



A Brighter Future for Mental Health

CSE: MBIO

---

## MINDBIO THERAPEUTICS

### CEO ISSUES LETTER TO SHAREHOLDERS

**Vancouver, British Columbia – July 8, 2024 – MindBio Therapeutics Corp. (CSE: MBIO; Frankfurt: WF6),** (the “Company” or “MindBio”), a leading biopharmaceutical company in psychiatric medicine development today issued a letter to shareholders from Justin Hanka, Co-Founder and Chief Executive Officer of MindBio.

Dear Shareholders,

We are delighted to provide an update on progress at MindBio, as we head into the second half of 2024 and continue with dosing in multiple Phase 2B clinical trials and we advance the Company closer towards its commercialisation objective.

The Company is pleased to report on its two currently dosing Phase 2B clinical trials which include assessing MB22001, MindBio’s lead candidate drug in treating the following conditions:

1. **Major Depressive Disorder:** The trial is assessing MB22001 on 90 patients with Major Depressive Disorder with 45 patients randomized to the placebo group and 45 patients to the MB22001 intervention group in a triple dummy, active placebo controlled clinical trial.
2. **Advanced Stage Cancer – End of Life Distress related Depression and Anxiety:** The trial is assessing MB22001 on 40 patients with advanced stage cancer, with 20 patients randomized to the placebo group and 20 patients to the MB22001 intervention group in a double blind, placebo controlled clinical trial.

MindBio has fully funded and paid in advance for these two Phase 2B clinical trials. Dosing is progressing as scheduled with recruiting of patients and initiation to take-home dosing in both trials progressing positively and both trials due for completion in 2025.

MindBio has a third Phase 2B clinical trial that has been approved to start dosing:

3. **Pre-Menstrual Syndrome & Pre-Menstrual Dysphoric Disorder** – The trial will initially gather baseline data from healthy menstruating persons in a Phase 1/2a trial

administering MB22001 during the luteal phase of the menstrual cycle. The trial will lead into a much larger randomized controlled trial in patients with Pre-Menstrual Syndrome and Pre-Menstrual Dysphoric Disorder.

### **MindBio Leads Global Public Companies in Non-hallucinogenic Psychedelic Clinical Trials**

MindBio is the only publicly listed company in the world specializing in a scalable psychedelic microdosing treatment model that is sub-hallucinogenic and the Company is the most advanced clinical trial stage biopharma company listed on the Canadian Securities Exchange. MB22001 is a psychedelic medicine, a proprietary titratable form of Lysergic Acid Diethylamide (LSD) designed for safe take home microdosing. LSD is hallucinogenic in nature if ingested in large doses. In small, microdoses however MB22001 is sub-hallucinogenic and can be taken by patients at home (rather than an in-clinic and clinician supervised setting, which is the model for 100% of publicly listed companies other than MindBio currently at Phase 2B level in clinical trials. In this way, MindBio stands apart from its peers and as the most advanced biopharma company in clinical trials testing a psychedelic drug at sub-hallucinogenic levels. Microdosing is fundamental to MindBio's strategy of take-home scalable, affordable treatments.

The Company is progressing both its drug development program and capital market strategy in parallel as it eyes a senior exchange listing. If data from Phase 2B trials is positive, the Company will look to Phase 3 clinical trials and commercialization at the end of Phase 2B by entering special access schemes and applying for exemptions, particularly in Canada, Australia and New Zealand.

### **World First and Only Take-home Dosing of a Classic Psychedelic Medicine**

MindBio's trials are the only clinical trials of a classic psychedelic medicine to be approved for take home dosing and currently dosing at Phase 2B level. Patients take the drug at home and then can get on with their day as they would if they were taking any other medication. The New Zealand government and local health regulators have approved the trials for take-home dosing give the current declining state of mental health in the country and the need for more effective treatments for mental health conditions. Australasia has a market size approximately equivalent to California and the jurisdiction has recently advanced with Australia the first country to approve psilocybin and MDMA for medical use in special circumstances. In New Zealand, MindBio's trials already have take-home approvals for MB22001 and the clinical trials have received over \$2million in government support.

### **MB22001 demonstrates positive top line data in Phase 2A depression trials**

A significant milestone for MindBio is the completion early this year of a Phase 2A trial of lead candidate drug MB22001 in patients with Major Depressive Disorder.

We are pleased to report the Phase 2A Major Depressive Disorder trial showed no serious adverse events or serious side effects, and at the end of an 8-week trial, 53% of participants were in complete remission from their depression, (marked by a 14.1 point drop in

Montgomery-Asberg Depression Rating Scale or MADRS). Overall, trial participants experienced a 60% reduction in depressive symptoms measured at week 8. Trial participants also experienced a drop in anxiety levels and improvements in quality of life scores in psychological testing. MB22001 has also demonstrated durability to 1 month post cessation of treatment showing a 65% overall drop in depressive symptoms sustained 1 month after ceasing treatment. Prior trials of MB22001 have also demonstrated improved sleep and subjective elevation of mood including increased energy, creativity, social connectivity, happiness and wellbeing. Improvements in mood, sleep and depression scores are significant developments for MB2201 advancing into late-stage trials.

The evidence is mounting in support of MB22001 being a safe, tolerable and effective drug for treating depression without the side effects commonly experienced by patients who take antidepressant medications, particularly sexual impotence, gastro-intestinal upset and emotional numbing. Also significant is the unique treatment thesis of microdosing at sub-hallucinogenic levels, as a scalable accessible and affordable treatment model for treating depression and related conditions

### **MindBio's unique regulatory position in Australia and New Zealand**

MindBio's ability to demonstrate the safety and efficacy of microdosing interventions in real-world settings is revolutionary for the industry with the Company already having dosed 1000's of doses in the community. Regulators are seeking credible data to make special access approvals for psychedelic medicines, which have shown profound healing effects on patients with mental health conditions. Australia has recently advanced its regulatory framework by medically legalizing psilocybin, for example, a psychedelic medicine that has undergone only limited Phase 2 clinical trials for depression. Conceivably, the surprising change in regulatory sentiment and allowing pre-Phase 3 use of a drug in Australia is due to the ineffectiveness of existing treatments to abate the escalating mental health crisis in Australia.

### **Our Investment Thesis – globally scalable, accessible and affordable treatments**

MindBio's investment thesis, using microdosing, centers on the creation of a unique treatment model that is globally scalable, accessible, and affordable, aiming to address the existing challenges in mental health care.

We are not just about psychedelic medicines, MindBio is amassing the world's largest repository of biometric, physiological and psychometric data from Microdosing randomised controlled clinical trials in a big data play for the Company. MindBio is developing a unique treatment protocol that is safe, scalable and affordable for large populations.

I would like to thank all shareholders that continue to support MindBio. I look forward to providing regular progress updates.

We invite you to join us in support of creating a brighter future for mental health.

Receive our latest updates here: <https://www.mindbiotherapeutics.com/get-updates>

Follow MindBio on LinkedIn: <https://www.linkedin.com/company/mindbio-therapeutics/?viewAsMember=true>

Follow CEO Justin Hanka on LinkedIn: <https://www.linkedin.com/in/justinhanka/>

For further information, please contact:

**Justin Hanka, Chief Executive Officer**

**61 433140886**

[justin@mindbiotherapeutics.com](mailto:justin@mindbiotherapeutics.com)

### **Media Inquiries**

Kristina Spionjak

[pr@hlthcommunications.com](mailto:pr@hlthcommunications.com)

### **About MindBio Therapeutics**

MindBio is a leading biotech/biopharma company focused on creating novel and emerging treatments for mental health conditions and is conducting world first take-home Microdosing (MB22001) human clinical trials. MB22001 is MindBio's lead candidate drug, a proprietary titratable form of Lysergic Acid Diethylamide (LSD) designed for take-home microdosing. MindBio is a leader in microdosing of psychedelic medicines and is advancing its drug and technology protocols through clinical trials. MindBio has developed a multi-disciplinary platform for developing treatments and is involved in psychedelic medicine development and digital therapeutics, has completed Phase 1 clinical trials in 80 healthy participants and has completed a Phase 2a clinical trial in patients with Major Depressive Disorder, both trials with positive top line data reported. Currently underway are two Phase 2B trials, one in cancer patients experiencing existential distress and another in patients with Major Depressive Disorder. The Company is also approved for multiple Phase 1/Phase 2B trials in women's health. MindBio invests in research that forms the basis for developing novel and clinically proven treatments including digital technologies and interventions to treat debilitating health conditions such as depression, anxiety and other related mental health conditions.

### **Cautionary Note Concerning Forward-Looking Statements:**

The press release contains "forward-looking statements" within the meaning of applicable securities laws. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "budget," "believe," "project," "estimate," "expect," "scheduled," "forecast," "strategy," "future," "likely," "may," "to be," "could," "would," "should," "will" and similar references to future periods or the negative or comparable terminology, as well as terms usually used in the future and conditional. Forward-looking statements are based on assumptions as of the date they

are provided. However, there can be no assurance that such assumptions will reflect the actual outcome of such items or factors.

Additionally, there are known and unknown risk factors that could cause the Company's actual results and financial conditions to differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important risk factors that could cause actual results and financial conditions to differ materially from those indicated in the forward-looking statements, include among others: general economic, market and business conditions in Canada and Australia; market volatility; unforeseen delays in timelines for any of the transactions or events described in this press release. All forward-looking information is qualified in its entirety by this cautionary statement.

The Company disclaims any obligation to revise or update any such forward-looking statement or to publicly announce the result of any revisions to any of the forward-looking information contained herein to reflect future results, events or developments, except as required by law.

Neither the Canadian Securities Exchange nor its Regulation Service Provider (as that term is defined in the policies of the Canadian Securities Exchange) accepts responsibility for the adequacy or accuracy of this release.