
**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): May 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
Common Shares

Trading Symbol(s)
MNMD

Name of each exchange on which registered
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 2.02 Results of Operations and Financial Condition.

On May 8, 2024, Mind Medicine (MindMed) Inc. (the “Company”) issued a press release announcing its financial results for its first quarter ended March 31, 2024, as well as information regarding a conference call to discuss these financial results and the Company’s recent corporate highlights. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

The information contained in this Item 2.02 of this Current Report (including Exhibit 99.1) is being furnished and 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 liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

| Exhibit No. | Description |
|--------------------|---|
| 99.1 | Press Release, dated May 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: May 8, 2024

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



Exhibit 99.1

MindMed Reports First Quarter 2024 Financial Results and Business Updates

--Announced positive Phase 2b clinical trial results for MM120 in Generalized Anxiety Disorder (GAD), demonstrating clinically and statistically significant activity through 12 weeks after treatment--

--The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation to MM120 for the treatment of GAD in adults--

--Cash and cash equivalents of \$252.3 million as of March 31, 2024--

--Company to host a conference call today at 4:30 p.m. EDT--

NEW YORK, May 8, 2024 – Mind Medicine (MindMed) Inc. (NASDAQ: MNMD), (the "Company" or "MindMed"), a clinical stage biopharmaceutical company developing novel product candidates to treat brain health disorders, today announced its financial results for the quarter ended March 31, 2024, and provided a business update.

"Building on a highly productive 2023, we were pleased to start the year by announcing that our Phase 2b trial of MM120 in GAD hit its key secondary endpoint with clinically and statistically significant activity observed through Week 12 of the study," said Rob Barrow, Chief Executive Officer of MindMed. "Additionally, the results we shared from our Phase 1 pharmacokinetics bridging trial support the advancement of our MM120 oral dissolving tablet (ODT) formulation into pivotal clinical trials, with our Phase 3 program of MM120 in GAD on track to initiate in the second half of 2024. We also presented at several recent medical meetings highlighting the continued unmet need, burden and increasing prevalence of GAD. With a strong balance sheet expected to fund operations through numerous key milestones, we look forward to providing additional updates on our GAD program, as well as on our pipeline as we advance MM402 for the treatment of autism spectrum disorder (ASD), and potentially expand into additional indications for MM120."

Business Update

- The Company completed an underwritten offering and concurrent private placement for \$175.0 million in gross proceeds before deducting transaction fees and other offering related expenses.
- The Company voluntarily delisted its common shares from Cboe Canada. The Company's common shares continue to be listed and tradable on Nasdaq under the symbol "MNMD".

Program Updates and Anticipated Milestones

MM120 (lysergide D-tartrate) for GAD

- In March 2024, the Company announced that FDA granted Breakthrough Therapy Designation (BTD) to MM120 for the treatment of GAD in adults.
 - In March 2024, the Company announced that its Phase 2b study of MM120 in GAD met its key secondary endpoint with data demonstrating rapid, robust, and durable activity, which was clinically and statistically significant through Week 12.
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oMM120 100 µg – the dose with optimal clinical activity observed in the trial – demonstrated a 7.7-point improvement over placebo at Week 12 (-21.9 MM120 vs. -14.2 placebo; $p < 0.003$ Cohen's $d = 0.81$), with a 65% clinical response rate and a 48% clinical remission rate sustained to Week 12.

oClinical Global Impressions - Severity (CGI-S) scores, on average, improved from 4.8 to 2.2 in the 100-µg dose group, representing a two-category shift from 'markedly ill' to 'borderline ill' at Week 12 ($p < 0.004$). This clinical activity was rapid, observed as early as study day 2, and durable, with further improvements observed in mean HAM-A or CGI-S scores between Weeks 4 and 12.

oMM120 was generally well-tolerated in the trial, with most adverse events rated as mild to moderate, transient, occurring on dosing day, and consistent with expected acute effects of the study drug.

•In March 2024, the Company announced results from its pharmacokinetics (PK) bridging study to support the advancement of the MM120 Zydis® oral dissolving tablet (ODT) formulation into pivotal clinical trials.

oIn the trial, the Zydis® ODT formulation demonstrated 50% faster onset of action and meaningful improvements in both the overall area under the curve and the area under the curve above target or therapeutic concentrations compared to the non ODT formulation.

oWe believe the Zydis® ODT formulation offers numerous product performance, clinical, and intellectual property benefits.

•The Company presented detailed results from its Phase 2b study of MM120 in GAD, as well as multiple presentations describing the epidemiology and growing burden of GAD at the following conferences:

oEuropean Psychiatric Association (EPA) 2024 Congress

oAnxiety & Depression Association of America (ADAA) 2024 Conference

oAmerican Psychiatric Association (APA) 2024 Congress

oInternational Society for Pharmacoeconomics and Outcomes Research (ISPOR) 2024

•One-year follow-up data from a Phase 2 placebo-controlled investigator-initiated clinical trial of lysergide in the treatment of anxiety disorders will be presented at the Society of Biological Psychiatry (SOBP) 2024 Annual Meeting being held May 9-11 in Austin, Texas.

oThis trial was conducted by the Company's collaborators at University Hospital Basel (UHB) in Switzerland and extends on the previously reported positive findings from the LSD-Assist study presented in May 2022.

•The Company plans to hold an End-of-Phase 2 meeting with FDA in the second quarter^[DK1] of 2024 and is on track to initiate its Phase 3 clinical program of MM120 Zydis® ODT for the treatment of GAD in the second half of 2024.

MM402 (R(-)-MDMA) for ASD

•The Company initiated its first clinical trial of MM402 (R(-)-MDMA), a single-ascending dose trial in adult healthy volunteers in Q4 2023. This Phase 1 trial is intended to characterize the tolerability, pharmacokinetics and pharmacodynamics of MM402. It should enable further clinical trials to characterize the effects of repeated daily doses of MM402 and the exploration of early signs of efficacy in the ASD population.

•UHB has conducted a Phase 1 investigator-initiated trial of R(-)-MDMA, S(+)-MDMA and R/S- MDMA in healthy adult volunteers. This trial was designed to assess the tolerability, pharmacokinetics and acute subjective, physiological and endocrine effects of the three molecules. Topline results are anticipated to be presented in the second quarter of 2024.

First Quarter 2024 Financial Results

Cash Balance. As of March 31, 2024, MindMed had cash and cash equivalents totaling \$252.3 million compared to \$99.7 million as of December 31, 2023. The Company believes its available cash and cash equivalents will be sufficient to fund its operations into 2026 based on its current operating plan.

Net Cash Used in Operating Activities. For the quarter ended March 31, 2024, net cash used in operating activities was \$16.6 million, compared to \$13.3 million in the quarter ended March 31, 2023.

Research and Development (R&D). R&D expenses were \$11.7 million for the quarter ended March 31, 2024, compared to \$12.6 million for the quarter ended March 31, 2023, a decrease of \$0.9 million. The decrease was primarily due to decreases of \$0.6 million in expenses related to our MM402 program, a decrease of \$0.5 million in expenses related to preclinical activities, partially offset by an increase of \$0.3 million in internal personnel costs as a result of increasing research and development capacities.

General and Administrative (G&A). G&A expenses were \$10.5 million for the quarter ended March 31, 2024, compared to \$8.3 million for the quarter ended March 31, 2023, an increase of \$2.2 million. The increase was primarily attributable to increased stock-based compensation expense of \$1.1 million and an increase of \$0.7 million in personnel-related expenses due to an increase in headcount to support the growth of our business.

Net Loss. Net loss for the quarter ended March 31, 2024 was \$54.4 million, compared to \$24.8 million for the quarter ended March 31, 2023. The increase was primarily due to changes in the fair value of 2022 USD Financing Warrants of \$27.7 million.

CFO Transition

On May 3, 2024, the Company made a transition in the role of Chief Financial Officer resulting in the departure of Schond Greenway. "On behalf of the Board of Directors and Executive team, I would like to thank Schond for all his hard work and dedication over the past two years," said Robert Barrow, Chief Executive Officer and Director of MindMed. "Schond supported the Company through several significant milestones and has left us well positioned financially and strategically. As we continue to progress our development pipeline and advance preparations for the potential commercialization of MM120, we are committed to identifying leaders that will continue the Company's recent momentum and deliver long-term value to shareholders."

MindMed has retained an executive search firm to assist in identifying a new Chief Financial Officer.

Conference Call and Webcast Reminder

MindMed management will host a conference call at 4:30 PM EDT today to provide a corporate update and review the Company's first quarter 2024 financial results. Listeners can register for the webcast via this link. Analysts wishing to participate in the question and answer session should use this link. A replay of the webcast will be available via the Investor Relations section of the MindMed website, <https://ir.mindmed.co/>, and archived for at least 30 days after the webcast. Those who plan on participating are advised to join 15 minutes prior to the start time.

About MM120

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 MM120 (lysergide D-tartrate), the tartrate salt form of lysergide, for GAD and other psychiatric indications.

About MM402

MM402 is our proprietary form of R(-)-MDMA (rectus-3,4-methylenedioxyamphetamine), which we are developing for the treatment of core symptoms of 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.

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 the Company's belief that results from its Phase 1 pharmacokinetics bridging trial will support the advancement of its MM120 ODT formulation into pivotal clinical trials; the Company's belief that it is on track to initiate a Phase 3 clinical program for MM120 Zydis® ODTs in the second half of 2024; the Company's plans to provide additional updates on its GAD program and other product candidates in its pipeline; the Company's beliefs regarding potential benefits of its product candidates; the Company's plans to hold an End-of-Phase 2 meeting with the FDA in the second quarter of 2024; the Company's belief that its Phase 1 trial for MM402 (R(-)-MDMA) should enable further clinical trials to characterize the effects of repeated daily doses of MM402 and the exploration of early signs of efficacy in the ASD population; the Company's expectation that topline results from UHB's Phase 1 investigator-initiated clinical trial of R(-)-MDMA, S(+)-MDMA and R/S- MDMA will be presented in the second quarter of 2024; the Company's expectation that its cash and cash equivalents are expected to fund operations into 2026; anticipated upcoming milestones, trials and studies; results and timing of and reporting of data from clinical trials; and potential additional indications for MM120 and MM402. 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, 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.sedarplus.ca 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

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Mind Medicine (MindMed) Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

| | Three Months Ended March 31, | |
|---|---------------------------------|--------------|
| | 2024 | 2023 |
| Operating expenses: | | |
| Research and development | \$ 11,705 | \$ 12,599 |
| General and administrative | 10,499 | 8,263 |
| Total operating expenses | 22,204 | 20,862 |
| Loss from operations | (22,204) | (20,862) |
| Other income/(expense): | | |
| Interest income | 1,656 | 1,360 |
| Interest expense | (434) | (76) |
| Foreign exchange loss, net | (525) | (52) |
| Change in fair value of 2022 USD Financing Warrants | (32,893) | (5,185) |
| Total other expense, net | (32,196) | (3,953) |
| Net loss | (54,400) | (24,815) |
| Other comprehensive loss | | |
| Gain on foreign currency translation | 493 | 14 |
| Comprehensive loss | \$ (53,907) | \$ (24,801) |
| Net loss per common share, basic and diluted | \$ (1.14) | \$ (0.65) |
| Weighted-average common shares, basic and diluted | 47,860,757 | 38,077,251 |

Mind Medicine (MindMed) Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except share amounts)

| | March 31, 2024 (unaudited) | December 31, 2023 |
|---|-------------------------------|-------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 252,332 | \$ 99,704 |
| Prepaid and other current assets | 3,139 | 4,168 |
| Total current assets | 255,471 | 103,872 |
| Goodwill | 19,918 | 19,918 |
| Intangible assets, net | — | 527 |
| Other non-current assets | 144 | 224 |
| Total assets | <u>\$ 275,533</u> | <u>\$ 124,541</u> |
| Liabilities and Shareholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 7,595 | \$ 4,136 |
| Accrued expenses | 9,974 | 11,634 |
| 2022 USD Financing Warrants | 47,700 | 16,476 |
| Total current liabilities | 65,269 | 32,246 |
| Credit facility, long-term | 14,190 | 14,129 |
| Other liabilities, long-term | 15 | 32 |
| Total liabilities | 79,474 | 46,407 |
| Shareholders' Equity: | | |
| Common shares, no par value, unlimited authorized as of March 31, 2024 and December 31, 2023; 71,163,720 and 41,101,303 issued and outstanding as of March 31, 2024 and December 31, 2023, respectively | — | — |
| Additional paid-in capital | 539,823 | 367,991 |
| Accumulated other comprehensive income | 836 | 343 |
| Accumulated deficit | (344,600) | (290,200) |
| Total shareholders' equity | 196,059 | 78,134 |
| Total liabilities and shareholders' equity | <u>\$ 275,533</u> | <u>\$ 124,541</u> |

