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Psychedelic Trip to Wellness

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Psychedelics have been used throughout history for medical purposes before being classified as illicit drugs in the 1960s. But that's changing now, psychedelic drugs are gaining widespread attention as rigorous clinical trials have demonstrated their potential as a treatment for unmet needs in mental health. What explains this renaissance, how soon we will see psychedelic drugs in the market and most importantly where does big pharma stand in this? Let's find out.



The US Food and Drug Administration (US FDA) and European Medicines Agency (EMA) approved Johnson & Johnson's Spravato (esketamine) in 2019 for treatment-resistant depression, the first approval of a psychedelic treatment for a psychiatric disorder in both the US and the European Union. Esketamine is derived from the anaesthetic ketamine. This opened the floodgates of interest in psychedelic space. To date, two psilocybin-based drugs have received FDA breakthrough designation – UK's COMPASS Pathways for treatment-resistant depression and US' Usona Institute for major depressive disorder.

This, along with the fact that mental health disorders, have risen exponentially but the development of novel medications has not kept pace. Drugs such as use of MDMA (3-4 methylenedioxymethamphetamine), psilocybin, and LSD (lysergic acid diethylamide) are traditionally considered to be recreational but are increasingly being used in medical research.

A report from Research And Markets says that the psychedelic drugs market size is projected to reach $10.75 billion by 2027, from $4.75 billion in 2020 growing at a CAGR of 12.36 per cent during 2021-2027.

''The whole field is advancing in industry and academia, with many new groups in neuropsychopharmacology around the world developing and using techniques from animal models, to human studies with MRI to map neural networks in order to better understand the mechanisms of action. Add to that psychotherapy research and training to better apply these methods in combination with psychoactive compounds to achieve outcomes that exceed use of the drug alone. I think that the R&D is reaching a critical mass and really impactful innovations are not so far out,'' said Dr Nathan Bryson, Chief Scientific Officer at Field Trip Health Canada.

Unleashing potential of psychedelics

The research and development of psychedelic medicine and therapies has seen a renaissance period in the last few years resulting in key data, proving its potential to treat a wide range of mental health indications, including cancer related distress, depression, anxiety, addiction and many more.

‘‘People often forget that more than five decades of psychedelic research has already taken place. This research has been conducted by world class institutions, including US’ Johns Hopkins, NYU, UK’s King's College, University of Toronto, Canada and Imperial College,UK. Recently, there has been increased attention on research in this field for several reasons. First, the issue of mental health - which was already huge - is now at epidemic levels, exacerbated by the impact of COVID-19. Second, attitudes towards mental health have evolved and matured to the point where it is now “Ok to not be ok”. More people are seeking treatment and are interested in alternatives to traditional pharmaceuticals - whether it's because they are worried about side effects from medication like weight gain or sexual dysfunction, dependency, or other undesired consequences. A third driver is the evolving of public policy in this area. We're seeing a push for decriminalisation of certain restricted compounds in various jurisdictions. We're seeing the demand for more compassionate use - especially with respect to end-of-life exemptions for psychedelic assisted therapy. We're even seeing the Drug Enforcement Administration in the U.S. increase limits on the quantity of these compounds that researchers can hold. These forces have led to the “Shroom Boom” with many new companies pursuing various indications, including anxiety, depression, Post traumatic stress disorder (PTSD), and substance abuses. These companies have attracted investors, and new capital has flowed into the psychedelic research business resulting in an acceleration of the number of studies underway,’’ said Tim Moore, CEO of HAVN Life, Canada.

HAVN Life Sciences is a biotechnology company pursuing standardised extraction of psychedelic compounds for the creation of API.

For the last several decades, psychedelic drugs were the subject of multi-decades research led by select academic researchers and a small number of not-for-profit groups with the goal of establishing the safety of psychedelic drugs, along with some preliminary efficacy data demonstrating their potential to treat neuropsychiatric and mood disorders.

‘‘In the last few years, investment capital has begun to flow to for-profit ventures that were formed with the goal of developing psychedelic drugs into approved therapeutics by advancing them along established regulatory pathways. These efforts have mainly focused on formulations of known, public domain psychedelic drugs. On the back of these research efforts, MDMA and psilocybin have made significant progress towards gaining FDA approval for use in the treatment of post-traumatic stress and treatment-resistant depression,’’ said James Lanthier, Chief Executive Officer (CEO), Mindset Pharma, Canada.

Mindset Pharma was formed in order to discover and develop "next generation" psychedelic drugs that are chemically novel and have been optimised to address some of the shortcomings of "first generation" psychedelic drugs. In January 2022, Mindset partnered with Japans’ Otsuka Pharmaceuticals, which is the first entrance of a global pharma player into the new psychedelic drug space.

The most advanced programmes are American not for profit Multidisciplinary Association for Psychedelic Studies (MAPS)' successful Phase III trial for MDMA in Post traumatic stress disorder and UK’s Compass Pathways COMP360 (psilocybin) with a positive Phase 2b in treatment resistant depression.

“We expect MDMA to be approved for treating PTSD by 2023, and addiction by 2025,” said Anthony Tennyson, CEO of Awakn Life Sciences, Canada, a biotechnology company, researching, developing, and delivering psychedelic therapeutics to better treat addiction.

Apart from this there are 13 other candidates in Phase II trials and 12 in initial stages of the trial (I). Most of these compounds are being researched for treating different categories of depression.

Where’s big pharma?

In January 2022, Japan’s Otsuka Pharmaceutical inked a deal with Canada’s Mindset Pharma to support the development of psychedelic medicines. This is the first ever deal by a big pharma firm in this space. While big pharma has wholeheartedly invested in the cannabis sector in recent times, it hasn’t shown the same interest or investment in psychedelic drugs.

‘‘The “big pharma” industry is currently in the process of evaluating the merits of the biology, science and quality of ongoing research at academic centers, non-profit and commercial organisations. A few advanced programmes are currently leading the way to demonstrate significant benefits for patients and value for investors. Most psychedelic companies are not in a

position of producing revenue as they are engaging in clinical trials to prove that the compounds work on specific ailments. Once positive data is generated, big pharma is expected to take notice followed by investment action, which has recently been the case with Tokyo-based Otsuka Pharmaceutical,'' said Dr Bob Dagher, Chief Medical Officer at Enveric Biosciences, USA.

Enveric Biosciences is developing next-generation mental health and oncology supportive care treatments, along with a clinical discovery platform, leveraging psychedelic-derived molecules for the mind and synthetic cannabinoids for the body.

While the cannabis sector had a head-start, both the healthcare industry, as well as the general population are now embracing psychedelics as the next generation of mental health treatment, with growing acceptance and a change in public perception.

''In 2020, US' Oregon passed Measure 109 – a ballot allowing regulated use of psilocybin in a therapeutic setting. This served as a landmark moment for psychedelic medicine, as it paved the way for safe and legal treatment in the space.That being said, it is clear that there is interest from big pharma, however, we should expect gradual adoption as new and positive research is published,'' said Dr Dagher.

Despite the promising early research into psychedelic drugs, their regulatory status has meant that big pharma had few incentives to undertake the necessary research to develop psychedelic drugs into medicines. This along with the fact that the molecules that are most advanced clinically like psilocybin are non patentable.

"This makes those compounds less attractive to big Pharma. Typically, big pharma will wait for clinical evidence before entering into a partnership. The patent protected second generation molecules, such as ours at Bright Minds, have yet to reach those milestones. However, big pharma is on the sidelines and have started to dip their toes in. Expect this to accelerate as more clinical data comes in,'' said Josh Blacher, Vice President, Corporate Development, Bright Minds Biosciences, a Canadian biotech company that engages in the development of serotonergic therapeutics to treat mental health disorders.

"I think there is still a bit too much risk in the delivery and economics" said Dr Bryson.

He added, ''Today, therapy is a modern version of traditional shamanistic practices, with guided sessions to achieve drug-induced introspection a catalyst for therapy sessions. This delivery model is still in its infancy. In addition, very durable outcomes appear to be achievable with "generic" molecules (psilocybin and MDMA are unpatentable). So, it is difficult to understand the pharmacoeconomic model that leads to profitability. I think it will be the arrival of better tailored NCE molecules, designed for purpose, with safety and efficacy, convenience and most importantly patent exclusivity and which ultimately can be priced so as to be ROI positive that will make Big Pharma pay attention.''

The regulatory system for psychedelics is still patchy and most of these compounds are restricted to use and classified as controlled substances but the USFDA and other regulatory agencies around the world are working towards creating a strong regulatory network.

Psychedelic medicines offer a promising new treatment paradigm and will open a new frontier in mental health treatment.

Ayesha Siddiqui