

March 28, 2022



# MindMed Reports Full Year 2021 Financial Results and Business Highlights

*- FDA cleared MindMed's Investigational New Drug (IND) application for Phase 2b dose optimization trial of MM-120 -*

*- Progressed development programs for all three lead product candidates -*

*- Cash balance of \$133.5 million at year end 2021 -*

*- Company to host earnings conference call today at 8:30 AM EDT -*

NEW YORK, March 28, 2022 /CNW/ -- **Mind Medicine (MindMed) Inc.** (NASDAQ: MNMD), (NEO: MMED) (the "Company" or "MindMed"), a clinical stage biopharmaceutical company developing novel products to treat brain health disorders, today reported its financial results for the full-year ended December 31, 2021.



## MindMed

"2021 was a year of major advancements across all aspects of MindMed, with significant growth in our organization, development programs and research collaborations. We established a regulatory pathway for MM-120 in the treatment of GAD and, with MM-402, launched a program to develop a novel treatment for core symptoms of autism spectrum disorder – both of which represent meaningful leaps forward in the field of psychiatry," said Robert Barrow, Chief Executive Officer and Director of MindMed. "We expect 2022 to be a transformational year in which we continue to drive substantial growth across our pharmaceutical and digital medicine pipelines. I am incredibly proud of our team's achievements and I am more confident than ever in our ability to continue advancing our organization and development programs. We are keenly focused on our mission to deliver novel therapies to treat brain health disorders, leading to meaningful improvements in patient outcomes in these major areas of unmet medical need."

## Recent Highlights and Anticipated Upcoming Milestones

**MM-120 (LSD D-tartrate):** a proprietary, pharmaceutically optimized form of lysergic acid diethylamide (LSD) that is being developed for the treatment of generalized anxiety disorder

(GAD). MM-120 is also being studied under various dosing regimens for the treatment of adult attention deficit hyperactivity disorder (ADHD) and for the treatment of chronic pain.

- In January 2022, the U.S. Food and Drug Administration (FDA) cleared the Company's Investigational New Drug (IND) application for the Phase 2b dose-optimization trial of MM-120 for the treatment of GAD.
  - Study MMED008, a Phase 2b dose-optimization study of MM-120 for the treatment of GAD, is expected to begin in Q2 2022.
- In December 2021, Study MMED007, a Phase 2a proof-of-concept study, was initiated for the treatment of ADHD. The study is designed to assess the safety and efficacy of repeated low-dose MM-120 administration.
- A clinical study of MM-120 in a chronic pain condition is expected to be initiated in Q4 2022.

*MM-110 (zolunicant HCl or 18-MC)*: a derivative of ibogaine that the Company is developing for the treatment of opioid withdrawal. MM-110 is an  $\alpha 3\beta 4$  nicotinic cholinergic receptor antagonist that has been extensively tested in preclinical models of substance use disorders.

- In January 2022, the USAN Council assigned the non-proprietary name "zolunicant" (pronounced: zoe lun' i kant), to MM-110 or 18-MC.
- In December 2021, the Company completed a Phase 1 study of MM-110 with topline data expected in Q2 2022. These results will inform the design of the planned Phase 2a study in individuals undergoing standardized supervised opioid withdrawal, which is expected to commence in Q2 2022. The Phase 2a study will evaluate the safety, tolerability and efficacy of MM-110 in mitigating symptoms of opioid withdrawal and facilitating completion of detoxification.

*MM-402 (R(-)-MDMA)*: a synthetic enantiomer of MDMA that exhibits prosocial and empathogenic activity that the Company is developing for the treatment of core symptoms of autism spectrum disorder. Preclinical studies of R(-)-MDMA demonstrate its acute prosocial effects, while its diminished dopaminergic activity suggests that it may exhibit a favorable safety, tolerability and abuse liability profile when compared to racemic MDMA or the S(+)-enantiomer of MDMA.

- IND-enabling studies are currently ongoing and, through the Company's collaboration with University Hospital Basel, a comparative Phase 1 pharmacokinetic/pharmacodynamic study of R(-), S(+) and  $\pm$  MDMA is expected to commence in mid 2022.

## ***Digital Medicine Initiatives***

- In February 2021, the Company completed the acquisition of HealthMode and fully integrated its team to enable rapid progression of digital medicine and business operations functions.
- Having engaged in a productive Pre-Submission meeting with FDA in late 2021, in January 2022, the first subjects were enrolled into the Session Monitoring System (SMS-01) study evaluating the passive collection of sensory data during a consciousness-altering therapeutic session using the MindMed Session Monitoring System (MSMS).
- Anxiety Digital Diagnoses for Precision Psychiatry (ADDAPT, MMED-D001): A Natural

History Study and our newly developed mobile application to support the study is expected to launch in private beta in Q2 2022.

- In September 2021, the first participants were enrolled by invitation in the Quantifying the Processes and Events of Psychotherapy at Scale (MM061302) study.

## Collaborations and Partnerships

- University Hospital Basel (UHB): The Company continued to support the ongoing collaboration with the Liechti Lab at UHB in Switzerland. MindMed has exclusive worldwide rights to data, compounds and patent rights associated with the Liechti laboratory's research with LSD and other psychedelic compounds, including data from preclinical studies and over 15 completed and 9 ongoing clinical trials.
  - In March 2022, the peer-reviewed publication of a double-blind placebo-controlled comparative study of LSD and psilocybin was published in *Neuropsychopharmacology*. The study demonstrated that the key differences between LSD and psilocybin are dose-dependent rather than substance-dependent. These findings have the potential to assist with dose-finding, trial design and inform future studies evaluating the therapeutic utility of psychedelics.
  - In November 2021, the peer-reviewed publication of a randomized, double-blind, placebo-controlled study evaluating the interacting effects of an SSRI and psilocybin in healthy volunteers was published in *Clinical Pharmacology and Therapeutics*. The study suggests psilocybin is safe to take in combination with an SSRI.
- Nextage Therapeutics Ltd: The Company entered into a collaboration with Nextage Therapeutics in April 2021 to explore the therapeutic potential of noribogine in a proprietary brain targeted liposome drug delivery technology system to mitigate risks of peripheral adverse effects.
- MindShift Compounds AG: The Company continued to progress its collaborative research and development activities with MindShift Compounds AG in Basel, Switzerland, focusing on the discovery and optimization of next generation compounds, including those with and without acute perceptual effects.
- The Chopra Foundation: The company ultimately did not reach a definitive agreement for a potential collaboration and discontinued the engagement.

## Director & Officer Appointments

- In December 2021, [Robert Barrow](#) was appointed as Chief Executive Officer and as a member of the Board of Directors. Mr. Barrow previously served as interim Chief Executive Officer and Chief Development Officer of MindMed and brings strategic expertise and deep industry insight to his role.
- In December 2021, [Cynthia Hu, JD](#) was appointed as Chief Legal Officer and Corporate Secretary.
- In November 2021, [Carrie Liao, CPA](#) was appointed as VP, Corporate Controller and Principal Accounting Officer.
- In September 2021, [Carol Vallone](#) and [Andreas Krebs](#) were appointed to the Board of Directors and were subsequently appointed as chair and vice chair, respectively.
- In May 2021, [Sarah Vinson, MD](#) was appointed to the Board of Directors.
- In February 2021, [Daniel Karlin, MD, MA](#) was appointed as Chief Medical Officer.

## Scientific Advisory Board Appointments

- Over the course of 2021, we made significant additions to our Scientific Advisory Board (SAB), including:
  - [Robert C. Malenka, MD, PhD](#) (Professor, Stanford University) – SAB chair
  - [Maurizio Fava, MD](#) (Psychiatrist-In-Chief, Mass General Hospital; Associate Dean and Professor of Psychiatry, Harvard Medical School)
  - [Peter Bergethon, MD](#) (President, Symmetry Research; formerly Vice President, Biogen)
  - [Robert Dworkin, PhD](#) (Professor, Rochester University; Director, ACTION public-private partnership)
  - [Bryan Roth, MD, PhD](#) (Professor, University of North Carolina; Director, NIMH Psychoactive Drug Screening Program)
  - [Maria Oquendo, MD, PhD](#) (Chair and Professor of Psychiatry, University of Pennsylvania; Past President, American Psychiatric Association)

## 2021 Financial Results

*Cash Balance.* As of December 31, 2021, MindMed had cash totaling \$133.5 million compared to \$80.1 million as of December 31, 2020. MindMed believes its available cash and cash equivalents will be sufficient to meet its operating requirements beyond its key development milestones in 2023 and into 2024.

*Net Cash in Operating Activities.* The net cash used in operating activities was \$45.8 million for the year ended December 31, 2021, compared to \$23.6 million for the same period in 2020.

*Research and Development (R&D).* R&D expenses were \$34.8 million for the year ended December 31, 2021, compared to \$18.6 million for the year ended 2020. The increase was primarily due to an increase of \$2.7 million in expenses related to our MM-120 clinical research, \$2.3 million in expenses related to our MM-110 clinical research, \$3.5 million in expenses related to preclinical and other research programs, offset by a \$3.5 million decrease of expense in connection with various external R&D collaborations. Internal costs increased \$11.1 million primarily related to an increase in non-cash expenses of \$6.6 million of stock-based compensation expenses and \$2.6 million of amortization of our developed technology.

*General and Administrative (G&A).* G&A expenses were \$59.1 million for the year ended December 31, 2021, compared to \$14.4 million for the year ended 2020. The increase was primarily due to an increase of \$28.9 million in non-cash stock-based compensation expenses of which \$21.9 million related to the modification of stock options and RSUs. Other contributors to the increase included higher professional services including accounting, audit, legal, compliance, director and officer insurance, and investor and public relations and personnel costs to support the growth of the company.

*Net Loss.* The net and comprehensive loss for the year ended December 31, 2021 was \$92.3 million, compared to \$33.7 million for the year ended 2020.

## Conference Call and Webcast Reminder

MindMed management will host a conference call at 8:30 AM EDT today to provide a corporate update and review the Company's fiscal year 2021 financial results. Individuals may participate in the call via telephone by dialing (877) 407-0789 (domestic) or (201) 689-8562 (international) and using conference ID 13728028. The webcast can be accessed live [here](#) or on MindMed's [Investor Resources](#) webpage. 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 products to treat brain health disorders, with a particular focus on psychiatry, addiction, pain and neurology. 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 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 include, but are not limited to, statements regarding anticipated upcoming milestones and studies, results and timing of clinical studies, expected growth and developments of drugs and technologies, continuing collaborations and partnerships, and the availability of cash and cash equivalents. 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 under the headings "Risk Factors" in the Company's filings 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](http://www.sedar.com) and with the U.S. Securities and Exchange Commission on EDGAR at [www.sec.gov](http://www.sec.gov).

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

	For the Year Ended December 31, 2021	For the Year Ended December 31, 2020	For the Period from May 30, 2019 (Date of Incorporation) to December 31, 2019
Operating expenses:			
Research and development	\$ 34,789	\$ 18,631	\$ 7,549
General and administrative	59,065	14,399	3,178
Total operating expenses	<u>93,854</u>	<u>33,030</u>	<u>10,727</u>
Loss from operations	(93,854)	(33,030)	(10,727)
Other income (expense):			
Interest expense, net	(359)	(164)	10
Foreign exchange (loss) gain, net	(86)	130	18
Other income	106	—	—
Loss on revaluation of derivative liability	—	(873)	—
Total other expense, net	<u>(339)</u>	<u>(907)</u>	<u>28</u>
Loss before income taxes	(94,193)	(33,937)	(10,699)
Income tax benefit	(1,157)	—	—
Net loss	<u>(93,036)</u>	<u>(33,937)</u>	<u>(10,699)</u>
Other comprehensive gain:			
Gain on foreign currency translation	762	284	—
Comprehensive loss	<u>\$ (92,274)</u>	<u>\$ (33,653)</u>	<u>\$ (10,699)</u>
Net loss per common share, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.13)</u>	<u>\$ (0.10)</u>
Weighted-average common shares, basic and diluted (Note 2)	<u>410,656,231</u>	<u>266,220,592</u>	<u>102,763,621</u>

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

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Assets</b>		
Current assets:		
Cash	\$ 133,539	\$ 80,094
Prepaid and other current assets	3,676	1,425
Total current assets	<u>137,215</u>	<u>81,519</u>
Goodwill	19,918	—
Intangible assets, net	6,869	—
Total assets	<u>\$ 164,002</u>	<u>\$ 81,519</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 4,178	\$ 2,022
Accrued expenses	6,230	986
Total current liabilities	<u>10,408</u>	<u>3,008</u>
Contribution payable	1,930	2,643
Total liabilities	12,338	5,651
Commitments and contingencies (Note 11)		
Shareholders' Equity:		
Subordinate voting shares, no par value, unlimited authorized as of December 31, 2021 and 2020; 421,444,157 and 306,135,160 issued and outstanding as of December 31, 2021 and 2020, respectively	—	—
Multiple voting shares, no par value, unlimited authorized as of December 31, 2021 and 2020; 4,521 and 550,000 issued and outstanding as of December 31, 2021 and 2020, respectively	—	—
Additional paid-in capital	288,290	120,220
Accumulated other comprehensive income	1,046	284
Accumulated deficit	<u>(137,672)</u>	<u>(44,636)</u>
Total shareholders' equity	151,664	75,868
Total liabilities and shareholders' equity	<u>\$ 164,002</u>	<u>\$ 81,519</u>

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