# MindBio Therapeutics Chief Executive Officer Issues Letter to Shareholders Discussing the Company's Growth Plans

VANCOUVER, BC / ACCESSWIRE / May 16, 2023 / MindBio Therapeutics Corp. (CSE:MBIO)(Frankfurt:WF6), (the "Company" or "MindBio", today issued a letter to shareholders from Justin Hanka, Co-Founder and Chief Executive Officer of MindBio.

#### Dear Shareholders,

We are delighted to inform you that MindBio is now trading on the Canadian Securities Exchange (CSE:MBIO) and the Frankfurt Securities Exchange (Frankfurt: WF6), providing us access to the global capital markets. We are in the process of listing the Company for trading on the OTCQB markets in the United States to expand our investor audience even further.

MindBio is one of a few public listed biopharma companies with two fully funded Phase 2 clinical trials and the only one listed in North America that is specializing in a scalable microdosing treatment model. The Company is progressing both its drug development program and capital market strategy in parallel as it heads towards a NASDAQ listing.

#### World First take-home LSD-Microdosing clinical trials

A significant milestone for MindBio is the recent successful completion of a Phase 1 LSD-Microdosing clinical trial involving 80 healthy participants. MindBio is the only organization in the world to have obtained regulatory approvals for at-home use of LSD in clinical trials. Athome use is crucial for testing and modelling the safety and efficacy of psychedelics within the community, as we strive to have these life-saving medicines approved.

We are pleased to report that the Phase 1 trial showed no serious adverse events, and participants in the LSD-Microdosing treatment group reported statistically significant increases in feelings of happiness, social connectivity, wellness, creativity, and energy compared to the placebo group. Furthermore, we have developed a novel sublingual formulation for LSD-microdosing that allows patients to titrate their dosage based on their individual comfort levels.

## Two fully funded Phase 2 take-home LSD-Microdosing clinical trials

MindBio has two fully funded Phase 2 LSD-Microdosing clinical trials. The first trial focuses on Major Depressive Disorder, where 20 patients meeting DSM-V criteria will receive an open label 8-week LSD microdosing treatment regimen in a naturalistic at-home setting. This trial will serve as the basis for continuing a much larger Phase 2b triple-dummy, active placebo-controlled trial in depressed patients. The second trial explores the effectiveness of LSD-Microdosing in conjunction with Meaning Centred Psychotherapy in late-stage cancer patients experiencing emotional distress. This randomized, double-blind, and placebo-controlled trial will involve 40 participants and is set to begin recruiting participants for the trial shortly.

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

MindBio's ability to demonstrate the safety and efficacy of microdosing interventions in realworld settings is revolutionary for the industry. 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.

MindBio's proprietary technology will access a large repository of data as it continues to develop a targeted treatment approach for patients suffering from a variety of mental health conditions.

With regulatory approvals obtained for MindBio's LSD-Microdosing take-home use in clinical trials in New Zealand, and considering the sizable population of over 30 million in Australia and New Zealand, we plan to leverage the data generated from our Phase 1 and Phase 2 trials to advocate for special access to our microdosing treatment protocol. The support received from regulators and scientific collaborators, coupled with the changing landscape of medical legalization, positions MindBio favorably to advance these treatments in the primary healthcare system in Australasia, potentially preceding Phase 3 clinical trials in our local jurisdictions.

Our unique advantage lies in our ability to provide a proven intervention for take-home use, akin to how traditional antidepressant medications are taken. Presently, there are no other options available for sub-hallucinogenic psychedelic medicines with a demonstrated safe use case for take-home use. Our objective is to pursue advanced approval for special access use in specific patient populations, including those with Major Depressive Disorder and cancer patients experiencing emotional distress. Both of these patient groups present significant challenges to the healthcare systems globally, but they also present significant opportunities for MindBio in terms of microdosing commercialization objectives.

#### Our Scientific Thesis - Microdosing; a safe proven model for take home use of psychedelics

Our scientific thesis and our investment thesis in the sector are well aligned by using psychedelic medicines in a repeated sub-hallucinogenic treatment model, allowing patients to take small doses of psychedelics on a semi-regular repeated basis to continue with their day in the same way they would if they were taking an anti-depressant medication. The evidence for effective use

of LSD-Microdosing to treat depressive symptoms is mounting and MindBio will rely on its large Phase 1 study to produce a further 7 peer reviewed scientific papers in the coming year plus results from Phase 2 clinical trials to advance its treatment thesis for microdosing in patients suffering from mental health conditions.

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: <u>https://www.linkedin.com/company/mindbio-therapeutics/?viewAsMember=true</u>

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

## **About MindBio Therapeutics**

MindBio is a biotech/biopharma company focused on creating novel and emerging treatments for mental health conditions and is conducting world first take-home LSD-Microdosing human clinical trials. 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 microdosing Lysergic Acid Diethylamide (LSD) in 80 patients, has a Phase 2 clinical trial in development microdosing LSD in patients with Major Depressive Disorder and a Phase 2 clinical trial in development microdosing LSD in late stage cancer patients experiencing existential distress. 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.

**SOURCE:** MindBio Therapeutics