

## FSD Pharma Receives Institutional Review Board Approval to Study the Safety and Efficacy of Unbuzzd™ in Acute Alcohol Intoxication

**Toronto, ON – June 4, 2024** – FSD Pharma Inc. (NASDAQ: HUGE) (CSE: HUGE) (FRA: 0K9A) ("**FSD Pharma**"), a biopharmaceutical company dedicated to building a portfolio of innovative assets and biotech solutions to address ailments affecting millions worldwide, today confirms that it has received institutional review board (IRB) approval for its METAL-2 trial in the USA. This IRB approval allows our team to begin recruiting clinical trial participants and to plan the execution of the clinical study.

"We are excited that the METAL-2 trial has received IRB approval, allowing us to advance this clinical study in the United States. This marks an important milestone in our clinical research in the field of acute alcohol intoxication," said Dr. Andrzej Chruscinski, Vice-President of Clinical and Scientific Affairs at FSD Pharma.

## **About FSD Pharma**

FSD Pharma is a biopharmaceutical company dedicated to building a portfolio of innovative assets and biotech solutions for the treatment of challenging neurodegenerative and metabolic disorders and alcohol misuse disorders with drug candidates in different stages of development. Through its wholly owned subsidiary, Lucid Psycheceuticals Inc. ("Lucid"), FSD is focused on the research and development of its lead compound, Lucid-MS (formerly Lucid-21-302) ("Lucid-MS"). Lucid-MS is a patented new chemical entity shown to prevent and reverse myelin degradation, the underlying mechanism of multiple sclerosis, in preclinical models. FSD Pharma invented unbuzzd™ and spun it out its OTC version to a company, Celly Nutrition, led by industry veterans. FSD retains ownership of 25.71% (March 31, 2024) of Celly Nutrition Corp. at www.cellynutrition.com. The agreement with Celly Nutrition also includes royalty payments of 7% of sales from unbuzzd ™ until payments to FSD Pharma total \$250 million. Once \$250 million is reached, the royalty drops to 3% in perpetuity. Additionally, FSD Pharma retains a large tax loss carry forward of approximately CAD\$130 million and could be utilized in the future to offset tax payable obligations against future profits. FSD Pharma retains 100% of the rights to develop similar product or alternative formulations specifically for pharmaceutical / medical uses. FSD Pharma maintains a portfolio of strategic investments through its wholly owned subsidiary, FSD Strategic Investments Inc., which represent loans secured by residential or commercial property.

**Cautionary Note Regarding Forward-Looking Information** 

This press release contains forward-looking statements and forward-looking information (collectively, "forward-looking statements") within the meaning of applicable securities laws. Any statements that are contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements are often identified by terms such as "plans", "expects", "expected", "scheduled", "estimates", "intends", "anticipates", "hopes", "planned" or "believes", or variations of such words and phrases, or states that certain actions, events or results "may", "could", "would", "might", "potentially" or "will" be taken, occur or be achieved. More particularly, and without limitation, this press release contains forwardlooking statements contained in this press release include statements concerning the future of FSD Pharma and are based on certain assumptions that FSD Pharma has made in respect thereof as of the date of this press release, including those relating to Celly Nu and its launch of unbuzzd™; benefits, claims, and timelines with respect to unbuzzd™; details of the partnerships of Celly Nu, including the stated benefits of the BevSource partnership; the Company's business and goals, including the continued research and development of Lucid-MS, unbuzzd™, novel formulations for alcohol misuse disorders, and treatments for use in the healthcare sector; and the continued maintenance of its strategic investment portfolio. FSD Pharma cannot give any assurance that such forward-looking statements will prove to have been correct.

Since forward-looking statements relate to future events and conditions, by their very nature they require making assumptions and involve inherent risks and uncertainties. The Company cautions that although it believes the expectations and material factors and assumptions reflected in these forward-looking statements are reasonable as of the date hereof, there can be no assurance that these expectations, factors and assumptions will prove to be correct and these risks and uncertainties give rise to the possibility that actual results may differ materially from the expectations set out in the forward-looking statements, of which assumptions include: the Company will satisfy all applicable listing and regulatory requirements of the CSE and Nasdaq; the fact that the drug development efforts of the Company and Lucid are at a very early stage; the fact that preclinical drug development is uncertain, and the drug product candidates of the Company and Lucid may never advance to clinical trials; the fact that results of preclinical studies and early-stage clinical trials may not be predictive of the results of later stage clinical trials; the uncertain outcome, cost, and timing of product development activities, preclinical studies and clinical trials of the Company and Lucid; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; the potential inability to obtain or maintain regulatory approval of the drug product candidates of the Company and Lucid; the introduction of competing drugs that are safer, more effective or less expensive than, or otherwise superior to, the drug product candidates of the Company and Lucid; the initiation, conduct, and completion of preclinical studies and clinical trials may be delayed, adversely affected or impacted by unforeseen issues; the potential inability to obtain adequate financing; the potential inability to obtain or maintain intellectual property protection for the drug product candidates of the Company and Lucid; the Company's inability to benefit from Celly Nu and its launch of unbuzzd™; the Company's inability to realize upon the benefits, claims, and timelines with respect to unbuzzd™; the Company's inability to realize upon the stated benefit from the partnerships of Celly Nu; the Company's inability to carryout its business and goals, including the continued research and development of Lucid-MS, unbuzzd™, novel formulations for alcohol misuse disorders, and treatments for use in the healthcare sector; and the Company's inability to maintain its strategic investment portfolio. Accordingly, readers should not place undue reliance on the forward-looking statements contained in this press release, which speak only as of the date of this press release.

These forward-looking statements are not quarantees of future performance and are subject to a number of known and unknown risks and uncertainties including, but not limited to: the timing and ability to satisfy all applicable listing and regulatory requirements of the CSE and Nasdag; the fact that the drug development efforts of the Company and Lucid are at a very early stage; the fact that preclinical drug development is uncertain, and the drug product candidates of the Company and Lucid may never advance to clinical trials; the fact that results of preclinical studies and early-stage clinical trials may not be predictive of the results of later stage clinical trials; the uncertain outcome, cost, and timing of product development activities, preclinical studies and clinical trials of the Company and Lucid; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; the potential inability to obtain or maintain regulatory approval of the drug product candidates of the Company and Lucid; the introduction of competing drugs that are safer, more effective or less expensive than, or otherwise superior to, the drug product candidates of the Company and Lucid; the initiation, conduct, and completion of preclinical studies and clinical trials may be delayed, adversely affected or impacted by unforeseen issues; the potential inability to obtain adequate financing; the potential inability to obtain or maintain intellectual property protection for the drug product candidates of the Company and Lucid; the Company's inability to benefit from Celly Nu and its launch of unbuzzd™; the Company's inability to realize upon the benefits, claims, and timelines with respect to unbuzzd™; the Company's inability to realize upon the stated benefit from the partnerships of Celly Nu; the Company's inability to carryout its business and goals, including the continued research and development of Lucid-MS, unbuzzd™, novel formulations for alcohol misuse disorders, and treatments for use in the healthcare sector; and the Company's inability to maintain its strategic investment portfolio. Accordingly, readers should not place undue reliance on the forward-looking statements contained in this press release, which speak only as of the date of this press release.

Further information regarding factors that may cause actual results to differ materially are included in the Company's annual and other reports filed from time to time with the Canadian Securities Administrators on SEDAR+ (www.sedarplus.ca) and with the SEC on EDGAR (www.sec.gov), including the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2023, the Prospectus and Registration Statement, each under the heading "Risk Factors". This list of risk factors should not be construed as exhaustive. Readers are cautioned that events or circumstances could cause results to differ materially from those predicted, forecasted or projected. The forward-looking statements contained in this document speak only as of the date of this document. FSD Pharma does not undertake any obligation to publicly update or revise any forward-looking statements or information contained herein, except as required by applicable laws. The forward-looking statements contained in this document are expressly qualified by this cautionary statement.

The Company makes no medical, treatment or health benefit claims about unbuzzd™. The U.S. Food and Drug Administration, Health Canada or other similar regulatory authorities have not evaluated any claims regarding unbuzzd™. The efficacy of such products have not been confirmed by approved research. Rigorous scientific research and clinical trials are needed. No clinical trials for the use of the Company's proposed products have been conducted. Any references to quality, consistency, efficacy and safety of potential products do not imply that the Company verified such in clinical trials or that the Company will complete such trials.

Neither the CSE nor its regulation services provider accept responsibility for the adequacy or accuracy of this release.

## **Contacts:**

FSD Pharma Inc.

Zeeshan Saeed, Founder, CEO and Executive Co-Chairman of the Board, FSD Pharma Inc.

Email: <u>Zsaeed@fsdpharma.com</u> Telephone: (416) 854-8884

**Investor Relations** 

Email: ir@fsdpharma.com, info@fsdpharma.com

Website: www.fsdpharma.com