

# 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--(BUSINESS WIRE)-- 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 <u>link</u>. Analysts wishing to participate in the question-and-answer session should use this <u>link</u>. A replay of the webcast will be available via the Investor Relations section of the MindMed website, <u>ir.mindmed.co</u> 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-HT2A]) 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 guarter 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.

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

		Three Mor Septen			Nine Mont Septem				
		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	\$	(13,696)	\$	(17,508)	\$	(73,460)	\$	(71,718)	
Net loss per common share, basic	\$	(0.18)	\$	(0.45)	\$	(1.12)	\$	(1.85)	
Net loss per common share, diluted	\$	(0.27)	\$	(0.45)	\$	(1.12)	\$	(1.85)	
Weighted-average common shares, basic		77,909,441		39,720,007		65,938,025		38,798,374	
Weighted-average common shares, diluted		80,238,688		39,720,007		65,938,025		38,798,374	
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### Mind Medicine (MindMed) Inc. Condensed Consolidated Balance Sheets (In thousands, except share amounts)

	•	otember 30, 2024 Inaudited)	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	\$	319,769	\$	124,541	
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	\$	319,769	\$	124,541	

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