
**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): November 7, 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 2.02 Results of Operations and Financial Condition.

On November 7, 2024, Mind Medicine (MindMed) Inc. (the "Company") issued a press release announcing its financial results for its second quarter ended September 30, 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 November 7, 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: November 7, 2024

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



MindMed Reports Third Quarter 2024 Financial Results and Business Updates

--On track to initiate the Phase 3 Voyage study of MM120 Orally Disintegrating Tablet (ODT) in Generalized Anxiety Disorder (GAD) in the fourth quarter of 2024; 12-week topline data anticipated in the first half of 2026--

--On track to initiate the Phase 3 Panorama study of MM120 ODT in GAD and the Phase 3 Emerge study of MM120 ODT in Major Depressive Disorder (MDD) in the first half of 2025--

--Cash and cash equivalents of \$295.3 million as of September 30, 2024, expected to fund operations into 2027 and extend at least 12 months beyond the first Phase 3 topline data readout for MM120 ODT in GAD--

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

NEW YORK, November 7, 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 September 30, 2024, and provided a business update.

"This is a pivotal moment for MindMed as we prepare to initiate Voyage, our first Phase 3 study of MM120 ODT in GAD," said Rob Barrow, Chief Executive Officer of MindMed. "Beyond Voyage, we are on track to initiate two additional Phase 3 studies: the Panorama study, our second trial in GAD, and the Emerge study, our first trial of MM120 ODT in MDD. Our Phase 3 development strategy leverages high-performing clinical trial sites from our Phase 2 study, as well as thoughtfully aligned protocols, which we expect to enable efficient enrollment across GAD and MDD. Our strong execution throughout the year has positioned us as a well-financed, late-stage clinical leader, set to launch three Phase 3 studies targeting two indications affecting approximately 51 million adults in the U.S. I could not be more pleased with our progress as we continue to build a high-performing organization dedicated to transforming the standard of care for people with brain health disorders."

Program Updates and Anticipated Milestones

MM120 (lysergide D-tartrate) for GAD

•The Company is on track to initiate the Phase 3 Voyage study of MM120 ODT, a pharmaceutically optimized form of lysergide D-tartrate (LSD) for the treatment of adults with GAD in the fourth quarter of 2024. The Company expects the topline readout from the 12-week double-blind period (Part A) of Voyage in the first half of 2026.

•The Phase 3 clinical program for MM120 ODT in GAD consists of two clinical studies: the Voyage study (MM120-300) and the Panorama study (MM120-301).

◦Both studies are comprised of two parts: Part A, which is a 12-week, randomized, double-blind, placebo-controlled, parallel group study assessing the efficacy and safety of MM120 ODT versus placebo; and Part B, which is a 40-week extension period during which participants will be eligible for open-label treatment with MM120 ODT, subject to certain conditions for treatment eligibility.

◦Voyage is anticipated to enroll approximately 200 participants in the U.S. who will be randomized 1:1 to receive MM120 ODT 100 µg or placebo, and Panorama is anticipated to enroll approximately 240 participants (randomized 5:2:5 to receive MM120 ODT 100 µg, MM120 ODT 50 µg or placebo).

- The primary endpoint for each study is the change from baseline in Hamilton Anxiety Rating Scale (HAM-A) score at Week 12 between MM120 ODT 100 µg and placebo.

- Both studies are expected to employ an adaptive design with interim blinded sample size re-estimation based on nuisance parameters (e.g. participant retention rate, variability of primary outcome measure) which allows for an increase of sample size up to 50% to maintain statistical power.

- Panorama, the second Phase 3 study, will be conducted in the U.S. and Europe and is on track to initiate in the first half of 2025 with an anticipated topline readout from the 12-week double-blind period (Part A) in the second half of 2026.

MM120 (lysergide D-tartrate) for MDD

- The Company is also developing MM120 ODT for the treatment of adults with MDD, beginning with the Emerge study (MM120-310) which, like the Phase 3 studies in GAD, is comprised of two parts: Part A, which is a 12-week, randomized, double-blind, placebo-controlled, parallel-group study assessing the efficacy and safety of MM120 ODT versus placebo; and Part B, which is a 40-week extension period during which participants will be eligible for open-label treatment with MM120 ODT, subject to certain conditions for treatment eligibility.

- Emerge is anticipated to enroll at least 140 participants (randomized 1:1 to receive MM120 ODT 100 µg or placebo).

- The primary endpoint is the change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) score at Week 6 between MM120 ODT 100 µg and placebo.

- The Company expects to initiate Emerge in the first half of 2025 with an anticipated topline readout from the 12-week double-blinded period (Part A) in the second half of 2026.

- The Company expects to conduct a second Phase 3 registrational study in MDD, with the study design and timing to be informed by the progress of Emerge and additional regulatory discussion.

MM402 (R(-)-MDMA) for Autism Spectrum Disorder (ASD)

- In October, the Company completed a Phase 1 study of MM402, a single-ascending dose study in adult healthy volunteers. The study was intended to characterize the tolerability, pharmacokinetics and pharmacodynamics of MM402. The Company expects to initiate further studies of MM402 for the potential treatment of ASD, with the exact timing and scope of such studies to be determined.

Third Quarter 2024 Financial Results

Cash Balance. As of September 30, 2024, MindMed had cash and cash equivalents totaling \$295.3 million compared to \$99.7 million as of December 31, 2023.

The Company believes that its cash and cash equivalents as of September 30, 2024, will be sufficient to fund the Company's operations into 2027. Based on the Company's current operating plan and anticipated R&D milestones, the Company expects its cash runway to extend at least 12 months beyond its first Phase 3 topline data readout for MM120 ODT in GAD.

Net Cash Used in Operating Activities. For the nine months ended September 30, 2024, net cash used in operating activities was \$53.8 million, compared to \$43.8 million in the nine months ended September 30, 2023.

Research and Development (R&D). R&D expenses were \$17.2 million for the quarter ended September 30, 2024, compared to \$13.2 million for the quarter ended September 30, 2023, an increase of \$4.0 million. The increase was primarily due to \$2.1 million in expenses related to our MM120 program supporting the advancement into pivotal studies for the treatment of adults with GAD, \$0.9 million in expenses related to our MM402 program, \$0.6 million in internal personnel costs as a result of increasing research and development capacities, and an increase of \$0.4 million in expenses related to preclinical activities.

General and Administrative (G&A). G&A expenses were \$7.6 million for the quarter ended September 30, 2024, compared to \$8.4 million for the quarter ended September 30, 2023, a decrease of \$0.8 million. The decrease was primarily attributable to lower spending in legal and commercial activities, partially offset by an increase in stock-based compensation expense.

Net Loss. Net loss for the quarter ended September 30, 2024, was \$13.7 million, compared to \$17.9 million for the same period in 2023, a decrease of \$4.2 million. The decrease was primarily due to changes in the fair value of warrants issued in our September 2022 underwritten offering of \$5.3 million partially offset by an increase in research and development expense.

Conference Call and Webcast Reminder

MindMed management will host a conference call at 4:30 PM EST today to provide a corporate update and review the Company's third 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, 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

MM120 (lysergide D-tartrate or LSD) is a synthetic ergotamine 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, the tartrate salt form of lysergide, for GAD and MDD and is exploring its potential applications in other serious brain health disorders. Based on the significant unmet medical need in the treatment of GAD – especially in patients who do not respond to or tolerate currently available medications – along with the initial clinical data from Phase 2b and other research conducted by MindMed, the U.S. Food & Drug Administration (FDA) has designated MM120 for GAD as a breakthrough therapy. The MM120 ODT Phase 3 clinical development program includes the Voyage and Panaroma studies in GAD and the Emerge study in MDD. Additional clinical indications under consideration.

About MM402

MM402 is the Company's proprietary form of R(-)-MDMA (rectus-3,4-methylenedioxymethamphetamine), being developed 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 product candidates, with and without acute perceptual effects, targeting neurotransmitter pathways that play key roles in brain health. MindMed trades on NASDAQ under the symbol MNMD.

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 expectation to initiate the Phase 3 Voyage study of MM120 ODT in GAD in the fourth quarter of 2024 with an anticipated topline readout (Part A results) in the first half of 2026; the Company's expectation to initiate the Phase 3 Panorama study for MM120 ODT in GAD in the first half of 2025 with an anticipated topline readout (Part A results) in the second half of 2026; the Company's expectation to initiate the Phase 3 Emerge study for MM120 ODT in MDD in the first half of 2025 with an anticipated topline readout (Part A results) in the second half of 2026; the Company's plans to conduct a second Phase 3 study in MDD; the Company's expectations regarding the enrollment for each of the Voyage, Panorama and Emerge studies; the Company's beliefs regarding potential benefits of its product candidates; the Company's expectation to conduct further studies of MM402; the Company's expectation that its cash and cash equivalents will fund operations into 2027; the Company's expectation that its cash runway will extend at least 12 months beyond its first Phase 3 topline data readout for MM120 ODT in GAD; the Company's anticipated upcoming milestones, trials and studies; 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 studies or studies; heightened regulatory scrutiny; early stage product development; clinical study 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 17,188	\$ 13,203	\$ 43,538	\$ 40,578
General and administrative	7,604	8,413	27,916	31,083
Total operating expenses	24,792	21,616	71,454	71,661
Loss from operations	(24,792)	(21,616)	(71,454)	(71,661)
Other income/(expense):				
Interest income	3,507	1,491	8,279	4,240
Interest expense	(727)	(328)	(1,627)	(481)
Foreign exchange loss, net	(32)	(439)	(589)	(244)
Change in fair value of 2022 USD Financing Warrants	8,360	3,020	(11,088)	(3,671)
Gain on extinguishment of contribution payable	—	—	2,541	—
Other expense	—	(51)	—	(51)
Total other income/(expense), net	11,108	3,693	(2,484)	(207)
Net loss	(13,684)	(17,923)	(73,938)	(71,868)
Other comprehensive loss				
Gain/(loss) on foreign currency translation	(12)	415	478	150
Comprehensive loss	<u>\$ (13,696)</u>	<u>\$ (17,508)</u>	<u>\$ (73,460)</u>	<u>\$ (71,718)</u>
Net loss per common share, basic	<u>\$ (0.18)</u>	<u>\$ (0.45)</u>	<u>\$ (1.12)</u>	<u>\$ (1.85)</u>
Net loss per common share, diluted	<u>\$ (0.27)</u>	<u>\$ (0.45)</u>	<u>\$ (1.12)</u>	<u>\$ (1.85)</u>
Weighted-average common shares, basic	<u>77,909,441</u>	<u>39,720,007</u>	<u>65,938,025</u>	<u>38,798,374</u>
Weighted-average common shares, diluted	<u>80,238,688</u>	<u>39,720,007</u>	<u>65,938,025</u>	<u>38,798,374</u>

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

	September 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 295,284	\$ 99,704
Prepaid and other current assets	4,074	4,168
Total current assets	299,358	103,872
Goodwill	19,918	19,918
Intangible assets, net	—	527
Other non-current assets	493	224
Total assets	<u>\$ 319,769</u>	<u>\$ 124,541</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,149	\$ 4,136
Accrued expenses	8,796	11,634
2022 USD Financing Warrants	22,320	16,476
Total current liabilities	33,265	32,246
Credit facility, long-term	24,311	14,129
Other liabilities, long-term	—	32
Total liabilities	57,576	46,407
Shareholders' Equity:		
Common shares, no par value, unlimited authorized as of September 30, 2024 and December 31, 2023; 81,590,491 and 41,101,303 issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	625,510	367,991
Accumulated other comprehensive income	821	343
Accumulated deficit	(364,138)	(290,200)
Total shareholders' equity	262,193	78,134
Total liabilities and shareholders' equity	<u>\$ 319,769</u>	<u>\$ 124,541</u>

