


FSD Pharma Inc.

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Ticker (Exchange)	HUGE-NASDAQ HUGE-CSE
Recent Price (03/10/2022)	\$1.02
52-week Range	\$0.80 - \$3.09
Shares Outstanding	39.5 mm
Market Capitalization	\$40.3 mm
Average 10-day volume	169,600
Insider Ownership +>5%	7.3%
Institutional Ownership	10.7%
EPS (Year ended 09/30/21)	(\$0.15)
Employees	~ 20

HUGE (NASDAQ) One-year Stock Chart

 Figure xx
 FSD PHARMA PIPELINE

Idea/Target	Phase 1	Phase 2	Phase 3	Launch
LUCID-PSYCH Major Depression Disorder	4Q22 Est.			
LUCID-MS Multiple Sclerosis	4Q22 Est.			
FSD-PEA Inflammatory Disorders		2Q22 Est.		

Source: FSD Pharma Inc.

All amounts in U.S. dollars unless stated otherwise.

COMPANY DESCRIPTION

FSD Pharma Inc. ("FSD Pharma" or "the Company") is a biopharmaceutical company focused on developing innovative therapies for brain and inflammatory disorders to improve patient quality of life. The Company has three drug candidates in its pipeline: (1) LUCID-PSYCH, a unique psychedelic molecule currently undergoing **Investigational New Drug Application (IND)**†-enabling studies with a targeted treatment for neuropsychiatric disorders, including **major depressive disorder (MDD)**; (2) LUCID-MS, a patented, proprietary neuroprotective **new chemical entity (NCE)**, with demonstrated efficacy in preclinical animal models for the potential to reverse and prevent **myelin degradation** (an underlying cause of **Multiple Sclerosis [MS]**); (3) FSD-PEA (FSD-201), a patented **ultramicrozonized** formulation of **palmitoylethanolamide (PEA)**, with the potential to address a range of inflammatory conditions. PEA interacts with the endocannabinoid system (ECS) in the body and exhibits anti-inflammatory activities. FSD-PEA has completed FDA approved Phase 1 clinical trials with positive topline results and the Company is currently evaluating potential Phase 2 indications.

KEY POINTS

- In September 2021, FSD Pharma acquired 100% of the issued and outstanding shares of Lucid Psycheceuticals Inc., a Canadian biotechnology company (and the developer of LUCID-PSYCH and LUCID-MS), for roughly \$9 million (CAD\$11.3 million) in FSD Pharma stock at a higher share price of \$1.97.
- LUCID-PSYCH was discovered using a state-of-the-art artificial intelligence (AI) screening system that has been identified by the Lucid team for accelerated development due to its unique pharmaceutical properties and potential for treating depression.
- LUCID-MS has shown excellent efficacy in pre-clinical animal models of MS, without suppressing the immune system. This may potentially complement MS therapies that address autoimmune-related symptoms. An IND submission for this compound is possible by the end of 2022. Composition of matter patents protect this family of compounds (2035 U.S. expiration).
- FSD Pharma has a strong intellectual property (IP) portfolio covering ultramicrozonized composition of matter and use of FSD-PEA (2029-2034 U.S. expiration). FSD-PEA is a potential candidate for the treatment of a variety of inflammation-mediated disorders.
- The Lucid acquisition brings a highly capable clinical research and development (R&D) team with access to world-class organizations. Dr. Lakshmi Kotra, prof. of Medicinal Chemistry at the University of Toronto, and a senior scientist at Krembil Research Institute, UHN, is the CEO of FSD Pharma's newly formed Lucid subsidiary. Dr. Kotra is leading the development of all FSD Pharma's biotech assets.
- As of September 2021, FSD Pharma held over \$39.3 million in cash and cash equivalents, with the Company continuing to pursue additional investment and acquisition opportunities.
- FSD Pharma established offices in the Discovery District in Toronto and in Sparks, Maryland to spearhead its global drug development operations.

All amounts in U.S. dollars unless stated otherwise.

Table of Contents

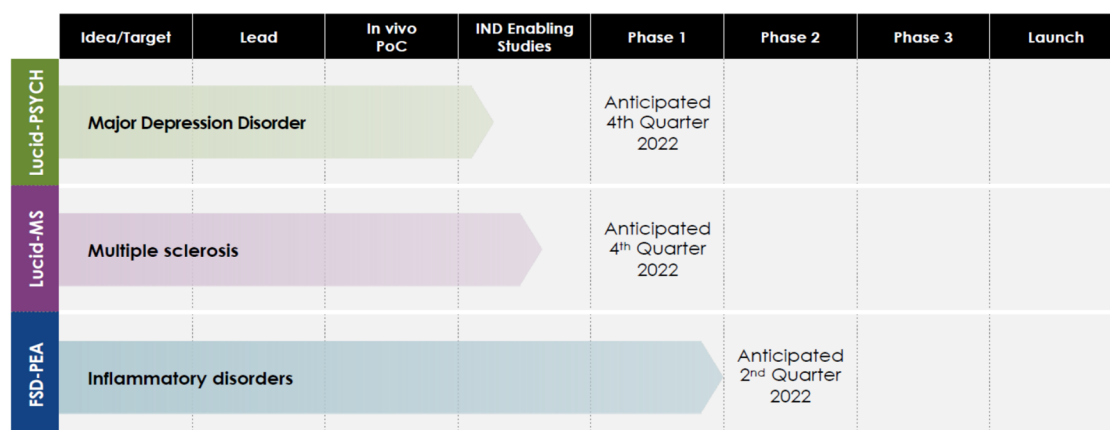
Executive Overview	3
Company Leadership	7
Intellectual Property.....	13
Core Story	15
LUCID-PSYCH	18
LUCID-MS	23
FSD-PEA (FSD201)	28
Milestones	33
Investment Highlights.....	34
Competition.....	36
Historical Financial Results	39
Recent Events	42
Risks and Disclosures	45
Glossary	55

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Executive Overview

FSD Pharma Inc. (“FSD Pharma” or “the Company”) is a biopharmaceutical company focused on developing innovative therapies for brain and inflammatory disorders to improve patient quality of life. The Company has three drug candidates within its pipeline, as shown in Figure 1: (1) LUCID-PSYCH, a unique psychedelic molecule currently undergoing investigational new drug application (IND)-enabling studies with a targeted treatment for neuropsychiatric disorders, including major depressive disorder (MDD); (2) LUCID-MS, a patented, proprietary neuroprotective new chemical entity (NCE), which has demonstrated in preclinical models the potential to reverse and prevent myelin degradation, an underlying cause of Multiple Sclerosis (MS) and other neurodegenerative orders, currently undergoing new drug application (IND)-enabling studies; and (3) FSD-PEA (FSD-201), an ultramicronized formulation of palmitoylethanolamide (PEA), or ultramicronized PEA, with the potential to address a range of inflammatory conditions. PEA interacts with the endocannabinoid system (ECS) throughout the body and exhibits anti-inflammatory effects. The Company has completed FDA approved Phase 1 clinical trials of FSD-PEA with positive topline results, and is embarking onto Phase 2 clinical trials.

Figure 1
FSD PHARMA PIPELINE



Source: FSD Pharma Inc.

Lucid Psycheceuticals Inc. Acquisition

In September 2021, FSD Pharma acquired 100% of the issued and outstanding shares of Lucid Psycheceuticals Inc., a Canadian biotechnology company focused on developing therapies to treat neurodegenerative diseases, for approximately \$9 million (CAD\$11.3 million) in FSD Pharma stock. This acquisition strengthens FSD Pharma’s efforts to build a portfolio of biotechnology assets with the potential to treat mental health disorders and neurodegenerative diseases in a new and unique way. Lucid’s pipeline of novel therapeutic compounds is supported by intellectual property (IP) and evidence-based drug development programs.

Lucid’s two unique drug candidates—LUCID-PSYCH targeting major depressive disorder (MDD) and LUCID-MS to treat MS—are complementary to FSD Pharma’s existing FSD-PEA candidate carrying a similar connection to all aspects of the brain that involve total brain health. LUCID-MS was developed over many years by doctors, scientists, and researchers at the University Health Network (UHN), one of the largest health research organizations in North America, with Lucid exclusively licensing the compound from UHN in 2021. Since its acquisition, Lucid is also spearheading the development of FSD-PEA.

LUCID-PSYCH

There is a worldwide mental health crisis that continues to mount with over 2 billion people suffering from treatable but untreated mental health disorders. Clinical evidence continues to show that psychedelic compounds can and will revolutionize the treatment of mental health disorders similar to the way antibiotics revolutionized the treatment of bacterial infections, with a growing body of research suggesting that psychedelics have the potential to treat a variety of neuropsychiatric disorders, including post-traumatic stress disorder (PTSD), depression, treatment resistant depression (TRD), major depressive disorder (MDD), and anxiety. FSD Pharma is developing LUCID-PSYCH, a psychedelic-inspired medicine that was identified using a state-of-the-art artificial intelligence (AI) screening system. This compound has been identified by the Lucid team for accelerated development due to its unique pharmaceutical properties and potential for treating depression.

Preclinical development and IND-enabling studies on LUCID-PSYCH are underway, in partnership with Covar Pharmaceuticals Inc. (Covar), a contract development and manufacturing services organization (CDMO), on an exclusive basis and other contract organizations. FSD Pharma has access to licensed facilities to handle Controlled Substances listed under the Controlled Drugs and Substances Act, Canada. Research-grade and good manufacturing practices (GMP)-grade LUCID-PSYCH is being produced for use in FSD Pharma's planned pre-clinical and Phase 1 clinical trials, respectively. This potentially sets the stage for the Company to achieve its goal of moving LUCID-PSYCH from bench to clinic.

LUCID-MS

On the MS side, the Company is developing new chemical entities (NCEs) discovered over decades of research by some of the top researchers. FSD Pharma has a worldwide exclusive license to this patent portfolio from UHN. Today's approved MS drugs have largely been designed to target the immune system in one way or another because MS has been considered an autoimmune disease. New scientific advances in the past decade, including those from the Lucid scientific team, are changing this paradigm. The Company strongly believes that therapeutic applications involving LUCID-MS could be disease modifying by possibly reversing neurodegeneration without modulating the immune system. This application is unique in that it targets mechanisms that promote myelin degradation.

The majority of individuals with MS will lose control of their muscles over time (due to neurodegeneration), which makes it difficult to maintain balance when walking and/or performing delicate tasks with their hands. LUCID-MS could become complementary to existing MS therapies due to its non-immunomodulatory mechanism by helping patients regain the function they may have lost. In MS patients, specifically **progressive MS**, the patient's condition get worse and over time and he/she loses the ability to walk, ending up in a wheelchair. FSD Pharma's compound has demonstrated not only protection of myelin but also increased myelin in MS animal models. The Company is developing this compound for potential clinical trials, with it considered complementary to current MS drugs, which are focused on the immune system (versus the specific focus on the central nervous system [CNS] and myelin by FSD Pharma).

Over the past 11 years, multiple animal efficacy studies were conducted on this group of compounds licensed by FSD Pharma. It was observed that its lead molecule can prevent, and in some instances, reverse the physical disability that is witnessed in animals with an MS-like condition. To achieve a notable impact on a patients' quality of life and the potential for disease modification, therapeutics need to affect the early stages of the disease so that inflammation is reduced, autoimmunity is addressed (without the toxicities of immunosuppression), and demyelination is slowed or stopped. Latest science suggests neurodegeneration exists from early stages of the disease, which is why compounds such as LUCID-MS are sought as potential treatments for MS. FSD Pharma is currently conducting pre-clinical, IND enabling studies with anticipated IND submission by end of 2022.

FSD-PEA

An ultramicrosized formulation of palmitoylethanolamide (PEA), FSD-PEA (FSD-201) is a proprietary anti-inflammatory product, which has completed Phase 1 clinical trials with an excellent safety profile and is under consideration to launch Phase 2. The compound is a part of the ECS, and is shown to be an agonist to the cannabinoid-like G protein-coupled receptor 55 (GPR55), 119 (GPR119), vanilloid receptor 1 (VR1), and peroxisome proliferator-activated receptor- α (PPAR- α). PEA is being investigated for its anti-inflammatory, analgesic, and neuroprotective effects; FSD-PEA has shown a great promise as a therapeutic agent. FSD Pharma holds exclusive worldwide licensing rights (except Italy and Spain) to FSD-PEA for all conditions in all regulatory categories. There is also a strong IP portfolio covering FSD-PEA composition of matter and use (2029-2034 U.S. expiration). FSD Pharma is strategically positioning these assets for a Phase 2 clinical trial in Q2 2022 and to further develop its full potential as a therapeutic agent.

In connection with the Lucid acquisition, Dr. Lakshmi P. Kotra, B.Pharm. (Hons), Ph.D. (biography on page 7), Lucid's co-founder, senior scientist at Krembil Brain Institute, UHN, and Professor of Medicinal Chemistry at the University of Toronto, has joined FSD Pharma as CEO of Lucid, which is now the Company's wholly-owned subsidiary. In this newly created role, Dr. Kotra continues to assess and advance FSD Pharma's drug development programs. Under his leadership, FSD Pharma has significantly expanded its drug development team, scientific advisory board, regulatory advisory board, and has increased its partnerships with experienced organizations worldwide as it focuses on completing advanced preclinical studies and scaling-up activities to successfully move the Company's compounds through clinical trials.

Recent Restructuring

FSD Pharma currently maintains three subsidiaries:

- (1) FSD Biosciences Inc. ("FSD Biosciences"), which is wholly owned by the Company and incorporated under the laws of the State of Delaware;
- (2) FV Pharma Inc. ("FV Pharma"), which is wholly owned by the Company and incorporated under the Ontario Business Corporations Act (OBCA);
- (3) Lucid Psycheceuticals Inc. ("Lucid"), which is wholly owned by the Company and incorporated under the OBCA.

Ended All Activities of FV Pharma

In July 2020, the Company opted to primarily focus its efforts and resources on the pharmaceutical business. As of September 30, 2020, FSD Pharma ended all activities of FV Pharma. As a result, the Company is no longer engaged in cannabis-related activities and is in the process of liquidating all of FV Pharma's assets, including the sale of its facility and/or its adjacent real estate. On February 25, 2022, FSD Pharma announced that it had entered into a firm agreement in connection with the sale of its former cannabis processing facility located in Cobourg, Ontario and the 64.43 acre property on which the facility is located. In consideration for the purchase of the facility, the purchaser has agreed to pay a cash sum of CAD\$16,500,000, including a deposit of CAD\$660,000. The deposit was received by the Company on February 24, 2022 and the transaction is expected to close on May 31, 2022. If closed, the injection of money will be non-dilutive to shareholders. The sale remains subject to the satisfaction of a number of conditions.

Terminated Phase 2 FSD-201 COVID-19 Clinical Trial

On August 28, 2020, the Company filed an IND with the FDA for PEA and was approved on September 25, 2020 to initiate a Phase 2 clinical program for the use of PEA to treat COVID-19, the disease caused by the SARS-CoV-2 virus. The trial was targeting a total of 352 random patients in a controlled, double-blind multicenter study. Following the Company's May 14, 2021 annual general and special meeting of shareholders, FSD Pharma retained an experienced biotechnology investment bank to undertake a review of its Phase 2 clinical program to assist in determining its viability and, more broadly, evaluate the general current commercial viability of PEA. FSD Pharma was concerned

with the pace of progress in advancing the Phase 2 clinical program during a period in which COVID-19 treatments and vaccination rates evolved significantly and competitive products were being successfully advanced. The biotechnology investment bank reported its findings and based on this, FSD Pharma concluded while there are potential commercial opportunities for PEA, the treatment of COVID-19 by PEA is unlikely to be commercially viable. On August 24, 2021, FSD officially announced the termination of Phase 2 clinical trial of FSD-201 to treat COVID-19 and continues to evaluate Phase 2 indications.

Manufacturing

FSD Pharma is manufacturing its products through contract development and manufacturing organization (CDMO), Covar Pharmaceuticals Inc. (explained on page 22), and others in Canada, the U.S., India, and Europe.

Offices in Canada and the USA

In December 2021, FSD Pharma leased office space at 243 College Street, Toronto, Ontario, Canada to centralize its drug development operations. This is located in the heart of Discovery District in Toronto, adjacent to world-class research hospitals and the campus of University of Toronto. Global operations of FSD Pharma are managed from this location. In February, 2022, FSD Pharma leased space at 53 Loveton Circle, Sparks, Maryland (U.S.) with office and a small warehouse space for its U.S. operations.

Corporate History and Employees

The Company was formed under and is governed by the provisions of the Business Corporations Act (Ontario) (the “OBCA”) on November 1, 1998 pursuant to the amalgamation of Olympic ROM World Inc., 1305206 Ontario Company, 1305207 Ontario Inc., Century Financial Capital Group Inc., and Dunberry Graphic Associates Ltd. On May 24, 2018, the Company changed its name to “FSD Pharma Inc.” The Company’s registered office is located at 199 Bay Street, Suite 4000, Toronto, Ontario, M5L 1A9. On January 9, 2020, FSD Pharma’s shares began trading on the NASDAQ Capital Market under the ticker symbol HUGE (Figure 2). As of December 2021, FSD Pharma directly employed approximately 20 full-time employees and consultants. FSD Pharma was founded by Thomas Fairfull (retired), Zeeshan Saeed, and Anthony Durkacz—with the first initial of the last names of each of the founders represent the letters FSD.

Figure 2
FSD PHARMA INC. RINGING THE BELL AT NASDAQ ON JANUARY 22, 2020



Source: FSD Pharma Inc.

Company Leadership

In order to execute on its pipeline, FSD Pharma has made significant efforts into strengthening its management team along with its board of directors, regulatory advisory board, and expert research and clinical team. These individuals have diverse industry knowledge as well as a commitment to science, therapeutic drug discovery, and development. Biographies of these key individuals are provided in the accompanying sections.

Management Team

Dr. Lakshmi P. Kotra, BPharm (Hons), PhD, Chief Executive Officer (CEO) of Lucid Psycheceuticals Inc.

Dr. Lakshmi Kotra leads Lucid's operations and strategy as CEO since completing the acquisition of Lucid Psycheceuticals in September 2021 by FSD Pharma. Dr. Kotra brings a wealth of experience, from discovery to advanced stages of drug development, building products and business based on fundamentals and pragmatism. He is a Senior Scientist at Krembil Brain Institute, University Health Network (UHN), and Professor of Medicinal Chemistry at the University of Toronto, with international experience in leading multi-disciplinary expert teams spanning private and public sectors. Dr. Kotra is an inventor of multiple technologies and holds several patents. He has authored/co-authored over 130 publications and delivered over 140 scientific talks internationally. Dr. Kotra is the recipient of several recognitions and awards over the years, including the Julia Levy Award from the Society of Chemical Industry (SCI) Canada in 2021 in recognition of his substantial contribution to the successful commercialization of innovation in Canada in the field of biomedical science and engineering. Dr. Kotra has led or participated in a number of important drug discovery and development projects, including anti-HIV drugs, antibacterials, insulin, antimalarials, medical cannabis-based therapeutics, and drugs targeting multiple sclerosis (MS). In addition to Lucid Psycheceuticals, he co-founded WinSanTor Biosciences, a San Diego, CA-based company developing treatments for peripheral neuropathies, and CannScience Innovations (Scientus Pharma), a Toronto, ON-based company focused on medical cannabis and cannabinoids. Dr. Kotra received B.Pharm.(Hons) from Birla Institute of Technology and Science (India), Ph.D. in Pharmacy (Medicinal Chemistry) from the University of Georgia, and completed postdoctoral training at Wayne State University.

Kevin Cassidy, Vice-President, Quality Systems

Mr. Kevin Cassidy brings over 39 years of biotechnology experience to FSD Pharma. His experience includes biotherapeutic, vaccine development and **good manufacturing practice (GMP)** manufacturing. Mr. Cassidy's medical device experience also includes development of infectious diseases diagnostics. His most recent success was registration of medical devices for COVID-19 testing in the U.S., Europe, UK, Canada, and Australia. Mr. Cassidy has established and run operations, validated facilities for GMP manufacturing, biotherapeutic development, and quality testing in Canada, Chile, and China. He was lead on process and business development, resulting in the first approved adenovirus-vectored vaccine. The rabies vaccine is the predecessor to several vaccines deployed in the COVID-19 pandemic. Mr. Cassidy was trained in Business Management at George Brown College and received a Bachelor of Science degree from University of Toronto.

Joanne Speed, Senior Director, Drug Development

Ms. Joanne Speed has over fifteen years of experience in the biotech industry with a focus on early-stage drug development and moving development candidates into clinical trials. Ms. Speed also has experience with late-stage candidate development, including being a key contributor to the CMC regulatory package for a new drug submissions to U.S. FDA and Health Canada. She is familiar with and has working experience on many aspects of drug development—from bench-level chemistry, management of CMC drug substance and drug formulations to regulatory submissions to U.S./Canadian/European drug regulatory agencies. Ms. Speed is also experienced in monitoring clinical studies, implementation of organization-wide quality systems and SOPs. Ms. Speed received a Honours Bachelor of Science in Biological Chemistry (University of Toronto), Certificate in Biotech Project Management from University of Washington and University of California and Clinical Research Associate Certificate from Michener Institute, Toronto, ON.

Dr. Oksana Akhova, PhD, MBA, Director, Licensing, Partnerships and IP

Dr. Oksana Akhova has extensive experience both within industry and academia in business development, IP management, and commercialization of innovative technologies. She holds a PhD in oncology and an MBA with specialization in biotechnology management. Ms. Akhova has a passion for bringing early-stage assets in life sciences to market. Her dedicated experience has demonstrated successes in licensing and collaboration deals through her extensive knowledge of technology, finance, and marketing.

Ashwini Joshi, MS, PG Diploma (QA&RA), Director, Pharmaceutical Development

Ms. Ashwini Joshi is a pharmaceutical drug development professional with over 9 years of experience developing formulations on small molecules for global markets in mid to large generic and pharmaceutical industries. She worked in various drug developmental stages, starting from product development at R&D to its successful scale-up and subsequent regulatory filings. Ms. Joshi received a Master's in Pharmacy (Pharmaceutics) from NMIMS, Mumbai, India and a Post Graduate Diploma in QA & RA from Academy of Applied Pharmaceutical Sciences, Toronto, Canada.

Dr. Sima Salahshor, BSc, MSc, PMP, PhD, Associate Director, Scientific and Clinical Affairs

Dr. Sima Salahshor holds a bachelor's degree in Clinical Chemistry, a Master's in Molecular Biology, and a Ph.D. in Medical Genetics from Karolinska Institute, Sweden. She is a certified Project Management Professional (PMP) and an adjunct professor at the University of Toronto's Faculty of Medicine. She has over 20 years of experience in oncology and cell signalling research working at the Karolinska Institute (Sweden), University Health Network (UHN), and Lunenfeld Research Institute at Mount Sinai Hospital (Canada). She has published numerous pre-reviewed articles in cancer diagnostic and biomarker discovery and development. For ten years, she led and managed a scientific-business advisory firm focusing on life-sciences and healthcare-related projects and programs. During that time, she worked extensively with early-stage as well as larger corporate companies, and has experience in product evaluation, clinical studies, early stage investment, commercialization, and industry partnership development.

Dr. Patrick Oyanango, PhD, Director, Operations (U.S.)

Dr. Patrick Onyango joined FSD Pharma in early 2022, and in his role is focused on facilitating FSD/Lucid operations in the U.S., with the goal of fulfilling the FSD/Lucid-USA mission of developing novel solutions for brain and inflammatory disorders. Dr. Onyango is the founder of Sparks-based American BioInnovations LLC (ABI), a biotech company implementing innovative technologies to help improve human health by manufacturing pharmaceutical ingredients, advanced drug intermediates, and cell culture solutions. Prior to founding ABI, Dr. Onyango was on the faculty in the Department of Medicine at Johns Hopkins University School of Medicine for over a decade. At John Hopkins, Dr. Onyango trained more than 20 trainees, gave talks at several international scientific meetings, authored more than 25 peer reviewed scientific research publications, including pioneering work on functional genomics and discovery of protein deacetylation in mitochondria. Dr. Onyango received the 2003 Eminent Scientist of the year award from International Research Promotion Council in recognition of his Functional Genomics research. He did his postdoctoral studies on Neuroblastoma Tumor Suppressor genes at the International Institute of Molecular Pathology in Vienna and on Epigenetics in the division of Medical Genetics at Johns Hopkins University School of Medicine. Dr. Onyango earned a PhD in Human Molecular Genetics from the University of Vienna. Prior to that, he graduated from University of Nairobi, where he obtained both his BSc (Hons. in Chemistry and Biochemistry) and MSc in Biochemistry.

The above team is complemented with additional employees in scientific, medical, and regulatory fields.

Expert Research and Clinical Team

Albert H.C. Wong, MD, PhD, FRCP(C), Expert Advisory Committee Member

Dr. Albert Wong, Professor of Psychiatry, University of Toronto, and a Research Scientist in the Neuroscience Department and Staff Psychiatrist in the Schizophrenia Division at the Centre for Addiction and Mental Health, is a world-renowned expert on schizophrenia. His research focuses on the investigation of genetic, cellular, and developmental mechanisms underlying psychiatric symptoms.

Peter K. Stys, MD, FRCP(C), FRSC, Expert Advisory Committee Member

Dr. Peter Stys, Professor of Clinical Neurosciences, Hotchkiss Brain Institute, University of Calgary, is a neurologist/neuroscientist and a world leader in the detailed study of pathophysiological mechanisms of white matter injury in stroke and trauma. Dr. Stys and his team have discovered several novel injury mechanisms responsible for axo-glia damage in ischemia/trauma and glutamate excitotoxicity, due to reversal of Na-dependent glutamate transport in damaged spinal axons. Dr. Stys' insights provide a rational basis for devising drug therapy for the acute phases of stroke, spinal cord injury, brain trauma, and neuroinflammatory conditions (such as MS), in which axons, oligodendrocytes, and myelin are prominent targets of damage. Dr. Stys is the recipient of the Dr. Frank LeBlanc Chair in Spinal Cord Research, Canada Research Chair (Tier 1) in Axo-glia biology, and Alberta Heritage Foundation for Research (AHFMR) scientist award. He is an Adjunct Research Professor at the Department of Systems and Computer Engineering at Carleton University, an Adjunct Professor at the Cumming School of Medicine at the University of Ottawa, and a Visiting Assistant Professor at the Department of Neurology at Yale School of Medicine. In addition, Dr. Stys has published 88 peer reviewed articles, 17 book chapters, and two books.

Shannon Dunn, PhD, Expert Advisory Committee Member

Dr. Shannon Dunn, a scientist at the University Health Network (UHN) and Women's College Hospital, and an Associate Professor in the Department of Immunology at the University of Toronto, currently leads a research program focused on various risk factors for the development of T cell-mediated autoimmune diseases, such as MS. Dr. Dunn holds operating grants from the Canadian Institute of Health Research and MS Society of Canada to conduct her research and has been awarded a Don Paty Salary award from the MS Society of Canada. She was awarded a doctoral degree from the University of Western Ontario in 2002, after which she conducted post-doctoral training in the field of neuroimmunology at Stanford University.

Hance Clarke, MD, FRCPC, Expert Advisory Committee Member

Dr. Hance Clarke is a staff anesthesiologist and the Director of Pain Services at the Pain Research Unit at the Toronto General Hospital (TGH). He is currently the Knowledge Translation Chair for the University of Toronto Centre for the Study of Pain, and in 2016, was awarded an early Career Award from the Canadian Pain Society. His research interests include identifying novel acute pain treatments following major surgery, identifying the factors involved in the transition of acute post-surgical pain to chronic pain, studying the genetics of acute and chronic pain after surgery, and identifying risk factors associated with continued opioid use and poor health related quality of life after major surgery as well as the efficacy of hyperbaric medicine. To-date, Dr. Clarke has authored over 100 peer reviewed manuscripts. Dr. Clarke has played a leading role in educating the Canadian public about pain control, risk factors for chronic opioid use, alternatives to opioids as a pioneering strategy at TGH, misconceptions about opioid use, and the need for further studies to understand the beneficial and adverse effects of cannabis. He is a public champion of evidence-based solutions for the opioid crisis and a national pain and addictions strategist.

Eleanor Fish, PhD, Research and Clinical Advisory Board

Dr. Fish is Professor and Associate Chair for the Department of Immunology, University of Toronto. She is a world-renowned immunologist and cytokines researcher as well as a World Health Organization (WHO) Consultant and a member and expert scientific panel to Chief Scientific Advisor to the Government of Canada.

Daniele Piomelli, PhD, MD, Research and Clinical Advisory Board

Dr. Daniele Piomelli is a professor at the University of California at Irvine. He is a leading expert in endocannabinoids and associated treatments as well as chief editor for *Cannabis and Cannabinoids Research*—the premier peer-reviewed journal dedicated to the scientific, medical, and psychosocial exploration of clinical cannabis, cannabinoids, and the endocannabinoid system.

Regulatory Advisory Board

Joga Gobburu, B.Pharm.(Hons), M.Sc., Ph.D., Regulatory Advisory Board

Dr. Joga Gobburu is Professor with the School of Pharmacy and the School of Medicine, University of Maryland, Baltimore, MD. He held various positions at the U.S. FDA between 1998 and 2011, and has experience overseeing the review of thousands of Investigational New Drug Applications (INDs), over 250 New Drug and Biological Licensing Applications, and numerous FDA Guidance and policies pertaining to drug approval and labeling. At the FDA, he was part of the committee responsible for 21st Review Process and provided input into Prescription Drug User Fee Act (PDUFA) planning. He received numerous FDA awards, such as the Outstanding Achievement Award and recognized with the Senior Biomedical Research Scientist appointment. He also received the Outstanding Leadership Award from the American Conference on Pharmacometrics (2008), the Tanabe's Young Investigator Award from the American College of Clinical Pharmacology (2008), and Sheiner-Beal Pharmacometrics Award from the American Society of Clinical Pharmacology and Therapeutics (2019). He is furthermore a Fellow of AAPS and ACCP. Dr. Gobburu is on the Editorial Boards of several journals. He has published over 100 papers and book chapters.

Mary Melnyk, M.Sc., Ph.D., Regulatory Advisory Board

Dr. Mary Melnyk has over 25 years of pharmaceutical/biotechnology experience in all phases of manufacturing, global regulatory landscape, technology transfer, and business leadership. Her expertise spans small molecule drugs, biologics and medical devices, especially during development phases and late stage for approvals, in the context of manufacturing and regulatory compliance.

Kwok Chow, PhD, Regulatory Advisory Board

Dr. Kwok Chow is President, Covar Pharmaceuticals Inc., a contract development and manufacturing organization (CDMO) with global drug development expertise. He specializes in regulatory strategies and product development.

Board of Directors

Anthony Durkacz, Founder, Interim CEO, and Executive Co-Chairman of the Board

Mr. Anthony Durkacz is the “D” in FSD. Mr. Durkacz has served as a director and the executive vice president of First Republic Capital Corporation since 2014. Prior to co-founding the Company, Mr. Durkacz was president of Capital Ideas Investor Relations. He previously served as the CFO and a director of Snipp Interactive Inc., a global marketing solutions company that provides a modular software-as-a-service technology suite. Mr. Durkacz was instrumental in the financing and public listing of Snipp Interactive Inc., with operations in Canada, the U.S., Mexico, and India. From 2006 to 2009, he served as chief operating officer (COO) and CFO of MKU Canada Inc. and engaged in mergers and acquisitions of companies around the world. Mr. Durkacz also served as the CFO and a director of Astris Energi Inc., a dual-listed public company in the U.S. and Canada, which was acquired by an international conglomerate. Mr. Durkacz began his career at TD Securities on the capital markets trading floor. He holds an Honors Bachelor of Business Administration from Brock University with a major in both Accounting and Finance.

Zeeshan Saeed, Founder, President and Executive Co-Chairman of the Board

Mr. Zeeshan Saeed is the “S” in FSD Pharma. Mr. Saeed started as a partner when the Company was just a business plan on paper. He was instrumental in raising the initial seed capital and assisted FSD Pharma’s transition into a public company. He played a key role in bringing together a team of professionals to facilitate crucial relationships and develop the Company’s business plan. Prior to founding the Company, Mr. Saeed served as President of ZZ Telecommunications Inc., a long-distance telecommunications common carrier. He has experience in international capital markets and has helped various start-ups with raising initial funding and obtaining listings on various stock exchanges. Before entering capital markets, Mr. Saeed was the founder and CEO of Platinum Telecommunications Inc. He has a Bachelor of Science in Mechanical Engineering.

Donal Carroll, Director

Mr. Donal Carroll joined FSD Pharma as interim CFO in 2018 and was appointed to the position on a permanent basis in December 2019. An experienced business executive, Mr. Carroll has 20 years of corporate finance leadership and public company experience, as well as deep expertise in syndicate investing both in equity and debt securities. With a balance of prudent financing practices and business insights, Mr. Carroll has successfully guided companies through expansion and growth. He was previously with Danaher, Alberto Culver (now Unilever [UL-NYSE]) and Cardinal Meats, where he was instrumental in major restructuring activities, mergers and acquisitions, and the implementations of new internal controls and enterprise resource planning (ERP) systems resulting in significant efficiencies through periods of substantial change and strong company growth. Mr. Carroll has been a Director of Bird River Resources Inc., since September 15, 2017. He holds a CPA-CMA designation as well as a Bachelor of Commerce degree from University College Dublin.

Lawrence (Larry) Latowsky, Director

Mr. Lawrence Latowsky is currently CEO of Canntab Therapeutics Ltd., an innovator in cannabinoid and terpene blends in hard pill form for therapeutic application. He has held a number of leadership positions throughout his career, including Chairman and CEO of Top Drug Corp. from 2014 to 2020 and previously president and CEO of Katz Group Canada, overseeing the largest network of pharmacy retailers in Canada operating as Rexall, Pharmaplus, IDA, and Guardian Drugstores. Mr. Latowsky also led Propharm Technology and DC Labs, a vertical manufacturing and packaging division of pharmaceuticals and over-the-counter (OTC) drug store product. Mr. Latowsky is a graduate of the University of Toronto Rotman Business School and Institute of Corporate Directors of Canada program and has served on many profit and non-profit boards, including as Chairman of the Board for Well.ca, one of Canada’s leading E-commerce companies. Mr. Latowsky’s experience is a unique blend of traditional retail bricks and mortar, distribution, manufacturing, and e-commerce/internet-based marketing and sales.

Adnan Bashir, Director

Mr. Adnan Bashir is one of the first investors of FSD Pharma. He brings over 14 years of experience in strategic management and operations. In the last decade, Mr. Bashir was general manager for Al Batha group, a diversified business conglomerate based in Dubai, UAE. Mr. Bashir was responsible for overseeing the management and operations of four companies within the group and was instrumental in acquiring and developing new businesses and partners from Europe, the U.S., and China. Mr. Bashir also has extensive experience in executing turnaround strategies, transforming weak businesses into sustainable and profitable ones, and implementing new technologies. Mr. Bashir holds a Bachelor of Science Degree in Mechanical Engineering from University of Engineering and Technology Lahore and has completed extensive executive education, including in strategic management, audit, sales management, and technical management.

Fernando Cugliari, Director

Mr. Fernando Cugliari has over 20 years of experience in finance and law, and is an attorney qualified to practice in Ontario and the Cayman Islands. Mr. Cugliari is currently an international investment advisor at CIBC FirstCaribbean International Bank, where he provides comprehensive investment advisory services to high and ultra-high-net-worth individuals and their families, as well as insurance, corporate, institutional, and pension fund clients. From November 2017 to April 2018, Mr. Cugliari worked as the head of the Private Client and Private Equity Group at Etienne Blake Attorneys at Law, a law firm in the Cayman Islands, and from September 2016 to September 2017, he worked as general counsel and COO for FasPay Global, an international financial and payments technology company. He previously held senior positions at law firms in Ontario.

Nitin Kaushal, Director

Since March 2020, Mr. Nitin Kaushal has served as President of Anik Capital Corp., his family's holding company. In February 2020, he retired from PricewaterhouseCoopers Canada ("PwC"), where he was a managing director in the corporate finance practice, which focused on the pharmaceutical and healthcare spaces. He had worked at PwC since 2012. Mr. Kaushal has over 30 years of experience in the healthcare and financial services industries, focusing on the biotechnology, medical devices, and healthcare services markets. He was a managing director of leading healthcare investment banking teams at a number of Canadian investment banks, including Desjardins Securities Inc., Orion Securities Inc., Vengate Capital, HSBC Securities Inc., and Gordon Capital. He has been involved in over 50 mergers and acquisitions, strategic advisory roles, and licensing assignments for a range of companies from early-stage biotechnology companies to large pharmaceutical companies. He has participated in capital market transactions ranging from private placements to initial public offerings (IPOs) to bought deal underwritings in excess of \$2 billion and has been a speaker at leading biotech conferences, including BIO and BioFinance. His entry into the biotech/healthcare space was in 1991 with MDS Capital Corp., a leading healthcare venture capital firm. Mr. Kaushal sits on a number of public and private company boards in the biotech and healthcare space, including Delta 9 Cannabis Inc., The Valens Company Inc., High Tide Inc., VieMed Healthcare Inc., Starton Therapeutics Inc., Flower One Holdings Inc., PsyBio Therapeutics Corp., and 3 Sixty Risk Solutions Ltd. Mr. Kaushal has a Bachelor of Science in Chemistry from the University of Toronto and is a Chartered Professional Accountant.

Nathan Coyle, CPA, Chief Financial Officer (CFO)

Mr. Nathan Coyle joined FSD Pharma in 2020 as corporate controller and was appointed to the interim CFO role in 2021. Mr. Coyle has 15 years of executive business experience as a finance leader in both public and private roles. He was previously with Illinois Tool Works (ITW-NYSE), where he played a key role in restructuring the organization, shaping the growth, and streamlining businesses within his industrial packaging segment. His involvement in multiple mergers and acquisitions and integrating those organizations was key to company growth. After ITW, he worked with a private organization implementing the same corporate strategies to maximize growth. Mr. Coyle holds a Bachelor of Business Administration with honors from Brock University and is a Chartered Professional Accountant.

Intellectual Property

FSD Pharma continues to protect and strengthen its proprietary position by filing patent applications in the U.S. and abroad related to FSD-PEA, LUCID-MS, LUCID-PSYCH, or other product candidates that it may identify. In addition, the Company seeks additional protection for its confidential proprietary information, in part, by executing confidentiality agreements and invention assignment agreements with its employees, consultants, scientific advisors, contractors, and collaborators. The Company strengthens its intellectual property (IP) portfolio by extending their validity in various jurisdictions globally, including through the use of the **Hatch-Waxman Act** in the U.S. The Hatch-Waxman Act allows a maximum of one patent to be extended for up to five years per FDA approved product as compensation for the patent term lost during the FDA regulatory review process.

FSD-PEA

A key part of FSD Pharma’s IP was achieved through its 2019 acquisition of Prismic Pharmaceuticals. Prismic has the worldwide rights (except for Italy and Spain) for FSD-PEA. The micronization technique, which allows PEA to be orally bioavailable, was invented by Italian company, Epitech, and is protected by patents until 2030, as summarized in Figure 3. Patents related to FSD-PEA on its own are essentially composition and use patents. The combination patents include issued patents for FSD-PEA in combination with opioids for pain and FSD-PEA in combination with silymarin for the treatment of chronic kidney disease.

Figure 3
EPITECH GROUP ULTRAMICRONIZED PEA PATENT POSITION

Patent #	Name	Granted	Expiration
US 8,470,373 EP 2,475,352	Composition containing ultra-micronized palmitoyl-ethanolamide	June 25, 2013 September 5, 2018	February 7, 2029 September 7, 2029
US 8,663,701 EP 2,475,352	Compositions containing ultra-micronized palmitoyl-ethanolamide	March 4, 2014 September 5, 2018	February 8, 2029 September 7, 2029
US 9,399,031 EP 2,821,083	Combined use of amides of mono- and dicarboxylic acids and silymarin in the treatment of renal diseases	July 26, 2016 June 29, 2016	July 5, 2033 June 19, 2034
US 9,801,836 EP 2,944,309	Using palmitoylethanolamide in combination with opioids	October 31, 2017 March 20, 2019	May 14, 2034 May 4, 2035

Sources: FSD Pharma Inc., USPTO, and Google Patents.

LUCID-MS

FSD Pharma, through the acquisition of Lucid, obtained the licensed patent rights for peptidyl arginine deiminase enzyme inhibitors to develop novel treatments. The inhibitors are designed to treat the disorders which include hypercitrullination, the process implicated in MS, and other neurodegenerative diseases. This technology was developed and tested at the University Health Network (UHN). The patent family covers composition of matter of the therapeutic compounds and the method of treatment. The patents are issued in major jurisdictions of Europe and North America.

LUCID-PSYCH

One of the challenges to the psychedelic industry is difficulties in formulating IP that will stand institutional- or big pharmaceutical tests since much of this IP has been around for years. Lucid has taken a unique approach of investigating a known psychoactive class of compounds and is developing LUCID-PSYCH, a psilocybin-family of compounds, with unique drug formulation for a proprietary position. The novelty of the pharmacological mechanism, coupled with new molecules and the ability to address unmet needs in MS and other neurodegenerative disorders, presents an exciting opportunity to develop unique and novel treatments.

TRADEMARKS

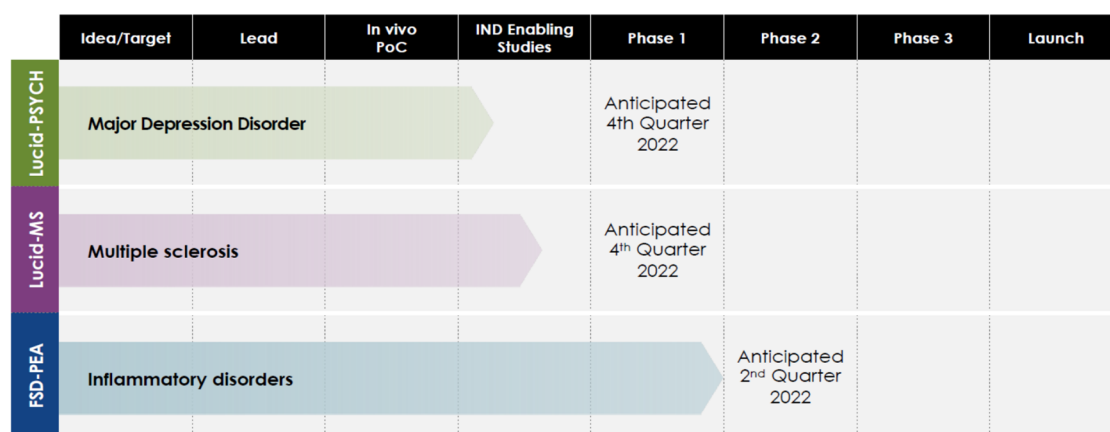
The Company has applied for two trademarks, *In Pursuit of Total Brain Health* and *Pharmaceutically Green*, for use during development of its three drug candidates and commercialization of approved drugs.

All amounts in U.S. dollars unless stated otherwise.

Core Story

FSD Pharma Inc., through its wholly owned subsidiaries, FSD Biosciences, Inc., FV Pharma Inc., and Lucid Psycheceuticals Inc., is a pharmaceutical research and development (R&D) company developing novel therapeutic solutions for multiple indications, as shown in Figure 4: (1) LUCID-PSYCH (LUCID-201); (2) LUCID-MS (LUCID-21-302); and (3) FSD-PEA (FSD-201). The Company is using chemical and physical properties to treat diseases that do not currently have satisfactory treatments surrounding the brain disorders and chronic inflammation. FSD Pharma’s approach is to employ innovative technologies to develop globally-competitive therapeutics to significantly improve the quality of patient lives.

Figure 4
FSD PHARMA PIPELINE



Source: FSD Pharma Inc.

The Company holds assets targeting three therapeutic areas—depression, MS, and inflammation—in alignment with the Company’s trademark, *In Pursuit of Total Brain Health*. There is clinical evidence that mental health and neurodegenerative disorders, including MS, are co-morbid conditions, and mental health conditions are diagnosed as prodromes to subsequent diagnosis of neurodegenerative diseases. The Company strives to be in-tune with the thought leaders in basic and clinical research in these areas and, as such, expects to fine-tune its drug development approaches.

Acquisition of Lucid Psycheceuticals Expands Pipeline

In August 2021, FSD Pharma announced that it had entered into a definitive agreement to acquire 100% of the issued and outstanding shares of Lucid Psycheceuticals Inc. (Lucid), a Canadian-based biotechnology company focused on developing therapies to treat challenging neurodegenerative and mental health disorders. This acquisition strengthens FSD Pharma’s efforts to build and synergize a portfolio of biotechnology assets in a new and unique way. Lucid’s pipeline of novel therapeutic compounds is supported by intellectual property (IP) and provides additional compounds to advance to future clinical trials.

The transaction was completed by way of a three-cornered amalgamation between Lucid, FSD Pharma, and a wholly-owned subsidiary of FSD Pharma. It involved the issuance of approximately 4.5 million Class B subordinate voting shares in the capital of FSD Pharma as the acquisition consideration, with a deemed aggregate purchase price of approximately \$9 million (CAD\$11.3 million) based on an exchange rate of \$1 to CAD\$1.2721 at a deemed price of approximately \$1.97 (CAD\$2.51) per FSD Pharma share. As well, all of the outstanding Lucid stock options and warrants became exercisable into FSD Pharma shares, with the number and exercise price of such securities adjusted in accordance with the transaction's exchange ratio. Shareholder approval for the transaction was obtained at a special meeting of Lucid shareholders held on September 13, 2021. Directly following the transaction's completion, 40,557,896 FSD Pharma Shares were outstanding.

Lucid's two drug candidates—LUCID-PSYCH targeting depression and LUCID-MS for the treatment of MS—are complementary to FSD's existing FSD-PEA drug candidate. LUCID-MS was developed over many years by doctors and researchers at the University Health Network (UHN), North America's largest health research organization, with Lucid recently exclusively licensing the patent portfolio from UHN.

Licensing Agreement

FSD Pharma Inc.

From the acquisition of Prismic Pharmaceuticals Inc., FSD Pharma acquired an exclusive, worldwide license (excluding Italy and Spain) to exploit certain specified pharmaceutical purpose patents and other intellectual property (IP) rights to ultramicrotonized PEA (FSD-PEA, FSD-201) owned by Epitech Group SpA (Epitech). PEA is a part of the endocannabinoid system (ECS) in the body and is shown to be an agonist to the cannabinoid-like G protein-coupled receptor 55 (GPR55), 119 (GPR119), vanilloid receptor 1 (VR1), and peroxisome proliferator-activated receptor- α (PPAR- α).

FSD Pharma is engaged in the clinical development of FSD-PEA that meet one or more selected criteria. These efforts are aimed at determining clinical efficacy with a high safety profile. The Company has successfully completed a Phase 1 first-in-human safety and tolerability study for FSD-PEA and has found the product to be safe with no serious adverse side effects. The Company is further developing this product through Phase 2 clinical trials for unique indications where the pharmacology of the compound is expected to offer optimal efficacy.

Recent Restructuring

FSD Pharma currently has three material subsidiaries:

- (1) FSD Biosciences Inc. (FSD Biosciences), which is wholly owned by the Company and incorporated under the laws of the State of Delaware;
- (2) FV Pharma Inc. (FV Pharma), which is wholly owned by the Company and incorporated under the OBCA; and
- (3) Lucid Psycheceuticals Inc. (Lucid), which is wholly owned by the Company and incorporated under the OBCA.

Ended All Activities of FV Pharma

In July 2020, FSD Pharma decided to primarily focus its efforts and resources on the pharmaceutical business operated through FSD Biosciences Inc. As of September 30, 2020, FSD Pharma ended all activities of FV Pharma. As a result, the Company is no longer engaged in cannabis-related activities and is in the process of liquidating all of FV Pharma's assets, including the sale of its facility and/or its adjacent real estate.

On February 25, 2022, FSD Pharma Inc. announced that it has entered into a firm agreement in connection with the sale of its former cannabis processing facility located in Cobourg, Ontario and the 64.43 acre property on which the facility is located. In consideration for the purchase of the facility, the purchaser has agreed to pay a cash sum of CAD\$16,500,000, including a deposit of CAD\$660,000. The deposit was received by the Company on February 24, 2022 and the transaction is expected to close on May 31, 2022. If closed, the injection of money will be non-dilutive to shareholders. The sale remains subject to the satisfaction of a number of conditions.

Terminated Phase 2 FSD-201 COVID-19 Clinical Trial

On August 28, 2020, the Company filed an Investigational New Drug Application with the FDA for PEA and was approved on September 25, 2020 to initiate a Phase 2 clinical program for the use of PEA to treat COVID-19, the disease caused by the SARS-CoV-2 virus. The trial was targeting a total of 352 random patients in a controlled, double-blind multicenter study. FSD retained an independent biotechnology and pharmaceutical firm to evaluate PEA's commercial viability for the SARS-CoV-2 virus indication.

Following the May 14, 2021 annual general and special meeting of shareholders, the Company retained an experienced biotechnology investment bank to undertake a review of its Phase 2 clinical program to assist in determining its viability and, more broadly, evaluating the general current commercial viability of PEA. FSD Pharma was concerned with the pace of progress in advancing the Phase 2 clinical program during a period in which COVID-19 treatments and vaccination rates evolved significantly and competitive products were being successfully advanced. The biotechnology investment bank reported its findings and the Company concluded that, while there are potential commercial opportunities for PEA, the treatment of COVID-19 by PEA is unlikely to be commercially viable. Based on this information, on August 24, 2021, FSD announced that it was terminating the Phase 2 clinical trial. FSD Pharma is committed to fulfilling the strategic and operational goals and pleased that the independent review supported the belief that there are other viable commercial opportunities for FSD-PEA.

LUCID-PSYCH**PSYCHEDELIC (PSYCHOACTIVE) DRUG INDUSTRY OVERVIEW**

There is a worldwide mental health crisis that continues to mount, with over 2 billion people suffering from treatable but untreated mental health disorders. With a deep history in other cultures dating back thousands of years, psychedelics for therapeutic healing have recently come back into western medicine and are increasingly supported by research and scientific evidence. Specifically, there is a growing body of research suggesting that psychedelics have the potential to treat a variety of neuropsychiatric disorders, including post-traumatic stress disorder (PTSD), depression (in particular, complex treatment resistant depression [TRD] and major depressive disorder [MDD]), and anxiety.

It is widely believed that psychedelic medicine may represent the future of mental health as clinical evidence continues to show that psychedelic medicine can and will revolutionize treating mental health disorders similar to the way antibiotics revolutionized treating bacterial infections. The majority of drugs available to psychiatrists today were developed decades ago when very little was understood about the pathophysiology of neuropsychiatric disorders. Consequently, even the best medicines to treat illnesses, such as depression, could offer relief to only a subgroup of patients and for a limited time period.

In order to transition from treating symptoms to actually curing mental illness, innovative therapeutic approaches must be adopted. The use of psychedelics as medicines may be one of the most exciting developments in neuropsychiatry given that these drugs appear to produce both rapid and sustained therapeutic effects across multiple neuropsychiatric disorders, including depression, PTSD, and substance use disorder (SUD).

While the federal government does not recognize a medical use for most psychedelics drugs, stating that they have the potential for abuse, some of the most prominent universities in the world are studying four substances in particular: psilocybin, ketamine, MDMA, and LSD, recognizing that the bulk of available research suggests that these substances hold promise as part of larger treatment plans. For example, there has been promising Phase 2 clinical data on MDMA (3,4-Methylenedioxymethamphetamine, commonly known as ecstasy or molly)-assisted psychotherapy for PTSD treatment. There is also increasing evidence that psychedelic drugs operate differently in the brain than other addictive drugs.

The accompanying sections provide an overview of major depressive disorder (MDD), the indication that FSD Pharma is seeking to address with its psychoactive compound, LUCID-PSYCH, and greater details on this pipeline candidate.

Major Depressive Disorder (MDD) Overview

Depression (major depressive disorder [MDD] or clinical depression) is a widespread serious mood disorder, which causes severe symptoms that affect how an individual feels, thinks, and handles daily activities, including sleeping, eating, or working. Depressive symptoms must be present for at least two weeks in order to be diagnosed and patients can experience periods of remission and relapse over the course of their lifetime. Certain types of depression are slightly different, and may develop under unique circumstances, including the following:

- **Persistent depressive disorder** (also called **dysthymia**), which is a depressed mood that lasts for at least two years. A person diagnosed with persistent depressive disorder may have episodes of major depression along with periods of less severe symptoms, but symptoms must last for two years to be considered persistent depressive disorder.
- **Postpartum depression**, which is much more serious than the “baby blues” (which is a relatively mild depressive and anxiety symptom that typically clears within two weeks after delivery). Women with postpartum depression experience full-blown major depression during pregnancy or after delivery, with feelings of extreme sadness, anxiety, and exhaustion making it difficult for these new mothers to complete daily care activities for themselves and/or for their babies.

- **Psychotic depression**, which is when a person has severe depression accompanied by some form of psychosis, such as having disturbing false fixed beliefs (**delusions**) or hearing or seeing upsetting things that others cannot hear or see (**hallucinations**). The psychotic symptoms typically have a depressive “theme,” such as delusions of guilt, poverty, or illness.
- **Seasonal affective disorder**, which is characterized by the onset of depression during the winter months, when there is less natural sunlight. This depression generally lifts during spring and summer. Winter depression—typically accompanied by social withdrawal, increased sleep, and weight gain—predictably returns every year in seasonal affective disorder.
- **Bipolar disorder**, while different from depression, is included in this list since someone with bipolar disorder experiences episodes of extremely low moods that meet the criteria for major depression (called “bipolar depression”). A person with bipolar disorder, however, also experiences extreme high—euphoric or irritable—moods called “mania” or a less severe form called “**hypomania**.”

Risk Factors

Depression is one of the most common mental disorders in the U.S. Recent research suggests that it is caused by a combination of genetic, biological, environmental, and psychological factors. Depression can happen at any age, but often begins in adulthood. It is now recognized as happening in children and adolescents, however, depression sometimes presents with more prominent irritability than low mood. Numerous chronic mood and anxiety disorders in adults begin as high levels of anxiety in children.

Depression, especially in midlife or older adults, can co-occur with other serious medical illnesses, including diabetes, cancer, heart disease, and Parkinson’s disease, where medications taken for these physical illnesses may sometimes cause side effects that contribute to depression. Risk factors for depression may include personal or family history of depression; major life changes, trauma, or stress; and/or certain physical illnesses and medications.

Symptoms

An indication that an individual is suffering with depression may be that he/she is experiencing the following signs and symptoms most of the day, nearly every day, for at least two weeks, as outlined in Figure 5.

Figure 5
SYMPTOMS OF DEPRESSION

- Persistent sad, anxious, or “empty” mood
- Feelings of hopelessness or pessimism
- Irritability
- Feelings of guilt, worthlessness, or helplessness
- Loss of interest or pleasure in hobbies and activities
- Decreased energy or fatigue
- Moving or talking more slowly
- Feeling restless or having trouble sitting still
- Difficulty concentrating, remembering, or making decisions
- Difficulty sleeping, early-morning awakening, or oversleeping
- Appetite and/or weight changes
- Thoughts of death or suicide, or suicide attempts
- Aches or pains, headaches, cramps, or digestive problems without a clear physical cause and/or that do not ease even with treatment

Source: National Institute of Mental Health.

Treatment and Therapies

Depression is treatable, even in the most severe cases, where earlier treatment is generally more effective. The disorder is typically treated with medications, psychotherapy, or a combination of these, where first line treatment is antidepressants with or without psychotherapy (described below). If these treatments are not effective at reducing symptoms, **electroconvulsive therapy (ECT)** and/or other brain stimulation therapies may be used (described below). Importantly, no two people are affected the same way by depression; accordingly, there is no “one-size-fits-all” for treatment and it may take some trial and error to find the most effective treatment for a patient.

Even with known, effective treatments for mental disorders, greater than 75% of individuals in low- and middle-income countries receive no treatment. Obstacles to effective care may include a lack of resources, lack of trained healthcare providers, and social stigma associated with mental disorders. Additionally, in countries of all income levels, individuals who experience depression are often not correctly diagnosed, or others who do not have depression may be often misdiagnosed and prescribed antidepressants.

Descriptions of the primary modes of treatment currently approved are provided below.

Medication

Medicines that treat depression are called antidepressants. These treatments may help improve the way a patient’s brain uses certain chemicals that control mood or stress. Several different antidepressant medicines may need to be tested on a patient before finding the one that improves symptoms with a side effect profile that is manageable. Antidepressants can take approximately two to four weeks to work, and symptoms such as sleep, appetite, and concentration issues typically show improvement prior to a patient’s mood, which is the reason it is so important to give medication time to work before making conclusions regarding its effectiveness.

Psychotherapy

Psychotherapy, or talk therapy or counseling, can help people with a broad variety of mental illnesses and emotional difficulties, where it can help eliminate or control troubling symptoms so a person can function better and can increase well-being and healing. Challenges helped by psychotherapy include difficulties in coping with daily life; the impact of trauma, medical illness or loss, like the death of a loved one; and specific mental disorders, such as depression or anxiety. Some types of psychotherapy may work better with certain problems or issues or it may be used in combination with medication or other therapies. Evidence-based approaches specific to treating depression, include **cognitive-behavioral therapy (CBT)**, **interpersonal therapy (IPT)**, and problem-solving therapy.

Psychotherapy is frequently used in combination with medication to treat mental health conditions. In certain circumstances, medication may be useful, though in others psychotherapy may be a better alternative. For a large number of patients, combined medication and psychotherapy treatment has proven a better option than by itself. Healthy lifestyle improvements, such as good nutrition, regular exercise, and sufficient sleep, are also key in supporting recovery and general patient wellness.

Research has shown the majority of patients receiving psychotherapy experience relief of symptoms and can better function in their daily lives, with roughly 75% of individuals who enter psychotherapy showing some benefit. For example, psychotherapy has been shown to improve emotions and behaviors and to be connected to constructive changes within the brain and body—specifically fewer sick days, less disability, smaller number of medical problems, and greater work satisfaction.

Using brain imaging techniques, researchers have witnessed changes in the brains of patients following psychotherapy. In particular, various studies have identified brain changes in people with mental illness (including depression, panic disorder, PTSD, and other conditions) as a result of undergoing psychotherapy. In the majority of cases, brain changes stemming from psychotherapy were comparable to changes from medication.

Brain Stimulation Therapies

If medications are ineffective in reducing the symptoms of depression, electroconvulsive therapy (ECT) may be an option in which a mild electrical current is passed through the brain, triggering a brief seizure. For reasons yet unknown, the seizures help restore the normal balance of chemicals in the brain and ease symptoms.

Statistics and Market Size

Depression is a common illness worldwide with roughly 300 million people suffering with the condition and representing a multi-billion opportunity. In the U.S. approximately 13 million adults have major depressive disorder (MDD) and it is estimated that approximately 10% of Canadians will experience MDD at some point in their lives. Depression is different from usual mood fluctuations and short-lived emotional responses to challenges in everyday life and may become a serious health condition. The reason it is so severe is that it can cause the affected person to suffer greatly and function poorly at work, school, and in the family.

Depression can also lead to suicide, with over 800,000 individuals dying from suicide every year (one person every 40 seconds), and it being the fourth leading cause of death in 15 to 29 year-olds. In the U.S., suicide rates have increased 33% between 1999 and 2019, with a small decline in 2019 and is now the 10th leading cause of death in the U.S., responsible for more than 47,500 deaths in 2019 (which is about one death every 11 minutes). The number of people who think about or attempt suicide is even higher. In 2019, 12 million American adults seriously thought about suicide, 3.5 million planned a suicide attempt, and 1.4 million attempted suicide.

The pandemic has had an impact on patients with anxiety and depression. With 1 out of 4 people in the world already in need of treatment, rates of depression, anxiety, and substance abuse (in particular) are spiraling out of control due to COVID lockdowns and mandates. The percentage of Americans suffering from depression has nearly quadrupled since the start of COVID, with 80 million Americans now exhibiting clinical symptoms. Furthermore, U.S. drug overdose deaths increased by 16% in 2021, after soaring by more than 30% in 2020. Overdose deaths in the U.S. have doubled in the past 6 years.

In a survey conducted by the World Health Organization (WHO) in 2020, over 80% of high income countries employed telemedicine and teletherapy to produce medical consultations for patients suffering with anxiety and depression. Individuals experienced a decline in their cognitive behaviors due to the increasing financial and emotional burden stemming from the COVID-19, which has led to stress, fear, anxiety, and depression—directly attributing to the rise in demand and adoption of medical treatments for such indications.

With the worldwide impact of COVID-19 proving to be an unprecedented event, anxiety disorder and depression treatments have experienced high global demand. According to *Fortune Business Insights*, the global anxiety disorder and depression treatment market is expected to experience 28.2% growth in 2020 and projected to grow from \$10.89 billion in 2020 to \$13.03 billion in 2027 (at a CAGR of 2.6% between 2020-2027), though the market demand and growth is expected to return to prepandemic levels once the pandemic is over. Furthermore, it is estimated that the economic burden in the U.S. is approximately \$210 billion annually. The psychedelics market for treating mental illness is expected to grow at a CAGR of 16.3% between 2020-2027 and potentially reach \$6.9 billion by 2027 from \$2.0 billion in 2019.

LUCID-PSYCH

LUCID-PSYCH (Lucid-201), a psychoactive compound, has been selected by FSD Pharma to advance its research into the treatment of major depressive disorders (MDDs) based on analysis of the drug candidate's pharmaceutical and metabolic properties processed via machine learning algorithms (artificial intelligence [AI]), as well as for its potential proprietary position. This compound has shown good efficacy in research studies in animals and human for the treatment of depression (conducted by academic researchers). With such mitigated risk, FSD Pharma is developing novel formulations for its clinical development under the leadership of Dr. Lakshmi P. Kotra (biography on page 7).

Figure 6 summarizes the key differentiating factors of LUCID-PSYCH.

Figure 6
FSD PHARMA DIFFERENTIATION

LUCID-PSYCH	
Development Stage	Preclinical
Target Condition	Mental health and neurodegenerative conditions
Proprietary formulation	Yes
Time to Market	5-8 years
IP/Innovation	Yes
Market Access Strategy	Multiple entry points

Source: FSD Pharma Inc.

The psychedelic mental health component, both as a standalone treatment as well as in the context of neurodegenerative disorders in addressing the needs of patients in the clinic, is very challenging. FSD Pharma benefits from its relationship with the UHN, which is one of the largest healthcare research organization in North America. In terms of the psychedelic market (as described on page 18), there is a wide open area that is being underserved today by existing medications. Specifically within the depression and anxiety arena, there are hundreds of millions of people worldwide suffering with these disorders in a market that is significantly underserved (as described on page 18-21). FSD Pharma’s initial target is major depressive disorder (MDD), the heavier depression state that a patient can go through. FSD Pharma expects to be able to file its regulatory documentation for an IND by year end 2022 both in the U.S. as well as in Canada.

Covar Pharmaceuticals Inc. Agreement

Manufacturing of the compound was secured in October 2021 with Covar Pharmaceuticals Inc. (Covar), a contract development and manufacturing services organization (CDMO), to commence work on providing research quantities on an exclusive basis for further clinical evaluation, with the Company currently undergoing IND-enabling studies. Covar’s R&D facility is licensed to handle psychoactive compounds, such as LUCID-PSYCH. Pursuant to the agreement, Covar will produce non-GMP and GMP LUCID-PSYCH for use in FSD Pharma’s planned pre-clinical and Phase 1 clinical trials, respectively. This potentially sets the stage for the Company to achieve its goal of moving LUCID-PSYCH from bench to clinic by obtaining IND approval and initiating a Phase 1 clinical study.

Potential Competition

When compared to select companies within the psychedelic space, FSD Pharma believes that COMPASS Pathways plc (company description on page 37) may be its closest competitor. COMPASS is developing a new model of psilocybin therapy in which its proprietary formulation of synthetic psilocybin, COMP360, is administered in conjunction with psychological support. COMP360 has been designated a breakthrough therapy by the FDA for TRD. The company has completed a Phase IIb clinical trial of psilocybin therapy for TRD in 22 sites across Europe and North America.

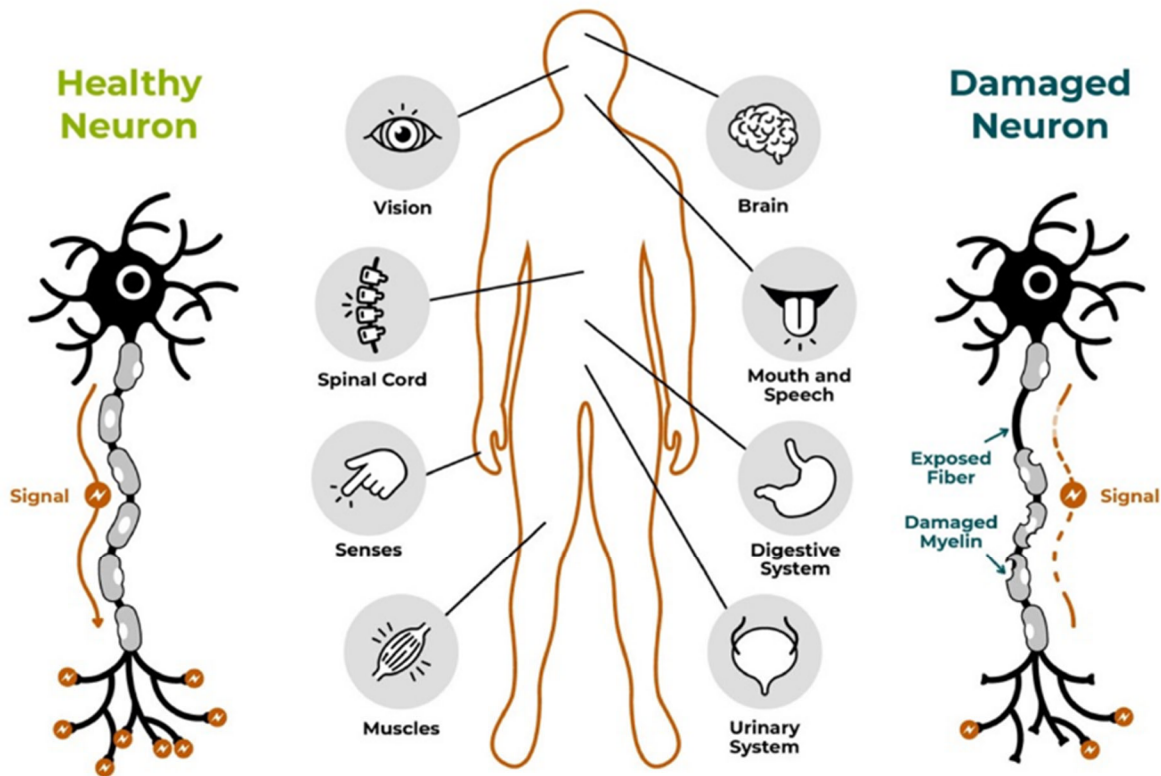
LUCID-MS

MULTIPLE SCLEROSIS (MS) OVERVIEW

Multiple sclerosis (MS) is a chronic, autoimmune disorder of the central nervous system (CNS) characterized by an unpredictable pattern of symptoms (tingling, vision problems, mobility issues, etc.) and where a patient’s own immune system attacks the neurons in the brain and spinal cord. The hallmark of MS is **demyelination**, which is the breakdown of the protective myelin sheath surrounding nerves that aid in conducting nerve impulses. This breakdown, which results in nerve damage that disrupts communication between the brain and the body, is initiated by autoimmune processes that cause inflammation. The damage MS does to nerves can also affect critical thinking and other cognitive (mental) skills.

Severe damage to the myelin sheath is not reversible naturally or through existing drugs, leading to disease progression. As MS progresses, it affects muscles, nerves, and joints, causing a wide variety of symptoms depending on the amount of nerve damage and which nerves are affected, as shown in Figure 7. Symptoms include considerable pain, as well as spasms, stiffness, tremors, body mobility limitations and weakness, difficulty chewing, swallowing and speaking, vision loss, and impaired coordination.

Figure 7
MYELIN (NEURONAL INSULATOR) IS ATTACKED BY MS PATIENT'S IMMUNE SYSTEM



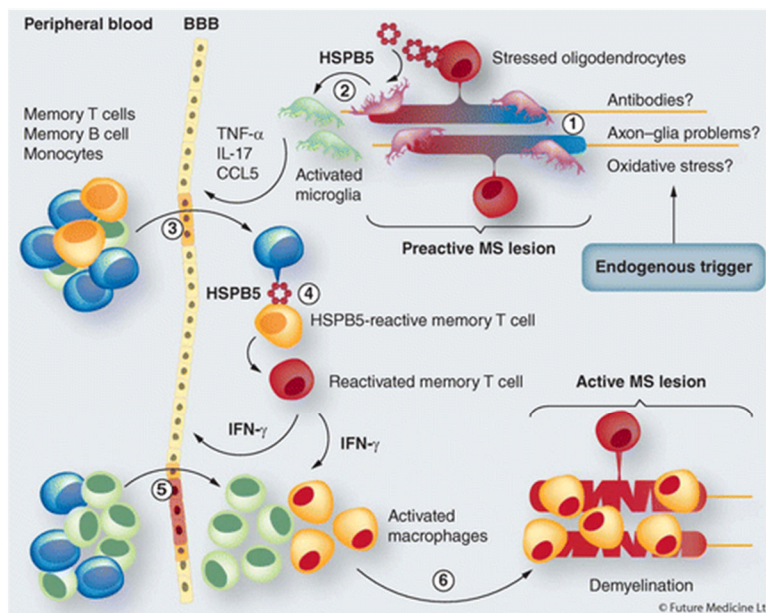
Source: FSD Pharma Inc.

Current MS Treatment Landscape

In autoimmune and neurodegenerative disorders, such as MS, the myelin sheath around the nerves gets damaged, where plaques are seen in various regions of brain and spinal cord, and there is a loss of signal between neurons. Currently, while there is no cure for MS, there are several approved drugs on the market to treat it, primarily anti-inflammatory steroids or immunosuppressives, all of which are aimed at relieving symptoms and preventing relapses. Although these therapeutics can help speed recovery from attacks, prevent or reduce relapses, and manage symptoms, none are curative and each can cause significant adverse effects, with no current therapy being able to **remyelinate** damaged neurons and reverse the course of the disease. Current MS therapies only address part of the disease, mainly inflammation and autoimmune-related symptoms.

As illustrated in Figure 8, MS starts with T cells entering the brain via a breakdown of the blood brain barrier (BBB), initializing an autoimmune process in which T cells identify myelin as foreign and attack it. The initial attack causes inflammation, which results in a subsequent immune reaction that causes further damage to the myelin sheath (causing demyelination) and nerve degeneration. Since most of the approved MS drugs affect the inflammatory and autoimmune responses, they have no effect on the early stage of the disease, and therefore no significant effect on the demyelination process.

Figure 8
MULTIPLE SCLEROSIS PATHOPHYSIOLOGY



Source: Future Medicine Ltd.

To achieve a notable impact on a patients’ quality of life and the potential for disease modification, therapeutics need to affect the early stages of the disease so that inflammation is reduced, autoimmunity is addressed (without the toxicities of immunosuppression), and demyelination is slowed or stopped.

MS Market Overview

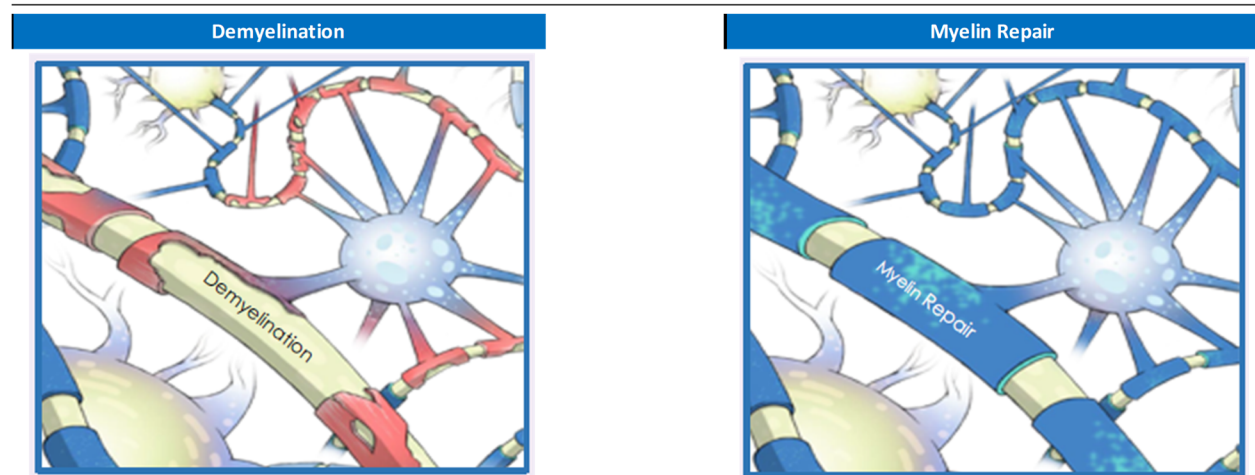
MS affects approximately 2.5 million people worldwide (one million people in the U.S. alone), with the global burden of the disease rising rapidly and becoming an issue of concern for healthcare providers as well as governments. The incidence of female to male MS patients is 2:1 with a 1/1000 prevalence. The rising prevalence of the disease has led governments to take proactive measures through guidelines and recommendations, including recommendations on the different therapeutic options available for treatment, as well as information campaigns (Source: Fortune Business Insights’ *MS Drugs Market Size*, 2021).

The global MS drug market size was valued at \$27.5 billion in 2020 (\$15.3 billion in the U.S., representing 55% of the total market) and is projected to reach \$42.5 billion in 2028. This growth is driven by significant R&D efforts, new product launches, as well as government and non-government organizations measures (Source: Verified Market Research’s *Multiple Sclerosis Drugs Market, 2021*).

LUCID-MS

FSD Pharma is developing LUCID-MS, a neuroprotective compound which, in pre-clinical models, has shown to prevent and reverse myelin degradation (shown in Figure 9). A patented new chemical entity (NCE), LUCID-MS has shown to accelerate functional recovery of diseased mice, preserve myelin, and reduce axonal degeneration, without suppressing the immune system (non-immunomodulatory). LUCID-MS has shown efficacy in various preclinical animal models and may be administered orally using easy dosing regimen. With over 11 years of R&D, FSD Pharma holds worldwide exclusive rights for development and commercialization of the family of compounds, with LUCID-MS in preclinical development and an anticipated IND in Fall 2022.

Figure 9
DEMYELINATION VS. REMYELINATION



Source: FSD Pharma Inc.

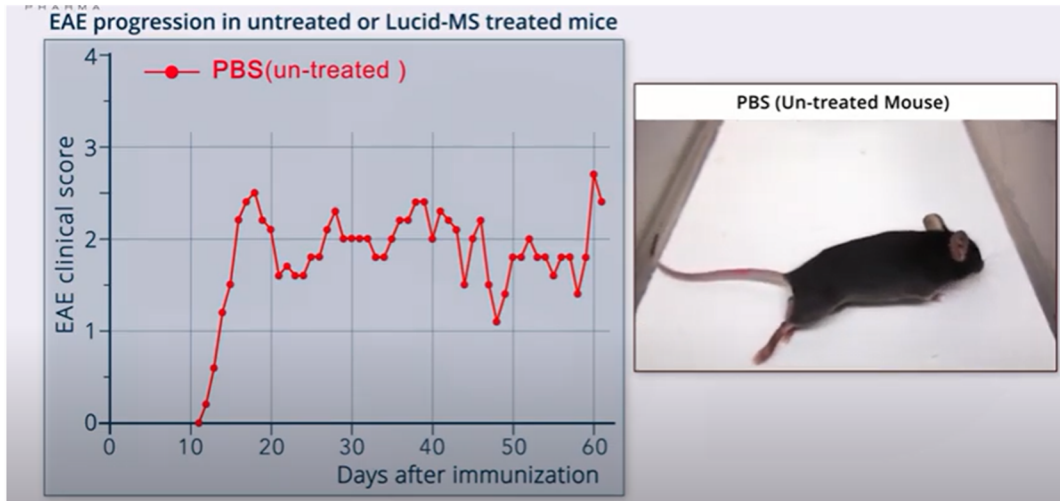
Video Demonstrating Positive Effects of Lucid-MS in Treating MS in Pre-Clinical Models (Mouse Models)

Scientists have conducted extensive research evaluating several compounds in a test tube as well as in animal models. To demonstrate the potential therapeutic value of this compound, FSD Pharma released a video explaining its pre-clinical results, including visual evidence of functional recovery on pre-clinical subjects. The following YouTube link presents the video: <https://youtu.be/DTyYSYq-4kU>. In this video, one can see that LUCID-MS exhibited positive activities in the animal subject used to test MS-like disease symptoms. Examples from many such studies conducted by the same researchers are part of the reason the Company believes LUCID-MS has the potential to affect functional recovery in MS.

Untreated Mouse

Figure 10 illustrates one of the animal models, called the experimental autoimmune encephalomyelitis (EAE) model, showing inflammatory symptoms as well as a loss of myelin in the brain, leading to loss of function. This shows the graph of a mouse that has not been treated with LUCID-MS, where the hind legs and tail of the mouse are still paralyzed after the experiment is completed.

Figure 10
EAE PROGRESSION IN UNTREATED MICE



Source: FSD Pharma Inc.

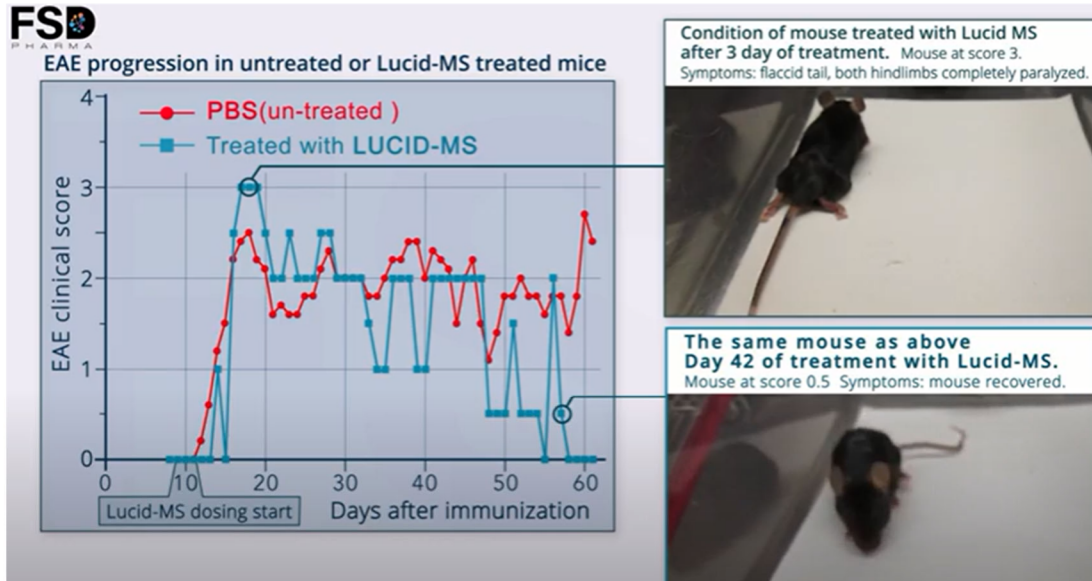
Treated Mouse

Figure 11 (page 27) shows the early days of treatment with LUCID-MS. On the third day of treatment, the clinical score for the mouse was 3, characterized by flaccid tail and completely paralyzed hind limbs (this is a high score, whereas a lower score indicates a healthier condition). Treatment was continued and health was monitored. In the study using an EAE mouse model, which is a commonly used immune-mediated mouse model of MS, ten days following immunization with the antigen, mice received 1 milligram of LUCID-MS or saline (placebo). Test subjects were monitored for 50 days and were continually assessed for clinical symptoms.

Symptoms begin to recede after 42 days, intermittent ups and downs are noted between scores 1 and 2, but a gradual reduction in symptoms and improvement in functional recovery was observed in the LUCID-MS treated mouse. On day 42 of treatment of the same mouse with LUCID-MS, which is 57 days since the day of the disease, the mouse mainly recovered with minor symptoms, such as a limp tail at the tip. The clinical score at this time was approximately 0.5, characterized by mild signs of the disease. After a several more days, the mouse appears to have recovered completely and functional recovery was observed. Overall, those that received LUCID-MS demonstrated an improvement in clinical score compared with subjects that received placebo.

LUCID-MS has demonstrated the potential to prevent the degradation and help re-establish myelin, which is shown by the functional recovery of mice and the immunohistochemistry evidence in this and several other studies in preclinical animal models. This effect carries promise for developing LUCID-MS as a potential treatment for MS, as well as the biochemical mechanism this compound represents as a potential industry first in treating MS.

Figure 11
LUCID-MS TREATED MOUSE AT DAY 3 VERSUS DAY 42



Source: FSD Pharma Inc.

FSD-PEA (FSD201)

An advanced stage compound in FSD Pharma’s pipeline, FSD-PEA is a proprietary formulation that enhances the bioavailability of PEA, a *N*-acylethanolamine family of compounds, making it suitable to treat a range of chronic inflammatory conditions. PEA is a part of the endocannabinoid system (ECS) in our body, and is shown to be an agonist to the cannabinoid-like G protein-coupled receptor 55 (GPR55), 119 (GPR119), vanilloid receptor 1 (VR1), and peroxisome proliferator-activated receptor- α (PPAR- α). FSD Pharma conducted a Phase I first-in-human safety and tolerability trial on FSD-PEA and no serious adverse effects were observed. Preclinical toxicology studies were also completed in rats and dogs, providing solid foundation for launching Phase 2 clinical studies.

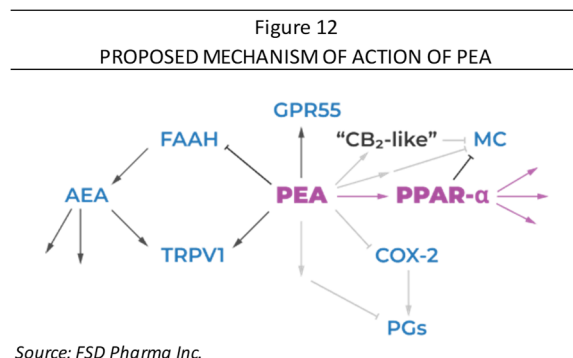
The Company is currently assessing potential target indications for Phase 2, including newly diagnosed osteoarthritis, endometriosis, or opioid replacement and/or sparing agent. FSD Pharma holds exclusive worldwide licensing rights (except Italy and Spain) to FSD-PEA for all conditions in all regulatory categories. IP portfolio for this molecule covers composition of matter and use (2029-2034 U.S. expiration) for FSD-PEA.

FSD-PEA Overview

Natural resolution of inflammation is driven in part by the secretion of soluble products, including lipid-mediated signaling molecules in our body. These lipid mediators act to suppress the inflammatory process, restore homeostasis in injured tissues, and moderate pain sensitivity by regulating the flow of nociceptive signals to the central nervous system. One promising family of such signaling molecules that could be part of a multi-drug therapeutic option for chronic pain in conjunction with opioid is the *N*-acylethanolamines (NAEs), whose principal members are the endocannabinoid *N*-arachidonoylethanolamine (anandamide) and its congeners *N*-stearoylethanolamine, *N*-oleoylethanolamine, and *N*-palmitoylethanolamine (PEA). PEA, in particular, is an endogenous fatty acid amide signaling molecule synthesized on demand in response to tissue injury/stress and plays a role in the mechanism to restore/maintain homeostasis with anti-inflammatory, pain-relieving, and neuroprotective actions (Source: *Journal of Neuroinflammation*, Vol. 11:136, 2014).

A growing body of studies and trials has demonstrated the ability of PEA to reduce inflammation and pain induced by various acute stimuli by acting as a mediator of resolution in inflammatory processes. The anti-inflammatory and analgesic effects of PEA have been confirmed in models of chronic inflammation and neuropathic pain. In these models, prolonged treatment with PEA not only reduced pain and inflammation, but also preserved peripheral nerve morphology, reduced endoneurial edema, and increased the presence of pro-inflammatory mediators at the injury site. Furthermore, as an endogenous compound, PEA has shown no serious adverse effects at pharmacological doses (Source: *Pain Therapy*, Vol. 7(1):59-75, 2018).

An Anti-Inflammatory Agent



FSD-PEA could address large markets with growth opportunities for various areas, such as pain, post-surgical pain, morphine tolerance, endometriosis, osteoarthritis, fibromyalgia etc. Figure 12 illustrates proposed pharmacological mechanisms of action of PEA, with purple lines indicating canonical signaling, black lines as strongly supported, and grey as hypothesized.

Thus, PEA is an endogenous signaling molecule and a key regulator of ECS in inflammation. PEA activates GPR55 and PPAR- α receptors, leading to increased expression of CB2 receptors. PEA also increases the endogenous levels of 2-AG and AEA, which directly activate CB1, CB2, and TRPV1 receptors and inhibits the activation of mast cells (peripheral). Furthermore, PEA reduces the activation of microglia and astrocytes (CNS). Figure 13 summarizes FSD-PEA as an anti-inflammatory agent.

PEA as a Therapeutic Agent

A key differentiator between classic steroidal and non-steroidal anti-inflammatory drugs and PEA is the fact that PEA's ability to act as an anti-inflammatory and pain-relieving agent is modulated by its direct effect on the inflammation process as well as its indirect mechanisms. The potential for PEA to interact with the opioid system may lie in its ability to modulate the ECS. Existing literature demonstrates that PEA, either directly or indirectly, affects a variety of receptors and pathways known to modify the responses to opioids, such as morphine. Thus, the use of a signaling molecule from the ECS in conjunction with opiates could lead to a greater cumulative relief of pain as well as a reduction in opioid tolerance development, resulting in a reduction in the opiates dosage (Sources: *British Journal of Pharmacology*, Vol. 174(11):1349-136, 2017; and *Journal of Psychoactive Drugs*, Vol. 44(2):125-33, 2012).

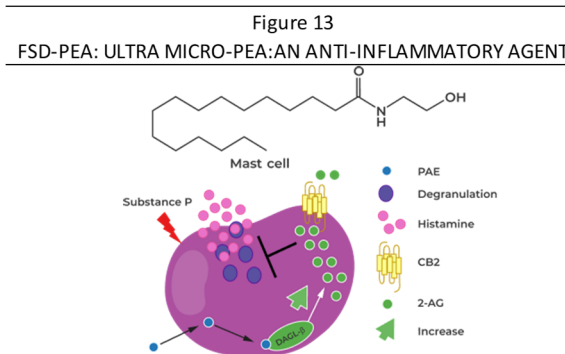
However, the lipophilic nature and large particle size of PEA in the native state limits its solubility and bioavailability when given orally, representing a challenge in its therapeutic use. PEA is practically insoluble in water and poorly soluble in most other aqueous solvents, significantly limiting its bioavailability when administered orally. Micronization is frequently applied to reduce particle size, enhance the rate of dissolution, and improve the bioavailability and efficacy of very low water-soluble molecules by increasing their dissolution rate. FSD-PEA is an ultramicrosized formulation, thus believed to be superior to other formulations of PEA, for use as a therapeutic agent.

Status

A proprietary formulation, the Company's FSD-PEA has enhanced bioavailability. Following a single dose ranging from 600 mg-2400 mg *p.o.* and multiple doses ranging from 600 mg-2,000 mg *p.o., b.i.d.* of FSD-PEA administration in normal healthy subjects, FSD Pharma confirmed that this product is safe and well-tolerated. Through these studies, the Company has successfully completed a Phase 1 clinical trial (safety and tolerability) and is currently assessing what indication will provide the greatest potential from an economic perspective in biotech. FSD Pharma is strategically positioning these assets for a Phase 2 clinical trial in Q2 2022 and to further develop for its full potential as a therapeutic agent. The Company holds exclusive worldwide licensing rights (except Italy and Spain) to FSD-PEA.

Competition

Within this area of development, FSD Pharma competes with Redmond, WA-based Eliem Therapeutics, Inc. (profiled on page 38), a clinical-stage biotechnology company similar to FSD Pharma in that it is focused on developing novel therapies for neuronal excitability disorders to address unmet needs in chronic pain, psychiatry, epilepsy, and other disorders of the peripheral and central nervous systems (CNS). Eliem's method of drug delivery is different from that of FSD Pharma—with FSD Pharma using an ultramicrosized form of this molecule.



Source: FSD Pharma Inc.

Terminated Phase 2 Clinical Trials of PEA to Treat COVID-19

On August 28, 2020, the Company filed an Investigational New Drug Application (IND) with the U.S. FDA for FSD-PEA, which was approved on September 25, 2020 to initiate a Phase 2 clinical program for the use of FSD-PEA to treat COVID-19, the disease caused by the SARS-CoV-2 virus. The trial was targeting a total of 352 random patients in a controlled, double-blind multicenter study. FSD Pharma retained an independent biotechnology and pharmaceutical firm to evaluate FSD-PEA's commercial viability for the SARS-CoV-2 virus indication.

Following the Company's May 14, 2021 annual general and special meeting of shareholders, FSD Pharma retained an experienced biotechnology investment bank to undertake a review of its Phase 2 clinical program to assist in determining its viability, and more broadly, evaluating the commercial viability of FSD-PEA for COVID treatment. The Company was concerned with the pace of progress in advancing its Phase 2 clinical program during a period in which COVID-19 treatments and vaccination rates evolved significantly and competitive products were being successfully advanced to commercial stages.

The biotechnology investment bank reported its findings and the Company concluded that, while there are potential commercial opportunities for FSD-PEA, the treatment of COVID-19 by FSD-PEA is unlikely to be commercially viable. Between big pharma and higher vaccination rates worldwide, by the time a Phase 3 study is complete, it would be too late. Based on this information, on August 24, 2021, FSD Pharma elected to terminate its current Phase 2 clinical trial for the treatment of COVID-19 to concentrate its resources on commercially viable opportunities for FSD-PEA and best return for its investments.

Summary of Select PEA Papers

The accompanying section provides a summary of select peer-reviewed publications as well as a summary of select PEA efficacy and bioavailability papers, available to date, for information only.

Review Articles

Palmitoylethanolamide, a naturally occurring disease-modifying agent in neuropathic pain.

(Source: *Inflammopharmacology*, Vol. 22(2):79-94, 2014).

The review lists over 25 pre-clinical studies and over 20 clinical studies that support the view of micronized and ultramicrotonized PEA as an endogenous anti-inflammatory and pain-relieving agent. PEA was found to have basically no adverse effects, while demonstrating a double therapeutic effect (i.e., anti-inflammatory and pain-relieving). Collectively, the findings of these studies propose that PEA merits further consideration as a disease-modifying agent for controlling inflammatory responses and related chronic and neuropathic pain.

A Pharmacological Rationale to Reduce the Incidence of Opioid Induced Tolerance and Hyperalgesia: A Review.

(Source: *Pain Therapy*, Vol. 7(1):59-75, 2018).

Researchers assessed the use of PEA as an innovative therapeutic tool to enhance the effects of opioid analgesics and impede the development of opioid tolerance and hyperalgesia. Pharmacological studies demonstrating the ability of PEA to affect opioid and cannabinoid receptors/pathways, coupled with opioid effects being modulated by the endocannabinoid system, lead researchers to infer that the use of PEA in conjunction with opioids could result in opioid's analgesic effects to be potentiated or last longer with reduced tolerance development.

An Inflammation-Centric View of Neurological Disease: Beyond the Neuron.

(Source: *Frontiers in Cellular Neuroscience*, Vol. 12: 72, 2018).

This review describes the current state of knowledge concerning the biology of neuroinflammation, and discusses an alternative approach to treat neuroinflammation by focusing on a cell's endogenous regulators of inflammation, mainly the use of the fatty acid molecule PEA, which shows promise by contributing to the resolution of neuroinflammation through modulation of mast cell and glia activity.

The pharmacology of palmitoylethanolamide and first data on the therapeutic efficacy of some of its new formulations.

(Source: *British Journal of Pharmacology*, Vol. 174(11):1349-136, 2017).

This review provides an overview of the pharmacology, efficacy, and safety of PEA in neurodegenerative disorders, pain perception, and inflammatory diseases, while also assessing new formulations of PEA with smaller particle size (i.e. micronized and ultramicrosized). Preclinical and human studies indicate that micronized or ultramicrosized PEA, especially in combination with antioxidants, show high potential for the effective treatment of different pathologies characterized by neurodegeneration, (neuro)inflammation, and pain.

The anti-inflammatory mediator palmitoylethanolamide enhances the levels of 2-arachidonoylglycerol and potentiates its actions at TRPV1 cation channels.

(Source: *British Journal of Pharmacology*, Vol. 173(7):1154-1156, 2015).

PEA's ability to act as an anti-inflammatory and pain-relieving agent is modulated by its direct effect on the inflammation process as well as its "entourage effect" affecting the endocannabinoid system. The report demonstrated that PEA raised levels of 2-AG both *in vivo* and *in vitro*, adding another mechanism of action to the multifaceted pharmacological properties of PEA.

Opioid Sparing**Ultramicrosized N-Palmitoylethanolamine Supplementation for Long-Lasting, Low-Dosed Morphine Antinociception.**

(Source: *Frontiers in Pharmacology*, Vol. 9:473, 2018).

The study demonstrated that a preemptive and continuative treatment with PEA enhanced the antinociceptive efficacy of morphine in rats and prolonged the responsiveness to the natural opioid. Moreover, PEA-treated animals had a more rapid recovery from tolerance, with animals receiving PEA needing four opioid free days to regain sensitivity to morphine compared to 31 days for control animals. PEA also acquired antinociceptive properties in tolerant animals, suggesting the possibility of an integrated morphine/PEA treatment protocol.

Efficacy**Efficacy of ultramicrosized palmitoylethanolamide in burning mouth syndrome-affected patients: a preliminary randomized double-blind controlled trial.**

(Source: *Clinical Oral Investigations*, Vol. 23(6):2743-2750, 2019).

This trial was performed to test the efficacy of ultramicrosized PEA treatment on 35 patients with Burning Mouth Syndrome. During the study, a statistically significant reduction of burning mouth sensation was registered in the ultramicrosized PEA group compared to the placebo one. This suggests PEA to be a viable option for the management of burning mouth syndrome.

Palmitoylethanolamide in the Treatment of Failed Back Surgery Syndrome.

(Source: *Pain Research and Treatment*, Vol. 2017, 2017).

The study was designed to evaluate the efficacy of ultramicrosized PEA administration, as add-on therapy for chronic pain, in the management of pain-resistant patients affected by failed back surgery syndrome. During the trial, addition of PEA to the therapy led to a significant decrease in pain intensity without showing any side effects. These results provide evidence for the efficacy and safety of ultramicrosized PEA as part of a multimodal treatment in patients suffering from failed back surgery syndrome.

Efficacy of Ultramicronized Palmitoylethanolamide on the Clinical Symptoms of Charcot-Marie Tooth Neuropathy.
(Source: *Archives of Neurology and Neurosurgery*, Vol. 1(1): 12-14, 2016).

This study investigates the efficacy of ultramicronized PEA in treating the clinical symptoms of Charcot-Marie Tooth (CMT) Neuropathy. A significant decrease in pain, fatigue, and cramps was observed after 20 days of treatment. Further clinical improvement was also observed after 80 days of treatment. Although limited as an open study, the data strongly suggest an efficacy of ultramicronized PEA in improving the clinical symptoms of CMT neuropathy.

Milestones

Milestones in 2021

- FSD Pharma successfully closed the acquisition of Lucid Psycheceuticals Inc. in September 2021, a specialty biotechnology company with two main compounds:
 - a treatment for Progressive MS, a new chemical entity (NCE), which FSD Pharma has worldwide rights to through Lucid with anticipated human trials in late 2022; and
 - a psychoactive compound (psychedelic), with molecules expected to enter trials in late 2022.
- With the acquisition of Lucid, the Company gained a world class team of scientists and individuals who are very familiar with R&D of small molecule drugs and the regulatory framework of getting compounds into FDA clinical trials (biographies on pages 7-8).
- FSD Pharma additionally has a world-class scientific advisory board as well as a newly formed regulatory advisory board with individuals who have experience in all aspects of clinical trials (biographies on pages 9-12).

Potential Milestones Next 12-24 Months

Over the next 12-24 months, FSD Pharma expects to focus on the anti-inflammatory and CNS markets as it continues to pursue synergistic and complementary technologies to address patients' needs. For its current product portfolio, the Company hopes to complete the following key milestones:

- For FSD-PEA, the Company expects to enter Phase 2 studies by the end second quarter 2022. The potential target indications for Phase 2 trials are expected to be announced where the pharmacological mechanisms of the substance will be most beneficial for disease treatment.
- For LUCID-MS, the Company expects to complete IND-enabling studies and enter into Phase 1 first-in-human clinical trials over the next 12-24 months.
- For LUCID-PSYCH, which is being developed primarily for mental health disorders, the amount of proof that FSD Pharma hopes to demonstrate is high compared to others, such as infectious diseases. The Company hopes to have IND enabling studies as well as enter into Phase 1 over the next 12-24 months.
- FSD Pharma is also focused on expanding its biotechnology pipeline and using its strong cash position, along with its NASDAQ listing, to look for other molecules to embark on a growth phase.
- Close the sale of FV Pharma. In consideration for the purchase of this facility, the purchaser has agreed to pay a cash sum of CAD\$16,500,000, including a deposit of CAD\$660,000. The deposit was received by the Company on February 24, 2022 and the transaction is expected to close on May 31, 2022.

Investment Highlights

- **FSD Pharma is working to accelerate the development of a robust pipeline of innovative treatments to address significant unmet treatment needs in brain and inflammatory disorders.**
- **In September 2021, the Company announced the completion of the previously announced acquisition of 100% of the issued and outstanding shares of Lucid Psycheceuticals Inc. (Lucid),** a Canadian-based biotechnology company focused on developing therapies to treat critical neurodegenerative diseases, for approximately US\$8.9 million (CAD\$11.3 million) in FSD Pharma stock.
- **Founded in 2020, Lucid is developing novel molecules and combinations with the goal of addressing total brain health.** They are targeting some of the most challenging neurodegenerative diseases, including MS, major depressive disorder (MDD), and other brain conditions.
- **Lucid has exclusive worldwide licensing rights from the University Health Network (UHN) to a patent-protected family of new chemical entities (NCEs)** on which Lucid's development platform is based and from which its lead neurodegenerative disorders therapeutic candidate, LUCID-MS, has been derived. Lucid's pipeline also includes LUCID-PSYCH, a psychedelic drug candidate targeting mental health disorders. These add to the current anti-inflammatory pipeline under development at FSD Pharma.
 - **LUCID-PSYCH** has been selected by researchers at FSD Pharma to advance its research into the treatment of major depressive disorders (MDDs) based on analysis of the drug candidate's pharmaceutical and metabolic properties processed via machine learning algorithms as well as for its potential proprietary position. To date, the compound has shown promising results and the Company has undertaken preclinical development activities.
 - **LUCID-MS** is a disease modifying agent that is targeted to treat neurodegenerative condition in MS patients, in other words, progressive MS condition. With over 11 years of R&D, FSD Pharma owns worldwide exclusive rights for this family of compounds for development and marketing. The compound has shown excellent efficacy in various preclinical animal models with the treatment accelerating functional recovery of diseased mice, preserving myelin, and reducing axonal degeneration, while not suppressing the immune system. LUCID-MS is currently in preclinical development with anticipated IND in the Fall 2022.
 - **FSD-PEA** is a proprietary formulation of PEA, a fatty acid amide with proven anti-inflammatory properties and superior bioavailability, making it suitable to treat a range of inflammatory conditions. FSD Pharma is expected to pursue potential target indications for Phase 2 trials based on the market need and the highest potential for success derived from the pharmacological mechanisms of this compound. FSD Pharma holds exclusive worldwide licensing rights (except Italy and Spain) to FSD-PEA for all conditions in all regulatory categories.
- **FSD Pharma's Intellectual Property.** FSD Pharma has a strong IP portfolio, which covers composition of matter and use of FSD-PEA (2029-2034 U.S. expiration), and composition of matter on LUCID-MS family of compounds (2035 U.S. expiration). The Company continues to evaluate and strengthen its patent portfolio. FSD Pharma has filed for two trademarks: *Pharmaceutically Green* and *In Pursuit of Total Brain Health* in various markets, reflecting its ambitious efforts around FSD-PEA and various CNS conditions, respectively.
- **The Company has a diversified business model, which helps lessen risk.** FSD Pharma seeks to de-risk investment by securing therapeutic assets that target large markets with significant unmet need. In addition, possessing multiple pipeline assets with the ability to pivot into different treatment targets based on the pharmacological response potentially reduces risk.

- ***In order to execute on the Company's pipeline operationally, FSD Pharma has brought on and strengthened world-class scientific and development team led by Dr. Lakshmi P. Kotra***, a senior scientist at Campbell Research Institute, Brain Institute at the University Health Network (biography on page 7). Dr. Kotra is also a Professor of Medical Chemistry at the University of Toronto, having spent decades in drug discovery and development, and is now FSD Pharma's R&D and Operations Biotechnology Lead.
- ***FSD Pharma expects to add complementary expertise to its team***, as well as partner with experienced organizations globally as it is focused on completing advanced preclinical studies and scaling up activities to successfully move FSD Pharma's assets through clinical trials.
- ***Close the sale of FV Pharma***. FSD Pharma Inc. announced that it has entered into a firm agreement in connection with the sale of its former cannabis processing facility located in Cobourg, Ontario, where the purchaser has agreed to pay a cash sum of CAD\$16,500,000, including a deposit of CAD\$660,000. The deposit was received by the Company on February 24, 2022 and the transaction is expected to close on May 31, 2022.
- ***The Company has just under 39 million shares issued and outstanding***, with roughly 137,000 shareholders as of September 29, 2021, with roughly 75% of the Company under the control of roughly 100 shareholders.
- ***FSD Pharma is well positioned financially***. As of September 2021, FSD had over \$39.3 million cash and cash equivalents, and continues to look for additional investment and acquisition opportunities.

Competition

As FSD Pharma continues to develop and commercialize its products, the Company may encounter competition from other pharmaceutical and biotechnologies companies. Potential competitors may also include academic institutions, government agencies, and other public and private research organizations that seek to establish collaborative arrangements for research, development, manufacturing, and commercialization. The list of companies presented in Figure 14 and this section is not intended to be an exhaustive collection of the Company’s competitors, however, it is believed to be a sample of the type of competition that FSD Pharma may face as it strives to commercialize its technologies and product candidates.

Figure 14
COMPARABLE COMPANIES WITH SIMILAR DRUG CANDIDATE TARGETS

COMPANY	TICKER SYMBOL	MARKET CAP	PSYCHEDELICS	MULTIPLE SCLEROSIS	PEA
Atai Life Sciences 	ATAI	\$813M	✓		
COMPASS Pathways 	CMPS	\$528M	✓		
Cybin Corp. 	CYBN	\$130M	✓		
Eliem Therapeutics 	ELYM	\$277M			✓
MediciNova 	MNOV	\$108M		✓	
Mind Medicine 	MNMD	\$417M	✓		
Longboard Pharmaceuticals 	LBPH	\$73M		✓	
FSD Pharma 	HUGE	\$41M	✓	✓	✓

Source: FSD Pharma Inc.

Note: Market Cap is as of March 9, 2022.

POTENTIAL PSYCHEDELIC COMPETITION

atai Life Sciences (ATAI-NASDAQ)

<https://www.atai.life/>

atai Life Sciences is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. The company was founded in 2018 in response to the significant unmet need and lack of innovation in the mental health treatment landscape. atai is dedicated to acquiring, incubating, and efficiently developing innovative therapeutics to treat depression, anxiety, addiction, and other mental health disorders. The company’s business model combines funding, technology, scientific and regulatory expertise with a focus on psychedelic therapy and other drugs with differentiated safety profiles and therapeutic potential. By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines across its companies, seeking to effectively treat and ultimately heal mental health disorders. The company has offices in New York and London, with headquarters in Berlin.

COMPASS Pathways plc (CMPS-NASDAQ)

<https://compasspathways.com/>

COMPASS Pathways is a mental healthcare company dedicated to accelerating patient access to evidence-based innovation in mental health. COMPASS' focus is on improving the lives of those who are suffering with mental health challenges and who are not helped by current treatments. COMPASS is developing a new model of psilocybin therapy, in which its proprietary formulation of synthetic psilocybin, COMP360, is administered in conjunction with psychological support. COMP360 has been designated a breakthrough therapy by the FDA for treatment-resistant depression (TRD). COMPASS has completed a Phase IIb clinical trial of psilocybin therapy for TRD in 22 sites across Europe and North America. This was the largest randomized, controlled, double-blind psilocybin therapy clinical trial ever conducted, and COMPASS' topline data showed a statistically significant ($p < 0.001$) and clinically relevant improvement in depressive symptom severity after three weeks for patients who received a single high dose of COMP360 psilocybin with psychological support. The company is also running a Phase II clinical trial of COMP360 psilocybin therapy for post-traumatic stress disorder (PTSD). COMPASS has headquarters in London, UK with offices in New York and San Francisco.

Cybin Corp. (CYBN-NASDAQ)

<https://cybin.com/>

Cybin is a leading ethical biopharmaceutical company, working with a network of world-class partners and internationally-recognized scientists, on a mission to create safe and effective therapeutics for patients to address a multitude of mental health issues. The company is focused on progressing psychedelics to therapeutics by engineering proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches, and treatment regimens for mental health disorders. Cybin is transforming the mental health treatment landscape by combining novel psychedelic molecules with controllable drug delivery systems through its proprietary deuterated process, creating patent-protected, commercially scalable drug candidates. Cybin has headquarters in Toronto, Ontario, Canada.

Mind Medicine Inc. (MNMD-NASDAQ)

<https://mindmed.co/>

MindMed is a clinical-stage psychedelic medicine biotechnology company that seeks to discover, develop, and deploy psychedelic-inspired medicines and therapies to address addiction and mental illness. MindMed is assembling a compelling drug development pipeline of innovative treatments based on psychedelic substances, including psilocybin, LSD, MDMA, DMT, and an ibogaine derivative, 18-MC. The MindMed executive team brings extensive biopharmaceutical experience to MindMed's approach of developing the next generation of psychedelic-inspired medicines and therapies. MindMed trades on the NASDAQ under the symbol MNMD and on the Canadian NEO Exchange under the symbol MMED. MindMed is also traded in Germany under the symbol MMQ. The company has headquarters in New York, NY.

POTENTIAL MS COMPETITION**MediciNova Inc. (MDOV-NASDAQ)**

MediciNova is a clinical-stage biopharmaceutical company developing a broad late-stage pipeline of novel small molecule therapies for inflammatory, fibrotic, and neurodegenerative diseases. Based on two compounds, MN-166 (ibudilast) and MN-001 (tipelukast), with multiple mechanisms of action and strong safety profiles, MediciNova has 11 programs in clinical development. MediciNova's lead asset, MN-166 (ibudilast), is currently in Phase 3 for amyotrophic lateral sclerosis (ALS) and degenerative cervical myelopathy (DCM), and is Phase 3-ready for progressive multiple sclerosis (MS). MN-166 (ibudilast) is also being evaluated in Phase 2 trials in glioblastoma, patients at risk of developing acute respiratory distress syndrome (ARDS), and substance dependence. MN-001 (tipelukast) was evaluated in a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) and is in preparation for a second Phase 2 trial in nonalcoholic steatohepatitis (NASH). MediciNova has a strong track record of securing investigator-sponsored clinical trials funded through government grants. MediciNova has headquarters in La Jolla, CA.

Longboard Pharmaceuticals, Inc. (LBPH-NASDAQ)

Longboard Pharmaceuticals is a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases, with an initial focus on rare diseases. The company is working toward advancing a portfolio of centrally acting product candidates designed to be highly selective for specific G protein-coupled receptors (GPCRs). Longboard's small molecule product candidates are based on more than 20 years of GPCR research. Longboard is evaluating LP352, an oral, centrally acting 5-HT_{2c} receptor superagonist, with negligible observed impact on 5-HT_{2b} and 5-HT_{2a} receptor subtypes, in development for the potential treatment of seizures associated with developmental and epileptic encephalopathies. Longboard is also evaluating LP143, a centrally acting, full CB₂ receptor agonist, in development for the potential treatment of neurodegenerative diseases associated with neuroinflammation caused by microglial activation, and LP659, a centrally acting, S_{1P} receptor subtypes 1 and 5 modulator, in development for the potential treatment of central nervous system neuroinflammatory diseases.

POTENTIAL FSD-PEA COMPETITION***Eliem Therapeutics, Inc. (ELYM-NASDAQ)***

Eliem Therapeutics is a clinical-stage biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in chronic pain, psychiatry, epilepsy, and other disorders of the peripheral and central nervous systems. These disorders often occur when neurons are overly excited or inhibited, leading to an imbalance. Eliem's focus is on restoring homeostasis. Eliem is developing a pipeline of clinically differentiated product candidates focused on validated mechanisms of action with broad therapeutic potential to deliver improved therapeutics for patients with these disorders. The molecule, PEA being used by Eliem is the same molecule that FSD Pharma has access, though the Eliem method of delivery is different from that of FSD Pharma—with FSD Pharma using an ultramicrosized form of this molecule. Eliem has recently raised approximately \$90 million and has an enterprise value on its IP of roughly \$430 million. Eliem has headquarters in Redmond, WA.

Historical Financial Results

Figures 15, 16, and 17 provide FSD Pharma's consolidated statements of loss and comprehensive loss, its consolidated statements of financial position, and its consolidated statements of cash flows for the three and nine months ended September 30, 2021 and 2020 [unaudited], expressed in U.S. dollars, except per share amounts. View accompanying notes related to the Company's financial statements at:

<https://sedar.com/GetFile.do?lang=EN&docClass=5&issuerNo=00000184&issuerType=03&projectNo=03301195&dclid=5080545>

Figure 15

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF LOSS AND COMPREHENSIVE LOSS

Notes	Three months ended September 30,		Nine months ended September 30,		
	2021	2020	2021	2020	
	[Restated - note 2b]		[Restated - note 2b]		
	\$	\$	\$	\$	
Expenses					
General and administrative	15	3,986,012	2,809,681	12,108,562	7,734,736
External research and development fees		(107,258)	3,511,927	5,475,711	5,376,837
Share-based payments	13	249,192	5,168,434	7,102,363	7,836,756
Depreciation and amortization	7	1,004,673	966,833	2,938,046	2,932,501
Legal provision		—	698,541	—	698,541
Impairment of right-of-use asset		—	—	—	89,860
Total operating expenses		5,132,619	13,155,416	27,624,682	24,669,231
Loss from continuing operations		(5,132,619)	(13,155,416)	(27,624,682)	(24,669,231)
Other income		—	23,166	(1,292)	(3,688)
Finance expense		1,957	60,977	40,199	202,614
Gain on settlement of financial liability	9	—	(218,818)	(49,792)	(259,228)
Loss (gain) on change in fair value of warrants and derivative liability	6 & 11	(280,716)	(672,744)	(19,107)	(1,307,157)
Loss (gain) on changes in fair value of investments	6	760,961	54,626	180,133	1,186,312
Net loss from continuing operations		(5,614,821)	(12,402,623)	(27,774,823)	(24,488,084)
Net loss from discontinued operations	4	(176,104)	(1,164,643)	(1,162,883)	(2,933,437)
Net loss		(5,790,925)	(13,567,266)	(28,937,706)	(27,421,521)
Other comprehensive income (loss)					
Items that may be subsequently reclassified to income (loss):					
Exchange gain (loss) on translation of foreign operations		125,570	(272,450)	46,252	398,183
Comprehensive loss		(5,665,355)	(13,839,716)	(28,891,454)	(27,023,338)
Net loss per share					
Basic and diluted - continuing operations	14	(0.15)	(0.98)	(0.84)	(2.46)
Basic and diluted - discontinued operations	14	—	(0.09)	(0.04)	(0.29)
Weighted average number of shares outstanding – basic and diluted	14	36,296,047	12,676,712	33,096,705	9,969,261

The accompanying notes are an integral part of these condensed consolidated interim financial statements.

Source: FSD Pharma Inc.

Figure 16

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

As at	Notes	September 30, 2021 \$	December 31, 2020 \$
ASSETS			
Current assets			
Cash and cash equivalents		39,315,267	17,524,822
Other receivables		604,467	161,342
Prepaid expenses and deposits	5	1,347,946	569,401
		<u>41,267,680</u>	<u>18,255,565</u>
Assets held for sale	4	8,605,022	8,610,504
		<u>49,872,702</u>	<u>26,866,069</u>
Non-current assets			
Investments	6	1,496,612	1,676,745
Intangible assets, net	3 & 7	17,300,916	13,424,391
		<u>68,670,230</u>	<u>41,967,205</u>
LIABILITIES			
Current liabilities			
Trade and other payables	8	6,692,064	3,700,103
Lease obligations	10	47,058	46,842
Warrants liability	11	1,428,803	1,447,910
Notes payable	9	300,549	384,647
		<u>8,468,474</u>	<u>5,579,502</u>
Non-current liabilities			
Lease obligations	10	50,126	79,120
		<u>8,518,600</u>	<u>5,658,622</u>
SHAREHOLDER'S EQUITY			
Class A share capital	12	151,588	151,588
Class B share capital	12	152,128,089	103,056,538
Warrants	12	5,137,417	4,968,958
Contributed surplus	13	22,287,081	18,792,590
Foreign exchange translation reserve		254,049	207,797
Accumulated deficit		<u>(119,806,594)</u>	<u>(90,868,888)</u>
		<u>60,151,630</u>	<u>36,308,583</u>
		<u>68,670,230</u>	<u>41,967,205</u>

Source: FSD Pharma Inc.

Figure 17
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

	2021	2020
	[Restated - note 2b]	
	\$	\$
Operating activities		
Net loss from continuing operations	(27,774,823)	(24,488,084)
Add (deduct) items not affecting cash		
Depreciation and amortization	2,938,046	2,932,501
Impairment of right-of-use asset	—	89,860
Interest expense	40,208	5,457
Share-based payments	7,102,363	7,836,756
Change in fair value of other investments	180,133	1,186,312
Change in fair value of derivative liability	(19,107)	(1,307,159)
Unrealized foreign exchange gain (loss)	—	3,203
Gain on settlement of financial liability	(49,792)	(259,228)
Changes in non-cash working capital balances		
Trade and other receivables	(208,114)	(2,894,291)
Prepaid expenses and deposits	(566,664)	(658,424)
Legal liability	—	4,137,650
Trade and other payables	2,928,621	(414,261)
Cash used in continuing operating activities	(15,429,129)	(13,829,708)
Cash used in discontinued operating activities	(1,226,495)	(530,051)
Cash used in operating activities	(16,655,624)	(14,359,759)
Investing activities		
Cash acquired from acquisition of Lucid Psycheceuticals Inc.	768,964	—
Additions to intangible assets	(547,890)	—
Proceeds from sale of investments	—	6,477,510
Cash provided by continuing investing activities	221,074	6,477,510
Cash used in discontinued investing activities	—	36,617
Cash provided by investing activities	221,074	6,514,127
Financing activities		
Proceeds from issuance of shares, net	38,341,407	16,480,087
Proceeds from exercise of stock options	—	59,548
Repayment of notes payable	(71,759)	(594,127)
Repayment of lease obligation	(44,653)	(29,207)
Cash provided by continuing financing activities	38,224,995	15,916,301
Cash provided by discontinued financing activities	—	—
Cash provided by financing activities	38,224,995	15,916,301
Net increase in cash during the period	21,790,445	8,070,669
Cash, beginning of period	17,524,822	5,967,798
Cash, end of period	39,315,267	14,038,467

The accompanying notes are an integral part of these condensed consolidated interim financial statements.

Source: FSD Pharma Inc.

Recent Events

February 25, 2022—FSD Pharma Inc. announced that it has entered into a firm agreement in connection with the sale of its former cannabis processing facility located in Cobourg, Ontario and the 64.43 acre property on which the facility is located. In consideration for the purchase of the facility, the purchaser has agreed to pay a cash sum of CAD\$16,500,000, including a deposit of CAD\$660,000. The deposit was received by the Company on February 24, 2022 and the transaction is expected to close on May 31, 2022. If closed, the injection of money will be non-dilutive to shareholders. The sale remains subject to the satisfaction of a number of conditions.

January 20, 2022—FSD Pharma announced the launch of its newly designed website. The new site conveys the Company's emerging position within the biopharmaceutical industry and its ongoing commitment to bring novel treatment solutions for brain and inflammatory disorders to millions of patients in need.

January 18, 2022—Announced that Eleanor N. Fish, Ph.D., a member of FSD Pharma's Research and Clinical Advisory Board, has been appointed to the Order of Canada. Dr. Fish was named a Member of the Order for her contributions to immunology, including her groundbreaking studies on the use of interferon-alpha in the treatment of disease. Created in 1967, the Order of Canada is one of the country's highest civilian honors and recognizes those "whose service shapes our society; whose innovations ignite our imaginations; and whose compassion unites our communities."

January 04, 2022—Announced that Anthony Durkacz, interim CEO of FSD Pharma, will present at the H.C. Wainwright Bioconnect Conference to be held virtually on January 10-13, 2022. Mr. Durkacz's presentation is available on-demand for conference attendees starting at 7:00 a.m. ET on January 10, 2022.

December 30, 2021—Announced that its Board of Directors has authorized the repurchase by the Company of up to 2,000,000 of its Subordinate Class B Voting Shares from time to time over the next 12 months at prevailing market prices in order to allow the Company to use its excess cash reserves to strategically return value to shareholders.

December 9, 2021—Announced 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.

December 3, 2021—Announced that Anthony Durkacz, interim CEO of FSD Pharma, will present at the H.C. Wainwright 2nd Annual Virtual Psychedelics Conference to be held on December 6, 2021. Mr. Durkacz's presentation is available on-demand for conference attendees starting at 7:00 a.m. ET and accessible to view on the investor relations section of FSD Pharma's website at <https://ir.fsdpharma.com/news-events/events-presentations>.

December 2, 2021—Announced that it is sharing pre-clinical data, supported by an explanatory video, demonstrating the potentially disease-modifying effects of LUCID-MS, the Company's lead drug candidate for the potential treatment of multiple sclerosis (MS), in the animal models of MS.

November 16, 2021—Announced the appointment of Eleanor N. Fish, Ph.D., to its Research and Clinical Advisory Board.

October 19, 2021—Announced it has entered into an agreement with Covar Pharmaceuticals Inc., a contract development and manufacturing services organization, to commence work on providing research quantities of FSD Pharma's drug candidate, LUCID-PSYCH, on an exclusive basis for further clinical evaluation.

October 13, 2021—Announced that Anthony Durkacz and Dr. Lakshmi P. Kotra, CEO of FSD Pharma's wholly-owned subsidiary Lucid Psycheceuticals, will participate in the KCSA Psychedelics Investor Conference, which was held at VirtualInvestorConferences.com on October 13-14, 2021.

September 22, 2021—Announced that it has retained the services of Hybrid Financial Ltd., North Equities Corp., Looking Glass Capital Consultants, Worldwide Media Solutions, LLC (BGTV Direct), KCSA Strategic Communications, and Digi Messaging & Advertising, which will each play a key role in assisting the Company to enhance its market awareness and foster productive, continuing dialogues with shareholders and other market participants. Management has made this decision following a thorough review of capital on hand and allocated these resources to investor relations.

September 21, 2021—Announced the completion of the previously announced acquisition of 100% of the issued and outstanding shares of Lucid Psycheceuticals Inc., a Canadian-based specialty psychedelic pharmaceutical company focused on developing therapies to treat critical neurodegenerative diseases, for approximately CAD\$11.3 million (US\$8.9 million) in FSD Pharma stock.

August 25, 2021—Announced that it has entered a definitive agreement to acquire 100% of the issued and outstanding shares Lucid Psycheceuticals Inc., a Canadian-based specialty psychedelic pharmaceutical company focused on the development of therapies to treat critical neurodegenerative diseases.

August 24, 2021—Announced that it intends to terminate the Phase 2 clinical trial of ultramicronized palmitoylethanolamide (PEA) or FSD-201 for use in treating COVID-19. FSD-201 stabilizes mast cells and down-regulates the pro-inflammatory cytokines to effectuate an anti-inflammatory response; it is also known to target the CB2 receptors of the endocannabinoid system of the human body.

July 27, 2021—Announced that the Board of Directors had terminated the employment of the Company's CEO, Dr. Raza Bokhari for cause.

June 03, 2021—Announced the appointment of Mr. Adnan Bashir as an independent member of its Board of Directors, upon the recommendation of the Company's Compensation, Nomination and Governance Committee.

May 17, 2021—Announced the results of its annual general and special meeting of the shareholders held on May 14, 2021, at which 54.17% of the votes attached to the issued and outstanding Class B Subordinate Voting Shares (Class B Shares) and Class A Multiple Voting Shares (Class A Shares) were represented. The board of directors of FSD Pharma was fixed at seven directors. Each of the nominees of the group of concerned shareholders led by Messrs. Anthony Durkacz and Zeeshan Saeed were elected to the Board, in addition to Messrs. Frank Lavelle and Donal Carroll, to hold office for the ensuing year. However, following his election, Mr. Lavelle communicated his resignation to the Board.

May 10, 2021—Announced that it has submitted to the U.S. Food and Drug Administration (FDA) an Investigational New Animal Drug Application (IND) for the use of FSD-201 (ultramicronized palmitoylethanolamide, or ultramicronized PEA) to treat gastrointestinal enteropathy in dogs. The application has been accepted for review. The proposed trial design is a randomized, double-blind, placebo-controlled, crossover, trial comparing FSD-201 (ultramicronized palmitoylethanolamide [PEA]) dosed twice daily for 30 days to placebo for the treatment of canine inflammatory bowel disease. The primary endpoint will be a validated diarrhea score, evaluated by both treating veterinarian and dog owner. The trial will be conducted at 5 to 10 sites in the U.S. and will enroll up to 200 dogs.

May 05, 2021—Announced that Institutional Shareholder Services Inc., a leading independent international corporate governance analysis and proxy advisory firm, has recommended that shareholders vote FOR all Company Director Nominees in a contested election for the Board of Directors and FOR the elimination of the dual-class share structure at the annual and special meeting of shareholders on May 14, 2021.

May 05, 2021—Announced the appointment of Nathan Coyle, the Company's Corporate Controller as its Interim CFO following the departure of Donal Carroll, effective immediately.

May 03, 2021—Issued important message to shareholders and response to dissident circular.

April 23, 2021—Announced the filing of its Management Information Circular and an accompanying letter to shareholders related to the Annual & Special Meeting scheduled for May 14, 2021, copies of which are available under the Company’s SEDAR profile.

March 31, 2021—Announced that it has commenced an application in the Ontario Superior Court seeking orders from the Court about the conduct of FSD Pharma’s annual general and special meeting of shareholders currently scheduled for May 14, 2021.

March 16, 2021—Announced that it has entered into a license agreement with Innovet Italia S.R.L., under which Innovet granted the Company a license to use ultramicrosized-palmitoylethanolamide (or ultramicrosized PEA) to develop U.S. FDA approved veterinary drugs for the treatment of gastrointestinal diseases in canine and feline (dogs and cats). In addition, the Company today announced filing of its year-end results and provided corporate updates.

February 11, 2021—Announced that it has entered into an Equity Distribution Agreement dated February 11, 2021 with A.G.P./Alliance Global Partners. Under the Sales Agreement, the Company may, at its discretion and from time-to-time during the term of the Sales Agreement, sell, through the Sales Agent, Class B Subordinate Voting Shares of the Company. Sales of Class B Shares will be made through “at-the-market distributions”, as defined in the Canadian Securities Administrators’ National Instrument 44-102-Shelf Distributions, including sales made directly on the Nasdaq Capital Market, or any other recognized trading market upon which the Class B Shares are listed or quoted in the U.S. No offers or sales of Class B Shares will be made in Canada on the Canadian Securities Exchange or other trading markets in Canada. The sale of the Class B Shares is being made by way of a prospectus supplement dated February 11, 2021, covering the sale of up to \$20 million of Class B Shares to the Company’s existing U.S. registration statement on Form F-10 and Canadian short form base shelf prospectus each dated June 16, 2020.

January 22, 2021—Announced that FSD Pharma was to hold its Annual Meeting of shareholders on June 29, 2021.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by FSD Pharma Inc. (“FSD Pharma” or “the Company”) with the assistance of Crystal Research Associates, LLC (“CRA”) based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in FSD Pharma’s statements on its financial and other reports filed from time to time.

The content of this report with respect to FSD Pharma has been compiled primarily from information available to the public released by the Company through news releases, presentations, Annual Reports, and other filings. FSD Pharma is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by FSD Pharma or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, CRA has been compensated by the Company in cash of forty two thousand U.S. dollars and thirty thousand restricted shares for its services in creating this report and for updates.

Investors should carefully consider the risks and information about FSD Pharma’s business. Investors should not interpret the order in which considerations are presented in this or other filings as an indication of their relative importance. In addition, the risks and uncertainties overviewed herein are not the only risks that the Company faces. Additional risks and uncertainties not presently known to FSD Pharma or that it currently believes to be immaterial may also adversely affect the Company’s business. If any of such risks and uncertainties develops into an actual event, FSD Pharma’s business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company’s shares could decline.

This report is published solely for informational purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. Additional information about FSD Pharma, as well as copies of this report, can be obtained in either a paper or electronic format by calling (416) 854-8884.

Risks Relating to the Developing Product Candidates

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. The Company has only one pharmaceutical product Phase 2 candidate, FSD-PEA (FSD-201), and two preclinical candidates, LUCID-MS and LUCID PSYCH, with no pharmaceutical product sales, which, together with its limited operating history, makes it difficult to evaluate its business and assess its future viability. Pharmaceutical and biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. FSD Pharma has a limited operating history. The Company has no pharmaceutical products approved for commercial sale and has not generated any revenue from pharmaceutical product sales.

The Company is currently focused on developing FSD-PEA (FSD-201), which is in early stages of development, LUCID-MS, and LUCID-PSYCH, which will each require substantial additional development time, including extensive resources and clinical testing, before it would be able to receive regulatory approvals and begin generating revenue from product sales. The Company expects to continue to incur significant research and development (R&D) and other expenses related to ongoing operations and expects to incur losses for the near future. FSD Pharma anticipates these losses will increase and will not generate any revenue from product sales until after it has successfully completed clinical development and received regulatory approval for commercial sale.

Because of the numerous risks and uncertainties associated with drug development, FSD Pharma is unable to predict the timing or amount of its expenses, or when the Company will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, FSD Pharma's expenses could increase beyond its current expectations if the Company is required by the FDA or comparable foreign regulatory authorities to perform nonclinical or preclinical studies or clinical trials in addition to those that it currently anticipates, or if there are any delays in any of its or its future collaborators' clinical trials. Even if its product candidates are approved for commercial sale, the Company anticipates incurring significant costs associated with commercializing the product and ongoing compliance efforts.

FSD Pharma may never be able to develop or commercialize its pipeline candidates or achieve profitability. If regulatory approval is obtained for any of its compounds, it will be dependent, in part, upon the size of the markets in the territories for which it obtains regulatory approval, the accepted price for the product, the ability to obtain reimbursement at any price and whether the Company owns the commercial rights for that territory, as well as the efficiency and availability of any comparable products.

The company's growth strategy depends on its ability to generate revenue. In addition, if the number of addressable patients is less than anticipated, the indication approved by regulatory authorities is narrower than expected, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, FSD Pharma may not generate significant revenue from sales of FSD-PEA (FSD-201), LUCID-MS or LUCID-PSYCH, even if approved.

Even if the Company is able to generate revenue from the sale of its product candidates, it may not become profitable and may need to obtain additional funding to continue operations. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. FSD Pharma's failure to achieve sustained profitability would depress its value and could impair its ability to raise capital, expand its business, diversify its research and development pipeline, market its products, and any other product candidates that the Company may identify and pursue or continue its operations.

FSD-PEA (FSD-201) trials are speculative and may not have conclusive or timely results, which may adversely affect the Company's business, financial condition, and/or results of operations. The Company's drug trials are still in early phases and the effectiveness of its products are not yet known. Therefore, FSD Pharma is subject to a number of financial risks and is unable to predict the timing or amount of expenses that may be required for ongoing trials, including further applications to the FDA.

FSD Pharma may never be able to develop or successfully commercialize its product candidates, which require significant additional development; management of clinical and manufacturing activities; and regulatory approval. In addition, the Company will need to obtain adequate manufacturing supply; build a commercial organization; commence marketing efforts; and obtain reimbursement, or contract for such services, before it generates any significant revenue from commercial product sales, if ever.

The Company cannot be certain that its product candidates will be successful in clinical trials or receive regulatory approval. Further, they may not receive regulatory approval even if successful in clinical trials. If the Company does not receive regulatory approvals for FSD-PEA (FSD-201), LUCID-MS, LUCID-PSYCH, or some other future product candidate that it may identify, FSD Pharma and its subsidiaries may not be able to continue operations, which may result in the Company out-licensing the technology or pursuing an alternative strategy.

Epitech License

FSD Pharma relies solely on the Epitech License to use for pharmaceutical purposes certain patents and other intellectual property rights to ultramicrosized-PEA that are material to its business. If the Epitech License were to be terminated or if other rights that may be necessary or deemed advisable for commercializing FSD-201 cannot be obtained, it would limit FSD Pharma's ability to market FSD-PEA (FSD-201), which would have a material adverse effect on its business, operating results, and financial condition.

FSD Pharma's Epitech License provides the Company with an exclusive, multi-jurisdictional license to use certain patents and other intellectual property rights to FSD-PEA (FSD-201) that are owned by Epitech. Under the Epitech License, FSD Pharma is obligated to use commercially reasonable efforts to develop FSD-PEA (FSD-201), with a view to filing a new drug application with the FDA as soon as practicable. The Company is also obligated to make milestone payments and royalties to Epitech, which may limit its future profitability and its ability to enter into marketing partnership agreements. If the Company materially breaches any of the terms of the Epitech License (and fails to cure such breach with the specified time, to the extent a cure period is available for such breach), Epitech could terminate the agreement. If FSD Pharma were to lose or otherwise be unable to maintain the Epitech License on acceptable terms, or find that it is necessary or appropriate to secure new licenses from other third parties, the Company would not be able to market FSD-PEA (FSD-201) and its current business model and plan would be impaired, which would have a material adverse effect on its business, operating results, and financial condition.

Patent terms may be inadequate to protect the Company's competitive position on FSD-PEA (FSD-201) for an adequate amount of time. In the U.S., if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering FSD-PEA (FSD-201) are extended, once the patent life has expired, the Company may be open to competition from competitive products, including generics or biosimilars. As a result, FSD Pharma's owned and licensed patent portfolio may not provide the Company with sufficient rights to exclude others from commercializing products similar or identical FSD-PEA (FSD-201).

Risks Related to the Pharmaceutical Business

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. The Company has incurred significant losses since its inception and anticipates that it will continue to incur significant losses for the foreseeable future.

The Company's product candidates will require substantial additional time to develop, including extensive clinical research and resources before being able to apply for or receive regulatory approvals and begin generating revenue from product sales. Because of the numerous risks and uncertainties associated with drug development, FSD Pharma is unable to predict the timing or amount of its expenses, or when it will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. FSD Pharma's product candidates are in preclinical development, which is a lengthy and costly process with uncertain outcomes and the potential for substantial delays. The Company's product candidates may not receive regulatory approval, which is necessary before they can be commercialized.

Clinical testing is expensive, time consuming, and subject to significant uncertainty. FSD Pharma cannot guarantee that any of its ongoing and planned clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, even if these trials are initiated or conducted on a timely basis, issues may arise that could result in the suspension or termination of such clinical trials. Failure of one or more clinical trials can occur at any stage of testing, and the Company's ongoing and future clinical trials may not be successful.

FSD Pharma's clinical trials may fail to demonstrate substantial evidence of the safety and/or effectiveness of product candidates that it may identify and pursue for their intended uses, which would prevent, delay, or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of the Company's product candidates, FSD Pharma must demonstrate, through preclinical studies and clinical trials, that the applicable product candidate is both safe and effective for use in each target indication. FSD Pharma cannot be certain that its current clinical trials or any other future clinical trials will be successful. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction.

If FSD Pharma is unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates it may develop, the Company may not be successful in commercializing those product candidates if and when they are approved.

FSD Pharma does not have a sales or marketing infrastructure and has little experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved product for which it retains sales and marketing responsibilities, the Company must either develop a sales and marketing organization or outsource these functions to third parties through collaborations or strategic partnerships to engage in commercialization activities with respect to selected product candidates, indications, or geographic territories, including territories outside the U.S.

The insurance coverage and reimbursement status of newly approved products is uncertain. FSD Pharma's product candidates may become subject to unfavorable pricing regulations, third-party coverage, and reimbursement practices, or healthcare reform initiatives, which would harm the Company's business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit FSD Pharma's ability to market those products and decrease its ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs varies widely from country to country. In the U.S., recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, the Company might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay its commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenue FSD Pharma is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder the Company's ability to recoup its investment in one or more product candidates, even if any product candidates it may develop obtain marketing approval.

FSD Pharma's ability to successfully commercialize its product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations (HMOs), decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments.

Sales of these or other product candidates that FSD Pharma may identify will depend substantially, both domestically and abroad, on the extent to which the costs of the Company's product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers, and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, FSD Pharma may not be able to successfully commercialize its product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow FSD Pharma to establish or maintain pricing sufficient to realize a sufficient return on its investment.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on FSD Pharma's business, results of operations, financial condition, and prospects.

The U.S. and many other jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of the Company's product candidates or any future product candidates, restrict, or regulate post-approval activities, and affect FSD Pharma's ability to profitably sell any product for which it obtains marketing approval.

There have been, and likely will continue to be, legislative and regulatory proposals in other jurisdictions as well as at the U.S. federal and state levels directed at containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent FSD Pharma from being able to generate revenue, attain profitability, or commercialize its product. The Company expects that the Patient Protection and Affordable Care Act (ACA), as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that FSD Pharma receives for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent the Company from being able to generate sufficient revenue, attain profitability, or commercialize its product candidates, if approved.

If FSD Pharma fails to comply with healthcare laws, it could face substantial penalties and its business, operations, and financial conditions could be adversely affected.

Healthcare providers, physicians, and third-party payors in the U.S. and elsewhere play a primary role in the recommendation of prescription pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute and the U.S. federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market, and distribute pharmaceutical products.

In particular, the promotion, sales, and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of ownership, pricing, discounting, marketing and promotion, structuring, and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of the Company's business activities, including compensation of physicians with stock or stock options, could, despite efforts to comply, be subject to challenge under one or more of such laws. It is possible that governmental and enforcement authorities will conclude that the Company's business practices may not comply with current or future healthcare laws. If any such actions are instituted against FSD Pharma and it is not successful in defending itself, those actions could have a significant impact on its business, including the imposition of significant civil, criminal, and administrative penalties, and exclusion from participation in Medicare, Medicaid, and other U.S. federal healthcare programs.

The Company expects to rely on third parties to conduct its clinical trials and some aspects of its research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.

FSD Pharma currently relies and expects to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct some aspects of research and preclinical testing and clinical trials. Any of these third parties may terminate their engagements or be unable to fulfill their contractual obligations. If any of the Company's relationships with these third parties terminate, it may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all.

If FSD Pharma needs to enter into alternative arrangements, it would delay product development activities. Furthermore, if these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct clinical trials in accordance with regulatory requirements or FSD Pharma's stated protocols, the Company will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates and will not be able to, or may be delayed in successfully commercializing its medicines.

The drug substance and drug product for certain of the Company's product candidates are currently acquired from single-source suppliers. The loss of these suppliers, or their failure to supply FSD Pharma with the drug substance or drug product, could materially and adversely affect its business.

The drug substance, and drug product for certain of FSD Pharma's product candidates, are manufactured by single-source suppliers or CMOs. FSD Pharma does not currently have any other suppliers for the drug substance or drug product of these product candidates and, although the Company believes that there are alternate sources of supply that could satisfy its clinical and commercial requirements, it cannot be sure that identifying alternate sources and establishing relationships with such sources would not result in significant delay in the development of its product candidates.

If the contract manufacturing facilities on which FSD Pharma relies do not continue to meet regulatory requirements or are unable to meet supply demands, the Company's business will be harmed.

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including the existing CMOs for all of the Company's product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with good manufacturing practice (GMP), or similar regulatory requirements outside the U.S. Although FSD Pharma oversees the CMOs, the Company cannot control the manufacturing process of, and are completely dependent on, its CMO partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. FSD Pharma's failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions, including clinical holds, fines, withdrawal of approvals, license revocation, suspension of production, or recalls of product candidates or marketed drugs, any of which could significantly and adversely affect clinical or commercial supplies of the Company's product candidates.

Company Specific Risks

There is substantial doubt about the Company's ability to continue as a going concern and if the Company is unable to obtain additional financing from outside sources and/or eventually generate enough revenues, it may be forced to sell a portion or all of its assets or curtail or discontinue its operations.

FSD Pharma's auditor has indicated in the Company's audited annual financial statements that there is substantial doubt about its ability to continue as a going concern. The continued operations of the Company and the recoverability of amounts shown for property, plant, and equipment in FSD Pharma's audited annual financial statements are dependent upon the ability of the Company to obtain sufficient financing to complete the development of its facilities and extraction processes. Importantly, the inclusion in the FSD Pharma's financial statements of a going concern opinion may negatively impact its ability to raise future financing and achieve future revenue. If the Company is unable to obtain additional financing from outside sources and/or eventually generate enough revenues, FSD Pharma may be forced to sell a portion or all of its assets or curtail or discontinue its operations. If any of these events happens, a prospective purchaser could lose all or part of its investment.

The success of FSD Pharma is dependent upon its senior management and key personnel and ability to hire skilled personnel. Any loss of the services of such individuals could have a material adverse effect on the Company's business, operating results, or financial condition.

The success of the Company will be dependent upon the ability, expertise, judgment, discretion, and good faith of its senior management and key personnel. The Company may not be able to find appropriate replacements for key personnel on a timely basis. Furthermore, each of FSD Pharma's executive officers may terminate their employment with the Company at any time. FSD Pharma does not maintain "key person" insurance for any of its executives or employees. The loss of the services of key personnel as well as the diversion of management's and the Board's attention to replace the services of such individuals could have a material adverse effect on the Company's business, operating results, or financial condition.

Management may not be able to successfully implement and maintain adequate internal controls over financial reporting or disclosure controls and procedures.

Effective internal controls are necessary for the Company to provide reliable financial reports and to help prevent fraud. Although FSD Pharma has undertaken a number of procedures and has implemented a number of safeguards in order to help ensure the reliability of its financial reports, including those imposed on the Company under Canadian securities law, it cannot be certain that such measures will ensure that the Company will maintain adequate control over financial processes and reporting. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm the Company's results of operations or cause it to fail to meet its reporting obligations.

The Company will incur increased costs as a result of operating as a public company in the U.S. and its management will be required to devote substantial time to new compliance initiatives.

As a public company in the U.S., FSD Pharma will incur significant legal, accounting, and other expenses that it did not incur prior to being listed in the U.S. In addition, the Sarbanes-Oxley Act (2002) and rules implemented by the SEC and the NYSE impose various other requirements on public companies, and FSD Pharma will need to spend time and resources to ensure compliance with its reporting obligations under Canadian securities laws, as well as its obligations in the U.S.

The Company may become party to litigation from time to time, which could adversely affect its business.

The Company may become party to litigation from time to time in the ordinary course of business, which could adversely affect its business. In addition, FSD Pharma may become subject to class actions, securities litigation, and other actions, including anti-trust and anti-competitive actions. Should any litigation in which the Company becomes involved be determined against it, such a decision could adversely affect FSD Pharma's ability to continue operating. Even if FSD Pharma is involved in litigation and wins, litigation can redirect significant corporate resources and management attention.

Conflicts of interest may arise between the Company and its directors and officers as a result of other business activities undertaken by such individuals.

Certain directors and officers of the Company are, and may in the future become, directors and officers of other entities, or are otherwise engaged, and will continue to be engaged, in activities that may put them in conflict with the business strategy of the Company.

Risks Related to the Company's Intellectual Property

If FSD Pharma is unable to obtain and maintain sufficient intellectual property protection for its products, or if the scope of the intellectual property protection obtained is not sufficiently broad, competitors could develop and commercialize product candidates similar or identical, and the Company's ability to successfully commercialize its products may be impaired. As is the case with other pharmaceutical and biopharmaceutical companies, FSD Pharma's success depends in large part on its ability to obtain and maintain protection of the intellectual property it may own solely and jointly with others, particularly patents, in the U.S. and other countries with respect to its product candidates and technology.

The Company seeks to protect its proprietary position by filing patent applications in the U.S. and abroad related to ultramicrosized-PEA (i.e. FSD-PEA, FSD-201), Lucid-MS or other product candidates that it may identify. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal, technological, and factual questions, and has in recent years been the subject of much litigation. In addition, the laws of other countries may not protect the Company's rights to the same extent as the laws of the U.S., or vice versa. FSD Pharma's pending and future patent applications may not result in patents being issued that protect its product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. Even if the Company's patent applications issue as patents, they may not issue in a form that

will provide FSD Pharma with any meaningful protection, prevent competitors from competing with the Company, or otherwise provide FSD Pharma with any competitive advantage. The Company's competitors may be able to circumvent FSD Pharma's patents by developing similar or alternative product candidates in a non-infringing manner.

Third-party claims of intellectual property infringement may prevent or delay FSD Pharma's development and commercialization efforts.

FSD Pharma's commercial success depends, in part, on avoiding infringement of the patents and proprietary rights of third parties. However, the Company's research, development, and commercialization activities may be subject to claims that it infringed or otherwise violated patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries.

Numerous U.S. and international issued patents and pending patent applications, which are owned by third parties, exist in the fields in which FSD Pharma is pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that the Company's products may be subject to claims of infringement of the patent rights of third parties. Any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on ability to raise additional funds or otherwise have a material adverse effect on FSD Pharma's business, results of operations, financial condition, and prospects.

Patent terms may be inadequate to protect the Company's competitive position on product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering FSD Pharma's product candidates are obtained, once the patent life has expired, the Company may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, the Company's owned and licensed patent portfolio may not provide it with sufficient rights to exclude others from commercializing products similar or identical to its product portfolio.

If FSD Pharma is not able to obtain patent term extension or non-patent exclusivity in the U.S. under the Hatch-Waxman Act and in other countries under similar legislation, thereby potentially extending the marketing exclusivity term of its product candidates, the Company's business may be materially harmed.

Depending upon the timing, duration, and specifics of FDA marketing approval of FSD Pharma's product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. The Company may not be granted patent term extension either in the U.S. or in any other country, or even if granted, the term of extension, as well as the scope of patent protection during any such extension, could be less than the Company's request. If FSD Pharma unable to obtain patent term extension or restoration, or the term of any such extension is less than requested, the period during which the Company will have the right to exclusively market its product may be shortened and competitors may obtain approval of competing products following the patent expiration.

If FSD Pharma is unable to protect the confidentiality of its trade secrets, the value of the Company's technology could be materially adversely affected, and its business would be harmed.

FSD Pharma seeks to protect its proprietary information, in part, by confidentiality agreements and invention assignment agreements with its employees, consultants, scientific advisors, contractors, and collaborators. These agreements are designed to protect the Company's proprietary information. However, FSD Pharma cannot be certain that such agreements have been entered into with all relevant parties, and it cannot be certain that its trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to its trade secrets.

If the Company's trademarks and trade names are not adequately protected, then FSD Pharma may not be able to build name recognition in its markets of interest and its business may be adversely affected.

The Company's registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic, or determined to be infringing on other marks. FSD Pharma may not be able to protect its rights to these trademarks and trade names. Over the long term, if FSD Pharma is unable to establish name recognition based on its trademarks and trade names, then it may not be able to compete effectively, and its business may be adversely affected.

FSD Pharma may be subject to claims challenging the inventorship of its patents and other intellectual property.

FSD Pharma's agreements with employees provide that any inventions conceived by an individual in the course of rendering services to the Company shall be FSD Pharma's exclusive property. Although the Company's policy is to have all such individuals complete these agreements, it may not obtain these agreements in all circumstances, and individuals with whom FSD Pharma has these agreements may not comply with their terms. In the event of unauthorized use or disclosure of trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection. The Company its licensors may be subject to claims that former employees, collaborators, or other third parties have an interest in the Company's owned or licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. If the Company or its licensors fail in defending any such claims, in addition to paying monetary damages, the Company may lose valuable intellectual property rights, which could have a material adverse effect on FSD Pharma's competitive position, business, results of operations, financial condition, and prospects.

FSD Pharma may be subject to claims that its employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that its employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, the Company employs individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including competitors or potential competitors. Although FSD Pharma tries to ensure that its employees, consultants, and independent contractors do not use the proprietary information or know-how of others in their work, the Company may be subject to claims that it or its employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of former employer or other third parties. Litigation may be necessary to defend against these claims. If FSD Pharma fails in defending any such claims, in addition to paying monetary damages, it may lose valuable intellectual property rights or personnel, which could adversely impact its business.

The Company may not be able to protect its intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on the Company's product candidates in all countries throughout the world would be prohibitively expensive, and FSD Pharma's intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some other countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, the Company may not be able to prevent third parties from practicing FSD Pharma's inventions in all countries outside the U.S., or from selling or importing products made using its inventions in and into the U.S. or other jurisdictions.

Competitors may use the Company's technologies in jurisdictions where it has not obtained patent protection to develop their own products and may also export infringing products to territories where FSD Pharma has patent protection, but enforcement is not as strong as in the U.S. Proceedings to enforce FSD Pharma's patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert the Company's efforts and attention from other aspects of its business. Accordingly, efforts to enforce FSD Pharma's intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that it develops or licenses.

Glossary

Bipolar disorder—A disorder associated with episodes of mood swings ranging from depressive lows to manic highs. The exact cause of bipolar disorder is not known, but a combination of genetics, environment, and altered brain structure and chemistry may play a role. Treatment is usually lifelong and often involves a combination of medications and psychotherapy.

Cognitive-behavioral therapy (CBT)—Cognitive behavioral therapy (CBT) is a psycho-social intervention that aims to reduce symptoms of various mental health conditions, primarily depression and anxiety disorders.

Delusions—A belief or altered reality that is persistently held despite evidence or agreement to the contrary, generally in reference to a mental disorder.

Demyelination—Occurs when myelin, which is the protective coating of nerve cells, sustains damage. When this happens, neurological problems can occur. Demyelination can result from various medical conditions, including multiple sclerosis (MS).

Dysthymia—A mild but long-term form of depression. Dysthymia is defined as a low mood occurring for at least two years, along with at least two other symptoms of depression. Examples of symptoms include lost interest in normal activities, hopelessness, low self-esteem, low appetite, low energy, sleep changes, and poor concentration. Treatments include medications and talk therapy.

Electroconvulsive therapy (ECT)—Electroconvulsive therapy is a psychiatric treatment where a generalized seizure is electrically induced to manage refractory mental disorders.

Good Manufacturing Practice (GMP)—Practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices.

Hallucinations—A perception of having seen, heard, touched, tasted, or smelled something that was not actually there.

Hatch-Waxman Act—The Drug Price Competition and Patent Term Restoration Act, better known as the Hatch-Waxman Act, is a 1984 United States federal law to streamline the process for generic pharmaceutical approvals and preserve incentives for innovation, including the creation of a procedure for patent litigation involving generic pharmaceuticals.

Hypomania—A condition in which an individual displays a revved up energy or activity level, mood, or behavior. The new “energized you” is recognized by others as beyond your usual self. Hypomania is a less severe form of mania, and both are commonly part of bipolar disorder.

Intraperitoneal—Administered through the peritoneum. The peritoneum is a thin, transparent membrane that lines the walls of the abdominal (peritoneal) cavity and contains/encloses the abdominal organs such as the stomach and intestines.

Investigational new drug application (IND)—Investigational New Drug (IND) program is the means by which a pharmaceutical company obtains permission to start human clinical trials and to ship an experimental drug across state lines (usually to clinical investigators) before a marketing application for the drug has been approved. Similar procedures are followed in the European Union, Japan, and Canada.

Major depressive disorder (MDD)—A mental health disorder characterized by persistently depressed mood or loss of interest in activities, causing significant impairment in daily life.

Multiple Sclerosis [MS]—A disease in which the immune system eats away at the protective covering of nerves. In MS, resulting nerve damage disrupts communication between the brain and the body.

Myelin degradation—A demyelinating disease is any condition that results in damage to the protective covering (myelin sheath) that surrounds nerve fibers in the brain, optic nerves, and spinal cord. When the myelin sheath is damaged, nerve impulses slow or even stop, causing neurological problems.

New chemical entity (NCE)—A new chemical entity is, according to the U.S. Food and Drug Administration, a drug that contains no active moiety that has been approved by the FDA in any other application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act.

Palmitoylethanolamide (PEA)—An endogenous fatty acid molecule demonstrated to bind to a receptor in the cell-nucleus and to exert a great variety of biological functions related to chronic pain and inflammation. Although not considered a classic endocannabinoid because it lacks affinity for the cannabinoid receptors CB1 and CB2, PEA has affinity to other cannabinoid-like receptors and its presence has been known to enhance the cannabinoid anandamide activity by an “entourage effect”.

Persistent depressive disorder—Dysthymia is defined as a low mood occurring for at least two years, along with at least two other symptoms of depression. Examples of symptoms include lost interest in normal activities, hopelessness, low self-esteem, low appetite, low energy, sleep changes, and poor concentration. Treatments include medications and talk therapy.

Postpartum depression—Depression that occurs after childbirth. Those who develop postpartum depression are at greater risk of developing major depression later on in life. Symptoms might include insomnia, loss of appetite, intense irritability, and difficulty bonding with the baby. Untreated, the condition may last months or longer. Treatment can include counseling, antidepressants, or hormone therapy.

Progressive Multiple Sclerosis (MS)—A form of the disease that is characterized from the beginning of the disease as a progressively worsening condition.

Psychotic depression—Also known as depressive psychosis, psychotic depression is a major depressive episode that is accompanied by psychotic symptoms.

Remyelinate—The process of propagating oligodendrocyte precursor cells to form oligodendrocytes to create new myelin sheaths on demyelinated axons in the CNS. This is a process naturally regulated in the body and tends to be very efficient in a healthy CNS.

Seasonal affective disorder—A mood disorder characterized by depression that occurs at the same time every year. Seasonal affective disorder occurs in climates where there is less sunlight at certain times of the year. Symptoms include fatigue, depression, hopelessness, and social withdrawal. Treatment includes light therapy (phototherapy), talk therapy, and medications.

Ultramicronized PEA—Micronization is a process of reducing the diameter of a solid material’s particles to improve the solubility and bioavailability of Active Pharmaceutical Ingredients (APIs). Micronization of PEA results in particle size of less than 10 micrometers (µm). Moreover, the ultramicronization process yields an even smaller and different crystalline structure with higher energy content. The smaller particle size (with higher surface-to-volume ratio) combined with increased potential energy contributes to better solubility.

Intentionally Blank



About Our Firm: For the past two decades, Crystal Research Associates, LLC has successfully articulated the exceptional stories of small- and mid-cap companies to the Wall Street investor community. Our methods are well-established and diverse, from compiling and disseminating objective, factual information for both institutional and retail investor audiences to capitalizing on our expansive line of targeted distribution channels, which include industry-leading financial data and information providers. Our distribution efforts are accompanied by the use of prominent social media channels and by strategic and targeted appearances on national news programs and print media.

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