
**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 8, 2024

MIND MEDICINE (MINDMED) INC.

(Exact name of Registrant as Specified in Its 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: (212) 220-6633

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
Common 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:

- 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 7.01 Regulation FD Disclosure.

On January 8, 2024, Mind Medicine (MindMed) Inc. (the "Company") issued a press release providing a corporate update and 2024 outlook. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or the Exchange Act, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, or the Securities Act. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the U.S. Securities Exchange Commission, or the SEC, made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated January 8, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MIND MEDICINE (MINDMED) INC.

Date: January 8, 2024

By: /s/ Robert Barrow
Name: Robert Barrow
Title: Chief Executive Officer

MindMed Announces Business Update and Anticipated Milestones for 2024

-- Recently announced statistically significant and clinically meaningful topline Phase 2b data for MM-120 in Generalized Anxiety Disorder (GAD) position for multiple data readouts and catalysts throughout 2024 including initiation of Phase 3 clinical program --

-- Proof-of-Concept study evaluating repeated sub-perceptual dose (20 µg) of lysergide in adults with Attention-Deficit/Hyperactivity Disorder (ADHD) did not meet primary endpoint; no further development activities planned for sub-perceptual dose regimen --

-- Phase 1 Single Ascending Dose Study of MM-402 in Healthy Participants initiated in Q4 2023 --

NEW YORK, January 8, 2024 – Mind Medicine (MindMed) Inc. (NASDAQ: MNMD), (NEO: MMED), (the "Company" or "MindMed"), a clinical stage biopharmaceutical company developing novel product candidates to treat brain health disorders, today provided a corporate update and outlook for 2024.

"Our strong progress in 2023 culminated in the delivery of statistically and clinically significant topline results for our lead program (MM-120) in our Phase 2b study of GAD. These positive results reinforce our scientific understanding of the mechanism of action for MM-120 and emphasize the critical role we believe the perceptual effects of MM-120 play in driving clinical outcomes," said Rob Barrow, Chief Executive Officer and Director of MindMed. "We are excited to enter 2024 with an enhanced focus on our lead program. In 2024, we plan to continue working diligently and efficiently to advance our MM-120 program into Phase 3, bringing us one step closer to potentially providing a new treatment option to the millions of patients suffering from GAD. We anticipate several key data milestones for our MM-120 program in 2024, including full 12-week results for MM-120 in GAD, results from our Phase 1 pharmacokinetics bridging study to support advancement of our MM-120 ODT formulation into pivotal clinical trials and additional results from our collaborator University Hospital Basel's one-year follow-up study of lysergide in anxiety disorders. We will be working closely with the FDA to finalize our Phase 3 development program for MM-120 in GAD and expect to hold our End-of-Phase 2 meeting with FDA in the first half of the year with initiation of our Phase 3 clinical program in the second half of the year."

Business Update

- MindMed's management team will participate in the BIO Partnering at the J.P. Morgan Healthcare Conference in San Francisco that is being held from January 8-11, 2024.
 - The Company expects to host an analyst and investor day in the first half of 2024, at which the Company plans for its senior management, a physician expert and other leading key opinion leaders to provide an update on the Company's lead development program MM-120 and discuss the treatment landscape, potential market and commercial opportunity for MM-120 in GAD and other psychiatric disorders.
-

Development Program Updates and Anticipated Milestones

MM-120 (lysergide D-tartrate)

- Generalized Anxiety Disorder (GAD): In December 2023, the Company announced statistically significant and clinically meaningful topline 4-week results from the 198-patient Phase 2b dose-optimization study of MM-120 for the treatment of GAD.
 - MM-120 100 µg – the dose achieving the highest level of clinical activity – demonstrated a 7.6-point reduction on the Hamilton Anxiety rating scale (HAM-A) compared to placebo at Week 4 (-21.3 MM-120 vs. -13.7 placebo; $p < 0.0004$; Cohen's d effect size=0.88), which is more than double the effect sizes seen with the current standards of care¹¹.
 - Clinical response (50% or greater improvement in HAM-A) at Week 4 was achieved in 78% of participants treated with MM-120 (100 µg or 200 µg) compared to 31% for placebo.
 - Clinical remission (HAM-A ≤ 7) at Week 4 was achieved in 50% of participants treated with MM-120 100 µg.
- The Company plans to share topline 12-week results from the Phase 2b study by the end of the first quarter of 2024, and present full results at a scientific meeting in 2024.
- The Company intends to share results in the first quarter of 2024 from its pharmacokinetics bridging study of the MM-120 Zydis® orally disintegrating tablet (ODT) formulation, its intended commercial formulation of MM-120 formulation that may enhance intellectual property and market protection with a potentially differentiated biopharmaceutical profile.
- The Company plans to hold an End-of-Phase 2 meeting with the FDA in the first half of 2024 and expects to initiate its Phase 3 clinical program in the second half of 2024.
- One-year follow-up data from a Phase 2 placebo-controlled investigator-initiated clinical trial of lysergide in the treatment of anxiety disorders is anticipated in 2024. This study was conducted by the Company's collaborators at University Hospital Basel (UHB) in Switzerland.
- Attention-Deficit/Hyperactivity Disorder (ADHD): The Company's 53-patient Phase 2a proof-of-concept trial in ADHD was designed to assess the safety and efficacy of repeated sub-perceptual dose (20 µg) lysergide administration and did not meet its primary endpoint. In conjunction with the findings from our study of MM-120 in GAD, we believe that these results support the critical role of perceptual effects of MM-120 in mediating a clinical response. The Company intends to continue prioritizing development of its MM-120 program in GAD and other psychiatric indications, using the single perceptual dose (100 µg or greater) regimen that has shown strong positive results in numerous studies.

MM-402 (R(-)-MDMA) for Autism Spectrum Disorder (ASD)

- The Company initiated its first clinical trial of MM-402 (R(-)-MDMA), a single-ascending dose study in adult healthy volunteers in Q4 2023. This Phase 1 study is intended to
-

characterize the tolerability, pharmacokinetics and pharmacodynamics of MM-402 and will enable further clinical studies to characterize the effects of repeated daily doses of MM402 and the exploration of early signs of efficacy in the ASD population.

- In October 2023, the Company presented results from a MM-402 nonclinical study in a model of ASD, titled “MM-402 demonstrates better efficacy than S(+)-3,4-MDMA or (±)-3,4-MDMA in Fmr1 knockout mice, an animal model of autism spectrum disorder” at the 36th Annual European College of Neuropsychopharmacology (ECNP) Congress.

- UHB is currently conducting a Phase 1 investigator-initiated trial of R(-)-MDMA, S(+)-MDMA and R/S-MDMA in healthy adult volunteers. This trial is designed to assess the tolerability, pharmacokinetics and acute subjective, physiological and endocrine effects of the three molecules. The Company anticipates topline results to be presented in the first half of 2024.

About MM-120

Lysergide is a synthetic tryptamine belonging to the group of classic, or serotonergic, psychedelics, which acts as a partial agonist at human serotonin-2A (5-hydroxytryptamine-2A [5-HT_{2A}]) receptors. MindMed is developing MM-120 (lysergide D-tartrate), the tartrate salt form of lysergide, for GAD and other psychiatric indications.

About MM-402

MM-402 is our proprietary form of R(-)-MDMA (rectus-3,4-methylenedioxymethamphetamine), which we are developing for the treatment of core symptoms of autism spectrum disorder (ASD). MDMA is a synthetic molecule that is often referred to as an empathogen because it is reported to increase feelings of connectedness and compassion. Preclinical studies of R(-)-MDMA demonstrate its acute pro-social and empathogenic effects, while its diminished dopaminergic activity suggest that it has the potential to exhibit less stimulant activity, neurotoxicity, hyperthermia and abuse liability compared to racemic MDMA or the S(+)-enantiomer.

About MindMed

MindMed is a clinical stage biopharmaceutical company developing novel product candidates to treat brain health disorders. Our mission is to be the global leader in the development and delivery of treatments that unlock new opportunities to improve patient outcomes. We are developing a pipeline of innovative drug candidates, with and without acute perceptual effects, targeting the serotonin, dopamine, and acetylcholine systems.

MindMed trades on NASDAQ under the symbol MNMD and on the Canadian NEO Exchange under the symbol MMED.

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. These statements generally can be identified by the use of forward-looking words such as "will", "may", "should", "could", "intend", "estimate", "plan", "anticipate", "expect", "believe", "potential" or "continue", or the negative thereof or similar variations. Forward-looking information in this news release includes, but is not limited to, statements regarding anticipated upcoming milestones, trials and studies; results and timing of and reporting of topline data from clinical trials, the potential benefits of the Company's product candidates; potential additional psychiatric indications for MM-120; the timing of a potential End-of-Phase 2 meeting with the FDA; and the Company's expectations to publish data from the Phase 2b trial for MM-120 in a peer-reviewed publication and present such data at a scientific meeting in 2024. 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; 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 in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and its Quarterly Report on Form 10-Q for the periods ended March 31, 2023, June 30, 2023 and September 30, 2023 under headings such as "Special Note Regarding Forward-Looking Statements," and "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other filings and furnishings made by the Company 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. Except as required by law, the Company undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events, changes in expectations or otherwise.

For Media: media@mindmed.co

For Investors: ir@mindmed.co

¹¹ Source: RB Hidalgo, J Psychopharmacol. 2007 Nov;21(8):864-72.
