MindMed

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MindMed seeks to harvest the power of psychedelics to treat mental health disorders

- Develops psychedelic medicines to improve health, promote wellness and alleviate suffering
- Working with LSD, DMT, 18-MC, and MDMA as possible therapies for anxiety, addiction, cluster headaches, and adult ADHD
- Eyeing Investigational New Drug application to US FDA to treat anxiety disorders with LSD

What Mind Medicine does:

Mind Medicine (MindMed) Inc (NEO:MMED) (OTCQB:MMEDF) is a neuro-pharmaceutical company developing psychedelic medicines to improve health, promote wellness, and alleviate suffering.

The New York City-based company currently has several projects in various stages from planning to ongoing clinical trials involving the legendary drug lysergic acid diethylamide (LSD) as well as NDimethyltryptamine (DMT), the active ingredient in the ayahuasca plant, and 18-MC, a non-hallucinogenic molecule derivative of ibogaine from the African plant iboga.

The company also has a fourth drug in its research and development pipeline - MDMA. The compound may have the potential to treat mental health disorders. MindMed has acquired the exclusive license to nine completed clinical trials of MDMA at University Hospital Basel's Liechti Lab in Switzerland.

Also, at the Liechti Lab, MindMed's researchers and clinicians are working on two other separate projects involving LSD treat anxiety disorders and cluster headaches (also known as suicide headaches). Both clinical trials are entering Phase 2.

The company is also advancing plans to launch a Phase 2 clinical trial in late 2020 to address adults suffering from attention deficit hyperactivity disorder (ADHD). The Liechti Lab and Maastricht University of The Netherlands will spear-head the study and hold trials in both countries.

In Australia, amid the coronavirus-related shutdowns and safety protocols, MindMed managed to remain on track for research on the treatment of opioid withdrawal and opioid abuse disorder. In July it completed a Phase 1 human safety trial of the 18-MC molecule, finding it well-tolerated. MindMed is planning to begin Phase 2 trials in the fourth quarter of 2020.

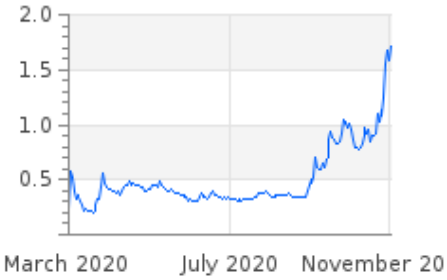
As for DMT, the company is providing startup funding to the Liechti Lab for a Phase 1 clinical trial, testing various intravenous dosing regimens. It is expected to begin in the fourth quarter of 2020, setting the stage for future potential Phase 2a proof of concept trials to understand how humans react to DMT, as it causes a rapid onset much like LSD. When administered as an ayahuasca brew, DMT can prolong experiential effects and slow metabolism. The company says the substance could help with addiction disorders.

How is it doing:

Price: 1.6557

Market Cap: $464.75 m

1 Year Share Price Graph



Share Information

Code:		MMEDF
Listing:		OTCQB
52 week	**High**	**Low**
	1.98	**0.0833**
Sector:		**Pharma & Biotech**
Website:		**www.mindmed.co**

Company Synopsis:

MindMed is a neuropharmaceutical drug development platform advancing medicines based on psychedelic substances through rigorous science and clinical trials. MindMed's mission is to discover, develop and deploy psychedelic inspired medicines that alleviate suffering and improve health.

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In March this year, MindMed made history by becoming the first psychedelics pharmaceutical firm to go public following a successful IPO on the NEO Exchange. Just before going public, the company completed a pre-IPO financing round that raised US$24.2 million, giving it a sufficient runway to fund operations and drug developments. Shark Tank's Kevin O'Leary is one of the lead investors.

On the testing front, MindMed is primarily focused on advancing plans in partnership with the Liechti Lab to test LSD as a possible treatment for anxiety disorders.

In fact, the company in June launched a commercial drug development program Project Lucy that calls for a Phase 2b human efficacy trial to focus on experiential LSD doses administered by a therapist. MindMed says the trial would be the first experiential, psychedelic-assisted therapy to be added to its drug development pipeline.

The company also has established a Project Lucy taskforce that is working to prepare and analyze data for an eventual US Food and Drug Administration (FDA) briefing package that could underpin a potential Investigational New Drug (IND) application for the treatment of anxiety disorders.

In addition, patients are currently being dosed with LSD in a Phase 2 clinical trial at the Liechti Lab as a possible treatment for cluster headaches -- also known as "suicide headaches" due to the severity of the pain caused.

These headaches are viewed as one of the most profoundly painful conditions known to mankind, as the pain occurs on one side of the head or above an eye and can last for weeks or months. Studies have demonstrated increased suicidality associated with patients experiencing cluster headache attacks. MindMed researchers hope LSD can help abort such attacks and decrease the frequency and intensity of the attacks.

The Phase 2 study involves 30 patients who will receive oral doses for three weeks compared with a placebo. The trial is a double-blind, randomized, placebo-controlled two-phase cross-over study design.

MindMed's collaboration on the study will assess if there is clinical evidence for a future commercial drug trial through the FDA. Treatments for cluster headaches may potentially qualify for an Orphan Drug Designation and be eligible for certain development incentives that the FDA provides for rare diseases.

At the Liechti Lab, the company has acquired exclusive, worldwide data rights to eight completed or ongoing LSD clinical trials conducted for 10 years. MindMed has also received the data and worldwide rights to an additional ongoing Phase 2 trial for the treatment of anxiety disorders administered by the world leader in psychedelics pharmacology and clinical research, Dr Matthias Liechti, and psychedelic therapy expert, Dr Peter Gasser.

MindMed, which hopes to turn its understanding of LSD into a prescription medication for serious mental health conditions, plans to assemble and use the data from the Phase 2 trial as part of its briefing package to the FDA for the IND.

The company has noted that many mental health disorders appear to be interconnected. For example, 50% of ADHD patients (MindMed wants to treat adult ADHD symptoms as well) also suffer from anxiety disorders and the vast majority of patients with General Anxiety Disorder also have symptoms of another mental health problem, such as depression or substance abuse.

Given such data, MindMed sees a large opportunity to create a novel treatment platform that incorporates both experiential psychedelic-assisted therapy and non-hallucinogenic take-home medicines.

To strengthen its intellectual property, MindMed has filed three patents in recent months. Two separate patent applications call for the protection of technologies that screen and optimize the dosing of MDMA and LSD. The third patent application is for an LSD neutralizer technology intended to shorten and stop the effects of an LSD trip (which can last 12 hours or more) during a therapy session.

Inflection points:

- Launch microdosing LSD clinical trial in late 2020 for ADHD adults
- Start Phase 2 trials of 18-MC for opioid use disorder treatments in late 2020
- Expect DMT dosing regimens to begin in 4Q 2020
- Anticipate Phase 2b human efficacy LSD trial to treat anxiety disorders
- Use data from current Phase 2 LSD-anxiety trial to form FDA briefing package for IND

What the boss says:

"We believe that hallucinogenic therapies have great merit and benefits for treating addiction. But, undergoing a 'psychedelic trip' might be a daunting proposition to some patients," said MindMed Co-Founder and Co-CEO JR Rahn.

"We want patients to pick up these medicines from their local pharmacy with a prescription. We feel there is an immense opportunity to create next-gen versions of psychedelics for approval as FDA drugs."

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