FSD Pharma Launches A New Research and Development Program Targeting Unmet Medical Needs for Alcohol Misuse

TORONTO--(BUSINESS WIRE)--February 14, 2023--FSD Pharma Inc. (NASDAQ: HUGE) (CSE: HUGE) (FRA: 0K9A) ("**FSD Pharma**" or the "**Company**"), a biopharmaceutical company dedicated to building a portfolio of innovative assets and biotech solutions for the treatment of challenging neurodegenerative, inflammatory, and metabolic disorders, today announced the launch of a new research and development program focused on unmet medical needs for alcohol misuse.

Inebriated people with high blood alcohol levels often present to hospital emergency rooms in a variety of contexts. Management of these patients often consumes significant staff time and other resources, because their behaviour can be dysregulated, and judgement is impaired.

"Alcohol intoxication is a common presentation in many patients who visit hospital emergency rooms, and I see this during every one of my shifts. These presentations can require substantial time and effort to manage. Anything that could accelerate recovery from alcohol-intoxication would free up valuable health care resources and provide additional treatment options for alcohol use disorders," said FSD Pharma's Expert Advisory Committee Member Dr. Albert Wong, a psychiatrist who works in the emergency department at the Centre for Addiction and Mental Health in Toronto, Canada.

Substance misuse is one of the most pervasive challenges in many countries, including Canada. According to US Substance Abuse and Mental Health Services Administration's 2021 National Survey on Drug Use and Health ("NSDUH") alcohol consumption, a ubiquitous part in most societies, is the biggest contributor to substance misuse disorders. Among the estimated 46.3 million people aged 12 or older who met the criteria for having a substance use disorder in 2021 in the United States, 29.5 million people were classified as having an alcohol use disorder.

"FSD Pharma has recently invited Drs. Ashwin Dhanda from the United Kingdom and Anh Lê from Canada to its Scientific and Clinical Expert Committee (SCEC) to strengthen its advisory board including for the treatment of alcohol-related indications," added Dr. Kotra. "Combined clinical and scientific expertise of our innovation-driven R&D team at Lucid, expanded SCEC, and the expert consultant team, are working to address this challenge to improve the quality of life for those affected by high alcohol consumption and alcohol misuse."

How our body reacts to alcohol depends on several factors, including, but not limited to, age, weight, sex, health status, type of alcohol, and tolerance. Alcohol metabolism, being the process through which alcohol is broken down in the body and eliminated, occurs through different biochemical pathways. On average, it takes 1 to 1.5 hours for the body to metabolize one drink, defined, according to National Institute on Alcohol, Abuse and Alcoholism (USA), as one 12-ounces of beer, 5 ounces of 12% alcohol, or 1.5 ounces of 40% alcohol.

When alcohol is consumed, it can have a multitude of effects; alcohol interferes with the brain's communication pathways, altering the way the brain functions. The disrupted pathways reduce function of areas of the brain responsible for balance, coordination, memory, speech, and judgment, which can lead to injury and negative outcomes related to poor decision making.

"FSD Pharma's existing pipelines and research priorities in brain and inflammatory disorders, including mental health, provides a natural extension to investigate the effects of alcohol on the brain. Our clinical and product development teams are exploring how to limit and potentially reverse the negative effects of alcohol on brain function," said Dr. Lakshmi Kotra, CEO of Lucid Psycheceuticals ("Lucid"), a subsidiary of FSD Pharma. "There is a significant amount of research in this area already conducted by pioneers in the field, and we are bringing together our knowledge in pharmacology, regulatory strategy and product development in our search for solutions to address the effects of alcohol consumption."

FSD has agreed to issue common share purchase warrants to purchase 800,000 shares of the company. The warrants will have a 13-month term with an exercise price ranging from $1.50 USD to $4.50 USD.

About FSD Pharma

FSD Pharma Inc. is a biotechnology company with three drug candidates in different stages of development. FSD BioSciences, Inc., a wholly owned subsidiary, is focused on pharmaceutical research and development of its lead compound, FSD201, a proprietary ultra-micronized PEA formulation, for the treatment of inflammatory diseases. Lucid Psycheceuticals Inc., a wholly owned subsidiary, is focused on the research and development of its lead compounds, Lucid-Psych and Lucid-MS. Lucid-Psych is a molecular compound identified for the potential treatment of mental health disorders, and expanding this category, the Company is investigating other products addressing acute medical needs due to the abuse of drugs such as alcohol. Lucid-MS is a molecular compound identified for the potential treatment of neurodegenerative disorders.

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 forward-looking statements contained in this press release include statements concerning the future of FSD Pharma Inc. and are based on certain assumptions that FSD Pharma has made in respect thereof as of the date of this press release. 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. These forward-looking statements are not guarantees of future performance and are subject to a number of known and unknown risks and uncertainties including, but not limited to: the fact that the drug development efforts of both Lucid and FSD BioSciences are at a very early stage; the fact that preclinical drug development is uncertain, and the drug product candidates of Lucid and FSD BioSciences 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 Lucid and FSD BioSciences; 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 Lucid and FSD BioSciences; the introduction of competing drugs that are safer, more effective or less expensive than, or otherwise superior to, the drug product candidates of Lucid and FSD BioSciences; the initiation, conduct, and completion of preclinical studies and clinical trials may be delayed, adversely affected, or impacted by COVID-19 related issues; the potential inability to obtain adequate financing; the potential inability to obtain or maintain intellectual property protection for the drug product candidates of Lucid and FSD BioSciences; and other risks. 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.sedar.com) and with the U.S. Securities and Exchange Commission on EDGAR (www.sec.gov), including the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2021, 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.

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

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