
**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): June 20, 2023

MIND MEDICINE (MINDMED) INC.

(Exact name of Registrant as Specified in Its Charter)

British Columbia, Canada (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)	Registrant's Telephone Number, Including Area Code: (212) 220-6633 Not Applicable <i>(Former Name or Former Address, if Changed Since Last Report)</i>	10007 (Zip Code)

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 7.01 Regulation FD Disclosure.

On June 20, 2023, Mind Medicine (MindMed) Inc. (the “Company”) hosted an Analyst Day in New York, NY focusing on the Company’s MM-120 program in generalized anxiety disorder (GAD). A copy of the presentation displayed during the Analyst Day, which the Company may use from time to time in communications or conferences, is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Investor Presentation, dated June 20, 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, 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: June 20, 2023

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



MindMed

Investor Presentation

Investor Day 2023:
MM-120 for Generalized Anxiety Disorder

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; 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 MindMed's most recently filed Annual Report on Form 10-K filed with 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 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.

Today's Agenda

SPEAKER	TOPIC
Rob Barrow – CEO, MindMed	Opening Remarks
Maria Oquendo, MD	Unmet Need & Patient Journey in Generalized Anxiety Disorder (GAD)
David Feifel, MD, PhD	Practical Aspects of Monitored Therapies & Digital Medicine
Experts and Management Team	Questions and Answers (Q&A) – Sessions 2 and 3
Michael Kobernick, MD	Payer Considerations in New Medication Coverage
W. Chad Shear, JD	The Intellectual Property (IP) Landscape
Rob Barrow	Corporate Update
Experts and Management Team	Questions and Answers (Q&A)
Rob Barrow	Concluding Remarks

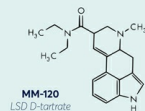
MindMed at a Glance: A Global Leader in Brain Health

Advancing Proprietary Drug Candidates Across Psychiatric Indications

MM-120

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

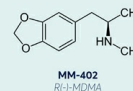
- Well-characterized pharmacology
- Accelerated development potential



MM-402

Autism Spectrum Disorder (ASD)

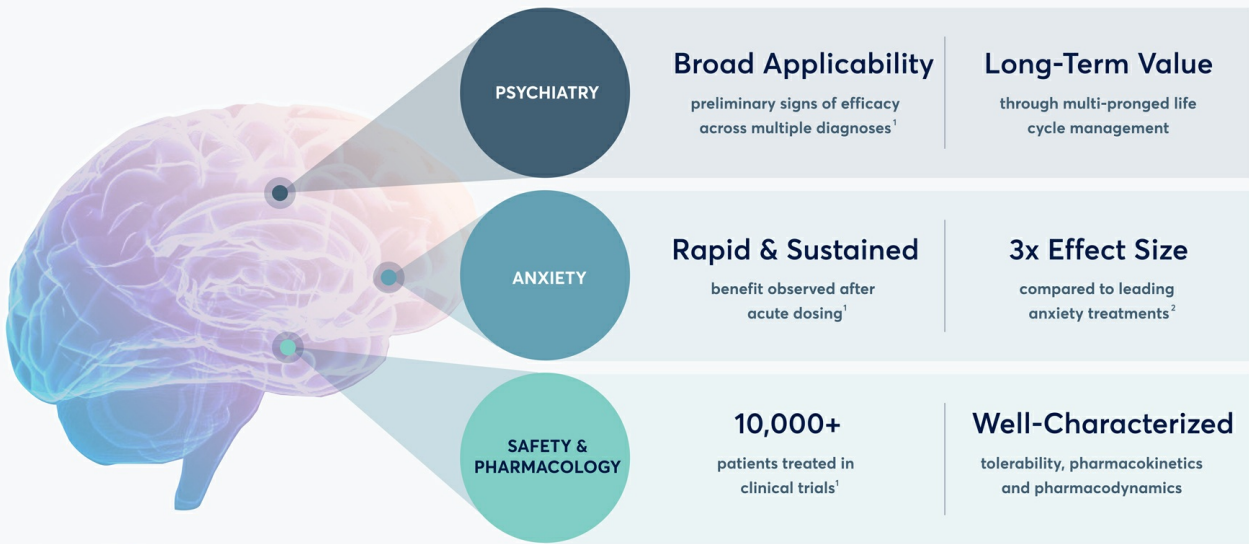
- Enhanced pharmacology
- Potential to overcome safety liabilities
- Standard delivery / dosing model



Business Highlights

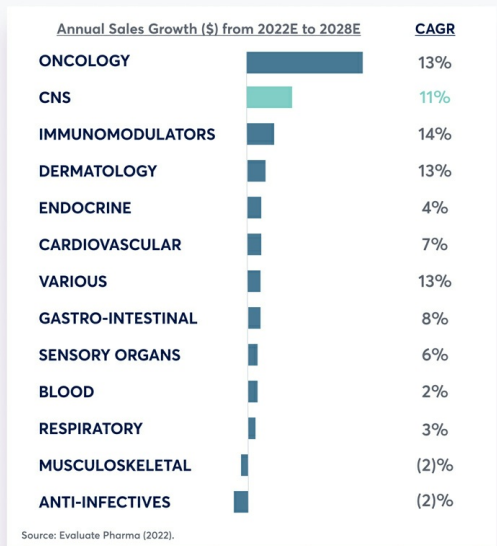
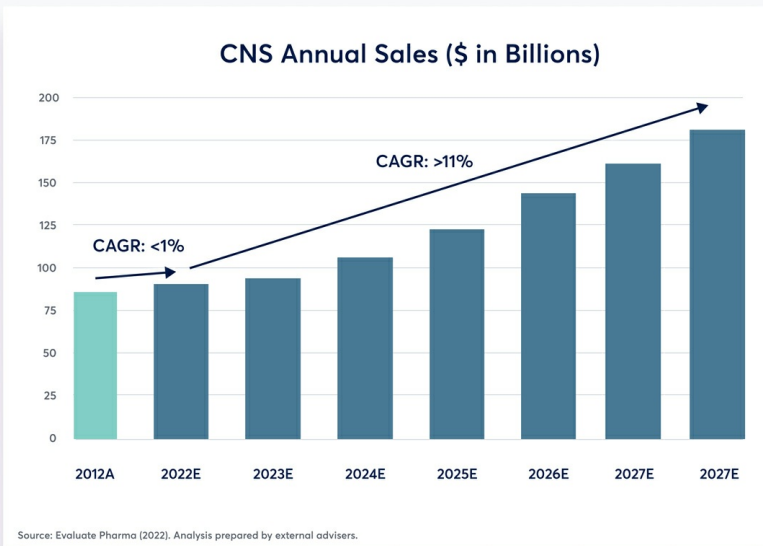
- **Diversified pipeline** of clinical programs targeting significant unmet medical needs
- **Pivotal inflection point** with two key clinical readouts expected in 2023
- **IP and R&D strategies** intended to maximize market exclusivity and protection
- **Expected cash runway** through key clinical readouts and into first half of 2025

MM-120 | Lead Candidate with Evidence Across Multiple Therapeutic Areas



1. Gasser 2014; J. Nerv. Ment. Dis.; 202(7).
2. Fuentes 2020; Front Psychiatry; 10:943.

Brain Health is One of the Fastest Growing Therapeutic Areas



US Market Revenue for GAD by Drug Class, 2022 – 2031 (\$ Million)

Drug Class	2022	2031 (expected)	CAGR % (2022-31)
ANTIDEPRESSANTS	1,675.7	2,370.9	3.9%
• SSRI	787.6	1,153.4	4.3%
• SNRI	737.3	1,058.1	4.1%
• OTHERS	150.8	159.3	0.6%
AZAPIRONES	117.6	137.0	1.7%
BENZODIAZEPINES	823.1	1,154.2	3.8%
OTHERS	323.4	366.6	1.4%
TOTAL	2,939.8	4,028.7	3.6%

Source: "Generalized Anxiety Disorder Therapeutics Market", Growth+ Market Reports

Anxiety Returning to Focus as Major Driver of Mental Health Disorders

The United States Preventive Services Task Force (USPSTF) recently issued a recommendation for screening for anxiety for children and adolescents aged 8 to 18 years and issued a draft recommendation for adults under the age of 65.

POPULATION	RECOMMENDATION	GRADE
Children and adolescents aged 8 to 18 years	The USPSTF recommends screening for anxiety in children and adolescents aged 8 to 18 years. ¹	B
Adults age 64 years or younger, including pregnant and postpartum persons	The USPSTF recommends screening for anxiety in adults, including pregnant and postpartum persons. ²	B

A "B" grade from the USPSTF indicates: "The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial."

1. "Anxiety in Children and Adolescents: Screening" (2022). The United States Preventive Services Task Force.
2. "Anxiety Disorders in Adults: Screening" Draft Recommendation (2022). The United States Preventive Services Task Force.

GAD Pipeline is Far Less Crowded than MDD Pipeline

6 FDA-approved drugs for GAD

SSRIs/SNRIs:

- *Paxil* (GSK)
- *Effexor* and *Effexor XR* (Pfizer-Viatris)
- *Lexapro* (Forest-AbbVie)
- *Cymbalta* (Eli Lilly)

Benzodiazapines:

- *Xanax* (Pfizer)
- *Klonopin* (Roche)

Key Players



GAD Pipeline

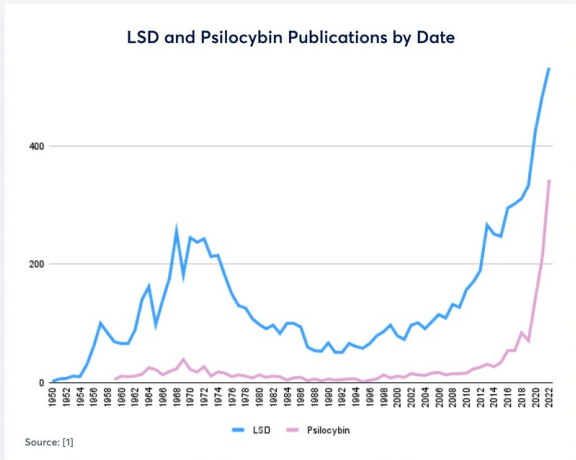
- **GRX 917** (*Gaba Therapeutics/Atai Life Sciences*) – Completed Ph1, Ph2 planned
- **PH94B** (*Vistagen*) – Ph3/registration for MDD, Ph2 for GAD
- **Zuranolone** (*Sage Therapeutics and Biogen*) – Ph3/registration for MDD, Ph2 for GAD
- **BNC210** (*Bionomics*) – Ph2 for social anxiety disorder

Source: Evaluate Pharma (2022); company reports.

Legacy of LSD Clinical Research in Psychiatric Disorders

The Unique Opportunity of LSD

- Most researched compound in the psychedelic drug class¹
- Compelling preliminary evidence in anxiety, depression, AUD and other indications²
- Due to potency, unique opportunities for formulation, delivery methods and intellectual property protection



1. U.S. Department of Health and Human Services (HHS) 2023. Retrieved from PubMed database.
2. Rucker 2016. J. Psychopharmacol; 30(12).

Key Drug Candidate: MM-120 Program

Proprietary drug candidate with evidence of clinical benefits across a broad range of brain health disorders

We are positioned for two key data readouts this year and have recently reached an enrollment milestone in our Phase 2b trial for GAD with **over 50% of patients dosed** across 20 active clinical sites

Phase 2b in GAD | Topline readout late 2023

200-patient Phase 2b dose-optimization trial to assess safety, determine effect size and inform dose selection for pivotal Phase 3 studies

Phase 2a in ADHD | Topline readout late 2023

52-patient Phase 2a proof-of-concept trial to assess safety and efficacy of repeated low-dose MM-120 administration



PRESS RELEASE

MindMed Announces Enrollment Milestone in Phase 2b Trial of MM-120 in Generalized Anxiety Disorder (GAD)

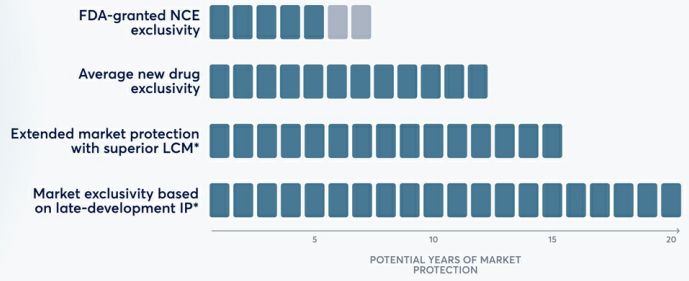
— Over 50% of patients dosed across 20 active clinical sites —
— On track for topline results in late 2023 —

NEW YORK, May 17, 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, announced today that the company's Phase 2b study evaluating MM-120 (lisdextroamphetamine) for GAD is over 50% enrolled and dosed. The trial plans to enroll up to 200 participants who will receive a single administration of 25 µg, 50 µg, 100 µg or 200 µg of MM-120 or placebo. Topline results are expected to be announced in late 2023.

Advancing the Field with Strong IP & Strategic Competitive Moats



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

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Unmet Need & Patient Journey in GAD – Maria Oquendo, MD

- Ruth Meltzer Professor and Chairman of Psychiatry at University of Pennsylvania
- Psychiatrist-in-Chief at the Hospital of the University of Pennsylvania
- President of the Board of Directors, American Foundation for Suicide Prevention
- Vice President, College of International Neuropsychopharmacology
- Board of Trustees, Tufts University
- Over 450 peer-reviewed publications with over 18,000 citations

Professor of Psychiatry,
Penn Medicine

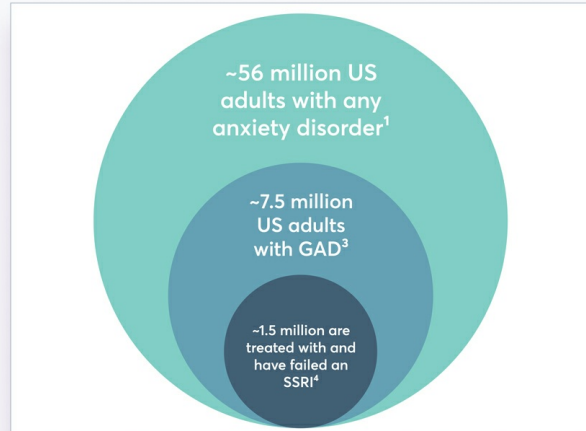


Disclaimer: Opinions expressed are the speaker's own and in no way reflect the opinions of any organization; Member, MindMed Scientific Advisory Board.

An Urgent Need for Better Anxiety Treatments

GAD presents large and unmet patient needs

- 1-year rate of prevalence of 2.9% among US adults¹
- 76% have moderate-to-severe GAD²
- Symptoms include: Clinically significant impairment at work and in social environments, restlessness, fatigue, concentration difficulties, irritability, muscle tension and insomnia³
- Half of those treated fail an SSRI³
- Beyond SSRIs, choices are limited to benzodiazepines, gamma-aminobutyric acid-related agents, and antipsychotics



1. Bandelow 2015; Dialogues Clin. Neurosci; 17(3). United States Census Bureau, company calculations.

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

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

4. Ibid and Jothi J Infect Public Health. 2021 Jan;14(1):103-108, company calculations.

Anxiety Correlated with Significant Impairment

- Evidence of greater impairment for those with higher anxiety severity¹
- An anxiety disorder is also associated with less accomplishment at work, reduced labor force participation²
- Associated with significantly higher rates of cardiac disorders, hypertension, gastrointestinal problems, genitourinary disorders and migraine³

1. Erickson SR, Guthrie S, VanEtten-Lee M, et al. Severity of anxiety and work-related outcomes of patients with anxiety disorders. *Depression and Anxiety*. 2009;26(12):1165-1171.

2. Waghorn G, Chant D, White P, Whiteford H. Disability, Employment and Work Performance Among People with ICD-10 Anxiety Disorders. *Australian and New Zealand Journal of Psychiatry*. 2005;39(1-2):55-66.

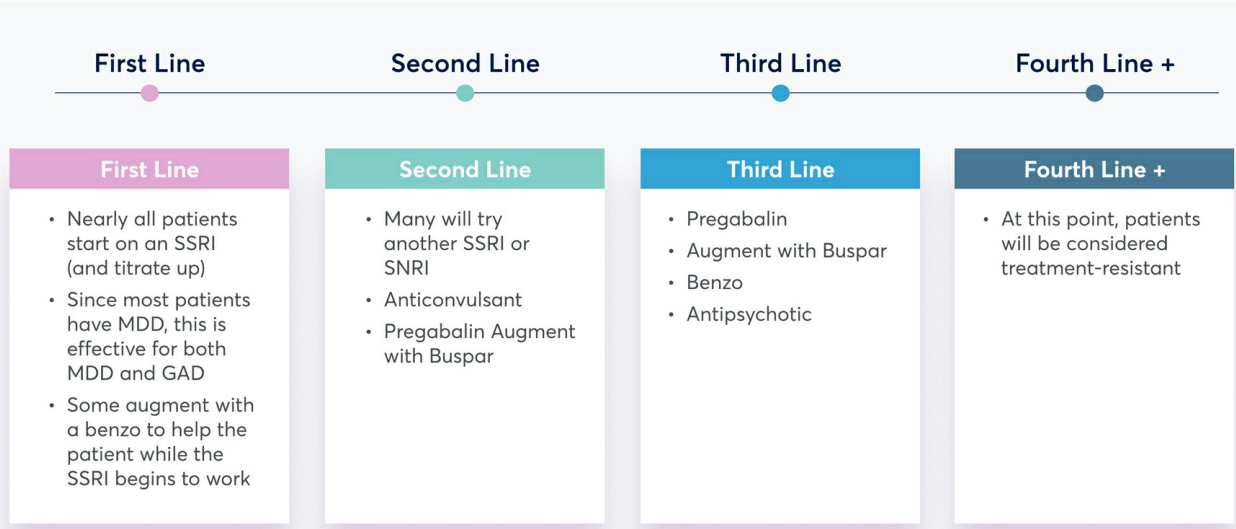
3. Kariuki-Nyuthe C, Stein DJ, Kariuki-Nyuthe C, Stein DJ. Anxiety and Related Disorders and Physical Illness. In: Maj M, ed. *Key Issues in Mental Health*. 2014:81-87.

Need for Additional Treatment Options is Clear

- **Individual variations:** GAD is not a one size fits all indication; it is a very diverse disorder
- **Co-occurring conditions** (e.g., depression or PTSD) may complicate treatment
- **Treatment resistance:** 50% fail first line (SSRI) treatment¹
- **Side effects:** Current choices come with the potential for long term side effects, which reduce compliance

1. Ansara, Ment Health Clin. 2020 Nov; 10(6): 326-334). United States Census Bureau, company calculations.

Many Patients Change Treatments Due to Lack of Efficacy and/or Side Effects



Patients are Underserved by Current Medications

	Mechanism	FDA Status in Anxiety	Comments
SSRI/SNRI	5-HT, NE (and DA) reuptake inhibitors	Approved (fluoxetine, sertraline, escitalopram, paroxetine, duloxetine, venlafaxine)	Generally front line, 50% failure rate, sexual side effects can be durable ¹
BENZODIAZEPINES	GABA-A agonists	Approved (clonazepam, alprazolam, lorazepam, chlordiazepoxide, oxazepam)	Generally used in short-term or as needed basis due to addiction, withdrawal and tolerance risk
BUSPIRONE	5-HT _{1A} partial agonist	Approved	Poor efficacy compared to SSRI/SNRI and benzodiazepines. Not well-tolerated nausea and dizziness
TRICYCLIC ANTIDEPRESSANTS	NE and 5-HT reuptake inhibitors	Off-label	Similar efficacy to SSRI/SNRI classes but with side effects of weight gain, sedation and arrhythmia
MAOI	MAO inhibitors	Off-label	Used as third line option
GABAergic DRUGS	Unclear, may modulate Ca channels	Off-label	Lack of significant evidence of efficacy, causes sedation, weight gain and edema
ANTI-PSYCHOTICS	D2, 5-HT ₂ H1 antagonists	Approved (trifluoperazine), otherwise off-label	Poor tolerability, short- and long-term risks

1. Ansara, Ment Health Clin. 2020 Nov; 10(6): 326-334). United States Census Bureau, company calculations.

Psychedelic Therapies Offer Promise

- Evidence of **rapid and durable impacts** in anxiety and depression
- **Lesser concern** for chronic safety issues
- Monitored and infrequent dosing promises **greater compliance**

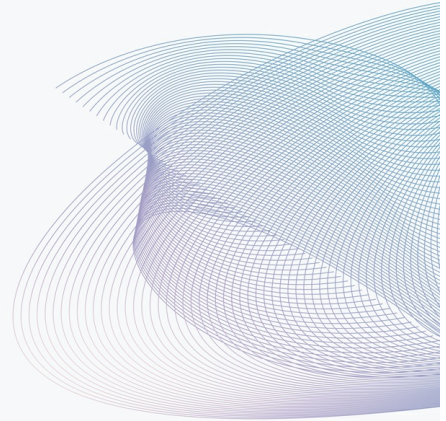


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Practical Aspects of Monitored Therapies – David Feifel, MD, PhD

- Founder and Medical Director, Kadima Neuropsychiatry Institute
- Professor Emeritus of Psychiatry, UC San Diego, where he was Director of the Neuropsychiatry and Behavioral Medicine Program and established world's first ketamine infusion program for depression
- Member, American College of Neuropharmacology
- Member, Psychedelic Task Force, National Network of Depression Centers
- Author or co-author of over 140 peer-reviewed publications on topics related to treating mental illness, including novel treatments such as Transcranial Magnetic Stimulation (TMS) and ketamine therapy

Founder, Kadima
Neuropsychiatry Institute



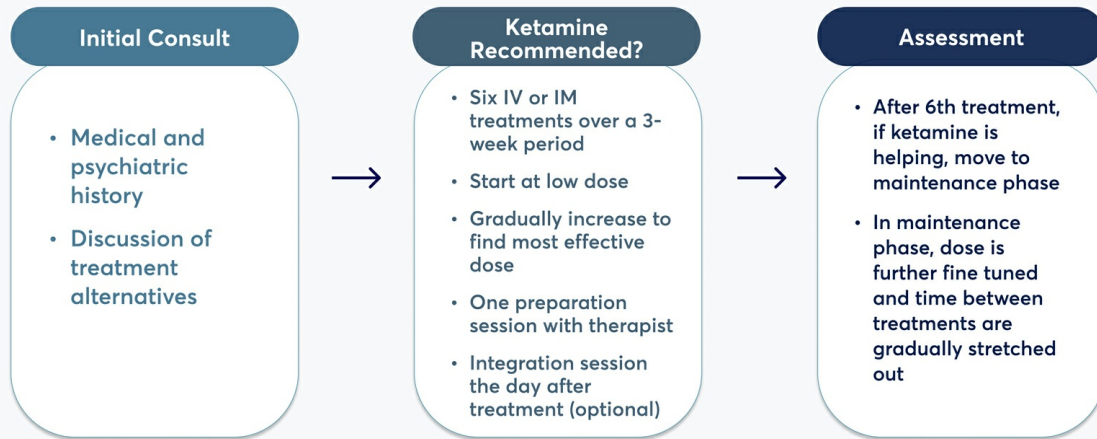
Disclaimer: Opinions expressed are the speaker's own and in no way reflect the opinions of Kadima or any other organization; Principal Investigator at a clinical site for MindMed's MMED008 Phase 2b trial.

The Kadima Neuropsychiatry Institute

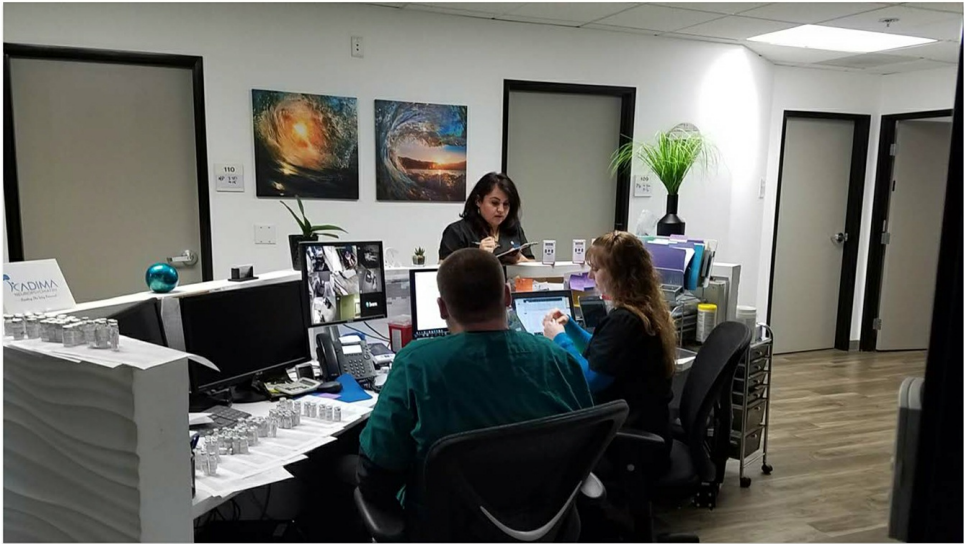


- Founded to more effectively pursue cutting edge, non-invasive treatments for **neuropsychiatric disorders**
- Specializing in depression, anxiety, PTSD, OCD, eating disorders and related conditions
- Providing **~75 ketamine treatments daily**
- Clinical site for **MindMed, Beckley Psytech and Compass Pathways trials**

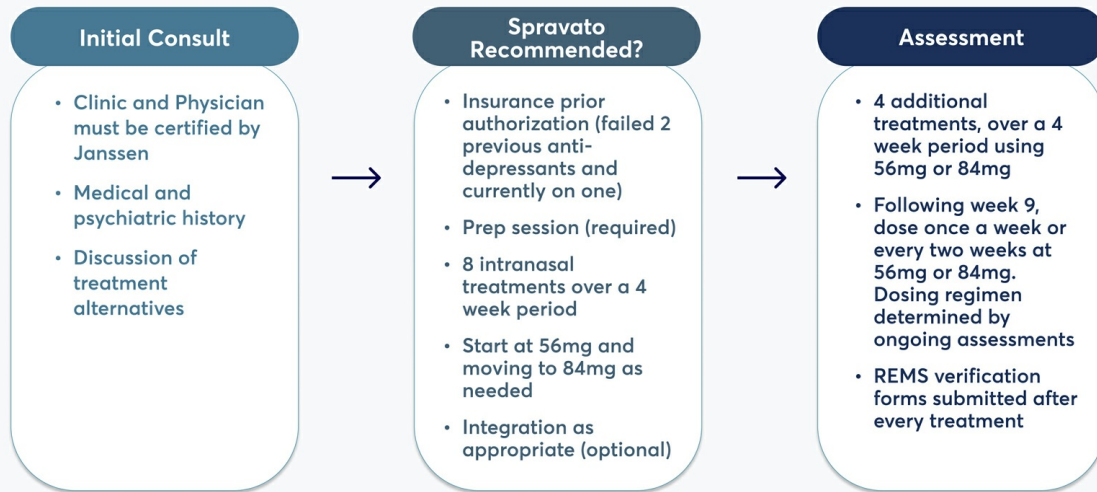
Case Study – How Ketamine Therapy Works at Kadima



Case Study – How Ketamine Therapy Works at Kadima



Case Study – How Spravato (esketamine) Therapy Works at Kadima



Evolution of Spravato – FDA Approval and Launch, 2019 to Today

Spravato (esketamine): 2019 vs. 2023

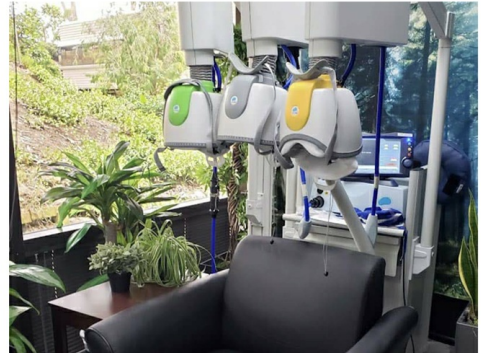
- 2019
 - Not ready for primetime
 - Insufficient billing codes
 - Unprofitable
- Today
 - Codes developed
 - Covered by major insurers (United, Cigna, BC/BS, etc.)
 - Two business models: "Buy and Bill," Administration billing only
 - Highly profitable for practices



1. Company Report Johnson & Johnson; April 18, 2023 Financial Results.

The Experience with TMS Therapy

- Deep Transcranial Magnetic Stimulation (TMS) therapy is a cutting-edge, non-medication treatment that is FDA approved for depression, anxiety, OCD and smoking addiction.
- TMS uses a pulsating magnetic field designed to stimulate nerve cells (neurons) in the specific brain regions that are underactive in people with depression, anxiety, and other neuropsychiatric disorders.
- Involves 30-40 outpatient sessions of 18-36 minutes each over a course of 6 weeks (9-24 hours of total session time over that period)
- Widely accepted and reimbursed by insurers



Potential and Promise of Psychedelic Therapy

- Potential for **rapid, long-lasting relief** from a variety of symptoms
- We have years of experience and infrastructure for monitoring multiple sessions simultaneously through our **work with ketamine and Spravato**, as well as a participant in MindMed and Compass trials
- While the MM-120 monitoring session would potentially be longer than with ketamine and Spravato, **total monitoring time is much shorter** due to fewer sessions
- With profitability will come **additional sites** willing to administer and monitor the treatment



Q&A for Sessions 2 and 3

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Payer Considerations in New Medication Coverage – Michael Kobernick, MD

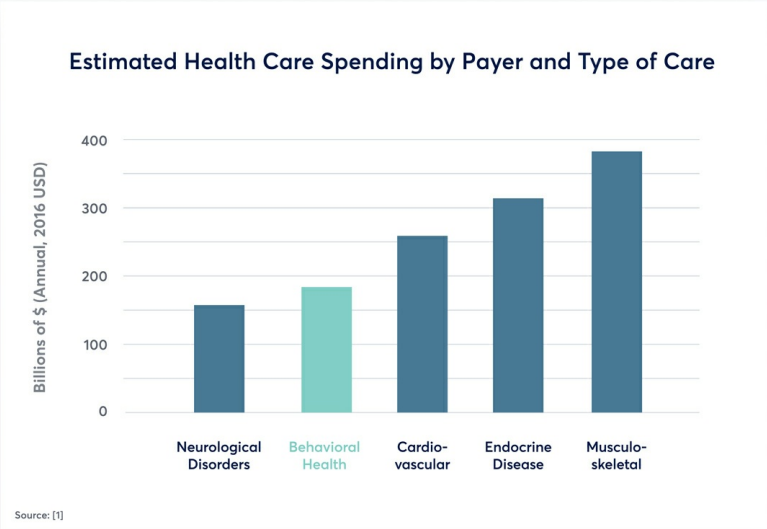
- Senior Medical Director, Blue Cross/Blue Shield of Michigan
- Advises large employers on opportunities to improve quality of care and reduce costs
- Lecturer, Jefferson College of Population Health
- Adjunct Assistant Professor, Madonna University
- Former Chief Medical Officer, SmartHealth
- Roles including Vice President of Medical Affairs at St. John Providence Health System

Senior Medical Director,
BCBS of Michigan



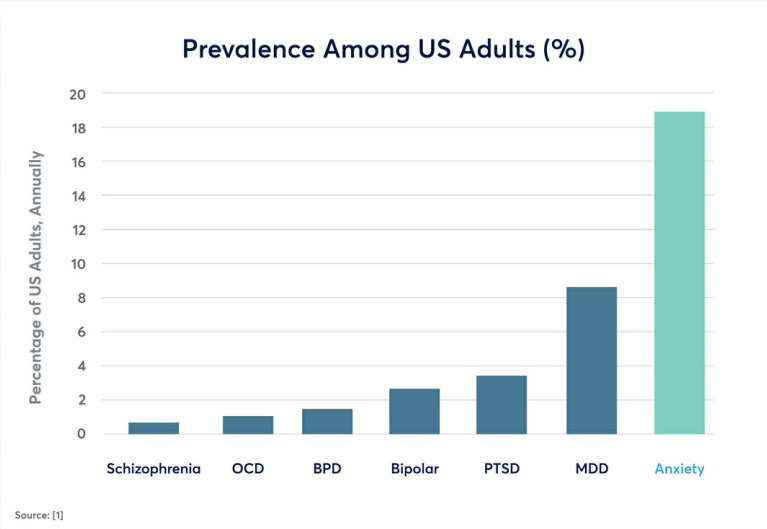
Disclaimer: Opinions expressed are the speaker's own and in no way reflect the opinions of Blue Cross Blue Shield of Michigan or any other organization.

Behavioral Health is a Leading Driver of Healthcare Costs



1. Dieleman JL, et al. 2020; JAMA;323(9):863-884.

Depression and Anxiety are Most Prevalent Among US Adults

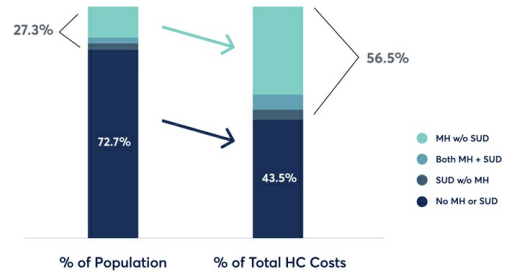


1. <https://nami.org/mhstats>

Behavioral Health Issues Tend to Bring Higher Overall Healthcare Costs

- 27% of patients who had a behavioral health condition in addition to other medical problems accounted for ~57% of total annual healthcare costs
- Annual costs were 3.5x higher for people who had a behavioral health condition such as anxiety, depression, or a substance abuse disorder, compared to costs for people without those conditions

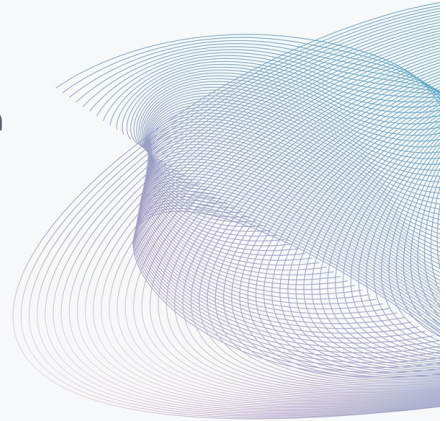
Distribution of the Population vs. Total Healthcare (HC) Costs Among Behavioral Health Groups (Mental Health & Substance Use)



1. Davenport et al. 2020; Milliman Research Report; pg. 7.

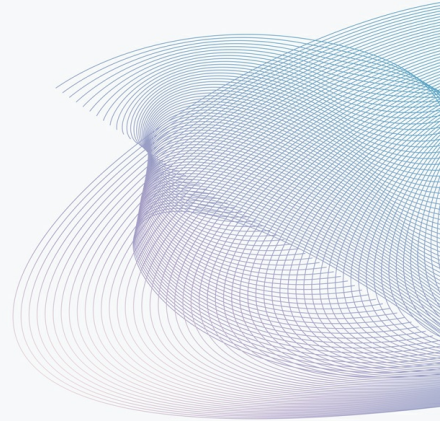
Behavioral Health is a Priority for Employers

- All employers want to address solutions for behavioral health
- Seen as an important social determinant of health
- All new approaches being embraced
 - Virtual Care Models
 - Co-Care Models – PCP + Psychiatrist
 - Interest in Ketamine and Psychedelics



Factors For Medication Coverage Determination

- FDA Approval
- Clinical Efficacy
- Peer Reviewed Publications
- Informative but not Decisive
 - Specialty Society Guidelines
 - Subject Matter Expert Opinion



Monitoring and Administration Coverage

- Codes Currently Exist
 - Observation
 - Psychological Evaluation
 - Evaluation and Management (EM)
- Precedents
 - Spravato
 - Sleep Studies

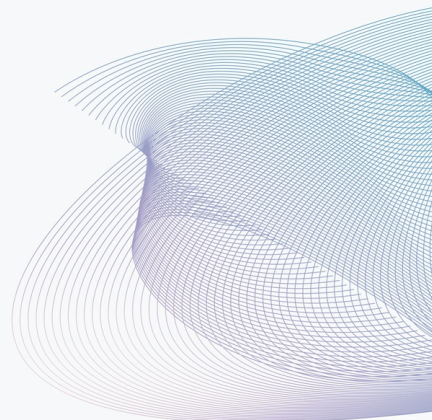


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- 06 **The IP Landscape**
- 07 Corporate Update
- 08 Q&A and Concluding Remarks

The IP Landscape – W. Chad Shear, JD

- Former principal in life sciences and pharmaceutical intellectual property (IP) at Fish & Richardson
- Led litigation on behalf of clients including Sunovion, Dainippon Sumitomo, Gilead Sciences, and Astellas
- Named an IP Trailblazer by The National Law Journal
- Former law clerk for the United States Court of Appeals for the Federal Circuit

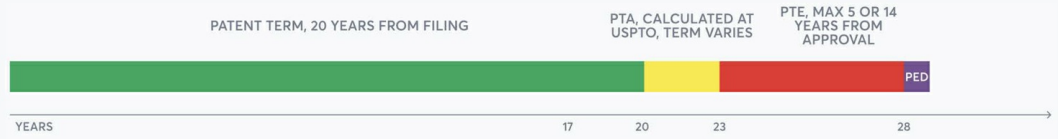
Partner, Intellectual
Property at Cooley LLP



Cooley

Disclaimer: Opinions expressed are the speaker's own and in no way reflect the opinions of Cooley LLP or any other organization; MindMed is a corporate client of Cooley LLP.

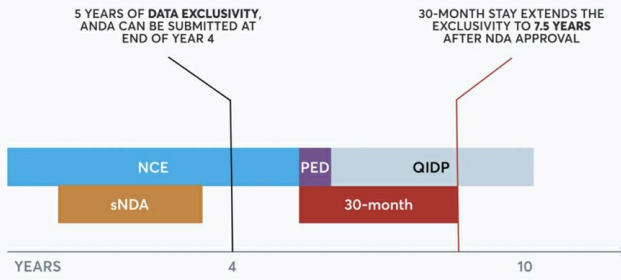
Intellectual Property (IP) in Biotech – Basics



Patent exclusivities

- Patent term – 20 years
- Patent term adjustment (PTA)
- Patent term extension (PTE)

Intellectual Property (IP) in Biotech – Basics



Regulatory exclusivities

- New Chemical Entity (NCE) – 5 years of data exclusivity
- 30-month stay – 3 years of market exclusivity
- Pediatric exclusivity – 0.5 years

What Can be Patented?

- **New Compounds:** These are new chemical compounds or molecules that have never been described before
- **Drug Formulations:** Novel combinations, dosages, delivery systems, controlled-release formulations, or improved stability of the drug
- **Manufacturing Processes:** Novel synthesis routes, purification techniques, or formulation processes
- **Medical Uses:** Patents can be obtained for new therapeutic applications or uses of existing drugs
- **Drug Delivery Systems:** Novel drug delivery systems, such as patches, implants, inhalers, or transdermal delivery methods, can be patented if they provide a unique and non-obvious solution
- **REMS/Other:** Specific technologies, devices, or drug delivery systems that are part of the overall REMS program

What are the Requirements for Patentability?

- **Novelty:** The invention should not have been previously known or used by others in any public form, such as in publications, patents, or public demonstrations
- **Non-obviousness:** The invention must involve an inventive step, meaning it must not be obvious to a person skilled in the relevant field
- **Utility:** The invention must have a specific and credible utility; it should be useful and serve a practical purpose

Hatch-Waxman Act

- **FDA Orange Book:** Identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information
- **30-month stay:** Gives the brand product sponsor and patent holder a prescribed amount of time to assert patent rights in court before a generic competitor is approved and can market the drug

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We've Seen Positive Momentum Across the Business



Meaningful Market Opportunity

21%

1-year prevalence of anxiety disorders in the US¹

4.4%

estimated prevalence of ADHD among all US adults²

\$461B

economic cost of ASD in the US predicted by 2025³



Significant Progress

\$129M **26**

Cash on hand as of Q1 2023

Pending US patent applications

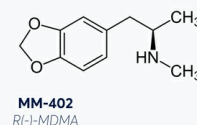
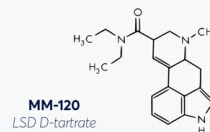
1 MindMed to Present Data on Pre-Clinical Activity of MM-402 at ASCP 2023 Annual Meeting

2 MindMed Announces Enrollment Milestone in Phase 2b Trial of MM-120 in Generalized Anxiety Disorder (GAD)

3 MindMed Collaborators Announce Positive Topline Data from Phase 2 Trial Evaluating LSD in Anxiety Disorders



Exciting Lead Drug Candidates



1. Bandelow 2015; Dialogues Clin. Neurosci; 17(3).
2. Kessler RC, Adler L, Barkley R, et al. 2005; Am J Psychiatry. 163(4).
3. Leigh & Du 2015; J. Autism Dev. Disord.; 45(12).

Our Leadership Team



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



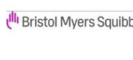
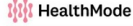
Mark Sullivan, JD
Chief Legal Officer and Corporate Secretary



Francois Lienthal, MD, MBA
Chief Commercial Officer



Carrie Liao, CPA
Chief Accounting Officer



Morgan Stanley

Our R&D Leadership Team



Peter Mack, PhD
VP, Pharmaceutical Development



Bridget Walton, MS, RAC
VP, Global Regulatory Affairs



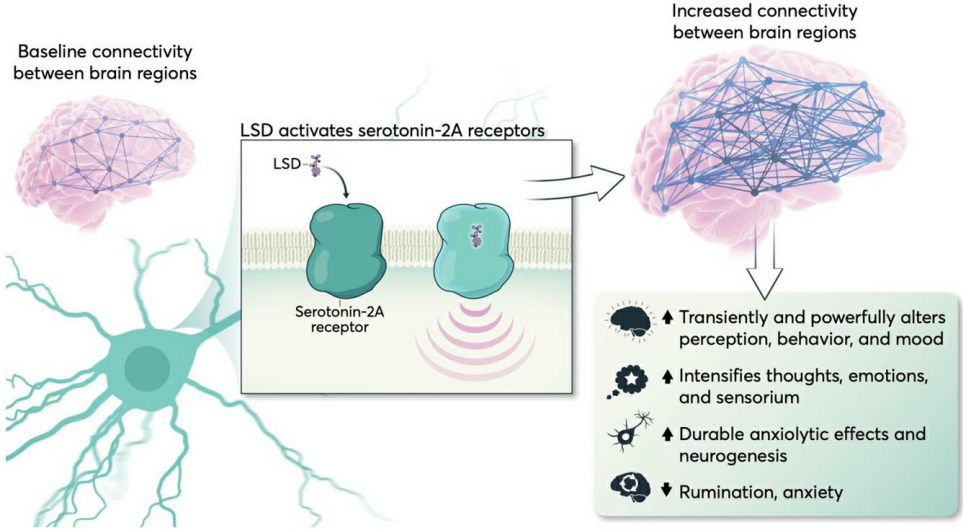
Robert Silva, PhD
VP, Head of Development



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



MM-120 | LSD Increases Neural Connectivity and Activity



MM-120 | Legacy of LSD Clinical Research in Psychiatric Disorders

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
UHB's LSD-ASSIST³	Anxiety	42 patients	Rapid and durable reduction in symptoms post-treatment. Clinical response in 65% of LSD patients vs. 9% in placebo

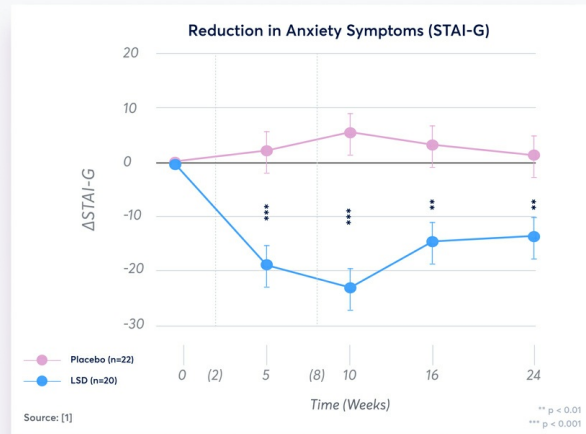


1. Rucker 2016. J. Psychopharmacol; 30(12).
2. Gasser 2014. J. Nerv. Ment. Dis.; 202(7).
3. Holze, Gasser et. al 2022. Biological Psychiatry.

MM-120 | Modern Preliminary Evidence in Anxiety Disorders

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



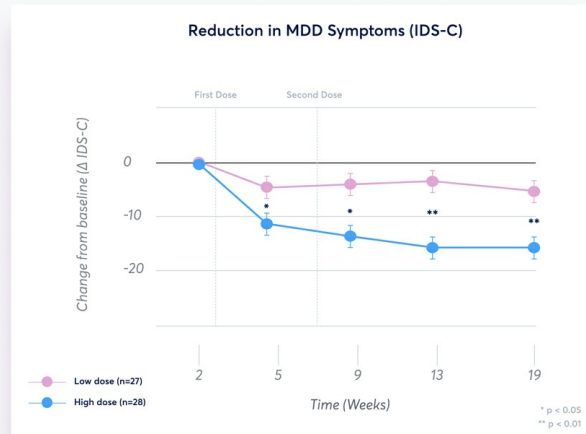
1. Holze, Gasser et. al. 2022. Biological Psychiatry.
STAI-G: State-Trait Anxiety Inventory; μg : microgram

MM-120 | Modern Preliminary Evidence in Depression

Significant, rapid, durable and beneficial effects on symptoms of MDD

- Reduction in depression symptoms; durable at 16 weeks post treatment
- Positive correlation between acute positive effects or mystical experiences and clinical outcomes
- Generally well-tolerated, as indicated by reported adverse events, changes in vital signs and laboratory values
- No acute suicidal ideation

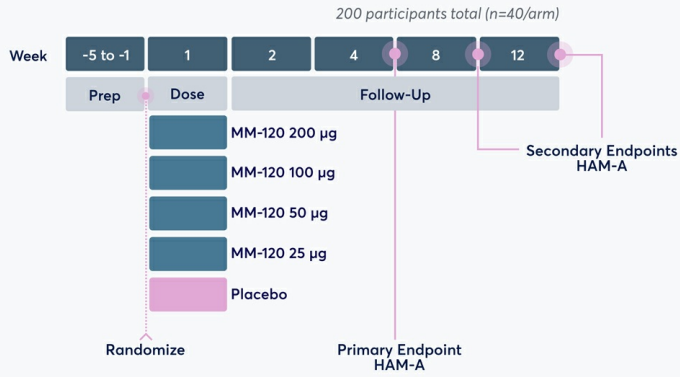
Source: [1]



1. Mueller, et. al 2023. University Hospital Basel.

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 \geq 20

ADDITIONAL ENDPOINTS

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

Source: MindMed internal study documents.

μ g: 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 | Phase 2b Enrollment Update

Over 50%

Patients dosed across 20 active sites¹

**Next
Update**

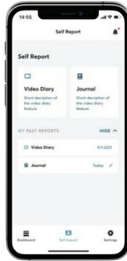
Additional update on enrollment and timing
of data during Q2 2023 earnings (August)

1. Dosing update as of May 17, 2023

MM-120 | Potential Clinical Care Model

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 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 

MM-120 | Digital to Complement Delivery Through the Patient Journey

Pre-Treatment	During Treatment	Post-Treatment
<ul style="list-style-type: none">• Patient education, engagement, preparation• Deep digital diagnosis• Support for treatment selection 	<ul style="list-style-type: none">• In-session monitoring• Clinician decision support• Predictive models that link interventions and outcomes 	<ul style="list-style-type: none">• Real world monitoring of trends• Engagement in health maintenance• AI models to inform psychotherapies 

MM-120 | Potential Pathway to Commercial Success

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.

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 first half of 2025
- **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 late 2023
 - Phase 2a study ongoing for the treatment of ADHD; topline results expected in late 2023
- **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 2023
 - Phase 1 pharmacokinetic/pharmacodynamic (UHB) investigator-initiated trial of R-, S- and R/S-MDMA in healthy volunteers ongoing



MindMed

Q&A

