
**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 3, 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
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 August 3, 2023, Mind Medicine (MindMed) Inc. (the “Company”) issued a press release (the “Press Release”) announcing its financial results for its fiscal quarter ended June 30, 2023 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 furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 3, 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: August 3, 2023

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



MindMed Reports Second Quarter 2023 Financial Results and Business Highlights

- Topline readout of MM-120 in GAD (Phase 2b) expected in Q4 2023 with enrollment to be concluded in Q3 2023 –
 - Topline readout of MM-120 in ADHD (Phase 2a proof-of-concept) anticipated in Q4 2023 / Q1 2024 –
 - MM-402 in ASD on track for Phase 1 clinical trial initiation in Q4 2023 –
- Entered into exclusive license agreement with Catalent for MM-120 Zydis® orally disintegrating tablet (ODT) formulation for advancement into pivotal clinical trials –
 - Cash and cash equivalents of \$116.9 million at June 30, 2023 –
 - Company to host conference call today at 4:30 PM ET –

NEW YORK, August 3, 2023 -- 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 reported its financial results for the quarter ended June 30, 2023.

“We’re coming up on a critical period for MindMed as we are close to wrapping up enrollment in our Phase 2b study of MM-120 for the treatment of generalized anxiety disorder” said Robert Barrow, Chief Executive Officer and Director of MindMed. “Our ability to enroll a study of this size in such an efficient manner stands out in the field and speaks to the remarkable quality of our R&D team. We are also excited to have licensed Catalent’s Zydis ODT technology for use with MM-120 which we believe significantly bolsters the differentiation and protectability of our MM-120 product candidate while potentially offering enhanced bioavailability and more rapid absorption, which may lead to a shorter treatment session. We could not be more excited about the progress we have made to date and the numerous upcoming milestones in the months ahead.”

Business Update

- The Company reiterates its guidance for its cash runway, which is expected to fund its current operating plan into the first half of 2025.
- MindMed’s management team will participate in the H.C. Wainwright 25th Annual Global Investment Conference that is being held in New York, NY from September 11-13, 2023 as well as the 2023 Cantor Global Healthcare Conference being held in New York, NY from September 26-28, 2023.

Recent Highlights and Anticipated Upcoming Milestones:

Phase 2b study evaluating MM-120 for generalized anxiety disorder (GAD) remains on track for topline readout in Q4 2023.

- Patient enrollment is expected to be completed by the end of Q3 2023 with topline results for the primary endpoint expected to be announced in Q4 2023. Based on a recent review of the Company's statistical assumptions, the target patient enrollment for the trial has been lowered from 200 to 180 participants while maintaining the statistical power (approximately 90%) to achieve the study's objectives.
- The primary objective of the study is to determine the dose-response relationship of four doses of MM-120 versus placebo as measured by the change in Hamilton Anxiety Rating Scale (HAM-A) from baseline to week 4.
- In August 2023, MindMed announced an exclusive licensing agreement with Catalent for its patented Zydis® ODT technology for use with MM-120. The Company is also in the process of initiating a Phase 1 pharmacokinetics bridging study to support advancement of the MM-120 ODT formulation into pivotal clinical trials.

Phase 2a study evaluating MM-120 for attention deficit hyperactivity disorder (ADHD) continues to advance toward a topline readout in Q4 2023 / Q1 2024.

- The Company's Phase 2a proof-of-concept trial for the treatment of ADHD is designed to assess the safety and efficacy of repeated low-dose MM-120 administration in 52 patients.
- The study is over 80% enrolled and on track for completion in Q4 2023.
- The Company expects to present topline results in Q4 2023 or Q1 2024.

Advancing development of MM-402 (also referred to as R(-)-MDMA) for autism spectrum disorder (ASD) into first clinical trial in Q4 2023.

- The Company plans to initiate its first clinical trial of MM-402 in Q4 2023. This Phase 1 study is intended to characterize the tolerability, pharmacokinetics and pharmacodynamics of MM-402, and to evaluate early signals of efficacy to support the Company's approach in targeting core symptoms of ASD.
- University Hospital Basel (UHB) in Switzerland, the Company's collaborator, is currently enrolling participants in a Phase 1 investigator-initiated trial of R(-)-MDMA, S(+)-MDMA and R/S-MDMA in healthy 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.
- In June 2023, the Company presented results from a pre-clinical study of MM-402 in a model of ASD, titled "MM-402, R(-)-3,4-Methylenedioxymethamphetamine, Demonstrates Prosocial and Therapeutic-Like Effects in Fmr1 Knockout mice, a Preclinical Model of Autism Spectrum Disorder (due to Fragile X syndrome)" at the American Society of Clinical Psychopharmacology (ASCP) 2023 Annual Meeting.

Collaborations and Partnerships

The Company continues to support its ongoing collaboration with the Liechti Lab at UHB in Switzerland. MindMed has exclusive worldwide rights to data, compounds and patent rights associated with UHB's

research on lysergide and other psychedelic compounds, including data from preclinical studies and investigator-initiated clinical trials.

Second Quarter 2023 Financial Results

Cash and Cash Equivalents Balance. As of June 30, 2023, MindMed had cash and cash equivalents totaling \$116.9 million compared to \$142.1 million as of December 31, 2022. The Company believes its available cash and cash equivalents will be sufficient to fund its operating requirements into the first half of 2025.

Net Cash Used in Operating Activities. The net cash used in operating activities was \$27.2 million for the six months ended June 30, 2023, compared to \$28.0 million in the six months ended June 30, 2022.

Research and Development (R&D). R&D expenses were \$14.8 million for the quarter ended June 30, 2023, compared to \$9.3 million for the quarter ended June 30, 2022, an increase of \$5.5 million. The increase was primarily due to increases of \$4.4 million in expenses related to clinical research for the MM-120 GAD study, \$0.8 million in preclinical activities, \$0.6 million in internal personnel costs as a result of increasing R&D capacity, and \$0.2 million in connection with various external R&D collaborations, partially offset by a decrease of \$0.5 million in expenses related to our MM-110 program, and a decrease of \$0.1 million related to our MM-402 program.

General and Administrative (G&A). G&A expenses were \$14.4 million for the quarter ended June 30, 2023, compared to \$7.6 million for the quarter ended June 30, 2022, an increase of \$6.8 million. The increase was attributable to professional services fees and expenses related to our proxy contest in connection with our 2023 annual general meeting of shareholders, and additional costs to support the growth of our business.

Net Loss. Net loss for the quarter ended June 30, 2023 was \$29.1 million, compared to \$17.0 million for the same period in 2022.

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 first quarter 2023 financial results. Individuals may participate in the live call via telephone by dialing (877) 407-3982 (domestic) or (201) 493-6780 (international). The webcast can be accessed live [here](#) on the Financials page in the Investors section of the MindMed website, <https://mindmed.co/>. The webcast will be archived on the Company's website for at least 30 days after the conference call.

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 upcoming milestones, and progress of enrollment of trials and studies; results and timing of and reporting of topline data from clinical trials; the potential benefits of the Company’s license with Catalent; the potential benefits of the Company’s product candidates, and the Company’s cash runway funding its operations into the first half of 2025. 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, the Company’s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2023 under headings such as “Special Note Regarding Forward-Looking Statements,” “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 & Investor Inquiries, please contact:

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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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 14,777	\$ 9,326	\$ 27,375	\$ 19,567
General and administrative	14,407	7,617	22,670	15,881
Total operating expenses	29,184	16,943	50,045	35,448
Loss from operations	(29,184)	(16,943)	(50,045)	(35,448)
Other income/(expense):				
Interest income, net	1,311	82	2,595	83
Foreign exchange gain/(loss), net	247	(89)	195	(44)
Change in fair value of 2022 USD Financing Warrants	(1,504)	—	(6,690)	—
Other income/(expense)	—	(7)	—	1
Total other income/(expense), net	54	(14)	(3,900)	40
Net loss	(29,130)	(16,957)	(53,945)	(35,408)
Other comprehensive loss				
Loss on foreign currency translation	(279)	(147)	(265)	(196)
Comprehensive loss	\$ (29,409)	\$ (17,104)	\$ (54,210)	\$ (35,604)
Net loss per common share, basic and diluted	\$ (0.76)	\$ (0.60)	\$ (1.41)	\$ (1.26)
Weighted-average common shares, basic and diluted	38,576,394	28,242,026	38,329,919	28,196,789

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

	June 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 116,895	\$ 142,142
Prepaid and other current assets	2,896	3,913
Total current assets	119,791	146,055
Goodwill	19,918	19,918
Intangible assets, net	2,108	3,689
Other non-current assets	268	331
Total assets	<u>\$ 142,085</u>	<u>\$ 169,993</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 8,577	\$ 2,111
Accrued expenses	9,950	5,877
2022 USD Financing Warrants	16,594	9,904
Total current liabilities	35,121	17,892
Other liabilities, long-term	992	1,184
Total liabilities	36,113	19,076
Shareholders' Equity:		
Common shares, no par value, unlimited authorized as of June 30, 2023 and December 31, 2022; 38,807,159 and 37,979,136 issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	354,023	344,758
Accumulated other comprehensive income	362	627
Accumulated deficit	(248,413)	(194,468)
Total shareholders' equity	105,972	150,917
Total liabilities and shareholders' equity	<u>\$ 142,085</u>	<u>\$ 169,993</u>

