
**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): April 14, 2023

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: (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
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 April 14, 2023, Mind Medicine (MindMed) Inc. (the “Company”) issued a press release titled “MindMed Collaborators Announce Positive Data from Phase 2 Trial of Lysergide (LSD) in Major Depressive Disorder,” (the “Press Release”), which presents positive topline data from a double-blind, investigator-initiated trial evaluating lysergide in the treatment of Major Depressive Disorder at the University Hospital Basel (UHB) and the University Hospital of Psychiatry. A copy of the Press Release is attached as Exhibit 99.1 to this Current Report on 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

As disclosed in the Press Release, the high dose lysergide regimen in which patients received 100 µg at their first dosing day and 200 µg at their second dosing day (separated by four weeks) resulted in statistically and clinically significant improvements on the primary endpoint, which was the change in clinician-rated Inventory of Depressive Symptomatology (IDS-C) scores 6 weeks after the first administration as compared to control (whether or not the patient received a second administration). The control group in this study received a lower dose regimen of 25 µg on both treatment days. Patients in the high dose arm (n=28) demonstrated a least square mean change from baseline in IDS-C scores of -12.9 points compared to -3.6 points in the lower dose arm (n=27, p=0.02). The statistically significant benefit as measured by IDS-C was maintained up to 16 weeks after the first administration compared to placebo (p=0.008). Data from the secondary endpoints were also encouraging. The investigational drug was generally well-tolerated, as indicated by reported adverse events, changes in vital signs and laboratory values.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated April 14, 2023
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: April 14, 2023

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

MindMed Collaborators Announce Positive Topline Data from Phase 2 Trial of Lysergide (LSD) in Major Depressive Disorder (MDD)

– Primary endpoint achieved statistically significant improvement in MDD symptoms –

– Confirmation of activity of lysergide in brain health disorders with direct relevance to MindMed’s MM-120 program in Generalized Anxiety Disorder (GAD) –

– Data presented on April 14, 2023 in Basel, Switzerland –

NEW YORK, April 14, 2023 — **Mind Medicine (MindMed) Inc** (NASDAQ: MNMD), (NEO: MMED), (the “Company” or “MindMed”), a clinical stage biopharmaceutical company developing novel products to treat brain health disorders, announced today that Prof. Matthias Liechti and Dr. Felix Mueller, MindMed collaborators at University Hospital Basel (UHB) and the University Hospital of Psychiatry, have released positive topline data from a double-blind, investigator-initiated trial evaluating lysergide in the treatment of MDD. These findings were presented on April 14, 2023 in Basel, Switzerland.

The topline data demonstrated significant, rapid, durable and beneficial effects of lysergide and its potential to mitigate symptoms of MDD. The high dose lysergide regimen in which patients received 100 µg at their first dosing day and 200 µg at their second dosing day (separated by four weeks) resulted in statistically and clinically significant improvements on the primary endpoint, which was the change in clinician-rated Inventory of Depressive Symptomatology (IDS-C) scores 6 weeks after the first administration as compared to control (whether or not the patient received a second administration). The control group in this study received a lower dose regimen of 25 µg on both treatment days. Patients in the high dose arm (n=28) demonstrated a least square mean change from baseline in IDS-C scores of -12.9 points compared to -3.6 points in the lower dose arm (n=27, p=0.02). The statistically significant benefit as measured by IDS-C was maintained up to 16 weeks after the first administration compared to placebo (p=0.008). Data from the secondary endpoints were also encouraging. The investigational drug was generally well-tolerated, as indicated by reported adverse events, changes in vital signs and laboratory values.

“We continue to be encouraged by the positive results being generated on the clinical activity of lysergide by our collaborators at UHB,” said Robert Barrow, Chief Executive Officer and Director of MindMed. “The statistically and clinically significant improvements observed in this study reinforce preliminary findings that have shown the clinical potential of lysergide in anxiety, depression and other brain health disorders. These positive findings are particularly relevant to our MM-120 program in generalized anxiety disorder, given the high degree of comorbidity of GAD and MDD. I would like to congratulate and thank our collaborators at UHB for once again generating high quality clinical data that continue to support the progression of our pipeline.”

Prof. Matthias Liechti, co-primary investigator of the trial, commented, “Historical studies of lysergide in MDD demonstrated rapid, robust and sustained improvement in depressive symptoms. We also observed improvement in depressive symptoms in patients with anxiety disorders in another of our [recently published trials](#). We believed it was necessary to confirm the historical studies with ones using modern methods. Hence, we designed this randomized-controlled trial to assess the benefits of lysergide treatment in MDD. Importantly, an active small dose of lysergide was used as the control. We are extremely encouraged by the results we presented today, which demonstrate the strong, rapid and enduring improvements of this compound in patients suffering from MDD. We look forward to publishing the completed results in a peer-reviewed journal along with additional analyses. Our lab will continue investigating the therapeutic potential of lysergide and other psychedelics.”

About the Phase 2 Investigator-Initiated Clinical Trial

The investigator-initiated clinical trial was a double-blind, active-controlled, Phase 2 trial that investigated the safety and efficacy of lysergide for treating 61 patients with MDD. Patients allocated to the treatment intervention received 100 µg of lysergide on the first dosing day and 200 µg on the second dosing day, with dosing days separated by approximately 4 weeks. Patients allocated to the active control intervention received 25 µg of lysergide on the first dosing day and 25 µg of lysergide on the second dosing day. The primary efficacy endpoint was improvement in MDD symptoms six weeks after the first administration (2 weeks after the second administration), as measured by the clinician-rated Inventory of Depressive Symptomatology (IDS-C). Secondary outcome measures included improvements in the self-rated version of the Inventory of Depressive Symptomatology (IDS-SR), Beck Depression Index (BDI), State-trait anxiety inventory (STAI-G)) along with other psychiatric symptom assessments. Patients were followed for up to 16 weeks following the first dosing session. For additional information on this trial, see [clinicaltrials.gov \[NCT03866252\]](https://clinicaltrials.gov/NCT03866252).

MindMed supports the UHB Liechti Lab in conducting investigator-initiated trials for lysergide and other novel therapies and has exclusive access and rights to the data generated by these studies.

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 product candidates, with and without acute perceptual effects, targeting neurotransmitter pathways that play key roles in brain health disorders.

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 results and timing of clinical trials and the potential benefits of the Company’s product candidates. 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 in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022 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.

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