
**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): May 19, 2022

MIND MEDICINE (MINDMED) INC.

(Exact Name of Registrant as Specified in 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)

10007
(Zip Code)

Registrant's telephone number, including area code: (650) 208-2454

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
Subordinate Voting 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 (see General Instruction A.2. below):

- 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 May 19, 2022, Mind Medicine (MindMed) Inc. (the “Company”) hosted a virtual Key Opinion Leader Webinar on Substance Use Disorders and Withdrawal Management and MM-110 (“KOL Event”). A copy of the Company’s presentation at the KOL Event is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information responsive to Item 7.01 of this Form 8-K, including Exhibit 99.1, 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 Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing and as set forth below in Item 8.01 of this Current Report on Form 8-K.

Item 8.01 Other Events.

As disclosed above, on May 19, 2022 the Company gave a presentation at the KOL Event, which is attached as Exhibit 99.1 hereto. The information on slides 2, 5, 6 and 13 - 19 of Exhibit 99.1 is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	MindMed KOL Event Presentation, dated May 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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: May 19, 2022

By: /s/ Cynthia Hu

Name: Cynthia Hu

Title: Chief Legal Officer & Secretary



MindMed

Opioid Use Disorder: Zolunicant's Potential For Unmet Treatment Needs

Thursday May 19, 2022 11:00 AM ET

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; availability of additional capital; 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 most recently filed Annual Report on Form 10-K 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 "18-MC", which is a synthetic organic molecule designed around a common coramandine chemical backbone. 18-MC 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 inspired compounds and classic psychedelics, 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 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.

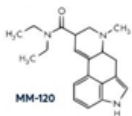

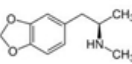
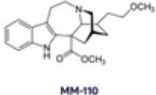
Business Highlights

Our mission is to deliver on the therapeutic potential of psychedelics and other novel targets to treat brain health disorders

- **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** to maximize market exclusivity and protection
- **Leveraging decades of research** on clinical and preclinical potential of product candidates
- **Industry-leading expertise** in drug and digital medicine development and commercialization
- **Fully funded** through key clinical readouts and into 2024

Advancing Multiple Generations of Drug Candidates

Our strategy is to deliver on well-characterized psychedelic candidates and next generation candidates with enhanced drug profiles

	CONCEPT	MINDMED PRODUCT CANDIDATES	PIPELINE EXPANSION OPPORTUNITIES
CLASSIC PSYCHEDELICS	<ul style="list-style-type: none"> Clinical evidence of efficacy¹ Well-characterized pharmacology Accelerated development potential 	 <p>MM-120</p>	<ul style="list-style-type: none"> Expanded clinical indications Psychedelics with distinct PK/PD 
2ND GENERATION / OPTIMIZED	<ul style="list-style-type: none"> Enhanced pharmacology Overcome safety liabilities Increased IP potential 	 <p>MM-402</p>	<ul style="list-style-type: none"> Advanced drug delivery Novel treatment models Novel treatment regimen
3RD GENERATION / NCEs	<ul style="list-style-type: none"> Analogues of classic psychedelics Require full development program Strongest IP potential 	 <p>MM-110</p>	<ul style="list-style-type: none"> Novel tryptamines Novel phenethylamines Non-hallucinogenic analogues

1. Gasser 2014, J. Nerv. Ment. Dis.; 202[7].

IP: intellectual property; DMT: N,N-dimethyltryptamine; NCE: new chemical entity; PD: pharmacodynamics; PK: pharmacokinetics

Research & Development Pipeline

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



ADHD: Attention-Deficit/Hyperactivity Disorder

Upcoming Portfolio Milestones

MindMed's clinical research portfolio creates multiple near-term and intermediate catalysts



ADHD: Attention-Deficit/Hyperactivity Disorder; IIT: Investigator-initiated trial; R&D: research & development; ESOE: early sign of efficacy

MM-110

Zolunicant HCl

Key Milestones

Phase 1 Topline Data Readout

Q2 2022 | Phase 1

Opioid W/D Study Initiation

Q2 2022 | Phase 2a

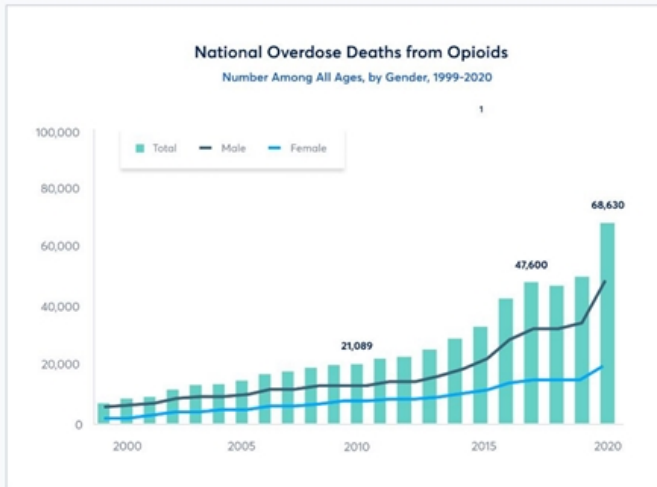
Opioid W/D ESOE Readout

Q1 2023 | Phase 2a (Part A)

ESOE: early sign of efficacy; W/D: withdrawal

Significant Unmet Need for Opioid Use Disorder (OUD) Treatments

Dangerous relapses during withdrawal period are mediated by withdrawal symptoms



68,630 people in the US overdosed on opioids in 2020 ¹

225% increase in opioid overdoses from 2010 to 2020 ¹

89% naltrexone induction failures were early relapses ¹

1. DrugAbuseStatistics.org/opioid-epidemic

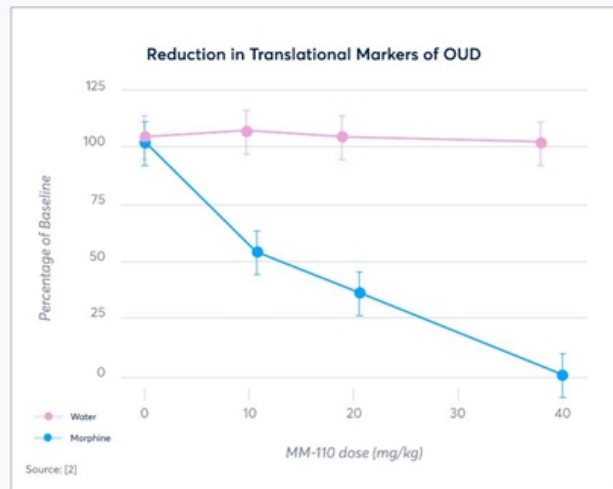
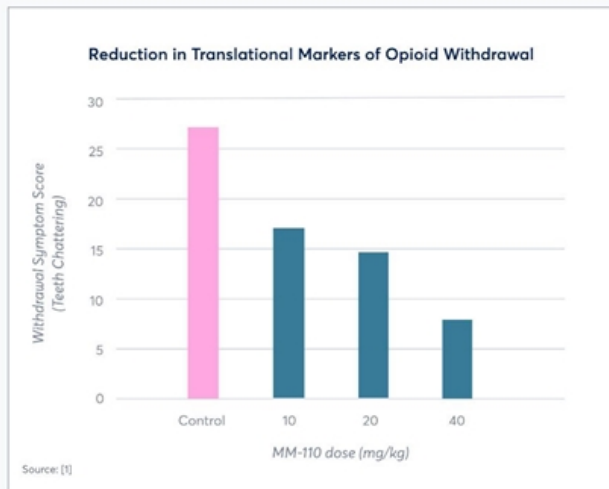
MM-110 | Novel Mechanism to Address a Critical Gap in OUD Treatment

Mechanism of action and target product profile complement standard-of-care and address a critical gap in available treatment landscape



MM-110 | Strong Preclinical Activity on Key Translational Outcomes

A single dose of MM-110 mitigates withdrawal symptoms and opioid self-administration in preclinical models^{1,2}

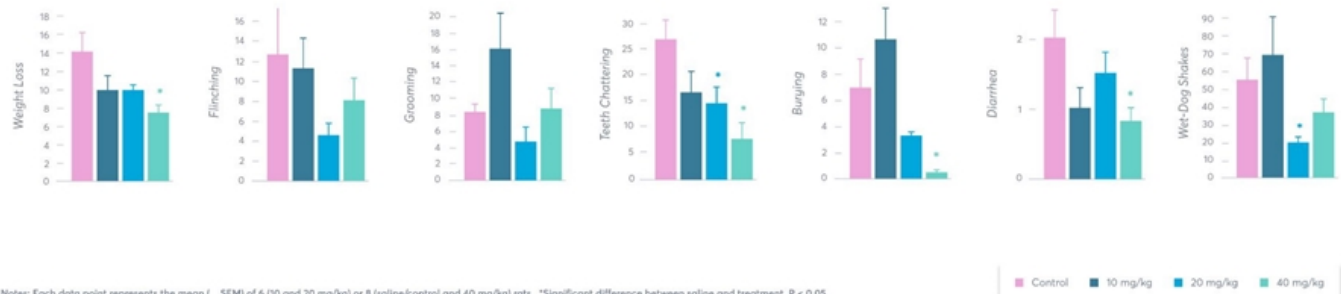


1. Rho & Glick 1998; NeuroReport; 9.
2. Maisonneuve & Glick 2003; Pharmacol Biochem Behav; 75.

MM-110 | Strong Preclinical Activity on Key Translational Outcomes

A single dose of MM-110 mitigates withdrawal symptoms and opioid self-administration in preclinical models^{1,2}

Morphine Withdrawal Following a Single Dose of 10, 20 or 40 mg/kg MM-110 in Rats
(Rho & Glick 1998)

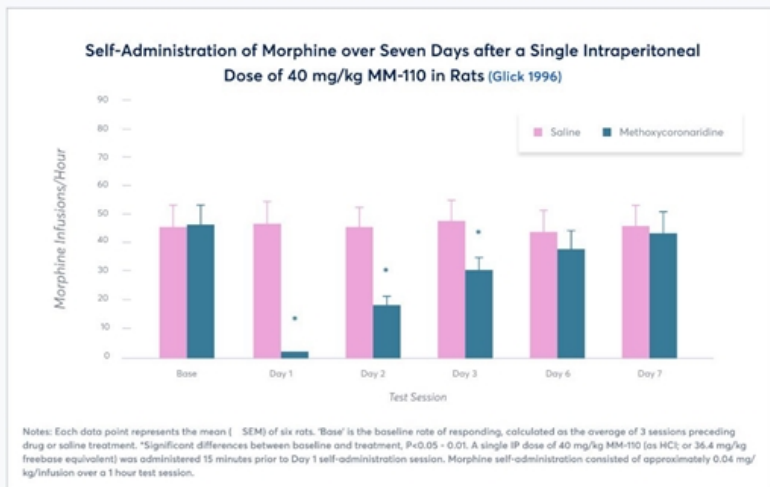


Notes: Each data point represents the mean (SEM) of 6 (10 and 20 mg/kg) or 8 (saline/control and 40 mg/kg) rats. *Significant difference between saline and treatment, $P < 0.05$. Saline or MM-110 (as HCl salt) was administered 30 minutes prior to naloxone. Weight loss is presented in grams.

1. Rho & Glick 1998; NeuroReport; 9.
2. Maisonneuve & Glick 2003; Pharmacol Biochem Behav; 75.

MM-110 | Strong Preclinical Activity on Key Translational Outcomes

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2. Maisonneuve & Glick 2003; Pharmacol Biochem Behav; 75.

Phase 1 Study Results - Key Takeaways

MM-110 (Zolunicant) is a Phase 2-Ready Asset

- **Well-tolerated** up to 500mg per day in SAD and 60mg per day in the MAD
- **Linear PK** maintained across the tested doses and frequencies
- **Clinical effects** align with potent CNS engagement
- **QOD regimen** aligns with preclinical evidence & offers potential to be a better regimen in opioid withdrawal

MM-110 | Phase 1 SAD/MAD Dosing Cohorts

Participants received up to 650mg of MM-110 on a single day or were administered up to 180mg/day for seven days or placebo

SUBSTANCE USE DISORDERS

MM-110 (zolunicant HCl; 18-MC)

Indication: Opioid Withdrawal

PHASE 1

Cohort(s)	Zolunicant Dose Group BID	Safety (N=72)	
		Zolunicant n (%)	Placebo n (%)
1	4 mg	5 (6.9)	2 (2.8)
2	8 mg	5 (6.9)	2 (2.8)
3	12 mg	5 (6.9)	2 (2.8)
4	16 mg	5 (6.9)	2 (2.8)
8	25 mg	5 (6.9)	2 (2.8)
9	40 mg	5 (6.9)	2 (2.8)
10	75 mg	5 (6.9)	2 (2.8)
11	150 mg	5 (6.9)	2 (2.8)
12, 15	250 mg	10 (13.9)	4 (5.6)
13	325 mg	1 (1.4)	1 (1.4)
Total:		51 (70.8)	21 (29.2)

Cohort	Zolunicant Dose Group BID x 7 Days	Safety (N=72)	
		Zolunicant n (%)	Placebo n (%)
5	2 mg	5 (13.9)	2 (5.6)
6	5 mg	5 (13.9)	2 (5.6)
7	10 mg	5 (13.6)	2 (5.6)
14	30 mg	5 (13.6)	2 (5.6)
16	90 mg	6 (16.7)	2 (5.6)
Total:		26 (72.2)	10 (27.8)

- SAD well tolerated at doses up to 500mg/day
- MAD well tolerated at doses up to 60mg/day

Source: MindMed internal study documents

MM-110 | Phase 1 SAD/MAD Adverse Event Tables

Treatment emergent adverse events were mild or moderate in severity and resolved without sequelae

SUBSTANCE USE DISORDERS

MM-110 (zalcitabine HCl, 18-MC)

Indication: Opioid Withdrawal

PHASE 1

SOC/PT	Zalcitabine x 1 Day n (%)										
	4 mg BID (N=5)	8 mg BID (N=5)	12 mg BID (N=5)	16 mg BID (N=5)	21 mg BID (N=5)	40 mg BID (N=5)	75 mg BID (N=5)	150 mg BID (N=5)	250 mg BID (N=5)	325 mg BID (N=5)	Placebo (N=2)
Any Related TEAE	0	0	1 (20)	1 (20)	2 (40)	0	1 (20)	1 (20)	7 (70)	1 (100)	4 (100)
Eye Disorders	0	0	0	0	0	0	0	0	0	1 (100)	0
Vision Blurred	0	0	0	0	0	0	0	0	0	1 (100)	0
GI Disorders	0	0	0	0	2 (40)	0	1 (20)	0	3 (30)	0	1 (4.8)
Abdominal Distention	0	0	0	0	0	0	1 (20)	0	0	0	0
Abdominal Pain	0	0	0	0	0	0	0	0	1 (100)	0	1 (4.8)
Nausea	0	0	0	0	2 (40)	0	0	0	3 (30)	0	0
Vomiting	0	0	0	0	0	0	0	0	1 (100)	0	0
General Disorders & Admin. Site Conditions	0	0	0	0	0	0	0	0	0	1 (100)	0
Fatigue	0	0	0	0	0	0	0	0	0	1 (100)	0
Musculoskeletal & Connective Tissue Disorders	0	0	0	0	0	0	0	0	2 (20)	0	0
Limb Discomfort	0	0	0	0	0	0	0	0	1 (100)	0	0
Muscle Tightness	0	0	0	0	0	0	0	0	1 (100)	0	0
Nervous System Disorders	0	0	1 (20)	1 (20)	2 (40)	0	0	1 (20)	4 (40)	1 (100)	2 (9.5)
Ataxia	0	0	0	0	0	0	0	0	0	1 (100)	0
Disturbance in Attention	0	0	0	0	0	0	0	0	0	1 (100)	0
Dizziness	0	0	0	1 (20)	1 (20)	0	0	0	4 (40)	0	2 (9.5)
Headache	0	0	1 (20)	0	1 (20)	0	0	1 (20)	0	0	1 (4.8)
Presyncope	0	0	0	0	0	0	0	0	1 (100)	0	0
Visual Perception	0	0	0	0	0	0	0	0	1 (100)	0	0
Psychiatric Disorders	0	0	0	0	1 (20)	0	0	0	0	0	1 (4.8)
Abnormal Dreams	0	0	0	0	0	0	0	0	0	0	1 (4.8)
Bradycardia	0	0	0	0	1 (20)	0	0	0	0	0	0

SOC/PT	Zalcitabine x 1 Day n (%)					
	4 mg BID (N=5)	5 mg BID (N=5)	10 mg BID (N=5)	30 mg BID (N=5)	90 mg BID (N=5)	Placebo (N=2)
Any Related TEAE	0	2 (40)	0	2 (40)	5 (83.3)	1 (100)
Eye Disorders	0	0	0	0	1 (16.7)	1 (100)
Emphoragocum	0	0	0	0	0	1 (100)
Visual Impairment	0	0	0	0	1 (16.7)	0
GI Disorders	0	1 (20)	0	2 (40)	2 (33.3)	1 (100)
Musculoskeletal & Connective Tissue Disorders	0	0	0	0	0	1 (100)
Muscle Twitching	0	0	0	0	0	1 (100)
Nervous System Disorders	0	1 (20)	0	1 (20)	1 (16.7)	1 (100)
Dizziness	0	1 (20)	0	0	0	0
Headache	0	0	0	1 (20)	1 (16.7)	0
Muscle Contractions Involuntary	0	0	0	0	0	1 (100)
Paresthesia	0	0	0	1 (20)	0	0
Psychiatric Disorders	0	1 (20)	0	0	3 (50)	0
Abnormal Dreams	0	1 (20)	0	0	0	0
Anhedonia	0	0	0	0	1 (16.7)	0
Depressed Mood	0	0	0	0	1 (16.7)	0
Mania	0	0	0	0	1 (16.7)	0

Note: SOC and PT were assigned using MedDRA version 23.0. Multiple events in the same SOC and PT were counted only once at each level of summation. Percentages were used on the number of subjects in the Safety population.

Related refers to the Investigator's assessment that the TEAE was possibly, probably, or had a highly probable relatedness to the study drug.

MM-110 | Phase 1 SAD/MAD Adverse Event Summaries

Across the SAD and MAD cohorts, only 5 TEAE led to discontinuation of MM-110 and there were no serious adverse events

SUBSTANCE USE DISORDERS

MM-110 (Zolonicant HCl; 18-MC)

Indication: Opioid Withdrawal

PHASE 1

	Zolonicant BID x 1 day n (%)									
	4 mg (N=5)	8 mg (N=5)	12 mg (N=5)	16 mg (N=5)	25 mg (N=5)	40 mg (N=5)	75 mg (N=5)	150 mg (N=5)	250 mg (N=5)	325 mg (N=5)
TEAE	1 (20)	0	2 (40)	2 (40)	4 (80)	2 (40)	4 (80)	3 (60)	10 (100)	1 (100)
Related TEAE	0	0	1 (20)	1 (20)	2 (40)	0	1 (20)	1 (20)	7 (70)	1 (100)
Drug withdrawn due to TEAE	0	0	0	0	0	0	0	0	1 (10)	1 (100)

	Zolonicant BID x 7 day n (%)					
	2 mg (N=5)	5 mg (N=5)	10 mg (N=5)	30 mg (N=5)	90 mg (N=5)	Placebo (pooled) N=21
TEAE	4 (80)	5 (100)	5 (100)	5 (100)	6 (100)	8 (80)
Related TEAE	0	2 (40)	0	2 (40)	5 (83.3)	1 (10)
Drug withdrawn due to TEAE	0	0	0	0	4 (66.7)	0

Related refers to the Investigator's assessment that the TEAE was possibly, probably, or had a highly probable relatedness to the study drug.
Source: MindMed internal study documents

MM-110 | Phase 1 SAD PK Curve

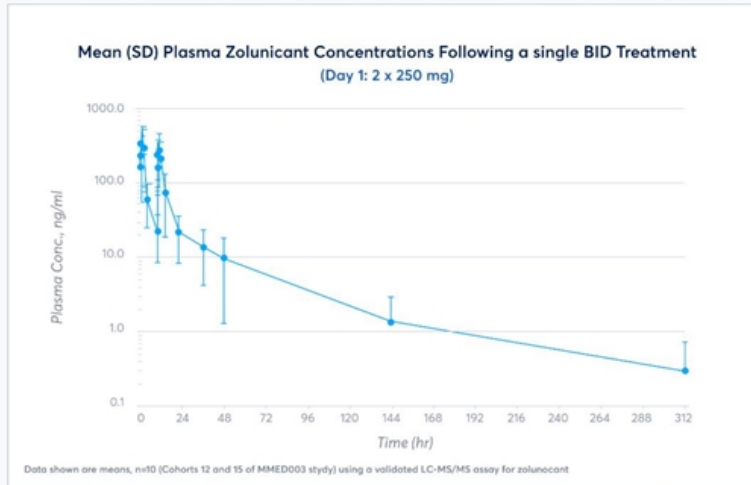
A linear pharmacokinetic profile was observed even at the highest doses

SUBSTANCE USE DISORDERS

MM-110 (zolonicant HCl, 18-MC)

Indication: Opioid Withdrawal

PHASE 1



Source: MindMed internal study documents

ESOE: early sign of efficacy; POC: proof of concept; QOD: Every Other Day (dosage timing); SOWS: Subjective Opiate Withdrawal Scale

MM-110 | Phase 1 MAD Comparison PK Curve

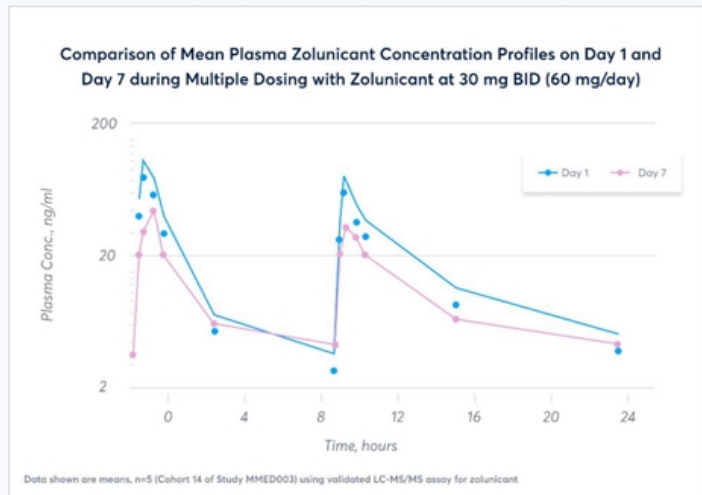
The pharmacokinetic profile was maintained across the tested doses and SAD/MAD dosing schedules.

SUBSTANCE USE DISORDERS

MM-110 (zolonicant HC; 18-MC)

Indication: Opioid Withdrawal

PHASE 1



Source: MindMed internal study documents

ESOE: early sign of efficacy; POC: proof of concept; QOD: Every Other Day (dosage timing); SOWS: Subjective Opiate Withdrawal Scale

MM-110 | Phase 2a Supervised Withdrawal in Opioid Use Disorder

Gated two-part study design provides opportunity for early signs of efficacy (ESOE) and informs randomized proof of concept design

SUBSTANCE USE DISORDERS

MM-110 (zalcitabine HCl, 18-MC)

Indication: Opioid Withdrawal

PHASE 2A

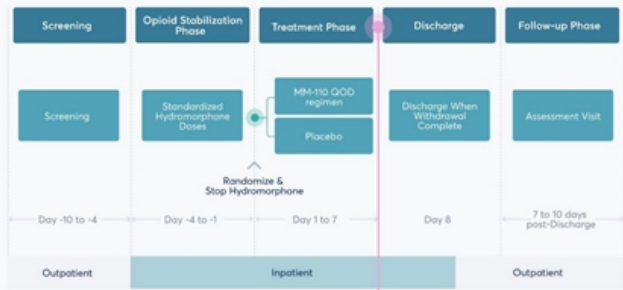
Part A | Open-Label Early Sign of Efficacy in Opioid Withdrawal (n=10)



Primary Endpoint
Mean SOWS-Gossop score over first 5 days of Treatment Phase

Interim Readout

Part B | Randomized Placebo-Controlled POC in Opioid Withdrawal (n=42/arm*)



Primary Endpoint
Mean SOWS-Gossop score over first 5 days of Treatment Phase

*Subject to revision based on Part A outcomes

Source: MindMed internal study documents

ESOE: early sign of efficacy; POC: proof of concept; QOD: Every Other Day (dosage timing); SOWS: Subjective Opiate Withdrawal Scale