

## **FSD Pharma Establishes New Regulatory Advisory Board with the Appointment of Joga Gobburu, Ph.D., and Mary Melnyk, Ph.D., as Members**

*Regulatory Advisory Board will oversee the drug development pathway for FSD Pharma's clinical drug candidates*

TORONTO--(BUSINESS WIRE)--December 9, 2021--FSD Pharma Inc. (NASDAQ: HUGE) (CSE: HUGE) (FRA: 0K9A) (“**FSD Pharma**” or the “**Company**”), a life sciences holding company dedicated to building a portfolio of assets and biotech solutions, announced today that it has formed a Regulatory Advisory Board (“RAB”) and has appointed Joga Gobburu, B.Pharm. (Hons), M.Sc. (Hons), Ph.D., M.B.A., and Mary Melnyk, M.Sc., Ph.D., as members.

A world-recognized scientific leader in pharmacometrics, Dr. Gobburu is a Professor at the School of Pharmacy and the School of Medicine, University of Maryland, Baltimore, MD. Between 1998 and 2011, he held various positions at the U.S. Food and Drug Administration (“FDA”), most recently as Director of the Division of Pharmacometrics and Office of Clinical Pharmacology. Dr. Gobburu led the review of thousands of Investigational New Drug Applications, more than three hundred New Drug and Biological Licensing Applications, numerous FDA drug approvals, labeling guidelines and policies. At the FDA, he established the Division of Pharmacometrics, was part of the committee responsible for the 21<sup>st</sup> Century Review Process and provided input into Prescription Drug User Fee Act planning. Dr. Gobburu received several FDA awards, including the 2001 Outstanding Achievement Award, and was recognized with the Senior Biomedical Research Scientist appointment in 2007. He also received the 2008 Outstanding Leadership Award from the American Conference on Pharmacometrics, the 2008 Tanabe Young Investigator Award from the American College of Clinical Pharmacology (“ACCP”) and the 2019 Sheiner-Beal Pharmacometrics Award from the American Society of Clinical Pharmacology and Therapeutics. Dr. Gobburu is a Fellow of the American Association of Pharmaceutical Scientists and the ACCP. He is on the Editorial Board of several journals; has published more than one hundred papers and book chapters; and is the inventor of two U.S. patents.

Dr. Gobburu said, “FSD Pharma has a world-class team of scientists in the area of neurology and inflammation. I look forward to supporting their development program and applying my regulatory expertise to bring their innovative assets to market.”

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Dr. Melnyk is an expert in manufacturing and regulatory requirements for pharmaceutical and medical device development. She is currently the Senior Regulatory Consultant at Innovalinks, a consulting firm serving the pharmaceutical industry in the quality and regulatory systems, process transfer, and validation and scale-up. Dr. Melnyk served as a Professor for the Academy of Applied Pharmaceutical Sciences (“AAPS”) and held senior leadership and executive roles in Quality Assurance and Quality Control at Biovail Corporation, EMD Merck Biomira, Novartis Canada/CIBA Division, GlaxoWellcome and Sanofi Pasteur. She played a key role in the FDA approvals of Wellbutrin XL, Cardizem LA and Rescula, as well as facility validations for Salk’s HIV Immunogen, the BCG vaccine, and Merck’s Hepatitis B vaccine. Dr. Melnyk also led the

scale-up and licensure of numerous biological products in global markets, including the Salk Polio and component pertussis vaccines. In addition to designing quality systems comprised of good laboratory, clinical and manufacturing practices for biologics, drugs, and medical devices, she oversaw global regulatory approvals of medical devices, natural health products, and medicinal products in the U.S., Canada, Australia, and the EU, with numerous successful applications. Dr. Melnyk is a member of the International Society of Pharmaceutical Engineers, Parenteral Drug Association (Canadian Chapter), and Calibration Validation Group. She has also served as a trainer for the World Health Organization and the International Pharmaceutical Academy.

The RAB was formed by Dr. Lakshmi P. Kotra, B.Pharm. (Hons), Ph.D., Chief Executive Officer of FSD Pharma's wholly-owned subsidiary, Lucid Psycheceuticals Inc., who commented, "We are thrilled to welcome Drs. Gobburu and Melnyk as members of our recently established board and are looking forward to applying their combined expertise in global quality and regulatory systems as we advance our drug candidates toward the clinic to serve global markets."

### **About FSD Pharma**

FSD Pharma is a life sciences holding company with two wholly-owned subsidiaries dedicated to building a portfolio of diversified therapeutic assets and innovative healthcare and biotech services.

FSD BioSciences, Inc. ("FSD BioSciences"), a wholly-owned subsidiary, is a specialty biotech pharmaceutical R&D company focused on developing applications of its lead compound, ultramicrosized PEA, by down-regulating the cytokines to effectuate an anti-inflammatory response.

Lucid Psycheceuticals Inc. ("Lucid"), a wholly-owned subsidiary, has exclusive worldwide rights to novel compounds shown to prevent and potentially reverse the biochemical mechanisms of progressive multiple sclerosis in multiple preclinical animal models. Additionally, FSD is seeking to develop a unique psychoactive (psychedelic-based) therapeutic aimed at addressing neurodegenerative disorders, a multibillion-dollar mental health market. The Company hopes to quickly advance its lead drug candidates through clinical trials.

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### ***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 the comments made with respect to the Company's formation and operation of its Regulatory Advisory Board and appointments thereto,

advancing the Company's research, including the advancement of the Company's drug candidates from research into clinical trials and any potential commercially viable therapeutic application therefor. 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](http://www.sedar.com)) and with the U.S. Securities and Exchange Commission on EDGAR ([www.sec.gov](http://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.

## **Contacts**

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