February 28, 2024

MindMed Reports 2023 Financial Results and Business Updates

--Announced statistically significant and clinically meaningful topline Phase 2b data for MM120 at 4 weeks in Generalized Anxiety Disorder (GAD)--

--Multiple planned milestones for MM120 in GAD, including 12-week Phase 2b data to be presented at March 7th investor event, and initiation of Phase 3 clinical program in second half of 2024--

--Initiated Phase 1 clinical trial of MM402 in Autism Spectrum Disorder (ASD)--

--Conference call to discuss year-end financial results at 8:00 a.m. EST--

NEW YORK--(BUSINESS WIRE)-- Mind Medicine (MindMed) Inc. (NASDAQ:MNMD), (Cboe Canada:MMED), (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 year ended December 31, 2023 and provided a business update.

“2023 was a highly productive year for MindMed, which concluded with positive Phase 2b results for MM120 in the treatment of adult patients with GAD,” said Rob Barrow, Chief Executive Officer and Director of the Company. “We believe the initial data we shared validates our scientific understanding of MM120’s mechanism of action and shows the potential to have a best-in-class product profile compared to today’s standard of care. We look forward to sharing 12-week safety, efficacy, and durability data and results from our Phase 1 pharmacokinetics bridging trial to support the advancement of our MM120 oral dissolving tablet (ODT) formulation into pivotal clinical trials at our virtual investor event in March. Looking further into 2024, we anticipate several additional milestones, including one-year follow-up results from an investigator-initiated clinical trial of lysergide in anxiety disorders conducted by our collaborators at University Hospital Basel. We will be working closely with the FDA to finalize our Phase 3 development program for MM120 in GAD and expect to hold our End-of-Phase 2 meeting with the FDA in the first half of the year. This is intended to enable the initiation of our Phase 3 clinical program in the second half of the year.”

Business Update

- The Company will host a virtual investor event on March 7, 2024 to provide 12-week data from the Phase 2 program for MM120 being developed for the treatment of GAD. Senior management and key opinion leaders will discuss the treatment landscape, market potential and commercial opportunity for MM120 in GAD and other psychiatric disorders.

Program Updates and Anticipated Milestones

MM120 (lysergide D-tartrate) for GAD

- In December 2023, the Company announced statistically significant and clinically meaningful topline 4- week data from the 198-patient Phase 2b dose-optimization trial of MM120 for the treatment of GAD.
    - MM120 100 µg – the dose achieving the highest level of clinical activity – demonstrated a 7.6- point reduction on the Hamilton Anxiety rating scale (HAM-A) compared to placebo at Week 4 (-21.3 MM120 vs. -13.7 placebo; $p<0.0004$; Cohen's d effect size=0.88), which is more than double the effect sizes seen with the current standards of care[1].
    - Clinical response (50% or greater improvement in HAM-A) at Week 4 was achieved in 78% of participants treated with MM120 (100 µg or 200 µg) compared to 31% for placebo.
    - Clinical remission (HAM-A≤ 7) at Week 4 was achieved in 50% of participants treated with MM120 100 µg compared to 18% for placebo.
- The Company plans to share topline 12-week safety, efficacy, and durability results from the Phase 2b study and results from its pharmacokinetics bridging trial of the MM120 Zydis® ODT formulation, its intended commercial formulation of MM120, at an upcoming virtual investor event on March 7, 2024.
- The Company anticipates that full results from the Phase 2b trial of MM120 in GAD will be presented at a scientific meeting in 2024.
- The Company plans to hold an End-of-Phase 2 meeting with the FDA in the first half of 2024 and expects to initiate its Phase 3 clinical program in the second half of 2024.
- One-year follow-up data from a Phase 2 placebo-controlled investigator-initiated clinical trial of lysergide in the treatment of anxiety disorders is anticipated in 2024. This trial was conducted by the Company's collaborators at University Hospital Basel (UHB) in Switzerland and completed in Q3 2023.

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 and 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.
- In October 2023, the Company presented results from a nonclinical study in a model of ASD, titled "MM402 demonstrates better efficacy than S(+)-3,4-MDMA or (±)-3,4-MDMA in Fmr1 knockout mice, an animal model of autism spectrum disorder" at the 36th Annual European College of Neuropsychopharmacology (ECNP) Congress.
- UHB is currently conducting a Phase 1 investigator-initiated trial of R(-)-MDMA, S(+)-MDMA and R/S- MDMA in healthy adult 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.

2023 Financial Results

Cash Balance. As of December 31, 2023, MindMed had cash and cash equivalents totaling $99.7 million compared to $142.1 million as of December 31, 2022. The Company believes its available cash and cash equivalents as well as its committed credit facility are expected to fund operations into 2026, if certain milestones are achieved that unlock additional capital.

Net Cash Used in Operating Activities. For the year ended December 31, 2023, net cash used in operating activities was $64.4 million, compared to $50.1 million for the year ended December 31, 2022.

Research and Development (R&D). R&D expenses were $52.1 million for the year ended December 31, 2023, compared to $36.2 million for the year ended December 31, 2022, an increase of $15.9 million. The increase was primarily due to increases of $16.1 million in expenses related to clinical research and product development for the MM120 GAD Phase 2b clinical trial, and $2.6 million in internal personnel costs as a result of increasing research and development capacities, offset by a decrease of $0.7 million in expenses related to our MM402 program, a decrease of $0.8 million in expenses related to various external research and development collaborations, and a decrease of $1.2 million in expenses related to preclinical activities and the MM110 program.

General and Administrative (G&A). G&A expenses were $41.7 million for the year ended December 31, 2023, compared to $30.2 million for the year ended December 31, 2022, an increase of $11.5 million. The increase was primarily attributable to professional services fees and expenses related to the proxy contest in connection with our 2023 annual general meeting of shareholders and costs to support the growth of our business.

Net Loss. Net loss for the year ended December 31, 2023 was $95.7 million, compared to $56.8 million for the year ended December 31, 2022.

Conference Call and Webcast Reminder

MindMed management will host a conference call at 8:00 AM EST today to provide a corporate update and review the Company's 2023 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-HT2A]) 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-methylenedioxymethamphetamine), 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.

MindMed trades on NASDAQ under the symbol MNMD and on the Canadian Cboe 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, trials and studies; results and timing of and reporting of topline data from clinical trials, including the Company's expectations to announce 12- week data from its Phase 2b clinical trial for MM120 in GAD at its upcoming investor day; the Company's expectations to share results from its Phase 1 pharmacokinetics bridging trial of the MM120 Zydis® ODT formulation at its upcoming investor day; the Company's expectation that follow-up data from UHB's Phase 2 placebo-controlled investigator-initiated clinical trial will be released in 2024; the potential benefits of the Company's product candidates; potential additional psychiatric indications for MM120; the timing of a potential End-of-Phase 2 meeting with the FDA; the timing of a potential Phase 3 clinical trial for MM120 in GAD; the Company's expectations to present data from the Phase 2b trial for MM120 at a scientific meeting in 2024; the Company's expectation that topline results from UHB's Phase 1 investigator initiated trial will be presented in the first half of 2024; and the Company's expectation that its cash and cash equivalents are expected to fund operations into 2026, if certain milestones are achieved that unlock additional capital. 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.

[1] Source: RB Hidalgo, J Psychopharmacol. 2007 Nov;21(8):864-72.

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

	Years Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 52,124	$ 36,169
General and administrative	41,742	30,162
Total operating expenses	93,866	66,331
Loss from operations	(93,866)	(66,331)
Other income/(expense):		
Interest income, net	4,664	1,495
Foreign exchange gain, net	157	195
Change in fair value of 2022 USD Financing Warrants	(6,636)	7,843
Other (expense)/income	(51)	2
Total other (expense)/income, net	(1,866)	9,535
Net loss	(95,732)	(56,796)
Other comprehensive loss:		
Loss on foreign currency translation	(284)	(419)
Comprehensive loss	$ (96,016)	$ (57,215)
Net loss per common share, basic and diluted	$ (2.44)	$ (1.84)
Weighted-average common shares, basic and diluted (Note 2)	39,157,420	30,857,463

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

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 99,704	$ 142,142
Prepaid and other current assets	4,168	3,913
Total current assets	103,872	146,055
Goodwill	19,918	19,918
Intangible assets, net	527	3,689
Other non-current assets	224	331
Total assets	$ 124,541	$ 169,993
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 4,136	$ 2,111
Accrued expenses	11,634	5,877
2022 USD Financing Warrants	16,476	9,904
Total current liabilities	32,246	17,892
Credit facility, long-term	14,129	—
Other liabilities, long-term	32	1,184
Total liabilities	46,407	19,076
Shareholders' Equity:		
Common shares, no par value, unlimited authorized as of December 31, 2023 and 2022; 41,101,303 and 37,979,136 issued and outstanding as of December 31, 2023 and 2022, respectively	—	—
Additional paid-in capital	367,991	344,758
Accumulated other comprehensive income	343	627
Accumulated deficit	(290,200)	(194,468)
Total shareholders' equity	78,134	150,917
Total liabilities and shareholders' equity	$ 124,541	$ 169,993

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