effects of DMT are typically more gradual, less jarring, and much shorter in duration.

A POWERFUL THERAPY TOOL

DMT

containing brew ayahuasca has been used for many centuries as a way of treating mood disorders, addiction, and psychological problems

Studies between 1990-2015 have found that ayahuasca does show capabilities of treating many problems including:

- Drug addiction of all kinds
- Depression
- Anxiety
- Addiction to cigarettes
- Addiction to alcohol



Courtesy: evergreendrugrehab.com

The potential for DMT to serve as the basis of novel treatments for drug addiction is potentially vast, yet largely untapped. Even today, scientists are grappling with the question of exactly what biological role DMT plays in the human body.

What we know already is that leading experts in the field suggest that the revolutionary healing potential of DMT and psychedelics (in general) is based on fundamental, positive shifts in how we think and how people see the world around them.

According to Timothy Ko, CEO of Entheon Biomedical (CAD: ENBI & US: ENTBF), the use of psychedelics can open up components of openness and self-transcendence in patients.

From a neuro-plasticity perspective, it allows the user to face more difficult elements of thinking. Psychedelics are known to change one’s relationship to the default mode network so that it increases brain entropy and allows for more connectivity.



Entheon Biomedical (US: ENTBF) was founded on the principle that people suffering from life-inhibiting addiction disorders should have access to all scientifically validated treatment protocols.

Entheon's science board is [comprised](#) of experts in the field of neuro-pharmacology, genetics, psychiatry, and substance use disorders. The team aims to formulate a proprietary DMT therapy that is intended to have specific therapeutic applications, which target addiction and substance-related disorders.

Along with an industry-leading science board, Mr. Ko has also assembled an all-star team of executives, including:

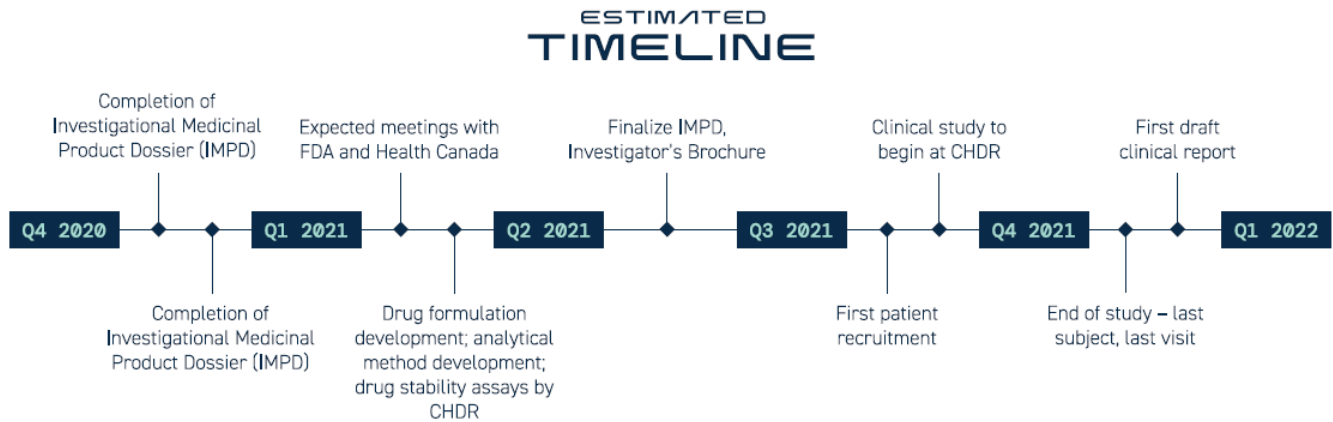
- » **CFO Brandon Schwabe**, who has extensive experience with private enterprises engaged in large capital projects and understands the unique challenges they face.
- » **Director of Operations and Chief Science Officer Andrew Hogle**, who has a background in molecular biology and biochemistry and has published research investigating the role of membrane receptor proteins in physiology, behavior and disease.
- » **Project Manager Yaron Eshel**, who has navigated the U.S., European, Israeli and Australian regulatory agencies including the registration of manufacturing facilities in the U.S., Central America, Israel, and Australia to Good Manufacturing Practice levels.
- » **Board Member Christopher Gondi**, a professor of cancer biology with extensive experience dealing with brain tumors and pancreatic cancer, for which the survival rates are very low.
- » **Board Member Ruth Chun**, a corporate commercial lawyer who served as the first female executive at a leading insurer in southern Africa as the head of legal and compliance and was a partner at Africa's largest law firm.

Entheon's CEO has noticeable expertise in the psychedelic medicine domain as well as a broad background of leading private ventures in different sectors. Together with his team of experts, Mr. Ko is ambitiously pursuing leading-edge research in pursuit of full FDA, Health Canada, and EMA regulatory approval for DMT-based therapeutics to treat addiction disorders.

Entheon's proposed delivery system is unique, since it titrates DMT into the body, allowing for a gradual, more comfortable transition to the psychedelic state.

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The ability to control the duration and intensity of DMT's effects, along with the ability to rapidly end the experience, will allow clinicians to provide the therapeutic effects of hallucinogens in a safer, more controlled and patient-specific manner.



Entheon Biomedical's Estimated Timeline

The ultimate objective is to invert the addiction-recovery ratio, thereby offering products to those that suffer from the above issues.

Entheon's progress has been consistent:

- ✓ The company has [entered](#) into a Clinical Study Agreement with the Contract Research Organization (CRO) Centre for Human Drug Research (CHDR) to conduct an early-phase human clinical trial with DMT.
- ✓ Furthermore, Entheon has made a value-added strategic [investment in](#) *Wonder Scientific Inc.*, whose team of university researchers and product development experts create custom, naturally derived, active pharmaceutical ingredients to supply the growing global clinical and commercial demand for psychedelics.

This investment will provide Entheon with exposure in other verticals of the psychedelic therapy space as well as increased access to psychoactive pharmaceutical ingredients.

- ✓ Entheon has also announced a business arrangement with and strategic investment in Heading Health, a Texas-based psychiatric clinic platform focused on the administration of psychedelics-assisted therapy to treat mental health disorders.

Heading Health provides a full suite of therapies and diagnostic tools for the treatment of mental health challenges, including Spravato (esketamine) nasal spray for treatment-resistant depression (which has already been approved by the FDA), intramuscular (IM) ketamine, trans-cranial magnetic stimulation (TMS), and tele-psychiatry for depression, anxiety, PTSD and OCD.

- » The company [signed on](#) Scott Keeney to serve as the company's media adviser. He has been behind marketing campaigns and promotions for highly successful companies including T-Mobile, Daimler-Chrysler, Google, and Nike.
- » And on January 14th 2021, Entheon [completed its 100% acquisition](#) of *HaluGen Life Sciences Inc.*, which specializes in DNA testing for psychedelic assisted psychotherapy.

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This acquisition supports Entheon's innovative data-driven approach to developing psychedelic-assisted psychotherapeutic protocols to treat substance use-disorders and provides an opportunity to strengthen category leadership in psychedelic therapy and drug discovery.

Since Entheon Biomedial has already filed the important provisional patents in association with DMT therapy as an addiction treatment – and started the formal process of beginning clinical trials with DMT with a Contract Research Organization partner, while also forming key partnerships and making strategic investments – the company is following its guidance closely and executing accordingly.

Entheon Biomedical aims to continue addressing high-need areas, to establish advantageous partnerships, and to help clear the pathway to regulatory approval.

Conduct due diligence on Entheon Biomedical (CAD: ENBI & US: ENTBF)!

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On Sept 30th, 2020, in connection with our agreement with Entheon Biomedical Corp, we received \$250,000USD to Gold Standard Media LLC. This was for a 4 month agreement. Wallace Hill Partners LTD on September 26, 2020 purchased 750,000 common shares at CAD0.10.