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): November 2, 2023

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 November 2, 2023, Mind Medicine (MindMed) Inc. (the “Company”) issued a press release (the "Press Release:) announcing its financial results for its fiscal quarter ended September 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 7.01 Regulation FD Disclosure

The Company presented the slides attached as Exhibit 99.2 at its earnings call on November 2, 2023. A copy of the slides is posted on the Company’s website and is furnished as Exhibit 99.2 and incorporated herein by reference.

The information contained in this Item 7.01 of this Current Report (including Exhibit 99.2) is being furnished and shall not be deemed filed for purposes of Section 18 of 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 November 2, 2023
99.2	Third Quarter 2023 Financial Results and Business Update Presentation
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: November 2, 2023

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

Exhibit 99.1

MindMed Reports Third Quarter 2023 Financial Results and Business Highlights

– Topline readout of MM-120 in GAD (Phase 2b) expected in Q4 2023 –

– Topline readout of MM-120 in ADHD (Phase 2a proof-of-concept) anticipated by the end of Q1 2024 –

– MM-402 in ASD on track for Phase 1 clinical trial initiation in Q4 2023 –

– Cash and cash equivalents of $117.7 million at September 30, 2023 –

– Company to host conference call today at 4:30 PM ET –

NEW YORK, November 2, 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 September 30, 2023.

“During the third quarter we continued to focus on execution ahead of several key data readouts in the coming months. This includes, in particular, topline results from our Phase 2b study of MM-120 in generalized anxiety disorder (GAD) which are anticipated by the end of this year. Additionally, we anticipate the initiation of our Phase 1 study of MM-402 by the end of this year and reporting topline data from our proof-of-concept study of MM-120 in ADHD by the end of Q1 2024.” said Robert Barrow, Chief Executive Officer and Director of MindMed. *“The continued growth in prevalence and impact of GAD, ASD and other brain health disorders highlights the importance and timeliness of our innovative programs. Our team remains singularly focused on delivering novel treatments for brain health disorders to the millions of patients in need and we are eager to share these important milestones in the months ahead.”*

Recent Highlights and Anticipated Upcoming Milestones:

Phase 2b study evaluating MM-120 for generalized anxiety disorder (GAD) in adults.

- Study MMED008 is a multi-center, parallel, randomized, double-blind, placebo-controlled, dose-optimization study. The trial enrolled 198 participants who were randomized to receive a single oral administration of MM-120 (25 µg, 50 µg, 100 µg or 200 µg) or placebo.
- 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.
- Dosing is complete with topline results for the primary endpoint (Week 4) expected to be announced in Q4 2023.

•We anticipate the announcement of 12-week safety and efficacy results by the end of Q1 2024 and the presentation of the full data from the study at a scientific meeting in 2024.

Proof-of-Concept study evaluating repeated low-dose administration of MM-120 for attention-deficit/hyperactivity disorder (ADHD) in adults.

•Study MMED007 is a multi-center, randomized, double-blind, placebo-controlled study. The trial enrolled 53 participants who were randomized to receive twice-weekly oral doses of MM-120 20 µg or placebo for 6 weeks.

•Topline results expected by the end of Q1 2024.

•The primary endpoint of this study is the mean change from baseline at Week 6 in ADHD symptoms, as assessed by the Adult ADHD Investigator Rating Scale (AISRS).

Advancing development of MM-402 (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 in adults.

•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 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.

•In October 2023, the Company presented results from a MM-402 nonclinical study in a model of ASD, titled "MM-402 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.

Third Quarter 2023 Financial Results

Cash and Cash Equivalents Balance. As of September 30, 2023, MindMed had cash and cash equivalents totaling $117.7 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 nine months ended September 30, 2023, net cash used in operating activities was $43.8 million, compared to $37.3 million in the nine months ended September 30, 2022.

Research and Development (R&D). R&D expenses were $13.2 million for the quarter ended September 30, 2023, compared to $7.8 million for the quarter ended September 30, 2022, an increase of $5.4 million. The increase was primarily due to increases of $6.4 million in expenses related to clinical research and product development for the MM-120 GAD study, and $0.4 million in internal personnel

costs as a result of increasing research and development capacities, partially offset by a decrease of $0.4 million in expenses related to our MM-402 program, a decrease of $0.2 million related to our paused MM-110 program, a decrease of $0.5 million in preclinical activities, and a decrease of $0.2 million in connection with various external R&D collaborations.

General and Administrative (G&A). G&A expenses were $8.4 million for the quarter ended September 30, 2023, compared to $9.2 million for the quarter ended September 30, 2022, a decrease of $0.8 million. The decrease was primarily related to issuance costs related to the Company's 2022 USD Financing Warrants that were issued as part of the Company's public equity offering which closed on September 30, 2022.

Net Loss. Net loss for the quarter ended September 30, 2023, was $17.9 million, compared to $16.5 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 third quarter 2023 financial results. Individuals may participate in the live call via telephone by dialing (855) 327-6837 (domestic) or (631) 891-4304 (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 the progress of trials and studies; results and timing of and reporting of topline data from clinical trials; the potential benefits of the Company's product candidates, and the Company's cash runway and committed credit facility funding its 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, 2022, the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 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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ir@mindmed.co
media@mindmed.co

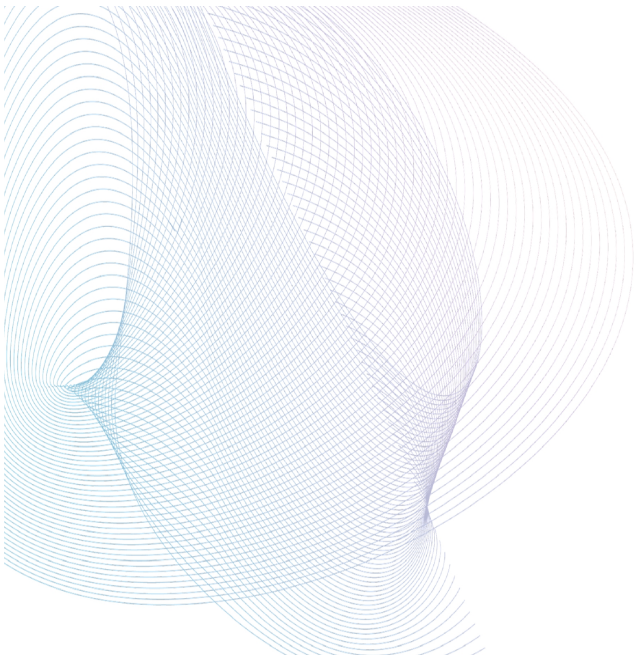
Mind Medicine (MindMed) Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited; in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 13,203	$ 7,772	$ 40,578	$ 27,339
General and administrative	8,413	9,211	31,083	25,092
Total operating expenses	21,616	16,983	71,661	52,431
Loss from operations	(21,616)	(16,983)	(71,661)	(52,431)
Other income/(expense):				
Interest income, net	1,163	360	3,759	443
Foreign exchange (loss)/gain, net	(439)	138	(244)	94
Change in fair value of 2022 USD Financing Warrants	3,020	—	(3,671)	—
Other (expense)/income	(51)	—	(51)	1
Total other income/(expense), net	3,693	498	(207)	538
Net loss	(17,923)	(16,485)	(71,868)	(51,893)
Other comprehensive loss				
Gain/(loss) on foreign currency translation	415	(107)	150	(303)
Comprehensive loss	$ (17,508)	$ (16,592)	$ (71,718)	$ (52,196)
Net loss per common share, basic and diluted	$ (0.45)	$ (0.56)	$ (1.85)	$ (1.82)
Weighted-average common shares, basic and diluted	39,720,007	29,296,333	38,798,374	28,566,161

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

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 117,699	$ 142,142
Prepaid and other current assets	2,387	3,913
Total current assets	120,086	146,055
Goodwill	19,918	19,918
Intangible assets, net	1,317	3,689
Other non-current assets	229	331
Total assets	$ 141,550	$ 169,993
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 7,686	$ 2,111
Accrued expenses	9,957	5,877
2022 USD Financing Warrants	13,511	9,904
Total current liabilities	31,154	17,892
Credit facility, long-term	14,068	—
Other liabilities, long-term	349	1,184
Total liabilities	45,571	19,076
Shareholders' Equity:		
Common shares, no par value, unlimited authorized as of September 30, 2023 and December 31, 2022; 40,094,708 and 37,979,136 issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	361,538	344,758
Accumulated other comprehensive income	777	627
Accumulated deficit	(266,336)	(194,468)
Total shareholders' equity	95,979	150,917
Total liabilities and shareholders' equity	$ 141,550	$ 169,993

Exhibit 99.2



MindMed

Third Quarter 2023 Financial Results and Business Update

November 2, 2023

Disclaimer

This presentation (the "Presentation") has been prepared by Mind Medicine (MindMed) Inc. ("MindMed" or the "Company") solely for informational purposes. None of MindMed, its affiliates or any of their respective employees, directors, officers, contractors, advisors, members, successors, representatives or agents makes any representation or warranty as to the accuracy or completeness of any information contained in this Presentation and shall have no liability for any representations (expressed or implied) contained in, or for any omissions from, this Presentation. This Presentation does not constitute an offering of, or a solicitation of an offer to purchase, securities of MindMed and under no circumstances is it to be construed as a prospectus or advertisement or public offering of securities. Any trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of the products or services of MindMed. Any amounts are in USD unless otherwise noted. MindMed's securities have not been approved or disapproved by the Securities and Exchange Commission (the "SEC") or by any state, provincial or other securities regulatory authority, nor has the SEC or any state, provincial or other securities regulatory authority passed on the accuracy or adequacy of this Presentation. Any representation to the contrary is a criminal offense.

Cautionary Note Regarding Forward-Looking Statements

This Presentation contains, and our officers and representatives may from time to time make, "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995 and other applicable securities laws. Forward-looking statements can often, but not always, be identified by words such as "plans", "expects", "is expected", "budget", "scheduled", "estimates", "forecasts", "intends", "anticipates", will", "projects", or "believes" or variations (including negative variations) of such words and phrases, or statements that certain actions, events, results or conditions "may", "could", "would", "might" or "will" be taken, occur or be achieved, and similar references to future periods. Except for statements of historical fact, examples of forward-looking statements include, among others, statements pertaining to: the development and commercialization of any medicine or treatment, or the efficacy of either of the foregoing, the success and timing of our development activities; the success and timing of our planned clinical trials; our ability to meet the milestones set forth herein; the likelihood of success of any clinical trials or of obtaining FDA or other regulatory approvals; the likelihood of obtaining patents or the efficacy of such patents once granted and the potential for the markets that MindMed is anticipating to access.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions as of the date of this Presentation. While MindMed considers these assumptions to be reasonable, the assumptions are inherently subject to significant business, social, economic, political, regulatory, competitive and other risks and uncertainties that are difficult to predict and many of which are outside of MindMed's control, and actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to raise capital to complete its plans and fund its studies; the medical and commercial viability of the contemplated medicines and treatments being developed; MindMed's history of negative cash flows; MindMed's limited operating history; incurrence of future losses; 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 throughout the "Risk Factors" sections of MindMed's most recently filed Annual Report on Form 10-K filed with the SEC, the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2023, and in other filings we make in the future with the SEC and the securities regulatory authorities in all provinces and territories of Canada, available under the Company's profile on SEDAR at www.sedar.com.

Any forward-looking statement made by MindMed in this Presentation is based only on information currently available to the Company and speaks only as of the date on which it is made. MindMed undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Cautionary Note Regarding Regulatory Matters

The United States federal government regulates drugs through the Controlled Substances Act. The Company works with a non-hallucinogenic synthetic derivative of the psychedelic substance ibogaine, known as zolunicant which is a synthetic organic molecule designed around a common coronaridine chemical backbone. Zolunicant is not a Schedule I substance in the United States and the Company does not foresee it becoming a Schedule I substance due to its non-hallucinogenic properties. While the Company is focused on programs using psychedelic or hallucinogenic compounds and non-hallucinogenic derivatives of these compounds, the Company does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances in the jurisdictions in which it operates. The Company is a neuro-pharmaceutical drug development company and does not deal with psychedelic or hallucinogenic substances except within laboratory and clinical trial settings conducted within approved regulatory frameworks. The Company's products will not be commercialized prior to applicable regulatory approval, which will only be granted if clinical evidence of safety and efficacy for the intended uses is successfully developed.

Market and Industry Data

This Presentation includes market and industry data that has been obtained from third party sources, including industry publications. MindMed believes that the industry data is accurate and that the estimates and assumptions are reasonable, but there is no assurance as to the accuracy or completeness of this data. Third party sources generally state that the information contained therein has been obtained from sources believed to be reliable, but there is no assurance as to the accuracy or completeness of included information. Although the data is believed to be reliable, MindMed has not independently verified any of the data from third party sources referred to in this Presentation or ascertained the underlying economic assumptions relied upon by such sources. References in this Presentation to research reports or to articles and publications should be not construed as depicting the complete findings of the entire referenced report or article. MindMed does not make any representation as to the accuracy of such information.

MindMed Third Quarter Financial Results and Business Update Call Participants

Robert Barrow
Chief Executive Officer and Board Director

Schond Greenway, MBA
Chief Financial Officer

Daniel Karlin, MD, MA
Chief Medical Officer

Francois Lilienthal, MD, MBA
Chief Commercial Officer

We Aim To Be A Global Leader In Brain Health

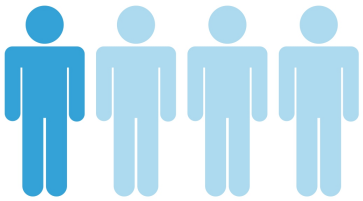
A Diversified pipeline
of clinical programs targeting significant unmet medical needs

Advanced clinical development of product candidates
- MM-120: Phase 2b – dose-optimization (GAD)
- MM-120: Phase 2a – proof-of-concept (ADHD)
- MM-402: IND-enabling
- MM-402: Phase 1 IIT – R-, S- and R/S-MDMA

Expected cash runway
through key clinical readouts and into 2026*

*The company's ending Q3 2023 cash and cash equivalents of $117.7 million and committed credit facility are expected to fund operations into 2026, if certain milestones are achieved that unlock additional capital.

Urgent Need for Better Treatments for Brain Health Disorders

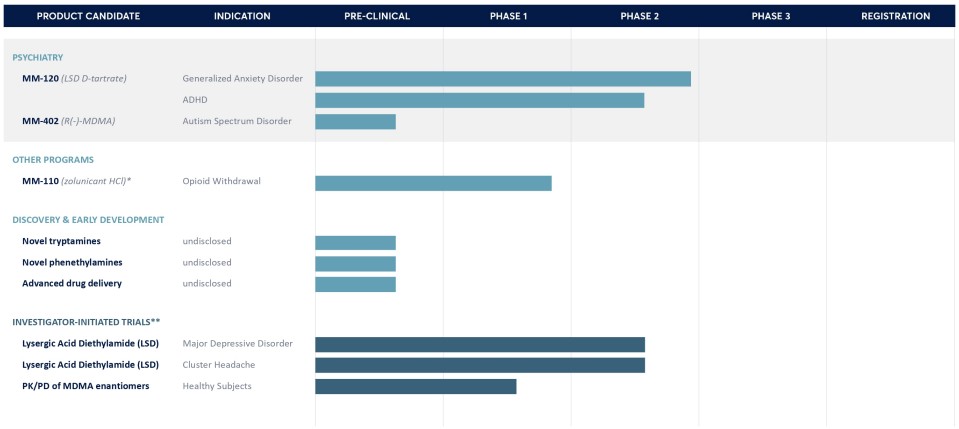


1 in 4 U.S. Adults
has a Diagnosable Mental Health Disorder[1]

GAD	10%	1-year prevalence of anxiety disorders in the US[1]
ADHD	4.4%	estimated prevalence of ADHD among US adults[2]
ASD	$461B	economic cost of ASD in the US predicted by 2025[3]

1. Mental and Substance Use Disorders Prevalence Study (MDPSU): Findings Report 2023.
2. Kessler RC, Adler L, Barkley R, et al. 2005; Am J Psychiatry; 163(4).
3. Leigh JP and Du J 2015; J. Autism Dev. Disord.; 45(12).

Diversified Pipeline Of Product Candidates Targeting Significant Unmet Needs



* Continued development of MM-110 is currently subject to the Company obtaining non-dilutive sources of capital and/or collaboration partners.
** Full trial details and clinical trials.gov links available at mindmed.co/clinical-digital-trials/
ADHD: Attention-Deficit/Hyperactivity Disorder; LSD: lysergic acid diethylamide; MDMA: 3,4-methylenedioxymethamphetamine

MM-120 | Addressing a Large Unmet Need for Better Anxiety Treatments

Opportunity in Generalized Anxiety Disorder (GAD)

- **GAD is the 2nd most common mental disorder** among adults 18 to 65 years old[1], yet choices are limited beyond SSRI/SNRIs
- **Symptoms are debilitating** and side effects / lack of efficacy often lead to frequent treatment change until patient is considered treatment resistant

Potential Best-in-Class Therapy with Novel MOA

Large Market Opportunity

~20 million US adults with GAD[1], 77% have moderate to severe GAD[2]

13 million receive treatment[1]

6.5 million do not respond to first-line treatment (SSRI)[3]

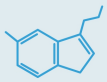
Significant Need for New Treatment Options

- **SSRI/SNRIs[1]:** 50% failure rate with often undesirable side effects
- **Benzodiazepines:** addiction, tolerance risk; generally used in short-term
- **Buspirone[4]:** poor efficacy vs. SSRI/SNRI and benzodiazepines; poorly tolerated
- **Antipsychotics:** short- and long-term risks; poorly tolerated

1. Mental and Substance Use Disorders Prevalence Study (MDPSU): Findings Report 2023.
2. Kessler RC, Chiu WT, Demler O et al. Prevalence, Severity, and Comorbidity of 12-month DSM-IV Disorders in the National Comorbidity Survey-Replication. 2005 Arch Gen Psychiatry; 62(6): 617-627.
3. Ansara, Management of Treatment-Resistant Generalized Anxiety Disorder, Ment Health Clin 2020 Nov; 10(6) 326-334) United States Census Bureau, company calculations.
4. Garakani A, et al., (2020) Pharmacotherapy of Anxiety Disorders: Current and Emerging Treatment Options. Front. Psychiatry 11:595584. doi: 10.3389/fpsyt.2020.595584

MM-120 | Proof-of-Concept of Outpatient Delivery in ADHD

- We are optimizing MM-120 across indications through the study of various doses and regimens, such as in the current Phase 2a trial in ADHD.
- Approach could be applicable to additional serotonin-mediated conditions with the potential for additional innovative dose and regimen combinations



Serotonin

MM-120 targets this **key neurotransmitter system** that is implicated in ADHD symptoms[1]

Innovative treatment paradigms
Phase 2a trial in ADHD exploring outpatient administration (20 µg twice weekly)

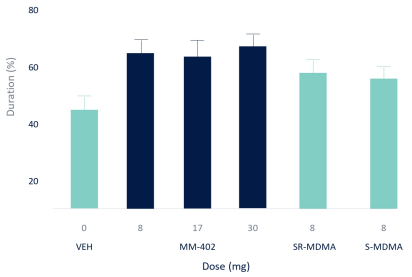
1. Wang LJ, Yu YH, Fu ML et al. 2018; Sci Rep 8(1):10229.

MM-402 | Addressing the Urgent Need For Novel ASD Therapies

Translational pre-clinical data suggest that MM-402's pharmacological profile may align with patient-desired treatment benefits in ASD

- MM-402 is a pharmaceutically preferential enantiomer of MDMA
- Potential first-in-class therapy for core symptoms of ASD
- Plan to develop for standard, at-home dose delivery

Increased duration of interaction in the three-chamber social interaction test[1]



Enhanced pro-social effects with potentially **reduced side effects** compared to MDMA

less stimulant activity	increasing social interaction[2]
Increasing feelings of connectedness	reduced dopaminergic-linked adverse effects[2]

1. "MM-402 demonstrates better efficacy than S(+)-3,4-MDMA or (±)-3,4-MDMA in Fmr1 knockout mice, an animal model of autism spectrum disorder". Presented at ECNP 2023. Data from "stranger" portion of "Duration in the arena" data.
2. Pitts EG, Curry DW, Hampshire KN et al. 2018; Psychopharmacology; 235(2):377-392.

MM-120
LSD D-tartrate

for Generalized Anxiety Disorder (GAD)

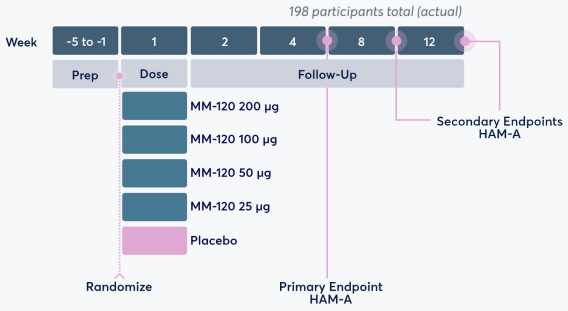
Lysergide Has Proven Potential Across Multiple Therapeutic Areas

PSYCHIATRY	**Broad Applicability** preliminary signs of efficacy across multiple diagnoses[1]	**Long-Term Value** through multi-pronged life cycle management
ANXIETY	**Rapid & Sustained** benefit observed after acute dosing[1]	**3x Effect Size** compared to leading anxiety treatments[2]
SAFETY & PHARMACOLOGY	**10,000+** patients treated in clinical trials[1]	**Well-Characterized** tolerability, pharmacokinetics and pharmacodynamics

1. Gasser P, Holstein D, Michel Y et al. 2014; J. Nerv. Ment. Dis.; 202(7).
2. Fuentes JJ, Fonseca F, Elices M et al. 2020; Front Psychiatry; 10:943.

MM-120 | Phase 2b Generalized Anxiety Disorder (GAD)

PSYCHIATRY | **MM-120** *(LSD D-tartrate)* | Indication: GAD | PHASE 2B



Study MMED008 | MM-120 for GAD

A Phase 2b Dose Optimization Study of a Single Dose of MM-120 in Generalized Anxiety Disorder

KEY ENTRY CRITERIA

- Men and Women
- Ages 18-74
- Diagnosis of GAD
- HAM-A ≥ 20

ADDITIONAL ENDPOINTS

- MADRS
- CGI-S / I
- PGI-S / C
- SDS
- EQ-5D-5L
- PSQI
- ASEX

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Source: MindMed internal study documents
µg: microgram; HAM-A: Hamilton Anxiety Rating Scale; MADRS: Montgomery-Asberg Depression Rating Scale; CGI-S: Clinical Global Impression - Severity; PGI-S: Patient Global Impression - Severity; SDS: Sheehan Disability Scale; EQ-5D-5L: EuroQol-5 Dimension; PSQI: Pittsburgh Sleep Quality Index; ASEX: Arizona Sexual Experiences Scale

MM-120 | Trial Design Milestones for Psychedelic Drug Class

FDA guidance and Phase 2b dose-finding study align with MindMed's framework for designing **well-controlled, scientifically rigorous trials** to assess **safety and efficacy** in the psychedelic drug class

FDA issues first draft guidance on clinical trials with psychedelic drugs

- Agency provides clarity on regulatory expectations and R&D considerations
- Guidance will "help researchers design studies that will yield interpretable results that will be capable of supporting future drug applications"[1]

Phase 2b design aligns well with FDA guidance

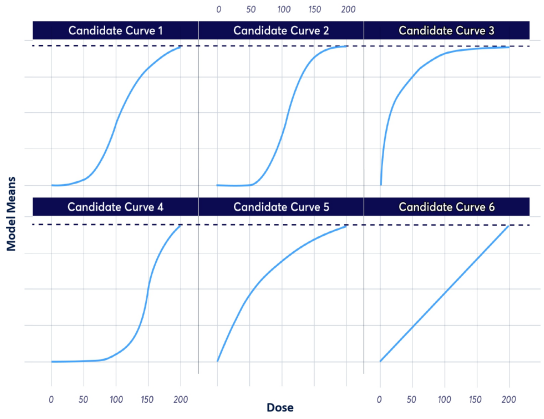
- **No concurrent psychotherapy** – "Psychotherapeutic interventions have the potential to increase expectancy and performance biases"[1]
- **Placebo-controlled** – "allows for better contextualization of safety findings"[1]
- **Dose-ranging** – "The dose-response relationship for most psychedelic drugs is poorly understood. Sponsors should take appropriate steps to characterize the dose-response relationship."[1]

1. FDA. "Psychedelic Drugs: Considerations for Clinical Investigations"

MM-120 | Phase 2b Generalized Anxiety Disorder (GAD) - Primary Analysis

Multiple Comparison Procedure Modelling (MCP-Mod)

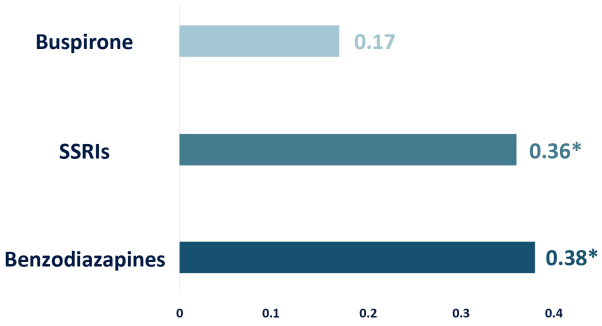
- Statistical methodology for dose-response developed by Novartis in 2004[1]
- Involves establishing a dose-response signal using multiple comparison procedures and then estimating the dose-response curve and target doses of interest using modelling techniques
- Qualification opinions from both FDA and EMA
  - FDA: "MCP-Mod method is found more effective than pairwise comparison due to its ability to utilize all available data"[2]
  - EMA: "The MCP-Mod approach is efficient in the sense that it uses the available data better than the commonly applied pairwise comparisons..."[3]



1. Novartis. "The MCP-Mod methodology – A statistical methodology for dose-response
2. FDA, Office of Clinical Pharmacology, Division of Pharmacometrics
3. EMA, Committee for Medicinal Products for Human Use

MM-120 | Illustrative Analysis of Pharmacologic Treatments for GAD[1]

Reported Mean Effect Size by Existing Therapeutic Drug Class[1,2]



* = P <0.05

- **Effect size (ES)** presents the adjusted to the mean difference in treatment response between placebo and active treatment
- ES useful to **compare overall treatment effects** across trials
- Results from published review of effect sizes for double-blind, placebo-controlled trials of GAD treatments primarily using **HAM-A as the main outcome measure**
- SSRIs and benzodiazepines, the major therapeutic classes of drugs approved for GAD, have mean effect sizes that **range between 0.36 to 0.38**

1. Examination of baseline group assignment for all of the studies (20 studies utilizing the HAM-A (Hamilton Anxiety Scale) and 1 study using the PARS (Pediatric Anxiety Scale) for the primary outcome measurement.
2. Source: RB Hidalgo, J Psychopharmacol. 2007 Nov;21(8):864-72.
3. ES is calculated by dividing the difference between the mean values of the two groups by the standard deviation value.

Potential to Leverage Existing Monitored Delivery Infrastructure

Spravato® (esketamine) for the treatment of Major Depressive Disorder (MDD)

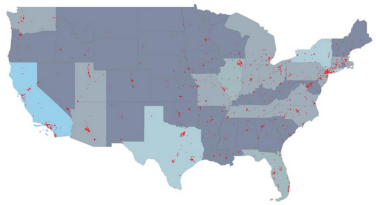
Monitored Delivery Paradigm Established for Spravato

- 8 intranasal 2-hr treatments over a 4-week period **(16 hours)**[1] with 4 additional 2-hr treatments over 4 weeks **(8 hours)**[1]; translating into ***at least 24 hours in treatment sessions over the first 8 weeks of treatment alone***[1]
- Once a week or every 2 weeks thereafter on an individualized basis[1]

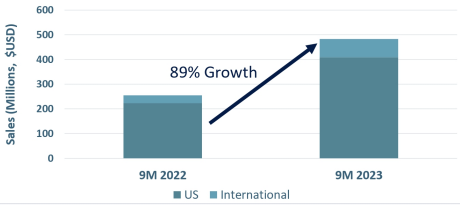
Attractive Commercial Opportunity

- Over 3,000 treatment centers nationwide[2]
- Certified clinicians and physicians
- Acceptance by major insurers (United, Cigna, Blue Cross/Blue Shield, etc.)[2]
- Reported 9M sales of $483m, up 89% compared to the first nine months of 2022[3]

Geographic Distribution of Spravato Treatment Centers[2]



Reported Spravato Sales[3]



1. Spravato FDA Prescribing Information
2. Johnson & Johnson; Spravato website. Compiled by company
3. Company Report Johnson & Johnson; July 20, 2023 Financial Results for 9 months ending September 30, 2023 and September 30, 2022

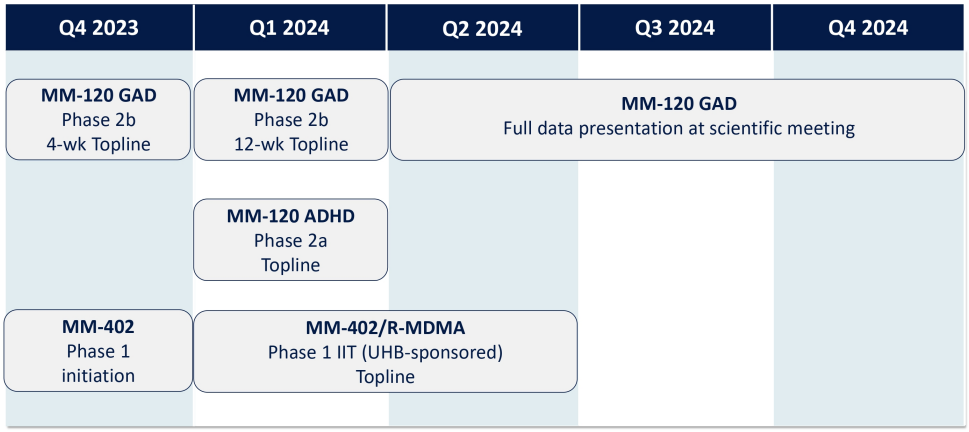
Financial Results

Third Quarter 2023 Financial Results

$ in Millions	Q3 2023	Q3 2022
R&D Spending	**$13.2**	**$7.8**
G&A Spending	**$8.4**	**$9.2**
Operating Expenses	**$21.6**	**$17.0**
Net cash used in operating activities	**$43.8** (9-month period ending Sept. 30, 2023)	**$37.3** (9-month period ending Sept. 30, 2022)
Cash and cash equivalents	**$117.7**	**$142.1** (as of Dec. 31, 2022)

Financial Guidance: The Company's ending 3Q2023 cash and cash equivalents of $117.7 million and committed credit facility are expected to fund operations into 2026, if certain milestones are achieved that unlock additional capital

Anticipated Near-Term Milestones



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Q&A