FSD Pharma Files Investigational New Drug Application ("IND") with FDA and Health Canada for Phase-2 Trial of FSD-201 for an Inflammatory disorder and Provides Corporate Updates

TORONTO--(BUSINESS WIRE)--May 31, 2022--FSD Pharma Inc. (NASDAQ: HUGE) (CSE: HUGE) (FRE: 0K9A) ("**FSD Pharma**" or the "**Company**"), a life sciences holding company dedicated to building a portfolio of assets and biotech solutions, today announces the submission of an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration ("FDA") and Health Canada detailing a planned Phase 2 clinical trial of FSD-PEA for the treatment of a yet-to-be-disclosed inflammatory disorder.

"Our current submissions of applications to FDA and Health Canada for FSD-201 efficacy trials represent a significant milestone in our drug development efforts," said Zeeshan Saeed, Co-Founder and President of FSD Pharma. "With our elite team and solid cash position, we find ourselves in a strong position initiating the efficacy trials with FSD-201. Further details on the clinical trial will be released as soon as the applications complete their review processes, and the clinical trial commences."

FSD Pharma holds exclusive worldwide (excluding Italy and Spain) licensing rights to FSD-201 for all conditions in all regulatory categories.

- FSD-201 is a proprietary formulation of ultra-micronized palmitoyl ethylamine (PEA)
- FSD Pharma's successfully completed Phase 1 clinical trial showed FSD-201 to be safe and well tolerated

Corporate Updates

FSD Pharma would also like to provide shareholders additional insight as the Company looks ahead to the second half of 2022. On May 6, 2022, FSD Pharma completed the sale of its former cannabis production facility in Cobourg, Ontario, Canada for CAD$16.4 million, growing its cash on hand to approximately CAD$50.0 million and completing its transition away from the cannabis industry to focus on its pipeline of novel therapeutics for inflammatory, neurodegenerative, and neuropsychiatric diseases.

"Over the last year, we have strategically exited the cannabis business, whilst making a generous profit on the sale of the Cobourg facility and in the process, providing sufficient capital for at least three years of operations and clinical trials," said Zeeshan Saeed. "No treatment currently exists to target neurodegeneration, Major Depressive Disorder is an indication in desperate need for new therapeutic approaches, and, as aforementioned, there are no PEA-based drugs approved by the FDA either. That said, we have unique drug candidates that have the potential to revolutionize patient outcomes in each of these notoriously hard-to-treat diseases via innovative mechanisms of action."

Mr. Anthony Durkacz, Co-Founder and Interim CEO said, “We are highly focused on creating shareholder value while mitigating risk, and all our efforts are concentrated on optimally structured trials that hit their primary endpoints, which we believe will have a cascade effect on potential partners, suitors, and a market valuation that is an accurate reflection of our company.”

“We recognize that Wall Street has under-appreciated the biotech sector and that we are lumped into the mix; that we cannot control,” concluded Mr. Durkacz. “What we can control is efficient execution of our model, assembling a team with a lengthy bio-tech track record of success to provide guidance, responsibly managing budgets. We’re checking all these boxes and will keep shareholders abreast of all pertinent developments as they happen,” concluded Mr. Durkacz

Since taking over the company’s control last year, the founders and the company’s leadership, has focused the company’s resources on building a globally recognized biotechnology firm, the Company since then has:

- Acquired Lucid Psycheceuticals Inc. (“Lucid”), a specialty pharmaceutical company focused on the development of therapies to treat critical neurodegenerative diseases led by Dr. Lakshmi P. Kotra, B.Pharm.(Hons), Ph.D., recipient of the Julia Levy Award, a Senior scientist at Krembil Brain Institute, University Health Network (“UHN”), and Professor of Medicinal Chemistry at the University of Toronto. Dr. Kotra remains as CEO of Lucid.
- Sold non-core assets, including the Company’s former cannabis processing facility located in Cobourg, Ontario, Canada, for CAD$16.4 million. FSD bought the facility and land for CAD$5.5 million in 2017.
- Amassed a cash position of which is enough to fund the company through 2025, inclusive of the three planned clinical trials this year, without raising new cash.
- Initiated a share repurchase plan, for which 1.52 million shares have been bought and returned to the treasury so far in 2022.
- Insiders of the company frequently buy shares in the open market. Since the beginning of 2022 both founders and executive co-chairmen, Zeeshan Saeed and Anthony Durkacz have bought additional 331,192 and 150,003 shares respectively
- Assembled world-class development and advisory teams. These teams include highly qualified scientists, regulatory and medical professionals with expertise spanning the entire drug development spectrum.
- Advanced each of the Company’s leading drug candidates: LUCID-MS, LUCID-PSYCH, and FSD-PEA (FSD-201).
    - FSD-201 is expected to be in Phase-2 clinical trials in the third quarter for an inflammatory disorder. Requisite documentations have been filed with the U.S. Food and Drug Administration and Health Canada.
    - LUCID-MS, a patented NCE (New Chemical Entity), has shown to slow and reverse demyelination, a hallmark of MS, in mouse models. The company feels LUCID-MS is de-risked to a certain extent with exponential upside since it has been extensively studied in the lab for decades and is designed based upon human brain scans. IND application for a phase 1 trial is expected to be filed by the end of 2022

- LUCID-PSYCH is undergoing IND-enabling studies and has shown indications of efficacy for Major Depressive Disorders. IND application for Phase 1 trials is expected to be filed by the end of 2022

About FSD Pharma

FSD Pharma Inc. is a biotechnology company with three drug candidates in different stages of development. FSD BioSciences, Inc. ("**FSD BioSciences**"), a wholly owned subsidiary, is focused on pharmaceutical research and development of its lead compound, ultra-micronized palmitoyl ethylamine ("**PEA**") or FSD-PEA (formerly called FSD-201). Lucid Psycheceuticals Inc. ("**Lucid**"), a wholly owned subsidiary, is focused on the research and development of its lead compounds, Lucid-PSYCH (formerly Lucid-201) and Lucid-MS (formerly Lucid-21-302). Lucid PSYCH is a molecular compound identified for the potential treatment of mental health disorders. Lucid-MS is a molecular compound identified for the potential treatment of neurodegenerative disorders.

Forward Looking Information

Certain statements contained herein are "forward-looking statements." Often, but not always, forward-looking statement can be identified by the use of words 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. Forward-looking statements contained in this press release include statements relating to the Company's Investigational New Drug Application ("IND") with FDA and Health Canada for Phase-2 Trial of FSD-201 for an Inflammatory disorder as well as corporate updates. FSD cannot give any assurance that such forward-looking statements will prove to have been correct. The reader is cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release.

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 is believed that the assumptions are reasonable in the circumstances, 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. Factors that may cause such material differences include without limitation: 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. 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) under the heading "Risk Factors." Any forward-looking statement contained in this release speaks only as of its date. The Company does not undertake to update any forward-looking statements, except to the extent required by applicable securities laws.

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