
**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 14, 2023

Mind Medicine (MindMed) Inc.

(Exact name of Registrant as Specified in Its Charter)

New York
(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: (212) 220-6633

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

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))

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

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 7.01 Regulation FD Disclosure.

On August 14, 2023, Mind Medicine (MindMed) Inc. (the “Company”) posted an updated corporate presentation on the Company’s website, which the Company may use from time to time in conversations with investors, analysts or other third parties.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01 and Exhibit 99.1 hereto 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 liability of that section, nor shall it be deemed incorporated by reference in any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

As disclosed above, on August 14, 2023, the Company updated its corporate presentation, which is attached as Exhibit 99.1 hereto. The information in Exhibit 99.1 is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Investor presentation dated August 14, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MIND MEDICINE (MINDMED) INC.

Date: August 14, 2023

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



MindMed

Investor Presentation

August 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 shall not constitute an offer, nor a solicitation of an offer, of the sale or purchase of securities. This Presentation does not constitute an offering of 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 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 we consider 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 our control, and our 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 our 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; our ability to raise additional capital in the future as we continue to develop our products; our history of negative cash flows; our limited operating history; incurrence of future losses; lack of 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 throughout the "Risk Factors" sections of our Annual Report on Form 10-K for the year ended December 31, 2022 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 filed with the Securities and Exchange Commission (the "SEC") 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 us in this Presentation is based only on information currently available to us 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 zoluncant which is a synthetic organic molecule designed around a common coranaridine chemical backbone. Zoluncant 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 at a Glance: A Global Leader in Brain Health

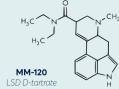
Using industry-leading drug development expertise to unlock the full therapeutic potential of psychedelics and other novel product candidates

Advancing Proprietary Drug Candidates Across Psychiatric Indications

MM-120

Generalized Anxiety Disorder (GAD) & Attention-Deficit/Hyperactivity Disorder (ADHD)

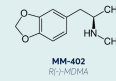
- Well-characterized pharmacology
- Accelerated development potential



MM-402

Autism Spectrum Disorder (ASD)

- Enhanced pharmacology
- Potential to overcome safety liabilities
- Standard delivery / dosing model



Business Highlights

- **Diversified pipeline** of clinical programs targeting significant unmet medical needs
- **Pivotal inflection point** with key clinical readout expected in Q4 2023
- **IP and R&D strategies** intended to maximize market exclusivity and protection
- **Expected cash runway** through key clinical readouts and into 2026¹

1. The company's ending Q2 2023 cash and cash equivalents of \$116.9 million and committed credit facility are expected to fund operations into 2026, if certain milestones are achieved that unlock additional capital

There is an Urgent Need for Better Treatments

Substantial opportunities exist to advance novel treatments for a wide range of brain health disorders



**1 in 4 U.S. Adults has a Diagnosable
Mental Health Disorder¹**

GAD

10%

1-year prevalence of anxiety disorders in the US¹

ADHD

4.4%

estimated prevalence rate of ADHD among all US adults²

ASD

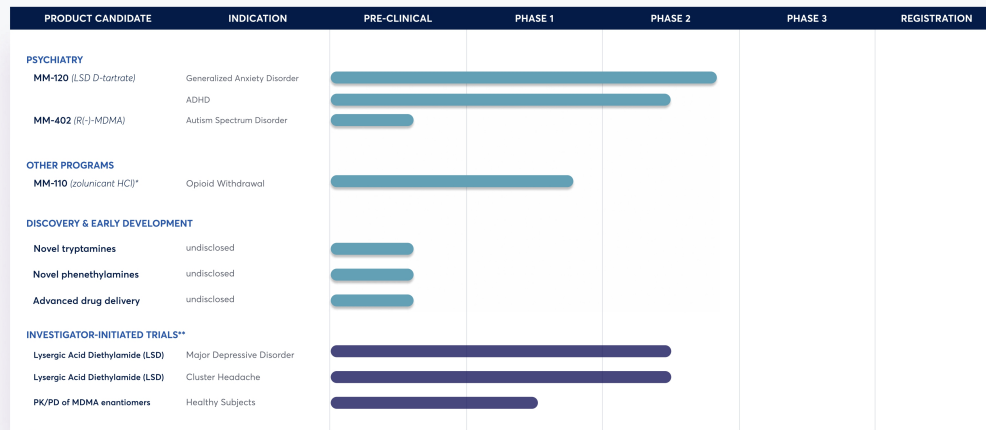
\$461B

economic cost of ASD in the US predicted by 2025³

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. 162(4).
3. Leigh & Du 2015; J Autism Dev Disord.; 45(12).

Research & Development Pipeline

Our pipeline diversification offers potential opportunities across therapeutic areas and mechanisms of action



* 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-trials

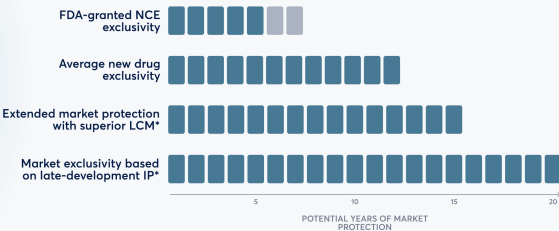
ADHD: Attention-Deficit/Hyperactivity Disorder; LSD: lysergic acid diethylamide; MDMA: 3,4-methylenedioxymethamphetamine

Advancing the Field with Strong IP & Strategic Competitive Moats

MindMed seeks to protect innovation and market potential through intellectual property-oriented R&D strategies



Strategic Life Cycle Management & Late-Stage IP Development Can Significantly Extend Market Protection



*For illustrative purposes only
R&D: Research & Development; LCM: Life Cycle Management; NCE: New Chemical Entity

MM-120

LSD D-tartrate

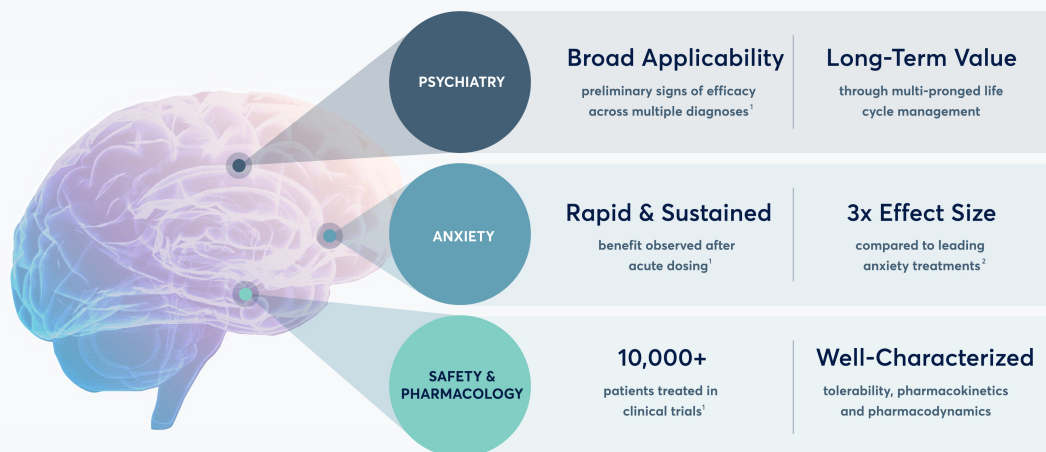
Key Milestones Anticipated

Phase 2b in GAD
Topline Data | Q4 2023

Phase 2a in ADHD
Topline Data | Q4 2023 / Q1 2024

Lead Candidate with Evidence Across Multiple Therapeutic Areas

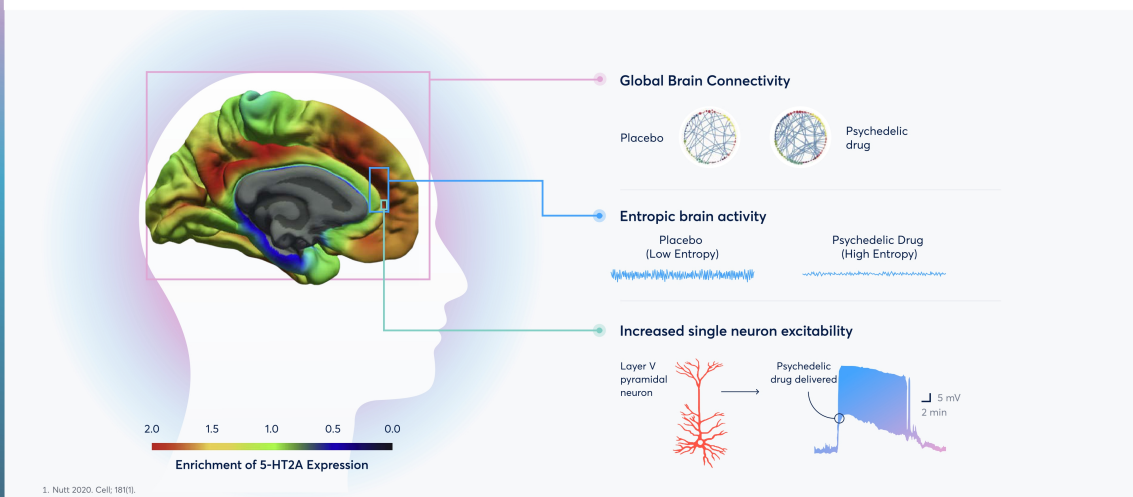
Extensive evidence of clinical benefit and mechanistic rationale in psychiatry and other brain disorders¹



1. Gasser 2016, J. Nerv. Ment. Dis., 202(7).
2. Fuentes 2020, Front Psychiatry, 10:943.

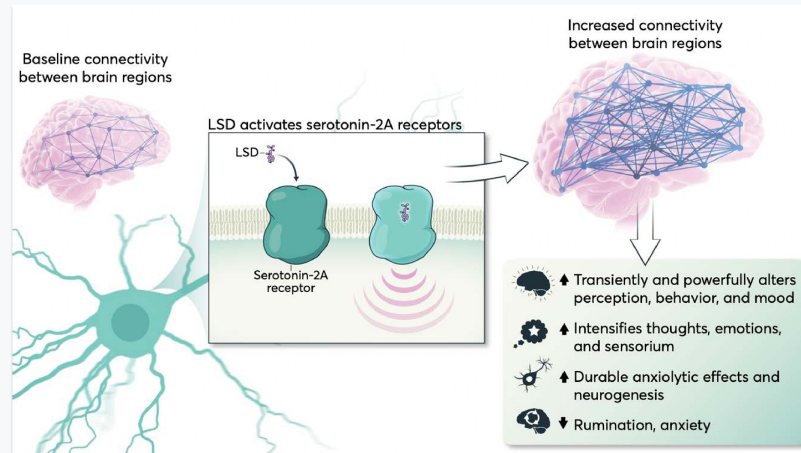
Emerging Treatment Paradigm for Brain Health Disorders

MM-120 is a potent serotonin agonist with potential applications to a broad range of brain health disorders ¹



Mechanism of Action Driving Potential Durable Clinical Response

Unique mechanism of action increases brain connectivity, enabling rapid and durable effects

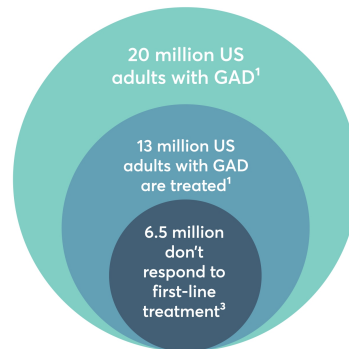


An Urgent Need for Better Anxiety Treatments

Generalized Anxiety Disorder is underdiagnosed, underserved and has lacked innovation for decades

GAD presents large and unmet patient need

- Prevalence of 10.0% among US adults¹
- 77% of patients present with moderate-to-severe GAD²
- 50% of those treated fail an SSRI³ and 10-20% have failed at least two treatments⁴
- Current standard of care dominated by SSRI/SNRIs and benzodiazepines



1. Mental and Substance Use Disorders Prevalence Study (MDPSU): Findings Report 2023

2. J. Kessler Arch Gen Psychiatry 2005 June; 62(6): 617-627

3. Arsava, Ment Health Clinu 2020 Nov; 10(6): 326-334; United States Census Bureau, company calculations.

4. Market research prepared by external advisers, 2022. Company calculations.

Extensive LSD Clinical Research in Psychiatric Disorders

MM-120 program builds on decades of clinical research of LSD, the most studied drug in its class

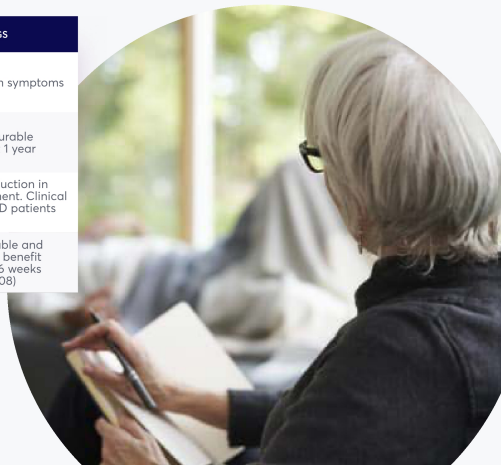
STUDIES	INDICATION(S)	SAMPLE SIZE	KEY FINDINGS
21 STUDIES PRIOR TO 1974¹	Anxiety, depression & neurotic illnesses	512 patients	Up to 95% reduction in symptoms
GASSER 2014²	Anxiety in terminal illness	12 patients	Effect size of 1.1 with durable reduction in anxiety at 1 year
HOLZE 2022³	Anxiety	42 patients	Rapid and durable reduction in symptoms post-treatment. Clinical response in 65% of LSD patients vs. 9% in placebo
HOLZE 2023⁴	Major Depressive Disorder	61 patients	Significant, rapid, durable and beneficial effects, with benefit maintained for up to 16 weeks post-treatment (p=0.008)

1. Rucker 2016. J. Psychopharmacol. 30(12).

2. Gasser 2014. J. Nerv. Ment. Dis. 202(7).

3. Holze, Gasser et. al. 2022. Biological Psychiatry.

4. UHB presentation; April 2023.

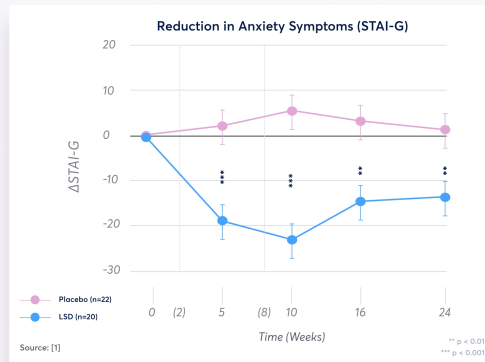


Modern Evidence in Anxiety Disorders

Results from UHB's LSD-Assist study support MindMed's clinical development of MM-120 for GAD

Rapid, durable and significant anxiolytic effects¹

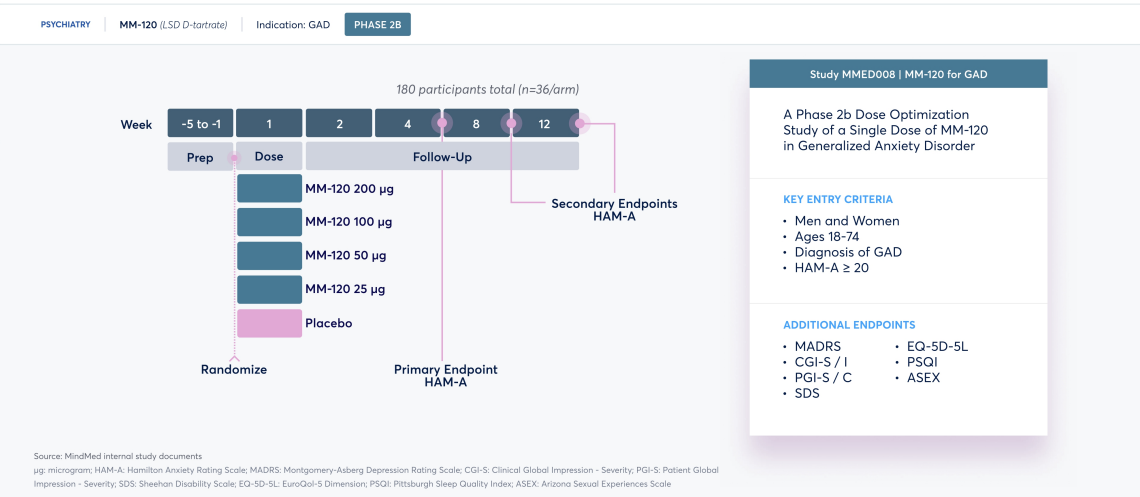
- Reduction in anxiety and depression symptoms; durable at 16 weeks post-treatment vs. placebo ($p < 0.007$)
- Clinical response ($\geq 30\%$ reduction) observed in 65% of LSD group vs 9% of placebo group ($p < 0.003$)
- Positive correlation between acute positive effects or mystical experiences and clinical outcomes
- Well-tolerated at 200 μg : 1 serious adverse event (acute transient anxiety and delusions) and no other adverse events attributed to treatment
- No instances of suicidal ideation with intent attributed to treatment



¹. Holze, Gasser et. al. 2022. Biological Psychiatry.
STAI-G: State-Trait Anxiety Inventory; μg : microgram

Phase 2b Generalized Anxiety Disorder (GAD)

Study design seeks to evaluate dose-responsive effects and identify optimal dose for pivotal clinical trials



Potential MM-120 Clinical Care Model

Advancing a delivery model that seeks to optimize outcomes

Pre-Treatment	During Treatment	Post-Treatment
<ul style="list-style-type: none">• Patient education, engagement, preparation• Eligibility evaluation• Care coordination with existing clinical team	<ul style="list-style-type: none">• Continuous monitoring by qualified session monitors• Non-directive psychosocial support• Accompanied discharge when release criteria met	<ul style="list-style-type: none">• Follow-up psychosocial support• Continuation of standard psychiatric care• Remote monitoring for re-treatment needs
		

Digital Unlocks Potential Opportunities Throughout the Product Lifecycle

Generating data, insights, models, and tools from early development through market management

Preclinical Research IND & Phases 1 - 3 Drug Launch Enhancement and Lifecycle Management

Clinical Development Tools



- Patient education, engagement, preparation
- Deep digital diagnosis

Companion Products



- In-session monitoring
- Predictive intervention
- Treatment selection

Post-Approval Research



- Surveillance & registries
- Remote management
- HEOR

Combination Products



- Drug-device combinations
- Lifecycle enhancement
- Efficient Phase 4 research

HEOR: health economics and outcomes research

Potential Pathway to Commercial Success for MM-120

Our approach seeks to leverage well-established pathways to bring novel therapeutics to patients at scale

Submit Marketing Applications	<ul style="list-style-type: none">• Seek approval for drug product candidates in major markets globally• Collaborate with healthcare authorities to seek targeted labeling• Strategic plans for long-term product life cycle management and market preservation
Rescheduling	<ul style="list-style-type: none">• Review rescheduling processes of preceding products• Advance conversations with national, federal, and state authorities• Propose rescheduling in marketing applications
Reimbursement	<ul style="list-style-type: none">• Engage payers to develop a comprehensive market access strategy• Generate HEOR evidence to maximize reimbursability of drug and dosing session• Develop provider tools to enhance reliability of reimbursement
Real-World Adoptability	<ul style="list-style-type: none">• Employ a precedent-based development strategy that bridges the novelty of the therapeutic class with the existing care delivery landscape

HEOR: health economics outcomes research

Phase 2a Attention-Deficit Hyperactivity Disorder (ADHD)

Multi-faceted approach directly targeting the serotonin system

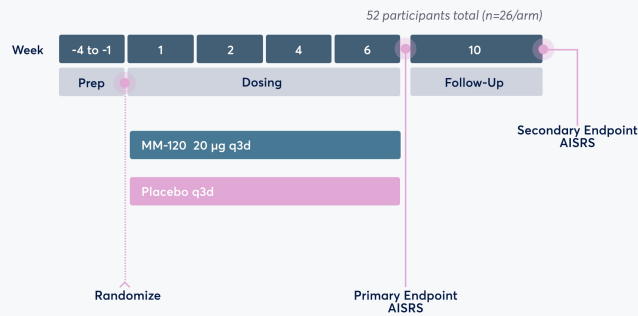
Maximizing MM-120 value through study of various doses and schedules to optimize the drug across indications

- Serotonin is a critical and increasingly **well-studied target** in psychiatry
- Creatively exploring **innovative treatment paradigms**
- Repeated sub-perceptual doses of MM-120 in ADHD seek to demonstrate proof of principle for both the regimen and **at-home delivery**.

Phase 2a Attention-Deficit Hyperactivity Disorder (ADHD)

Proof of concept study design seeks to explore potential clinical response in ADHD

PSYCHIATRY | MM-120 (LSD D-tartrate) | Indication: ADHD | PHASE 2A



Study MMED007 | MM-120 for ADHD

A Phase 2a Proof of Concept Study of Repeated Low Doses of MM-120 for the Treatment of ADHD in Adults

KEY ENTRY CRITERIA

- Men and Women
- Ages 18-65
- Diagnosis of ADHD
- AISRS ≥ 26
- CGI-S ≥ 4

ADDITIONAL ENDPOINTS

- AISRS
- CGI-S
- ASRS
- CAARS
- Sleep Diary

Source: MindMed internal study documents

AISRS: Adult ADHD Investigator Symptom Rating Scale; ASRS: Adult ADHD Self-Report Scale; CAARS: Conners' Adult ADHD Rating Scales; CGI-S: Clinical Global Impression - Severity

MM-402

R(-)-MDMA

Key Milestones Anticipated

Phase 1

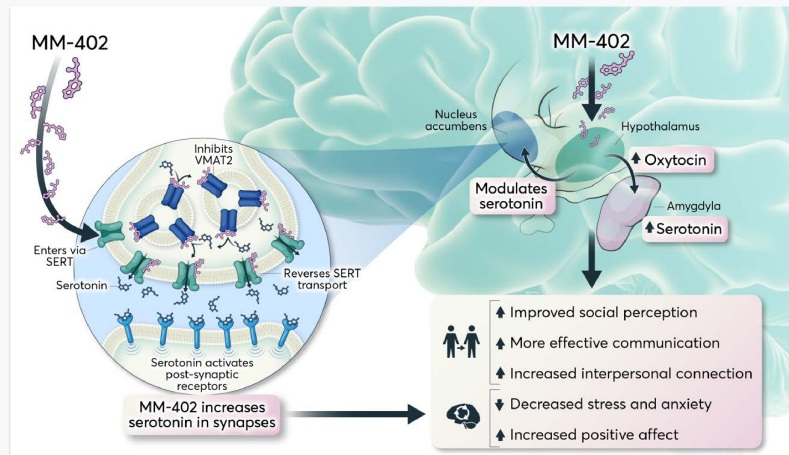
Study Initiation | Q4 2023

Phase 1 IIT (UHB-Sponsored)

Topline Data | H1 2024

Differentiated Mechanism of Action Targets Key Pathways

R-MDMA increases serotonin and oxytocin with potential prosocial and positive mood effects in patients with Autism Spectrum Disorder

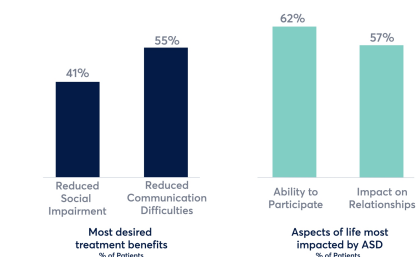


No Approved Drugs for Core Symptoms of Autism Spectrum Disorder (ASD)

Growing prevalence and impact of ASD yields an urgent need for novel therapies that target core symptoms and align with patient preferences



R(-)-MDMA Activity Aligns with Reported Needs and Desired Benefits for Individuals with ASD



Source: [1]

1. FDA Patient Focused Drug Development workshop on Autism Spectrum Disorder (2017)

Preclinical Data Indicate Potential Enhanced Benefit/Risk Profile

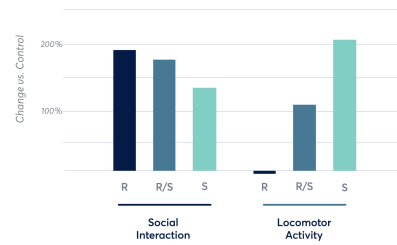
Preclinical data suggest the R-enantiomer of MDMA has prosocial effects with reduced stimulant activity

Translational preclinical data suggest that R(-)-MDMA may have:

- Strong prosocial effects
- Less stimulant activity compared to MDMA
- Plan to develop standard, at-home dose regimen

Source: [1][2]

R(-)-MDMA Maintains Prosocial Effects with Reduced Stimulant Activity



Source: [2]

1. Pitts 2018; Psychopharmacology; 235.
2. Curry 2018; Neuropsychopharmacology; 128.

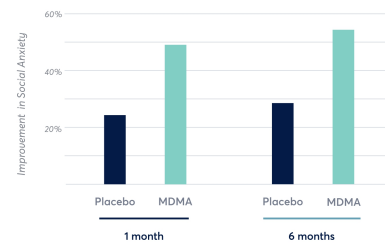
Clinical Data Support Opportunity for MDMA in ASD

Pilot clinical trial results of MDMA demonstrate acute and durable positive effects on social functioning in ASD population¹

MM-402 or R(-)-MDMA is a pharmaceutically optimized enantiomer of MDMA

- Potential first-in-class therapy for core symptoms of ASD
- Pilot clinical data suggest racemic MDMA could enhance social functioning
- Pharmacological profile aligns with patient-desired treatment benefits

MDMA Reduces Social Anxiety in ASD



Source: [1]

1. Danforth 2018, Psychopharmacology, 335.

MDMA: 3,4-methylenedioxymethamphetamine; ASD: Autism Spectrum Disorder

Collaborations & Early R&D

External Collaborations Aim to Accelerate Discovery & Development

Leveraging key partnerships and collaborations with intent to accelerate drug discovery and de-risk clinical development

MindShift
Compounds

Universitätsspital
Basel

NEW CHEMICAL ENTITY DISCOVERY ENGINE

ADVANCED DRUG DELIVERY

EFFICIENT CLINICAL PROVING GROUND



DISCOVERY &
LEAD OPTIMIZATION



NOVEL DOSAGE AND DELIVERY FORMS
TO ENABLE ENHANCED DELIVERY



RAPID DATA GENERATION &
CLINICAL CONCEPT TESTING

Exclusive Collaboration with Leading Researchers

MindMed's exclusive collaboration with the Liechti Lab at UHB enables efficient evidence generation to support R&D strategy



Our Leadership Team

Our management has decades of successful leadership, product development, and commercialization in pharma and biopharma



Robert Barrow
Chief Executive Officer and
Board Director



Miri Halperin Wernli, PhD
Executive President



Daniel Karlin, MD, MA
Chief Medical Officer



Schond Greenway, MBA
Chief Financial Officer



Mark Sullivan, JD
Chief Legal Officer and
Corporate Secretary



Francois Lilienthal, MD, MBA
Chief Commercial Officer



Carrie Liao, CPA
Chief Accounting Officer



OLATEC



Morgan Stanley



Our R&D Leadership Team

Our R&D team has decades of successful leadership, product development, and commercialization in pharma and biopharma



Peter Mack, PhD
VP, Pharmaceutical Development



Bridget Walton, MS, RAC
VP, Global Regulatory Affairs



Robert Silva, PhD
VP, Head of Development



Carole Abel, MBA
VP, Programs & Portfolio Office (PPO)



Our Team Has Significant Drug Development Experience

Our Management and R&D team's relevant experience overseeing the approval of drug candidates positions MindMed for success

CNS Products



Other Products



Business Highlights

- A leader in developing psychedelic product candidates to treat brain health disorders
- Diversified pipeline of clinical programs targeting significant unmet medical needs
- IP and R&D strategies intended to maximize market exclusivity and protection
- Leveraging decades of research on clinical and preclinical potential of product candidates
- Expertise in drug and digital medicine development and commercialization
- Expected cash runway through key clinical readouts and into 2026¹
- **MM-120 (LSD D-tartrate)** for the treatment of GAD and ADHD
 - Phase 2b dose-optimization study ongoing for the treatment of GAD; topline results expected in Q4 2023
 - Phase 2a study ongoing for the treatment of ADHD; topline results expected in Q4 2023 / Q1 2024
- **MM-402 or R(-)-MDMA** for the treatment of core symptoms of ASD
 - IND-enabling studies ongoing; initiation of a Phase 1 clinical trial is planned in Q4 2023
 - Phase 1 (UHB) investigator-initiated trial of R-, S- and R/S-MDMA in healthy volunteers ongoing; topline results expected H1 2024

1. The company's ending Q2 2023 cash and cash equivalents of \$116.9 million and committed credit facility are expected to fund operations into 2026, if certain milestones are achieved that unlock additional capital.



