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): August 13, 2024

MIND MEDICINE (MINDMED) INC.

(Exact name of Registrant as Specified in Its Charter)

British Columbia, Canada	**001-40360**	**98-1582438**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
One World Trade Center, Suite 8500 New York, New York		**10007**
(Address of Principal Executive Offices)		**(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 August 13, 2024, Mind Medicine (MindMed) Inc. (the "Company") issued a press release announcing its financial results for its second quarter ended June 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 August 13, 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: August 13, 2024

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

Exhibit 99.1

MindMed Reports Second Quarter 2024 Financial Results and Business Updates

--Completed End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA); on track to initiate Phase 3 clinical program for MM120 orally disintegrating tablet (ODT) in Generalized Anxiety Disorder (GAD) in the second half of 2024--

--Expanding pipeline with MM120 ODT clinical program in Major Depressive Disorder (MDD) with plans to initiate a registrational study in first half of 2025--

--New patent issued by the United States Patent and Trademark Office (USPTO) extends intellectual property protection for MM120 ODT through 2041--

--Company to host a conference call today at 8:00 a.m. EDT--

NEW YORK, August 13, 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 June 30, 2024, and provided a business update.

“Building on the positive momentum from our Phase 2b data for MM120 ODT in GAD, we are excited to be launching our Phase 3 clinical program in GAD later this year and to announce the expansion of our pipeline as we embark on a registrational study for MM120 ODT in MDD,” said Rob Barrow, Chief Executive Officer of MindMed. “In June, we successfully completed our End-of-Phase 2 meeting with the FDA, aligning on Phase 3 requirements for MM120 ODT in GAD, with initiation of our first Phase 3 trial on track for the second half of the year. We have also extended our intellectual property protection for MM120 ODT through 2041 bolstering our market protection strategy. With a cash balance of $243.1 million as of June 30, 2024, and our recently closed $75 million in gross proceeds, we are well-positioned to rapidly advance our R&D pipeline with exemplary operational and financial efficiency to numerous readouts beginning in the first half of 2026. The $250 million of equity investment into MindMed since the beginning of 2024 extends our cash runway into 2027, which we believe will be at least 12 months beyond our first Phase 3 clinical readout for MM120 ODT in GAD.”

Business Update

- Completed an underwriting offering of its common shares and pre-funded warrants to purchase common shares for $75.0 million in gross proceeds before deducting transaction fees and other offering related expenses.
- In July 2024, the Company announced issuance of a new patent (USPN 12,036,220) by the USPTO covering claims related to the pharmaceutical formulation, methods of manufacturing and method of treatment for MM120 ODT. This patent extends the Company’s intellectual property protection for MM120 through 2041.
- 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 June 2024, the Company announced the completion of its EOP2 meeting with the FDA, supporting the advancement of MM120 into pivotal trials for the treatment of adults with GAD.

- The Phase 3 clinical program for MM120 ODT consists of two clinical trials: the Voyage Study (MM120-300) and the Panorama Study (MM120-301).
  - Both trials 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 study during which participants will be eligible for open-label treatment with MM120, subject to certain conditions for re-treatment eligibility.
  - Voyage is anticipated to enroll approximately 200 participants (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 trial is the change from baseline in Hamilton Anxiety Rating Scale (HAM-A) score at Week 12 between MM120 ODT 100 µg and placebo.
  - Both trials will employ an adaptive design with interim blinded sample size re-estimation based on nuisance parameters (e.g. patient retention rate, variability of primary outcome measure) which allows for an increase of sample size up to 50% to maintain statistical power.
  - The Company expects to initiate Voyage in the second half of 2024 with an anticipated topline readout (Part A results) in the first half of 2026. Panorama is expected to start in the first half of 2025 with an anticipated topline readout (Part A results) in the second half of 2026.

MM120 (lysergide D-tartrate) for MDD

- The Company is also developing MM120 ODT for the treatment of Major Depressive Disorder (MDD), beginning with the Emerge Study (MM120-310), which like the pivotal 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 study during which participants will be eligible for open-label treatment with MM120, subject to certain conditions for re-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 (Part A results) in the second half of 2026. The Company expects to conduct a second registrational study in MDD with the study design and timing to be informed by Emerge and additional regulatory discussion.

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

- MM402 is being evaluated in a Phase 1, single-ascending dose trial in adult healthy volunteers intended to characterize its tolerability, pharmacokinetics and pharmacodynamics. Results from this trial are expected to 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.

Second Quarter 2024 Financial Results

Cash Balance. As of June 30, 2024, MindMed had cash and cash equivalents totaling $243.1 million compared to $99.7 million as of December 31, 2023. The Company recently completed an underwriting offering of its common shares and pre-funded warrants to purchase common shares for $75.0 million in gross proceeds before deducting transaction fees and other offering related expenses.

The Company believes that its cash and cash equivalents as of June 30, 2024, plus the approximately $70.0 million in net proceeds from the recently completed offering 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 six months ended June 30, 2024, net cash used in operating activities was $36.6 million, compared to $27.2 million in the six months ended June 30, 2023.

Research and Development (R&D). R&D expenses were $14.7 million for the quarter ended June 30, 2024, compared to $14.8 million for the quarter ended June 30, 2023, a decrease of $0.1 million. The decrease was primarily due to decreases of $0.5 million in expenses related to our MM120 program, and a decrease of $2.0 million in expenses related to preclinical activities, partially offset by an increase of $1.0 million in internal personnel costs as a result of increasing research and development capacities, and an increase of $1.4 million in expenses related to our MM402 program.

General and Administrative (G&A). G&A expenses were $9.8 million for the quarter ended June 30, 2024, compared to $14.4 million for the quarter ended June 30, 2023, a decrease of $4.6 million. The decrease was primarily attributable to professional services fees and expenses during the three months ended June 30, 2023 related to the proxy contest in connection with our 2023 annual general meeting of shareholders, partially offset by increased stock-based compensation expense.

Net Loss. Net loss for the quarter ended June 30, 2024, was $5.9 million, compared to $29.1 million for the same period in 2023. The decrease was primarily due to changes in the fair value of 2022 USD Financing Warrants of $15.0 million.

Conference Call and Webcast Reminder

MindMed management will host a conference call at 8:00 AM EDT today to provide a corporate update and review the Company's second 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

MM120 (LSD or lysergide D-tartrate) 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-HT2A]) receptors. MindMed is developing MM120, the tartrate salt form of lysergide, for GAD 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. MM120 is entering a Phase 3 clinical program for GAD in the second half of 2024 and a Phase 3 clinical program for MDD in the first half of 2025 with additional clinical indications under exploration.

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 disorders. 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 Voyage Study in the second half of 2024 with an anticipated topline readout (Part A results) in the first half of 2026; the Company's expectation to initiate the Panorama Study 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 Emerge Study 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 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 potential IP protection for MM120; 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 its cash and cash equivalents plus the gross proceeds from the recently completed offering will fund operations into 2027; the Company's expectation that its cash runway will extend at least 12 months beyond the topline data readout for its VOYAGE Phase 3 trial of MM120 in GAD; 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 14,645	$ 14,777	$ 26,350	$ 27,375
General and administrative	9,813	14,407	20,312	22,670
Total operating expenses	24,458	29,184	46,662	50,045
Loss from operations	(24,458)	(29,184)	(46,662)	(50,045)
Other income/(expense):				
Interest income	3,116	1,388	4,772	2,748
Interest expense	(466)	(77)	(900)	(153)
Foreign exchange gain/(loss), net	(32)	247	(557)	195
Change in fair value of 2022 USD Financing Warrants	13,445	(1,504)	(19,448)	(6,690)
Gain on extinguishment of contribution payable	2,541	—	2,541	—
Total other income/(expense), net	18,604	54	(13,592)	(3,900)
Net loss	(5,854)	(29,130)	(60,254)	(53,945)
Other comprehensive loss				
Gain/(loss) on foreign currency translation	(3)	(279)	490	(265)
Comprehensive loss	$ (5,857)	$ (29,409)	$ (59,764)	$ (54,210)
Net loss per common share, basic	$ (0.08)	$ (0.76)	$ (1.01)	$ (1.41)
Net loss per common share, diluted	$ (0.26)	$ (0.76)	$ (1.01)	$ (1.41)
Weighted-average common shares, basic	71,912,323	38,576,394	59,886,540	38,329,919
Weighted-average common shares, diluted	75,304,101	38,576,394	59,886,540	38,329,919

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

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 243,132	$ 99,704
Prepaid and other current assets	4,561	4,168
Total current assets	247,693	103,872
Goodwill	19,918	19,918
Intangible assets, net	—	527
Other non-current assets	534	224
Total assets	$ 268,145	$ 124,541
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,936	$ 4,136
Accrued expenses	8,231	11,634
2022 USD Financing Warrants	30,680	16,476
Total current liabilities	41,847	32,246
Credit facility, long-term	24,251	14,129
Other liabilities, long-term	—	32
Total liabilities	66,098	46,407
Commitments and contingencies		
Shareholders' Equity:		
Common shares, no par value, unlimited authorized as of June 30, 2024 and December 31, 2023; 72,075,076 and 41,101,303 issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	551,668	367,991
Accumulated other comprehensive income	833	343
Accumulated deficit	(350,454)	(290,200)
Total shareholders' equity	202,047	78,134
Total liabilities and shareholders' equity	$ 268,145	$ 124,541