

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): January 25, 2022

MIND MEDICINE (MINDMED) INC.

(Exact Name of Registrant as Specified in Charter)

British Columbia, Canada
(State or Other Jurisdiction of Incorporation)

001-40360
*(Commission
File Number)*

98-1582438
*(IRS Employer
Identification No.)*

One World Trade Center, Suite 8500
New York, New York
(Address of Principal Executive Offices)

10007
(Zip Code)

Registrant's telephone number, including area code: **(650) 208-2454**

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Subordinate Voting Shares	MNMD	The Nasdaq Stock Market LLC

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On January 25, 2022 Mind Medicine (MindMed) Inc. (the "Company"), issued a press release announcing that the U.S. Food and Drug Administration has allowed the Company's Phase 2b dose-optimization trial of lysergic acid diethylamid (LSD) for the treatment of generalized anxiety disorder to proceed. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated January 25, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto

duly authorized.

Date: January 25, 2022

MIND MEDICINE (MINDMED) INC.

By: /s/ Cynthia Hu

Name: Cynthia Hu

Title: Chief Legal Officer & Secretary



FDA Clears MindMed IND for MM-120 in Treatment of Generalized Anxiety Disorder

- FDA clearance leads to first commercial IND for LSD, enabling initiation of Phase 2b dose-optimization trial of MM-120 in early 2022 -

NEW YORK, January 25, 2021 -- **Mind Medicine (MindMed) Inc.** (NASDAQ: MNMD), (NEO: MMED), (DE: MMQ) (the “Company”), a clinical-stage biopharmaceutical company developing psychedelic-inspired therapies for the treatment of brain-based disorders, announced today that the U.S. Food and Drug Administration (FDA) has cleared MindMed’s Investigational New Drug (IND) application, allowing the Company’s Phase 2b dose-optimization trial of MM-120 for the treatment of generalized anxiety disorder (GAD) to proceed.

The previously announced clinical hold on the IND was lifted following MindMed’s rapid responses for additional information related to the participant monitoring protocol in the upcoming study. The Company is working with study investigators and clinical trial sites to prepare for participant enrollment, which is expected to start in early 2022.

“FDA clearance of our Phase 2b clinical trial represents a major milestone, for MindMed and for the industry as a whole,” said Robert Barrow, Chief Executive Officer and Director of MindMed. “This trial, the first commercial study of LSD in more than 40 years, builds on productive discussions with FDA and provides an opportunity to explore improvements in anxiety symptoms following a single administration of MM-120. Further, the results of this trial will guide the dose selection and development strategy for our pivotal Phase 3 clinical trials, as well as deepen our scientific understanding of the clinical effects of MM-120 and its underlying mechanisms of action.”

Mr. Barrow continued, “With a clear regulatory path, we look forward to building on this momentum and advancing this trial as quickly and efficiently as possible, bringing us significantly closer to transforming the treatment landscape for patients who suffer from anxiety.”

About Study MMED008

Study MMED008 is a multi-center, randomized, double-blind, placebo-controlled, dose-optimization Phase 2b trial in patients with GAD. The trial plans to enroll a total of 200 participants who will receive a single administration of up to 200 µg of MM-120 or a placebo control. The primary objective of the study is to determine the reduction in anxiety symptoms for up to twelve weeks after a single administration of MM-120, compared across five treatment arms.

About Generalized Anxiety Disorder (GAD)

GAD is a chronic, often debilitating mental health disorder that affects approximately 6% of U.S. adults in their lifetimes. Symptoms of GAD include excessive anxiety and worry that persists for over six months, which can lead to significant impairments in social, occupational and other functioning, according to the National Institute of Mental Health (NIMH). While there is substantial diagnostic overlap between GAD, Major Depressive Disorder (MDD) and other major mental health disorders, there has been very little innovation focused on the treatment of GAD in the past several decades due to the shift in focus from anxiety disorders like GAD toward depressive disorders like MDD, driven by the marketing of serotonin reuptake inhibitors starting in the 1990s.



About MM-120

MM-120 is MindMed’s proprietary drug candidate, a pharmacologically optimized form of LSD being developed for GAD and other brain-based disorders. LSD was first synthesized in 1938 and its psychoactive properties were discovered in 1943. From 1949 to 1966, LSD was used by psychiatrists and researchers to gain insights into the world of brain health and to assist psychotherapy. LSD has been investigated for its applications in the treatment of anxiety associated with terminal cancer, alcoholism, opioid use disorder, and depression, among other conditions.

About MindMed

MindMed is a clinical-stage psychedelic medicine biotech company that seeks to discover, develop and deploy psychedelic-inspired medicines and therapies to address addiction and mental illness. The Company is assembling a compelling drug development pipeline of innovative treatments based on psychedelic substances including psilocybin, LSD, MDMA, DMT and an ibogaine derivative, 18-MC. The MindMed executive team brings extensive biopharmaceutical experience to MindMed's approach to developing the next generation of psychedelic-inspired medicines and therapies. MindMed trades on the NASDAQ under the symbol MNMD and on the Canadian NEO Exchange under the symbol MMED. MindMed is also traded in Germany under the symbol MMQ.

Forward-Looking Statements

Certain statements in this news release related to the Company constitute “forward-looking information” within the meaning of applicable securities laws and are prospective in nature. Forward-looking information is not based on historical facts, but rather on current expectations and projections about future events and are therefore subject to risks and uncertainties which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. There are numerous risks and uncertainties that could cause actual results and the Company’s plans and objectives to differ materially from those expressed in the forward-looking information, including history of negative cash flows; limited operating history; incurrence of future losses; availability of additional capital; lack of product revenue; compliance with laws and regulations; difficulty associated with research and development; risks associated with clinical trials or studies; heightened regulatory scrutiny; early stage product development; clinical trial risks; regulatory approval processes; novelty of the psychedelic inspired medicines industry; as well as those risk factors discussed or referred to herein and the risks described under the headings “Risk Factors” in the Company’s filings with the securities regulatory authorities in all provinces and territories of Canada which are available under the Company’s profile on SEDAR at www.sedar.com and with the U.S. Securities and Exchange Commission on EDGAR at www.sec.gov.

For Media: media@mindmed.co

For Investors: ir@mindmed.co

