FSD Pharma Inc.
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Ticker (Exchange)	HUGE-NASDAQ HUGE-CSE
Recent Price (03/11/2020)	$4.25
52-week Range	$3.43 - $47.74
Shares Outstanding	8.1 mm
Market Capitalization	C$34.4 mm
Average 10-day volume	7,600
Insider Ownership +>5%	4%
Institutional Ownership	11%
EPS (Year ended 12/31/19)	C($7.37)
Employees	17

HUGE (NASDAQ) One-year Stock Chart

FSD PHARMA INC. SUBSIDIARIES
FSD BIOSCIENCES
Focused on developing a robust pipeline of FDA approved synthetic pharmaceutical compounds targeting the endocannabinoid system
FV PHARMA
Licensed Producer of cannabis under the Cannabis Act

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

COMPANY DESCRIPTION

FSD Pharma Inc. ("FSD" or "the Company") is a specialty biotech pharmaceutical company focused on developing FDA-approved **synthetic†** compounds targeting the **endocannabinoid system (ECS)** of the human body. The Company is addressing certain diseases of the central nervous system as well as autoimmune disorders of the skin, gastrointestinal (GI) tract, and musculoskeletal system. Following FSD's 2Q19 acquisition of Prismic Pharmaceuticals ("Prismic")—forming part of the Company's BioSciences subsidiary—FSD is also seeking to tackle the opioid crisis by developing non-addictive prescription drugs to treat pain and inflammation using a **ultramicronized** formulation of **palmitolylethonalamide (PEA)** or ultramicronized PEA. PEA interacts with endocannabinoid receptors throughout the body and is a naturally occurring anti-inflammatory. It's anti-inflammatory and analgesic effects may help overcome the problem created by prolonged opioid use as it reduces the development of **opioid tolerance** and potentiates drug efficacy, thus allowing for the use of lower doses of opioids. FSD's other subsidiary, FV Pharma, is a Licensed Producer under **Canada's Cannabis Act and Regulations**, having received its Cultivation License on October 13, 2017 and its full **Sale for Medical Purposes License** on June 21, 2019. The Company is licensed to cultivate **cannabis** at its Cobourg, Ontario facility, reporting approximately C$260,000 in medical cannabis sales during 4Q19.

KEY POINTS

- FSD seeks to target diseases/syndromes where synthetic compounds, including **cannabinoids** that target the ECS, may prove more effective than alternatives. Its lead candidate, FSD201 ultramicronized PEA, recently received approval to initiate Phase 1 first-in-human safety and tolerability trials.
- As evidence of cannabis' benefits mounts, so does the global pharmaceutical industry's interest. Their entry not only brings significant investment and research capabilities but could accelerate public understanding and confidence in synthetic compounds, including cannabinoids that target the ECS as an option for a range of ailments, fueling the industry's growth.
- On January 9, 2020, FSD's shares began trading on the NASDAQ Capital Market under the ticker symbol HUGE, joining a select group of 12 Canadian-domiciled cannabis companies that trade in the U.S. on either the NYSE or NASDAQ markets.
- The Company's worldwide patent portfolio is protected for ten more years, with ultramicronized composition-of-matter and use features patents extending though 2029 to 2034.
- FSD's management team is advised by an experienced Board of Directors and Scientific Advisory Board, who provide enormous insight and value.
- As of December 31, 2019, FSD had C$7.9 million in cash.

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

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

Executive Overview

FSD Pharma Inc. ("FSD" or "the Company") is a specialty biotech pharmaceutical company focused on developing a pipeline of synthetic compounds targeting the endocannabinoid system (ECS) of the human body. The Company is targeting certain diseases of the central nervous system as well as autoimmune disorders of the skin, gastrointestinal (GI) tract, and musculoskeletal system. FSD seeks to target diseases/syndromes where synthetic compounds, including cannabinoids that target the ECS, may prove more effective than alternative treatments. FSD is concentrated on high-value pharmaceuticals, specifically working to develop and commercialize Food and Drug Administration (FDA)-approved medications.

Gaining regulatory approvals for pharmaceutical products entails research and clinical trials. Thus, the Company is focused on using only high-quality synthetic compounds, including cannabinoids with consistency from batch to batch; in particular, synthetic compounds like ultramicronized palmitolylethonalamide (PEA), which functions comparably to natural cannabinoids in reducing inflammation by binding to the same receptors within the ECS, as these are likely to play a key role in delivering the required level of consistency that is sufficient to gain regulatory approval.

Through its recent acquisition of Prismic Pharmaceuticals ("Prismic") in 2Q19, which forms part of FSD Pharma's BioSciences subsidiary, FSD is seeking to address the opioid crisis by developing novel non-addictive prescription drugs to treat pain and inflammation. This may help overcome the problem created by prolonged opioid use as it reduces the development of tolerance or potentiates drug efficacy, thus enabling the use of alternative to opioids or lower doses of opioids. FSD's other wholly owned subsidiary, FV Pharma Inc., is a Licensed Producer under Canada's Cannabis Act and Regulations and intends to target all legal aspects of the cannabis industry, including cultivation, processing, manufacturing, extracts, and research and development (R&D). A summary of the Company's subsidiaries and their business operations is provided in Figure 1, followed by brief descriptions in the accompanying section. Greater details are provided within the Core Story (pages 17-36).

Figure 1
FSD PHARMA INC. SUBSIDIARIES

FSD BIOSCIENCES	FV PHARMA
Focused on developing a pipeline of FDA approved synthetic compounds targeting the endocannabinoid system of the human body to treat certain diseases of the central nervous system and autoimmune disorders of the skin, GI tract, and the musculoskeletal system.	A Licensed Producer of cannabis under the Cannabis Act, having received its Cultivation License on October 13, 2017.

Source: FSD Pharma Inc.

Medical Cannabis Market Overview

The global legal cannabis market size, including both recreational and medical use, is expected to reach $66.3 billion by the end of 2025 (Source: Grand View Research's *Legal Marijuana Market Size, Share & Trends Analysis Report by Type, By Product Type, By Medical Application, And Segment Forecasts, 2019-2025*, May 2019). Within this market, medical cannabis holds the largest share, with the worldwide medical cannabis market estimated at $13.4 billion in 2018 and expected to reach $44.4 billion by 2024 (Source: IMARC Group's *Medical Cannabis Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2019-2024*, April 2019). Growth in the medical cannabis market is fueled by two main factors: (1) increasing legalization of cannabis, and (2) growing adoption of cannabis as a pharmaceutical product. On a geographical front, North America enjoys the leading position within the market, with the recent legalization of cannabis in North America for both recreational and medical purposes being a major driver of the market growth. Canadian marijuana companies dominate the global market as a direct result of the legalization of cannabis in Canada in 2018. In the U.S., ten states have legalized cannabis for recreational use and 33 states plus the District of Columbia have legalized cannabis for medical purposes (Source: *Mordor Intelligence's Cannabis Market - Growth, Trends, And Forecast* [2020-2025]).

Medical Cannabis Potential

Also known as marijuana, cannabis is a psychoactive drug derived from the Cannabis plant (cannabis sativa) used for medical or recreational purposes. The use of cannabis for medical purposes involves the development of natural or synthetic cannabinoids that interact with the endogenous ECS in a way that results in a positive therapeutic effect. Cannabis has a long history of use in medicine, dating back thousands of years, and has been used historically to treat a variety of ailments. Current studies are assessing it effectiveness in a wide range of diseases and symptoms, including cancer, chronic pain, depression, arthritis, diabetes, glaucoma, migraines, epilepsy, multiple sclerosis (MS), Acquired Immunodeficiency Syndrome (AIDS), Amyotrophic Lateral Sclerosis (ALS), Alzheimer's disease, post-traumatic stress disorder (PTSD), Parkinson's disease, Tourette's, and other neurological conditions.

So far, the largest pharmaceutical companies in the world have mostly watched the cannabis industry from the sidelines, deterred by regulatory concerns. However, as the cannabis industry continues to advance and data regarding the effectiveness of cannabis to treat different conditions expands, so too does the interest from the global pharmaceutical industry. The cannabis industry could represent a needed source of growth for countless pharmaceutical companies and could bring significant investment and research capabilities into the pharmaceutical cannabis market.

Medical Cannabis As A Substitute For Opiates

There is a growing body of evidence to support the use of medical cannabis as an adjunct to or substitute for prescription opiates in treating chronic pain. Research shows that opiates and cannabinoids use overlapping signaling systems in the body relating to drug tolerance, pain, and dependence. This common mechanism would support the fact that when used in conjunction with opiates, cannabinoids lead to a greater cumulative relief of pain, resulting in a reduction in the use of opiates (and associated side-effects).

Fewer prescriptions and lower usage of opioids due to medical cannabis availability and use has a direct effect on opioid overdose deaths. An association between medical marijuana laws and decreased opioid-related mortality has been documented in a well conducted study published in 2014. The authors compared opioid analgesic overdose mortality from 1999 to 2010 in all 50 states with and without legal access to medical cannabis. They found that states with medical cannabis laws had a 24.8% lower annual opioid overdose mortality rate compared to states without medical cannabis laws. Furthermore, this decrease generally strengthened over time, with mortality rates decreasing in each year after medical cannabis law implementation, reaching a 33% reduction in the six years after medical marijuana was legalized (Source*: JAMA Internal Medicine*, Vol.174(10):1668-1673, 2014).

Prismic Pharmaceuticals Acquisition

Seeking to target inflammation and address the opioid epidemic, in June 2019, FSD acquired U.S.-based specialty pharmaceutical company, Prismic Pharmaceuticals, for $17.5 million (C$23.4 million) as a platform company to advance the R&D of FDA-approved applications of synthetic cannabinoids and other synergistic molecules. Led by Peter Moriarty, a founder of Shire Pharmaceuticals, Prismic has built a solid foundation for a specialty pharmaceutical company, where FSD is now working towards advancing proprietary drug candidates through the various development stages. Specifically, Prismic holds exclusive worldwide licensing rights, except for Italy and Spain, to a type of palmitolylethonalamide (PEA), which forms a base for the Company's development platform to its lead candidate, a 600mg ultramicronized PEA tablet.

PEA interacts with endocannabinoid receptors throughout the body, including the central nervous system, and is a naturally occurring anti-inflammatory. Micronization is a process of reducing the average diameter of a solid material's particles to allow for it to be orally bioavailable. Invented by Epitech Group SpA ("Epitech"), the micronization technique (ultramicronized particle size between 0.6µm and 10µm) is patent protected until 2030. FSD seeks to conduct a pharmaceutical R&D program initially through Prismic to advance the development of ultramicronized PEA. These efforts are based on a biologic plausibility of an efficacious cannabinoid effect with a high safety profile. Ultramicronized PEA is expected to be effective in many inflammatory diseases, such as chronic pain, arthritis, endometriosis, and various auto-immune disorders. The goal is to develop non-addictive prescription drugs to treat pain and inflammation employing ultramicronized PEA.

On March 9, 2020, the Company announced receipt of approval from the Ethics Committee of the Alfred Hospital, part of the Alfred Health group of hospitals serving the state of Victoria in Australia, to initiate a Phase 1, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, and pharmacokinetics of single and multiple ascending doses of ultramicronized-PEA in normal healthy volunteers. This study is expected to total nearly C$2 million, plus another C$1 to run toxicology studies to satisfy some FDA requirements. FSD expects the safety and tolerability to come back with positive datapoints since ultramicronized-PEA has been used for years as a prescription-based medical food supplement in Italy and Spain and other parts of Europe.

FV Pharma Inc.

FV Pharma, FSD's wholly owned subsidiary, is a Licensed Producer under Canada's Cannabis Act and Regulations, receiving its cultivation license on October 13, 2017 and its full Sale for Medical Purposes license on June 21, 2019. The Company is licensed to cultivate cannabis at its facility and intends to cover all aspects of the cannabis industry, including cultivation, legal, processing, manufacturing, extracts, and R&D. The facility has an electrical sub-station on site, natural gas lines, multiple water-intakes, rail lines directly into the facility, and 26 loading docks. On August 21, 2019, FSD announced that its online ordering system for the direct fulfillment of prescriptions of dried medicinal cannabis was operative through www.fvpharma.com. Individuals are required to have a prescription from a medical practitioner or a registration number with Health Canada to place an order. During 4Q19, FV Pharma reported approximately C$260,000 from the sale of medical cannabis.

Production Facility

Headquartered at a former Kraft Heinz Company [KHC-NASDAQ]) production plant, FSD's facility (Figure 2) is located at 520 William Street, Cobourg, Ontario, K9A 3A5—situated one-hour east of Toronto off the 401 highway, with access by car or rail to Toronto, Ottawa, and Montreal. The Company acquired this location in November 2017 and expanded operations in 2018 following approval from Health Canada and the completion of financing. The proximity to Toronto provides a cost-saving advantage, whereby consolidating all its operations under one roof, the Company has access to greater economies of scale and operational efficiencies.

Figure 2
FSD PHARMA COBOURG FACILITY

Source: FSD Pharma Inc.

The Cobourg facility, which sits on a 70-acre parcel of land, is currently licensed for 25,000 square feet that has been designated for several purposes: flowering, vegetation, drying, packaging, and ancillary space. The overall square footage also includes truck traps, hallways, etc., with 9,500 square feet canopy of space (flower rooms plus vegetation rooms). In total, there is an existing 620,000 square feet of building space.

Strategic Partnerships

In addition to its Prismic acquisition, which is developing pharmaceutical applications for the ultramicronized PEA molecule and its effect within the ECS, FSD has formed strategic alliances and collaborative agreements. These relationships are with Canntab Therapeutics Ltd., SciCann Therapeutics, Solarvest BioEnergy Inc., Huge Shops, and Aura Health Inc. FSD is further pursuing alternative production methods of cannabinoids through a collaborative effort with Solarvest BioEnergy Inc. These partnerships are summarized in Figure 3 and described in brief in the accompanying section, with greater details on each partnership on pages 34 to 36.

Figure 3
STRATEGIC PARTNERSHIPS

- Canntab Therapeutics Ltd.
- SciCann Therapeutics
- Solarvest BioEnergy Inc.
- Huge Shops
- Aura Health (now called Pharmadrug Inc.)

Source: FSD Pharma Inc.

- *Canntab Therapeutics Ltd. (PILL-CSE).* Canntab Therapeutics was founded on April 20, 2016 by pharmaceutical industry professionals as the first company exclusively dedicated to R&D of oral dosage therapeutic formulations of cannabis. The company developed a unique, patent pending technology that resulted in the creation of a range of oral dosage products to effectively treat different ailments by delivering a consistent dose of medicinal cannabis extract. FV Pharma has applied to expand its license to sell CBD oil via a partnership with Canntab, hoping to bring gel caps and extended release CBD tablets to market in Canada (described on page 34).

- *SciCann Therapeutics (privately-held).* SciCann Therapeutics is a Canadian-Israeli specialty pharmaceutical company, dedicated to developing and commercializing novel and disruptive pharmaceutical products that target and modulate the endocannabinoid system. SciCann is active in the fields of oncology, pain management, neurodegenerative diseases, and inflammatory disorders, and has developed a line of proprietary products to treat life-threatening conditions.

- *Solarvest BioEnergy Inc. (SVS-TSX)*. FSD has signed a letter of intent (LOI) with Solarvest to develop and test pharma-grade cannabinoids out of algae. The pharma-grade process could reduce the production time for targeted cannabinoid molecules by up to 95%. Solarvest is an algae technology company whose production platform provides an extremely flexible system capable of being adapted to produce numerous products. The company has completed a feasibility study for the expression of **cannabidiol (CBD)** and **tetrahydrocannabinol (THC)** as a way to produce cannabinoids in sterile **Good Manufacturing Practice (GMP)** facilities. The two companies further announced in February 2020 that they have agreed to amendments to the Research Agreement, where FSD has agreed to issue additional Class B subordinate voting shares to Solarvest, which will enable Solarvest to fund the CBD Research Project. Furthermore, effective February 4, 2020, Solarvest appointed Dr. Edward J. Brennan, Jr., M.D., FACS (President of FSD Pharma's BioSciences Subsidiary) to the board of directors of Solarvest (biography on page 10).

- *Huge Shops (privately-held)*. FSD has a strategic investment in Huge Shops, a Toronto-based cannabis retailer. Huge Shops has a strategic alliance with Chairman's Brands, parent company of Coffee Time, a well-established operator of retail coffee shops with more than 75 locations in Canada and other locations worldwide. As part of the investment, Huge Shops has the option to acquire a minimum of 10 retail locations under Chairman's umbrella of properties, and, subject to availability and further negotiation, purchase additional Coffee Time sites. FSD's investment in Huge Shops is projected to facilitate the company quickly tapping into a well-established consumer base of 14 million consumers in key demographic areas throughout Ontario.

- *Aura Health (now called Pharmadrug Inc.) (BUZZ-CSE)*. In April 2019, FSD completed a share exchange transaction with Aura Health (now called Pharmadrug Inc.), a Toronto-based medical cannabis company that is building a global network of vertically integrated businesses. FSD acquired 13.56 million shares valued at $3 million from Aura Health. In addition to the share exchange agreement, Aura (through Pharmadrug Production GmbH [Pharmadrug]), entered into: (1) a consulting agreement, whereby Pharmadrug will assist the Company with obtaining euGMP certification at its Cobourg Facility; and (2) a supply agreement, whereby Pharmadrug committed to purchase Canadian produced cannabis product from the Company, provided that such product is saleable in the German market. This transaction positions FSD to establish distribution in Germany and the Eurozone.

Corporate History and Employees

On March 9, 2018, the Company executed an agreement to provide for the reverse takeover by the shareholders of FV Pharma. Following the completion of the transaction, the Company continued the medical cannabis business of FV Pharma and changed its name to "FSD Pharma Inc." On May 29, 2018, the Class B Shares commenced trading on the CSE under the trading symbol "HUGE." Its shares have since been listed and subsequently uplisted on the U.S financial markets.

On January 9, 2020, the Company's shares began trading on the NASDAQ Capital Market under the ticker symbol HUGE, joining a select group of 12 Canadian-domiciled cannabis companies that trade in the U.S. on either the NYSE or NASDAQ markets. The NASDAQ listing is expected to benefit the Company via greater institutional investor participation and overall investor recognition, as well as improved share liquidity. This is important because a large number of institutional investors are prohibited from investing client funds into OTC stocks. The opportunity to trade on a major U.S. stock exchange, where the stock price over $5.00, makes the stock an institutional grade stock. FSD currently has a strong retail base of approximately 39,000 retail investors, largely in the U.S., Canada, and Europe. The Company expects to raise additional capital in order to support its BioSciences effort.

Figure 4 (page 8) shows members of the Company's Board of Directors, members of the leadership team, early investors, advisors, and other stakeholders, ringing the NASDAQ Stock Market opening bell on Wednesday, January 22, 2020 at NASDAQ'S MarketSite in New York City. As of September 30, 2019, the Company directly employed seventeen full-time employees and five consultants.

Figure 4
FSD PHARMA INC. RINGING THE BELL AT NASDAQ ON JANUARY 22, 2020

Source: FSD Pharma Inc.

Company Leadership

FSD has made significant efforts into strengthening its management team as well as its Board of Directors and Scientific Advisory Board. Biographies of key individuals are provided in the accompanying sections. The Company recently added Dr. Larry Kaiser (biography on page 13) to its Board of Directors, a renowned cardiovascular surgeon and veteran healthcare executive, having recently been President and Chief Executive Officer of Temple Health System. For its BioSciences subsidiary, the Company has recently hired Dr. Sandra Lottes as Vice President of Clinical Research. Dr. Lottes is a Doctor of Pharmacology, with 30-plus years in drug development (biography on page 10).

Management Team

Dr. Raza Bokhari, Executive Co-Chairman of the Board and Chief Executive Officer (CEO)

Dr. Bokhari joined the Board of FSD in August 2018 and was named Executive Co-Chairman in October 2018, interim CEO in February 2019, and permanent CEO in June 2019. Dr. Bokhari has been responsible for developing and leading FSD's strategic vision. As a serial entrepreneur with demonstrated track record over the past two decades, he has developed expertise in aggregating and accelerating life sciences and healthcare services companies. An effective "change agent," with several years of experience and expertise in start-up and turn-around businesses, he has a history of turning around financially struggling companies. Dr. Bokhari also selectively consults on due diligence projects for private equity (PE) and venture capital (VC) funds that are focused on investing in life sciences/biotech and healthcare services companies. Dr. Bokhari is additionally the Chairman of PCL, a global diagnostic provider of addiction screening and opioid prescription medication monitoring, including designer drugs and synthetic cannabinoids. He is also the managing partner of RBx Capital, LP. Dr. Bokhari holds a Doctor of Medicine degree from the University of Punjab, Rawalpindi Medical College, and an Executive MBA from Temple University, Fox School of Business and Management, where he was the Chairman of the Dean's Council from 2012 to 2019. He is the Vice Chairman of the World Affairs Council of Philadelphia. He was formerly the Trustee of the esteemed Foreign Policy Research Institute and the Franklin Institute.

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

Mr. Durkacz is a Director and Executive Vice President at First Republic Capital Corporation, which he joined in January 2014. First Republic has acted as the exclusive agent of the Company and has raised approximately $53 million of equity capital to date. Previously, Mr. Durkacz was President of Capital Ideas Investor Relations and, before that, Director and CFO of Snipp Interactive Inc. (SPN-TSXV). He was instrumental in the financing and public listing of the mobile marketing company with operations in Canada, U.S., Mexico, and India. Mr. Durkacz is also the owner and President of Fortius Research and Trading Corp., which provides financial and investor relations consulting services to micro- and small-cap companies in various sectors and develops investment strategies for high net worth individuals. He further served as Chief Operating Officer (COO) and Chief Financial Officer (CFO) of MKU Canada Inc., engaging in mergers and acquisitions globally, and from 2002 to 2006, served as the CFO of Astris Energi Inc., a dually listed public company in the U.S. and Canada, which was acquired by an international conglomerate. He began his career at TD Securities on the capital markets trading floor. Mr. Durkacz holds an Honors Bachelor of Business Administration from Brock University with a major in Accounting and Finance.

Zeeshan Saeed, President, Founder and Director

Mr. Saeed is President and Director of FSD. As co-founder of FV Pharma, now wholly owned by FSD, he has been involved with the company from the earliest stages. Mr. Saeed provided consulting advice to FV Pharma and was instrumental in raising the initial seed capital. He played a key role in bringing together a team of professionals to develop the business plan as well as bringing key relationships to the Company. Mr. Saeed has experience in international capital markets and has helped various startups with the process of raising initial funding and getting listed on various stock exchanges. Before entering capital markets, he was the founder and CEO of Platinum telecommunications Inc., growing the company to a stage at which it was taken over by a public company.

Donal Carroll, CPA, Chief Financial Officer

Mr. Carroll joined FSD as Interim CFO in 2018 and was named the permanent CFO on January 2, 2020. An experienced business executive, he 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 unique insights, Mr. Carroll has successfully guided companies for expansion and growth. Throughout his tenure with Danaher, Alberto Culver (now Unilever [UL-NYSE] and Cardinal Meats), he was instrumental in major restructuring activities, mergers and acquisitions, and the implementation 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 an Independent 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 (UCD).

Dr. Edward Brennan, JR., M.D., FACS, President, FSD Pharma BioSciences, Inc.

Dr. Brennan has more than 25 years of experience in leadership roles at major pharmaceutical companies and clinical research organizations. He is an accomplished biopharmaceutical executive with a proven track record in FDA submissions and drug development. Dr. Brennan has extensive experience in all phases of clinical development across multiple therapeutic areas. As a Medical Director with Wyeth-Ayerst Research and GlaxoSmithKline, he led teams through ten IND applications and advanced multiple compounds from pre-candidate selection (proof of concept) through clinical trial management and approval. At GlaxoSmithKline, he was also responsible for coordinating all clinical activities for external partners within its Center of Excellence in External Drug Discovery. He founded IndiPharm, a full-service global contract research organization (CRO), that was eventually acquired by private equity company, Velocity Fund Partners. Dr. Brennan received an undergraduate Bachelor of Science Degree in Pharmacy from the Philadelphia College of Pharmacy and Science. He studied Medicine at the Royal College of Surgeons in Ireland before receiving his medical degree from the Temple University School of Medicine.

Dr. Sandra Lottes, Pharma D, Vice President and Head of Clinical Research, FSD Pharma BioSciences, Inc.

Dr. Lottes brings almost three decades of pharmaceutical and healthcare industry experience to the Company. Her expertise spans the drug development, commercialization, and product lifecycle continuum that makes her an important and timely addition to the FSD Pharma BioSciences team. Dr. Lottes was the vice president of global clinical development and operations at United Biosource, a subsidiary of Express Scripts Inc. She also served as a key member of ESI Pharma Services leadership team, responsible for the largest business unit across multiple global offices. Dr. Lottes earned an undergraduate degree in Biology from the University of Delaware and a doctorate from the Philadelphia College of Pharmacy & Science. She completed her post-doctorate fellowship in cardiovascular pharmacology at Hahnemann University Medical College. Dr. Lottes has authored many articles and served on advisory boards in cardiology, gastroenterology, nephrology, and biosimilars.

Dr. Sara May, Ph.D., President, FV Pharma Inc.

Dr. May is a Ph.D. graduate with a multidisciplinary background in plant breeding and crop genetics with over ten years of experience designing, implementing, and managing large-scale projects in the field, lab, and greenhouse. She has extensive work experience in all aspects of national, international, provincial, and regional legislative acts and regulations. Dr. May has deep domain expertise in the Medical Cannabis industry, including managing large scale operations, developing and implementing quality control and quality assurance methods and standard operating procedures, and Hazard Analysis and Critical Control Point (HACCP). Her prior experience is in the U.S. growing and producing high quality medical cannabis in California. She was responsible for cloning, up-keep, harvesting, processing, and selling product into licensed dispensaries. Dr. May designed a specialized crop breeding program and successfully developed two new strains of cannabis. She has co-authored ten peer-reviewed published manuscripts and is an active peer reviewer for national and international scientific journals.

Shazad Shah, Chief Operating Office, FV Pharma Inc.

Mr. Shah has a proven track record of bringing operational efficiency to organizations. In his last role, he was responsible for overseeing continuous improvement initiatives and managed a P&L of $500 million in revenue. He holds an MBA from Queen's University, Kingston Ontario, and engineering and human resources diplomas from Humber College, Toronto.

Sandy Huard, Head of Communications and Investor Relations

Ms. Huard is a marketing and communications executive, senior strategist, and consultant with over 21 years of marketing and sales experience leading national marketing teams, driving sales performance, and launching national brands in the financial services industry. Prior to joining FSD, she was head of marketing and communications for FNF Canada, the Canadian subsidiary of the largest title insurer in North America. Prior to that, she was senior sales advisor to executives and sales leaders at BMO Financial Group and was responsible for building sales capabilities and driving sales results in the branch network, the national customer contact center, and across the national specialized sales teams. She was also director of marketing and communications at Alterna Savings and director and head of marketing and communications at Computershare Trust Company of Canada. Ms. Huard holds an MBA in Finance and Marketing from the Schulich School of Business, a Bachelor of Science Education from Brandon University, and an Honors Bachelor of Science from McMaster University. She is a CTA Certified Sales Coach, a Certified Positive Psychology Coach, and a Certified DiSC practitioner. Ms. Huard is a published author and is fluent in French.

Board of Directors

The Company currently has nine board members, the majority of whom are independent and are Americans residing in different parts of the U.S. Included on the Board is a former member of U.S. Congress, who believes in the promise of the synthetic cannabinoid molecule—so much that he not only took an independent seat but also invested roughly C$250,000 in the Company in its recent raise. Biographies of each Board member are provided in the accompanying section.

Dr. Raza Bokhari, Executive Co-Chairman of the Board and Chief Executive Officer (CEO)

Biography on page 9.

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

Biography on page 9.

Zeeshan Saeed, President, Founder and Director

Biography on page 9.

Stephen Buyer, Director

Mr. Buyer was a member of the United States House of Representatives, serving nine consecutive terms from January 1993 to January 2011. During Congressman Buyer's tenure in Congress, he served on the Committees of Veterans Affairs, Armed Services, Judiciary, Energy and Commerce Committees, and also on the Military Compensation and Retirement Modernization Commission. He is presently the managing partner of the 10-Square Solution, LLC, focusing on business development, mergers and acquisitions, and representation before the federal government. Congressman Buyer served as Chairman of the Committee on Veterans Affairs for the 109th Congress, as well as the Ranking Minority Member for the 110th and 111th Congresses. He centralized the VA's IT architecture and was named to the Federal IT top 100. Congressman Buyer also served on the House Armed Services Committee from 1993 to 2001, including as Chair of the Subcommittee on Military Personnel in the 105th and 106th Congresses. He founded and co-chaired the National Guard and Reserve Components Caucus. He created the renewable energy portfolio for the Department of Defense and Veteran Affairs and was the architect of TRICARE For Life and authored

the U.S. military's pharmacy redesign. Congressman Buyer's other Congressional assignments included service on the Health, Energy, and Technology subcommittees of the Committee on Energy and Commerce from 2001 to 2010, where he assisted in creating Medicare Part D, authored the electronic pedigree pharmaceuticals distribution system, served as a House Conferee on the Telecommunications Act of 1996, and lead the Congressional effort to reorganization of the U.S. Olympic Committee. He also served the House Committee on Judiciary from 1993 to 1999. Congressman Buyer, as an Army Reserve officer, served four years on active duty, including a tour of duty in Iraq during the first Gulf War (1990-91), where he was awarded the Bronze Star as an Operational Law Judge Advocate. Prior to JAG, he was a Medical Service Corps Officer for four years. After 30 years of service, he retired with the rank of Colonel in the U.S. Army Reserve Judge Advocate General Corps. Prior to his tenure in the United States Congress, Congressman Buyer served as a Special Assistant United States Attorney, Indiana Deputy Attorney General, and engaged in a private law practice. Congressman Buyer is a distinguished military graduate of The Citadel in 1980 with a B.S. degree, and received his J.D. from Valparaiso University School of Law in 1984. He is a member of the Indiana and Virginia state Bars.

Robert J. Ciaruffoli, CPA, Director

Mr. Ciaruffoli is a co-founder and vice-chairman of Broad Street Angels, a 100 member Philadelphia-based angel investor network, which invests in start-up entrepreneurial businesses with high growth potential. Broad Street Angels is the largest angel investor network in the Philadelphia region. Mr. Ciaruffoli is a CPA and served as the chairman and CEO of the Parente Beard/Baker Tilly accounting and advisory firm. During his tenure as chairman and CEO, he and his team transitioned the firm from a Pennsylvania practice to a multi-state super-regional firm. In 2014, he orchestrated a merger of the Parente Beard and Baker Tilly Virchow Krause firms to create the 12th largest U.S. accounting and advisory firm. Mr. Ciaruffoli also served on the board of directors and executive committee of Baker Tilly International, the eighth largest global accounting network. During his tenure on the board and the executive committee, Baker Tilly International grew from an unranked network to the eighth largest global accounting network. Throughout his career, Mr. Ciaruffoli has served on numerous for-profit and not-for-profit boards. Presently, he is the President of the board of directors of The Pennsylvania Society, a board member of Ben Franklin Technology Partners, a board member of eureQa, a SaaS cloud based automated platform for testing digital applications, and a member of the finance committee of the Archdiocese of Philadelphia. He was also the past chairman of the Pennsylvania State Board of Accountancy. Mr. Ciaruffoli holds a Bachelor of Science in Accounting from Kings College, Wilkes-Barre, Pennsylvania and served in the United States Marine Corps (1970–1972).

James A. Datin, Director

Over the course of his 30-plus year career, Mr. Datin has been a successful CEO, raised capital for entrepreneurs to grow companies, and has managed companies throughout the U.S., Europe, and Asia. He has also completed more than 50 transactions, including venture investments, buyouts, acquisitions, mergers, IPOs, licensing, and partnership agreements. Mr. Datin is the current President and CEO of BioAgilytix, a leading global bioanalytical contract research organization (CRO) that supports the development of novel therapeutic biologics. Since he became CEO, BioAgilytix has grown its customer base and significantly increased its facility footprint and capacity, including expansion to Europe with the acquisition of Hamburg-based laboratory IPM Biotech. With his leadership, the company has been named to the Inc. 5000 list of Fastest Growing Private Companies in America six times, was named CRO of the Year in North Carolina, and has achieved industry-leading customer satisfaction as measured by an independent marketing firm. BioAgilytix was recently acquired by Cobepa, a PE fund. Mr. Datin was previously Executive Vice President (EVP) and Managing Director at Safeguard Scientifics, Inc., where he led the deal/investment team. He was also CEO of Touchpoint Solutions and is a former board member of Intralinks, where he chaired the audit committee. The company was acquired by TA & Associates. Mr. Datin was also Chairman of the Board for five years at Clarient, a cancer diagnostics company, when it was acquired by GE Healthcare in December 2010. In addition, he was Chairman of the Board of Laureate Pharma. Mr. Datin holds an Advanced Management Degree from the Wharton School at The University of Pennsylvania, a Master of Business Administration Degree from the University of New Haven, and a Bachelor of Business Administration Degree from Marshall University.

Gerald Goldberg, CPA, CA, Director

Mr. Goldberg, CPA, CA, has over 30 years of experience in the service, distribution, retail, mining, natural resources, and oil and gas, real estate, not-for-profit entities and manufacturing industries, with a strong emphasis in taxation and business advisory services. He was interim CEO of Canada House Wellness Group Inc. from April 2016 to December 2017. He has also been the President at Leo Acquisitions Corp. since October 2009 and serves as its CEO. He serves as the President of SLF Capital Markets Inc. He joined the accounting firm of Schwartz Levitsky Feldman LLP in 1992 and currently serves as a Senior Partner and Head of the Audit Division. Mr. Goldberg served as CEO, President, and CFO of Victory Capital Corp. until March 2017 and served as the CEO, President of Prime City One Capital Corp. until July 2016. Mr. Goldberg served as a Partner in the predecessor firm of Grant Thornton for over 15 years before he headed the U.S. Public Company audit division of Academy Capital Corp. He has also served in various roles at the following companies: Gravitas Financial Inc., Gilla Inc., Capricorn Business Acquisitions Inc., Baymount Inc., Blue Nordic Partners Inc., InterAmerican Gaming Inc., Grasslands Entertainment Inc., Pinetree Capital Ltd., Emerge Resources Corp., Lakeside Minerals Inc., and Keyuan Petrochemicals Inc.

David Urban, Director

David Urban joined the FSD Board of Directors in November 2018. He is a driven leader and board member with accomplishments leading corporate development, government affairs, coalitions, legislative influence, and political campaigns. He currently serves as President of American Continental Group (ACG), one of Washington's premier bipartisan government affairs and strategic consulting firms. Known as an innovative thinker with strong telecommunications, finance, healthcare, technology, defense, legal, trade and energy acumen, Mr. Urban has a record of demonstrated success advising business and government leaders in complex, regulated organizations, notably as an advisor to political campaigns at the highest levels, including the President of the United States, the United States Senate, and United States House of Representatives. In addition to his role as a government consultant and political advisor, Mr. Urban is a frequent contributor to CNN as a political commentator. Mr. Urban earned a Master of Public Administration degree from the University of Pennsylvania, a Juris Doctor degree from Temple University, and a Bachelor of Science degree from the United States Military Academy at West Point.

Dr. Larry Kaiser, MD, FACS, Chairman of Scientific Advisory Board and Director

Dr. Kaiser is the Dean, Lewis Katz School of Medicine at Temple University, President and CEO of Temple Health System and Senior Executive Vice President for Health Affairs at Temple University in Philadelphia and was named one of the "50 Most Influential Clinical Executives" for 2019 by Modern Healthcare. Before joining Temple University in 2011, Dr. Kaiser served as the President of the University of Texas Health Science Center at Houston. He graduated from Tulane University School of Medicine and completed a residency in general surgery as well as a fellowship in surgical oncology at UCLA. Dr. Kaiser then completed a residency in cardiovascular and thoracic surgery at the University of Toronto. Following faculty appointments at Memorial Sloan-Kettering Cancer Center and the Washington University School of Medicine, Dr. Kaiser joined the University of Pennsylvania in 1991, where he held positions including Associate Professor of Surgery, Chief of General Thoracic Surgery, Founder and Director of Penn's Lung Transplantation Program, and Director of its Center for Lung Cancers and Related Disorders. In 2001, he was named the John Rhea Barton Professor and Chairman of the Department of Surgery and the University Health System's Surgeon-in-Chief. Dr. Kaiser is the author or co-author of 16 books and more than 300 peer-reviewed papers and is a member of every major surgical society. In 2005, he was elected to the National Academy of Medicine (formerly the Institute of Medicine of the National Academy of Sciences). His recent honors include citations in Castle Connolly's America's Top Doctors for Cancer, Who's Who in the World and Philadelphia magazine's "Top Doctors," among others. Dr. Kaiser maintains time in his schedule at Temple for a limited surgical practice.

Scientific Advisory Board

The Company has formed a robust Scientific Advisory Board, made up of MDs and PhDs who are well published in clinical research in cannabinoid, mostly related to fidocannabinoid molecules. The Scientific Advisory Board is chaired by Dr. Larry Kaiser, a well know individual who is stepping down as Chairman and CEO of Temple Health System. This is significant because as FSD looks to enhance its outlook as a global cannabinoid pharmaceutical company, it is key to have an independent Scientific Advisory Board. Also, as FSD seeks to expand its intellectual property (IP) in its platform company and looks for additional targets, the role of an independent Scientific Advisory Board is essential.

Dr. Larry Kaiser, MD, FACS, Chairman and Director

Biography on page 13.

Dr. Ziva Cooper, Ph.D.

Dr. Cooper is the Research Director of UCLA's Cannabis Research Initiative in the Semel Institute for Neuroscience and Human Behavior in the Department of Psychiatry and Biobehavioral Sciences. She has been overseeing and publishing studies investigating cannabis neurobiology and dependence for over 10 years, including studies examining the effects of these drugs on experimentally induced pain. After receiving a Ph.D. in Biopsychology in 2007 in the field of preclinical psychopharmacology, she moved to Columbia University to focus on translating preclinical studies of psychoactive substances to the clinic using controlled human drug-administration studies. Dr. Cooper's current research involves understanding the neurobiological, pharmacological, and behavioral variables that influence both the therapeutic potential and adverse effects of cannabis and cannabinoids. She previously served on the National Academies of Sciences Committee on the Health Effects of Cannabis that recently published a comprehensive consensus report of the health effects of cannabis and cannabinoids. Dr. Cooper is a member of the Editorial Board of Cannabis and Cannabinoid Research, the only peer-reviewed journal entirely dedicated to the scientific, medical, and psychosocial exploration of clinical cannabis, cannabinoids, and the endocannabinoid system.

Dr. Adam Friedman, MD, FAAD

Dr. Friedman is Professor and Interim Chair of Dermatology and serves as Residency Program Director, Director of Translational Research and Director of the Supportive Oncodermatology Program in the Department of Dermatology at The George Washington University School of Medicine and Health Sciences. He graduated with Distinction in Dermatologic Research at the Albert Einstein College of Medicine in New York. Dr. Friedman is currently investigating novel nanotechnologies that allow for controlled and sustained delivery of a wide spectrum of physiologically and medicinally relevant molecules with an emphasis on treating infectious diseases, accelerating wound healing, immune modulation, and correcting vascular dysfunction. He holds multiple patents derived from these investigations and has published over 170 papers/chapters and two textbooks on both his research as well as a variety of clinical areas in dermatology with an emphasis on emerging medical therapies, including various cannabinoids. He has received multiple awards and has been on the Washingtonian Top Doctors list since 2017. Dr. Friedman's clinical interests span the array of medical and pediatric dermatology. He is frequently cited as an expert in the potential application of cannabinoid-based therapies to dermatologic disease.

Dr. Mallory Loflin, Ph.D.

Dr. Loflin is a research scientist for Veterans Affairs San Diego Healthcare System (VASDHCS) and an Assistant Professor of Psychiatry within the University of California, San Diego (UCSD) School of Medicine. Dr. Loflin's entire research career has been dedicated to the study of cannabinoids, with the aim of informing both prevention efforts for problematic use and development of cannabinoid-based therapeutics. She is currently conducting as Principal Investigator (PI) the first VA-funded cannabinoid clinical trial, "Cannabidiol as an Adjunctive to Prolonged Exposure for the Treatment of PTSD," as part of a Career Development Award (CDA-2) funded by VA Clinical Science Research & Development (CSR&D). Dr. Loflin is also a co-investigator and consultant on four other ongoing cannabis and cannabinoid research studies, and currently holds a DEA research registration for schedule 1 controlled substances at VA San Diego. She is currently engaged in training efforts for advanced specialization in private-public drug development as part of her CDA-2 award's training plan.

Dr. Ken Mackie, MD

Dr. Mackie is Professor and Linda and Jack Gill Chair of Neuroscience in the Department of Psychological and Brain Sciences at Indiana University, and Adjunct Professor of Anesthesiology at the Indiana University School of Medicine. Dr. Mackie earned an MD at Yale University and completed his residency in anesthesiology at the University of Washington. Trained as a clinician-scientist, his research for the past 25 years has focused on identifying GPCR signaling pathways, investigating the regulation of these pathways, and understanding cannabinoid receptor function in health and disease. Throughout this time, he has served as training faculty on 32 grants both at the University of Washington and Indiana University, and has worked on several collaborative and interdisciplinary studies. He has been a member of the American Society of Anesthesiologists since 1987 and a member of the International Cannabinoid Research Society since 1992. He is a recipient of the Mechoulam award for lifetime contributions to cannabinoid research and has been twice recognized by Thompson-Reuters/Clarivate Analytics in the Top 1% of cited researchers. Dr. Mackie is a member of the Editorial Board of Cannabis and Cannabinoid Research.

Dr. Daniel Piomelli, Ph.D.

Dr. Piomelli is the Louise Turner Arnold Chair in Neurosciences and Distinguished Professor of Anatomy and Neurobiology, Pharmacology and Biological Chemistry at the University of California, Irvine, where he is also the Director of the Center for the Study of Cannabis. He has authored more than 400 peer-reviewed articles in high-impact journals, three full-length books, and 34 patents and founded the Department of Drug Discovery and Development at the Italian Institute of Technology in Genoa, Italy, which he directed from 2007 to 2016. He is Editor-in-Chief of Cannabis and Cannabinoid Research.

Dr. Ryan Vandrey, Ph.D.

Dr. Vandrey is an experimental psychologist and an Associate Professor at the Behavioral Pharmacology Research Unit at Johns Hopkins University. Dr. Vandrey's research focuses primarily on the impact of route of administration, dose, and chemical composition of cannabis products on resultant drug effects and pharmacokinetics. In addition, Dr. Vandrey has been involved with a broad range of studies related to the risks and benefits of medicinal cannabis use, the effects of cannabis use on sleep, cannabis withdrawal and the treatment of Cannabis Use Disorder, cannabis product testing, and developing measures of cannabis use behavior.

Dr. Sara Jane Ward, Ph.D.

Dr. Ward is Assistant Professor in the Center for Substance Abuse Research and Department of Pharmacology at the Lewis Katz School of Medicine at Temple University. She earned a PhD in neuroscience at Wake Forest University, studying the neurobiology of cocaine and heroin addiction and their interactive effects. She conducted her own NIH-funded research under a postdoctoral fellowship at the University of North Carolina at Chapel Hill and Temple University, where she began to study the role of cannabinoids in learning and memory and reward processing. Dr. Ward is currently working on several projects to elucidate the therapeutic potential of non-psychoactive cannabinoids using animal models of CNS injury and disease. She has received funding from both the National Institutes of Health and Department of Defense investigating the efficacy of cannabidiol for the treatment of peripheral and central neuropathic pain. Other projects ongoing in her laboratory investigate the efficacy of cannabidiol and synthetic cannabinoids on a range of nervous system targets, including stroke, traumatic brain injury, dental pain, and substance use disorders.

Intellectual Property

FSD seeks to protect its proprietary position by filing patent applications in the U.S. and abroad related to ultramicronized-PEA 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 plans to strengthen its intellectual property (IP) portfolio by extending their validity through the use of the **Hatch-Waxman Act**. 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.

A key part of the Company's IP was achieved through its acquisition of Prismic Pharmaceuticals. Prismic has the worldwide rights (except for Italy and Spain) for ultramicronized-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 5. Patents related to ultramicronized PEA on its own are essentially composition and use patents. The combination patents include issued patents for ultramicronized PEA in combination with opioids for pain and ultramicronized PEA in combination with silymarin for the treatment of chronic kidney disease.

Figure 5

EPITECH GROUP ULTRAMICRONIZED PEA PATENT POSITION

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

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

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

Core Story

CANNABIS OVERVIEW

Also known as marijuana, cannabis is a psychoactive drug derived from the Cannabis plant (cannabis sativa, Figure 6) and has had a long history of use in medicine. Dating back thousands of years to treat a variety of ailments, cannabis has been used medicinally in ancient Indian, Chinese, Egyptian, and Islamic cultures. Evidence suggests that it was first used medicinally around 400 AD. In more recent times, within the U.S., cannabis was widely utilized as a patient medicine during the 19th and early 20th centuries, described in the United States Pharmacopoeia for the first time in 1850 (Figure 7). However, Federal restriction of cannabis' use first occurred in 1937 with the passage of the Marihuana Tax Act of 1937. Cannabis was dropped from the United States Pharmacopoeia in 1942, with legal penalties for possession increasing in 1951 and 1956 with the enactment of the Boggs and Narcotic Control Acts, respectively, and prohibition under federal law occurring with the Controlled Substances Act of 1970. Beyond criminalization, these legislative actions contributed to creating limitations on research by restricting procurement of cannabis for academic purposes (Source: *Pharmacy and Therapeutics*, Vol. 42(3):180–188, 2017).

Figure 6

CANNABIS PLANT

Source: WebMD.com.

Figure 7

CANNABIS HISTORICAL MEDICINAL USE

Source: Wikipedia.

In 1985, however, the FDA approved dronabinol and nabilone (two synthetic cannabinoid-based medicines) for therapeutic use, and as a result, cannabinoids were reintroduced into the medical research ingredients. Today, the medicinal cannabis market is in its infancy as industry and academic experts have yet to identify all the potential uses for the plant (Source: National Academies of Sciences, Engineering, and Medicine's *The Health Effects of Cannabis and Cannabinoids*, 2017). Current studies are assessing its effectiveness in a wide range of diseases and symptoms, including cancer, chronic pain, depression, arthritis, diabetes, glaucoma, migraines, epilepsy, multiple sclerosis (MS), Acquired Immunodeficiency Syndrome (AIDS), Amyotrophic Lateral Sclerosis (ALS), Alzheimer's disease, posttraumatic stress disorder (PTSD), Parkinson's disease, Tourette's, and other neurological conditions.

Cannabinoids

The cannabis plant has been shown to be chemically rich, with 565 known constituents belonging to 23 classes of compounds. Perhaps the most recognized class of compounds in cannabis are the namesake cannabinoids, with 120 different cannabinoids, plant-derived molecules unique to cannabis, identified in the cannabis plant (Source: *International Review of Psychiatry*, Vol. 30(3): 277–284, 2018). Delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) are the main chemicals used in medicine. CBD is widely used for medical purposes due to its non-psychotic effect and low levels of toxicity, whereas THC—the substance primarily responsible for the psychoactive effects of cannabis—is utilized, for example, to reduce the side-effects of AIDS and cancer treatment (Source: University of Washington's Alcohol and Drug Abuse Institute [ADAI]).

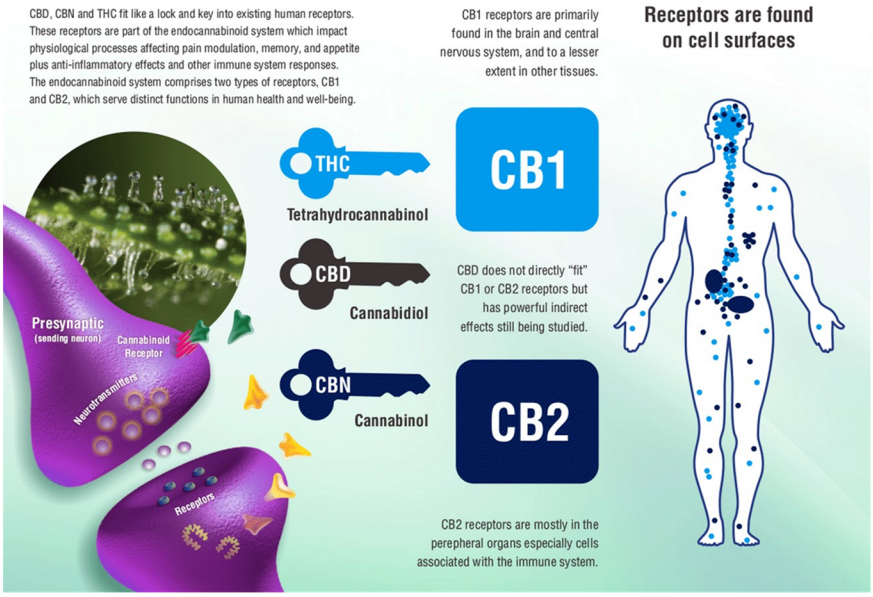
Like opiates (substances derived from the opium poppy, such as heroin), cannabinoids affect the user by interacting with specific receptors located throughout the body: nervous system, internal organs, connective tissues, glands, and immune cells. To date, two kinds of cannabinoid receptors have been found, termed **CB1** and **CB2**. Naturally occurring substances that bind to these receptors, known as **endocannabinoids**, have since been discovered, and these, together with the receptors, are termed the "endocannabinoid system (ECS)."

The Endocannabinoid System (ECS)

The endocannabinoid system (ECS) is a complex cell-signaling biological system identified in the early 1990s and composed of three core components: endocannabinoids, receptors, and enzymes (Figure 8). The ECS remains under preliminary research, but studies reveal it may be involved in regulating a broad range of physiological and cognitive processes, including pain, stress, appetite, energy, metabolism, inflammation, cardiovascular function, learning and memory, reproduction and fertility, muscle formation, bone remodeling and growth, liver function, and sleep. These functions all contribute to **homeostasis**, which refers to stability of the body's internal environment.

Figure 8

THE ENDOCANNABINOID SYSTEM (ECS)



Source: www.the-human-solution.org.

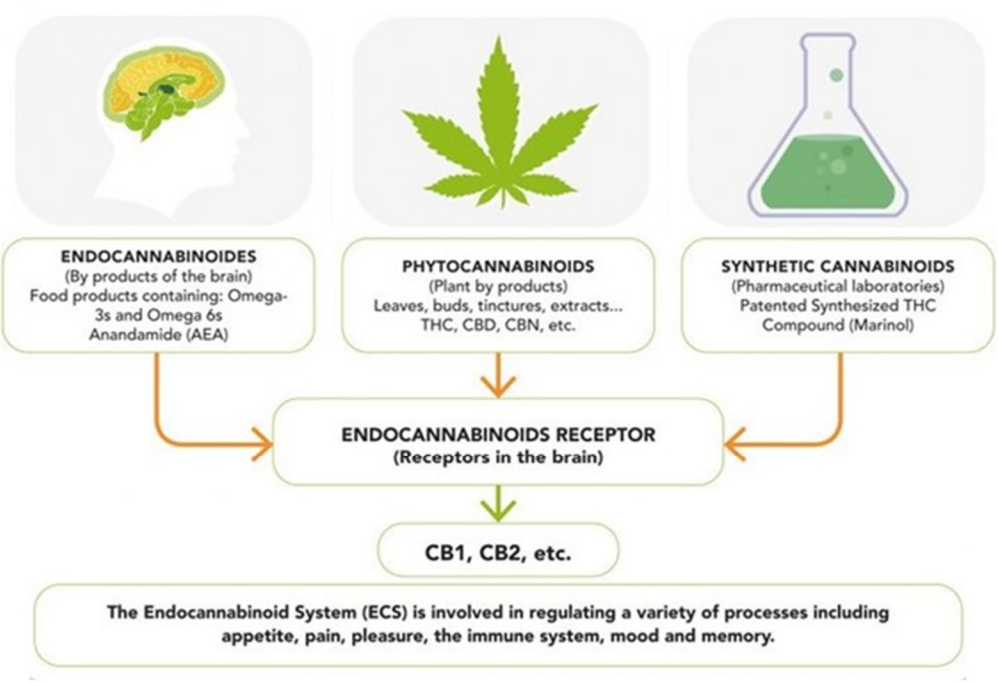
Many of the effects the ECS are mediated by two cannabinoid receptors: Cannabinoid receptor type 1 (CB1) and Cannabinoid receptor type 2 (CB2), although additional receptors may be involved. CB1 is expressed in the peripheral nervous system and central nervous system and mediate many of the psychoactive effects of cannabinoids. CB2 is expressed primarily in immune cells that travel throughout the body and plays an important role in fighting inflammation. These receptors sit on cell surfaces, waiting for specific neurotransmitters to bind to them, resulting in different effects on the body depending on the neurotransmitter and location of the receptor.

The neurotransmitters that the ECS use are called endocannabinoids—substances produced from within the body that activate cannabinoid receptors. Two of the main endocannabinoids are anandamide, considered the primary activator of CB1, and AG-2, which binds to both the CB1 and CB2 receptors with similar affinity. The use of cannabis for medical applications rely on the interaction of the plant-derived cannabinoids with the ECS. For example, THC also binds with CB1, resulting in cannabis' psychoactive effect. Although CBD does not directly trigger either receptor, it modifies the receptors' ability to bind to other cannabinoids.

Endocannabinoids have been found to play a role in the pathology of many disorders. It has been proposed that migraine, fibromyalgia, irritable bowel syndrome (IBS), and other related conditions represent **clinical eCB deficiency syndromes (CEDS)**. Deficiencies in eCB signaling could be also involved in the pathogenesis of depression, schizophrenia, multiple sclerosis (MS), Huntington's disease, Parkinson's disease, anorexia, chronic motion sickness, and failure to thrive in infants (Source: *Pharmacy and Therapeutics*, Vol. 42(3):180–188, 2017). Medical cannabis may provide natural or synthetic cannabinoids that interact with the ECS in a way that results in a positive therapeutic effect (Figure 9).

Figure 9

CANNABINOIDS EFFECT MECHANISM



Source: Kalapa Clinic.

Medical Cannabis

Medical cannabis refers to the use of cannabis or cannabinoids as medical therapy to treat disease or alleviate symptoms. The plant can be used in three different ways: (1) direct use of cannabis—with the most common methods of administration being inhalation via smoking, inhalation via vaporization, and ingestion of edible products; (2) cannabis-based products—therapeutic agents containing cannabis or cannabinoids derived from the cannabis plant (e.g., THC and/or CBD); and (3) synthetic cannabinoids—therapeutic agents containing synthetically produced cannabinoids, which typically mimic the effects of the natural ingredients.

Until recently, cannabis and its derivatives were widely restricted under legislation stating they had no medical value and carried a substantial risk of misuse. However, efforts have been underway to expand legalization of cannabis both in North America as well as globally. Policy is rapidly changing, and cannabis can now be prescribed for medicinal use in many countries. According to the U.S. Government Accountability Office, under State Medical Marijuana Laws, symptoms and conditions that can be treated by cannabis include Alzheimer's disease, eating disorders such as anorexia, HIV-AIDS, glaucoma, cancer, arthritis, epilepsy, nausea, pain, cachexia, Crohn's disease, migraines, MS, spasticity, and wasting syndrome, as well as some mental health conditions, such as schizophrenia and PTSD.

As a result, there are currently three cannabis-based therapeutic agents approved by the FDA. Two synthetic cannabinoid-based medicines—dronabinol (Marinol [manufactured by AbbVie, Inc.], Syndros [manufactured by Insys Therapeutics, Inc.]) and nabilone (Cesamet [manufactured by Meda Pharmaceuticals, Inc.]), to treat nausea and vomiting from chemotherapy—and the cannabidiol drug Epidiolex® (made by GW Pharmaceuticals), an oral formulation of purified cannabidiol for the treatment of seizures associated with two rare and severe forms of epilepsy, **Lennox-Gastaut syndrome**, and **Dravet syndrome**. Approved in 2018, Epidiolex® is the first cannabis plant-derived medicine ever approved by the FDA. In addition, GW Pharmaceuticals also markets Sativex®—the world's first prescription medicine derived from the cannabis plant—an **oromucosal** spray for the treatment of spasticity due to MS, which is now approved in over 25 countries outside of the U.S.

These developments reflect the increasing awareness and acknowledgement by scientists and policy makers of the therapeutic potential of cannabis and the role the cannabis industry could play in improving public health. Internationally, the United Nations has called for a change in how cannabis is scheduled throughout the world. In February 2019, its global health agency—the World Health Organization (WHO)—recommended that cannabis and its key components be rescheduled under international drug treaties after having analyzed their epidemiological, pharmacological, chemistry, toxicology, and therapeutic impacts (Source: Medical Marijuana, Inc.'s *Industry Overview*).

Furthermore, a nationwide poll showed that 68% of voters in the U.S. support legalizing adult use marijuana without additional constraints, while a recent Quinnipiac University poll concluded 81% of respondents favored legalization of cannabis for medicinal purpose. A 2014 WebMD/Medscape survey of 1,544 doctors also found that 80% of physicians supported medical cannabis legalization. These results reveal nationwide support for marijuana to now be at an all-time high (Source: *Pharmacy and Therapeutics*, Vol. 42(3):180–188, 2017; and Medical Marijuana, Inc.'s *Industry Overview*).

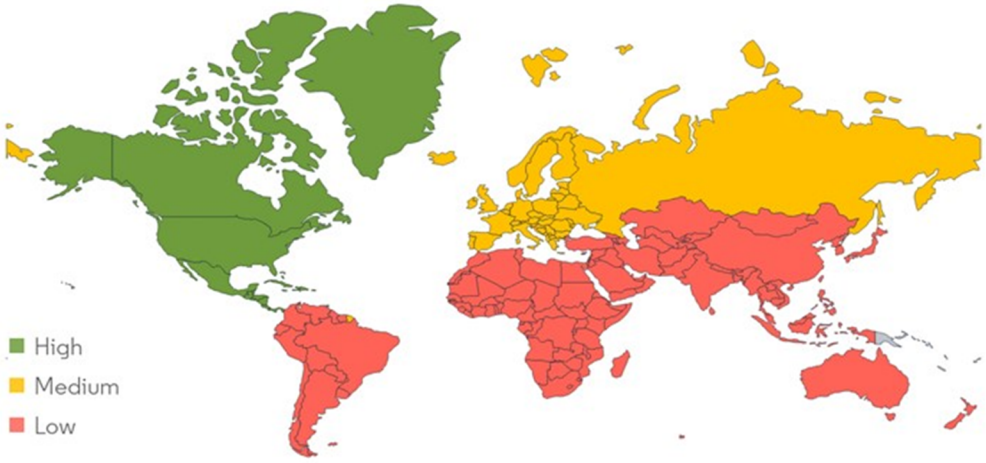
Medical Cannabis Market

The global legal cannabis market, including both recreational and medical use, is expected to reach $66.3 billion by the end of 2025, with an anticipated CAGR of 23.9% (Source: Grand View Research's *Legal Marijuana Market Size, Share & Trends Analysis Report by Type, By Product Type, By Medical Application, And Segment Forecasts, 2019 - 2025*, May 2019). Within this market, medical cannabis holds the largest share, with the worldwide medical cannabis market estimated at $13.4 billion in 2018 and expected to reach $44.4 billion by 2024 (Source: IMARC Group's *Medical Cannabis Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2019-2024*, April 2019). The growth in the medical cannabis market is fueled by two main factors: (1) increasing legalization of cannabis, and (2) growing adoption of cannabis as a pharmaceutical product.

Increasing legalization of cannabis is anticipated to promote industry growth. The first country that completely legalized marijuana was Uruguay in 2013, followed by Canada in 2018. Many countries have legalized the use of cannabis for medicinal purposes, with varying degrees of legal restriction, including Argentina, Australia, Brazil, Canada, Chile, Colombia, Germany, Israel, Italy, the Netherlands, Portugal, the United Kingdom, and the U.S., among others (Source: Mordor Intelligence's *Cannabis Market - Growth, Trends, And Forecast [2020–2025]*). On a geographical front, North America enjoys the leading position in the market, as shown in Figure 10 (page 21).

Figure 10

CANNABIS MARKET GROWTH - BY REGION



Source: Mordor Intelligence.

Recent legalization of cannabis in North America for both recreational and medical purposes has been a major driver for the market growth in the region. Canadian marijuana companies dominate the global market as a direct result of the legalization of cannabis in Canada in 2018. In the U.S., ten states have legalized cannabis for recreational use and 33 states plus the District of Columbia have legalized cannabis for medical purposes.

Another factor driving the legalization efforts in the U.S. is the additional government revenue through taxation. Some recent examples of annual taxation revenue at the state level in 2018 include: Washington ($319 million), California ($300 million), Colorado ($266 million), Oregon ($64.4 million), Nevada ($69.8 million), Alaska ($11 million), and Massachusetts ($5.2 million). If marijuana were to be legal on the federal level, the U.S. Treasury would be able to collect a significant sum of money (Source: Insider Monkey's *25 Biggest Marijuana Companies in the World*, August 13, 2019).

On the medical front, growing clinical evidence of cannabis' medical properties and potential therapeutic applications is expected to increase demand based on its potential for treating severe medical conditions. Cannabis is also found to enhance the effectiveness or to combat negative side effects of other therapeutic compounds. For instance, cannabis is effective in reducing nausea and increasing appetite among chemotherapy patients. Similarly, it is also used in combination with traditional opioid painkillers, which enables patients to significantly reduce the dosage and frequency of opioids, and also imparts greater pain relief (noting that this is the application being addressed through FSD's development efforts). A steadily rising ageing population has further played a significant role in driving the demand for medical cannabis, as geriatric patients are more likely to develop chronic illnesses and require more physician visits.

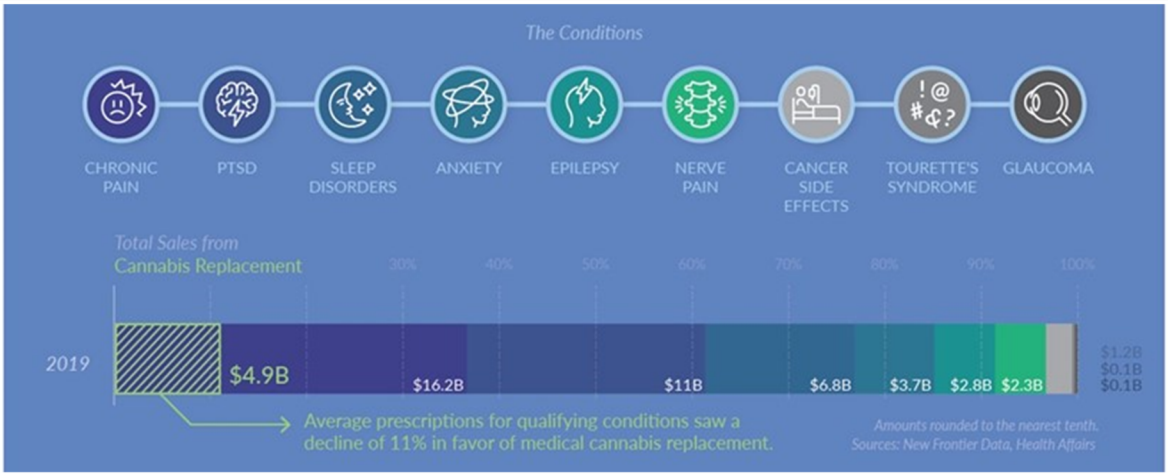
Large Pharmaceutical Companies and the Cannabis Industry

Until now, the largest pharmaceutical companies in the world have mostly watched the cannabis industry from the sidelines, deterred by regulatory concerns. However, as evidence of cannabis' benefits mounts, so does the interest from the global pharmaceutical industry. The cannabis industry could represent a needed source of growth for countless companies. Entry by large pharmaceutical companies into this space not only brings significant investment and research capabilities into the cannabis market, but also accelerates public understanding and confidence in cannabis as a viable option for a range of ailments, further fueling the growth of the industry.

A key factor driving the entry of big pharmaceutical companies into the cannabis market is the fact that further legalization of cannabis could challenge pharmaceutical companies' bottom line, as it could go after more than $4 billion in sales annually. In fact, medical cannabis sales are projected to reach $5.9 billion in 2019, from an estimated 24 million patients. Figure 11 illustrates the different conditions that medical marijuana is able to treat and the current spending within each segment, demonstrating that large pharmaceutical companies have a significant incentive to enter the market to reduce the threat medical marijuana poses to their market share and profit (Source: Visual Capitalist's *The Big Pharma Takeover of Medical Cannabis*, August 12, 2019).

Figure 11

PRESCRIPTION MEDICATION SPENDING BY CONDITION



Sources: Visual Capitalist and New Frontier Data, Health Affairs.

As the cannabis industry continues to advance and data regarding its effectiveness to treat different conditions expands, it's no surprise that many pharmaceutical giants have already formed partnerships with cannabis companies, with some even making their own way into the industry.

Novartis AG (NVS-NYSE) and Tilray, Inc. (TLRY-NASDAQ)

In December 2018, Novartis, through its generic drug division, Sandoz, signed an agreement with Tilray Canada to develop and distribute medical cannabis products in legal jurisdictions around the world. The expanded agreement allows Sandoz to commercialize Tilray's non-smokable products globally, to cobrand products, and to promote the products to pharmacists and physicians. Although a handful of alcohol and tobacco companies have announced partnerships in the growing cannabis industry, Novartis is the first pharmaceutical firm to publicly enter the space.

Tilray engages in the research, cultivation, production, and distribution of medical cannabis and cannabinoid products worldwide. Its products include dried cannabis and cannabis extracts. It also supplies cannabis products to patients in a number of countries spanning five continents through its subsidiaries in Australia, Canada, and Germany, and it produces medical cannabis in Canada and Europe. The company was founded on January 24, 2018 and is headquartered in Nanaimo, Canada.

Teva Pharmaceutical Industries Ltd (TEVA-NYSE) and Canndoc (a subsidiary of Intercure Ltd [IRCLF-OTC])

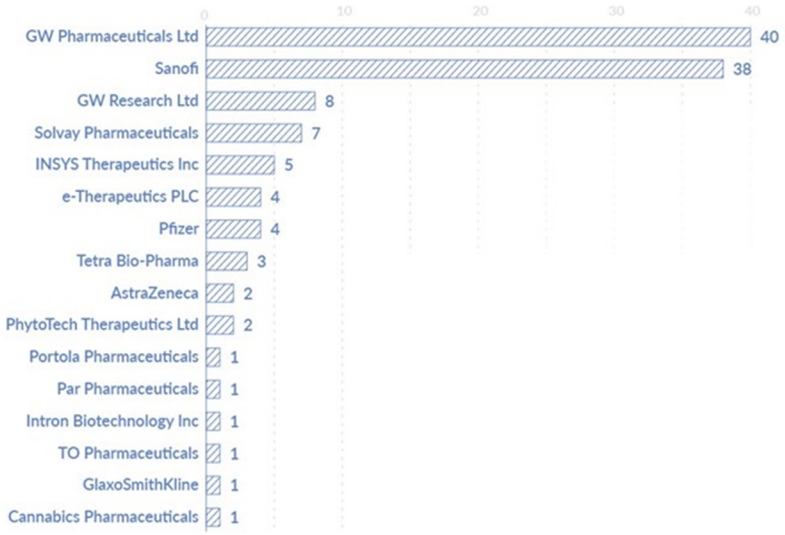
In September 2019, Teva's subsidiary Salomon, Levin, Elstein, better known as S.L.E., and Canndoc, a subsidiary of Intercure Ltd, executed a strategic distribution agreement, under which Teva's subsidiary will distribute Canndoc's GMP products to its customers, which include hospitals, health maintenance organization (HMOs), and pharmacies in Israel. The agreement also allows S.L.E. to provide logistics capability to export Canndoc's products to countries where sale and distribution of medical cannabis products are legalized.

Other Large Cap Pharma Participants

Johnson & Johnson has also made strides into the cannabis market. In 2017, the company's incubator, JLABS @ Toronto, admitted a cannabinoid biotech research company for the first time ever. Beyond specific deals, several big pharmaceutical companies have registered cannabinoid-related clinical trials in the U.S. and Canada or have conducted research with cannabis-related compounds. The U.S. National Library of Medicine's ClinicalTrials.org lists more than 350 completed or on-going clinical trials in cannabis medicine, as seen in Figure 12 (Source: Investor's Business Daily's *Which Biopharma Stocks Are Looking To Score Big In Cannabis Medicine?* January 2019). Following the top position by cannabis-company GW Pharmaceuticals, large pharmaceutical companies, including Sanofi S.A. (SNY-NASDAQ), Solvay Pharmaceuticals, and Pfizer, Inc. (PFE-NYSE) are among the leaders in terms of registered trials.

Figure 12

NUMBER OF CANNABINOID CLINICAL TRIALS BY SELECTED COMPANIES (as of June 2018)



Source: Clinical Trials, Cannabis Business Executive.

This trend continues when analyzing the cannabis-related patent positions in both Canada and the U.S. Seven of Canada's top 10 cannabis patent holders are major multinational pharmaceutical companies, with Novartis and Pfizer leading the way, as seen in Figure 13. A similar situation occurs with cannabis-related patents in the U.S. AbbVie stands out as a leader—as it is the only large pharmaceutical company that markets a cannabis-based drug, Marinol (dronabinol), a synthetic form of THC that treats certain types of nausea and anorexia, and on the market since 1985—followed by companies such as Sanofi SA (SNY-NASDAQ), Merck & Co. Inc. (MRK-NYSE), and Bristol-Myers Squibb Company (BMY-NYSE).

Figure 13
CANNABIS PATENTS

Company Rank	Canadian Patents	Company Rank	U.S. Patents
1. Novartis	21	1. AbbVie	59
2. Pfizer	14	2. Sanofie	39
3. GW Pharmaceuticals	13	3. Merck	35
4. Ericsson	13	4. Bristol-Myers Squibb	34
5. Merck	11	5. GW Pharmaceuticals	28
6. Solvay Pharmaceuticals	7	6. Pfizer	25
7. Kao Corporation	7	7. Hebrew University of Jerusalem	19
8. Ogeda SA	7	8. Roche	17
9. Sanofi	6	9. University of Connecticut	16
10. University of Connecticut	6	10. U.S. Health and Human Services	13

Source: New Frontier Data.

ADDRESSING CHRONIC PAIN

Chronic pain—pain lasting beyond the normal healing time and persisting or recurring for longer than three months—affects an estimated 20% of the world's population and accounts for nearly one fifth of physician visits. It often becomes the predominant clinical problem in some patients and its burden on patients, on healthcare systems, and on society has been clearly demonstrated. Furthermore, management of chronic pain is made more difficult by its multifactorial origins, including its close relationship with inflammation (Source: *Pain Therapy*, Vol. 7(1):59-75, 2018).

Neuroinflammation in both the peripheral and central nervous systems plays an important role in the pathogenesis of chronic pain. Inflammation is a natural protective cellular process aimed at removing harmful and injurious stimuli and is an integral immune response needed to initiate healing. However, there are occasions in which the inflammatory response itself damages host tissue and causes organ dysfunction. Researchers now believe that inflammation related problems are caused not by how often inflammation starts, but how often it fails to subside. Non-resolving inflammation is one of the principal contributors to the medical burden in industrialized societies. Inflammation is particularly insidious in cases where the peripheral and central nervous systems are involved (neuroinflammation), playing an important role in the pathogenesis of chronic pain, as well as chronic neurodegenerative diseases and neuropsychiatric illness. Thus, therapeutic targeting of the inflammatory response is an area of intense research activity (Source*: Journal of Neuroinflammation*, Vol. 11:136, 2014).

For many chronic pain conditions, the standard of care is the long-term use of analgesics that were originally developed for acute pain. Among these are opioids, which comprise natural, semi-synthetic, or synthetic analgesic molecules with a pharmacological action similar to opium. However, long-term use of opioids is accompanied by decreasing levels of analgesic response (opioid tolerance), necessitating dose escalation to manage pain. In addition to the development of tolerance, opioid use can paradoxically lead to **hyperalgesia**, or enhanced pain response where a patient becomes more sensitive to pain. This is because prolonged exposure to opioid therapeutic agents can lead to exacerbation of pro-inflammatory and **pro-nociceptive** processes and promote, over the long-term, opioid-induced hyperalgesia and tolerance.

Furthermore, the needed increase in dosage due to the development of tolerance increases the possibility of opioid abuse, as well as other adverse events (e.g., over-sedation, respiratory depression, etc.). The use of opioids has evolved to the point of becoming an epidemic of abuse, with increasing overdose deaths involving prescription of opioid pain relievers (Source: *Pain Therapy*, Vol. 7(1):59-75, 2018).

There is a growing body of evidence to support the use of medical cannabis as an adjunct to or substitute for prescription opiates in treating chronic pain. Research shows that opiates and cannabinoids use overlapping signaling systems in the body relating to drug tolerance, pain, and dependence. This common mechanism would support the fact that when used in conjunction with opiates, cannabinoids lead to a greater cumulative relief of pain, resulting in a reduction in the use of opiates (and associated side-effects).

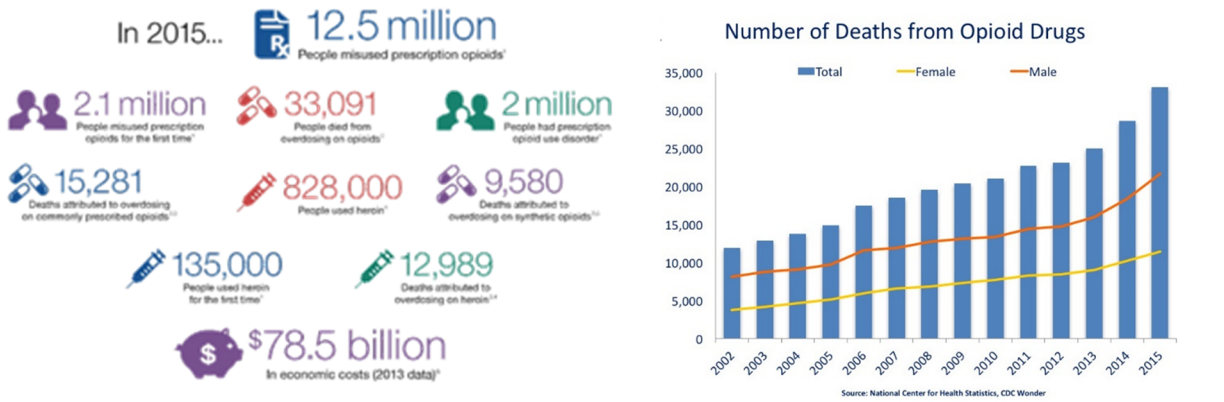
Prescription Drug Overdose and Opioid Epidemic

Opioids are a class of drugs that include prescription pain relievers, heroin, and synthetic opioids, such as **fentanyl**. All opioids are chemically related and interact with opioid receptors on nerve cells in the brain and nervous system to produce pleasurable effects and relieve pain. The misuse of opioids and its addiction are a serious national crisis that affects public health as well as social and economic welfare. In May 2017, during the new FDA Commissioner Scott Gottlieb's first all-hands address to agency staff, he declared the opioid abuse epidemic as the agency's "greatest immediate challenge." Drug overdose deaths and opioid-involved deaths continue to increase in the U.S., with the majority of drug overdose deaths (more than six out of ten) involving an opioid.

As depicted in Figure 14, every day, more than 130 people in the U.S. die after overdosing on opioids, resulting in approximately 47,600 deaths in 2017 (68% of all drug overdose deaths), a nearly six-fold increase since 1999. From 1999 to 2017, more than 700,000 people died from a drug overdose, with approximately 400,000 of those deaths attributed to opioid overdose (Source: Centers for Disease Control and Prevention [CDC]).

Figure 14

THE OPIOID EPIDEMIC IN THE U.S.



Sources: U.S. Department of Health & Human Services and NIH's National Institute on Drug Abuse.

Overdose death is not the only risk related to prescription opioids. Misuse, abuse, and opioid use disorder (addiction) are also potential dangers. During 2016, over 2.1 million people in the U.S. suffered from substance use disorders related to prescription opioid pain relievers. Approximately 1 in 4 of the people who receive prescription opioids for non-cancer pain struggles with addiction, with 21% to 29% of patients prescribed opioids for chronic pain misusing them. In 2016, more than 11.8 million Americans reported misusing prescription opioids. (Sources: CDC National Center for Injury Prevention and Control's *Annual Surveillance Report of Drug-Related Risks and Outcomes,* 2018).

The Centers for Disease Control and Prevention (CDC) estimates that the total economic burden of prescription opioid misuse in the U.S. is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement (Source: NIH's National Institute on Drug Abuse).

Overdoses from prescription opioids—drugs like oxycodone, hydrocodone, and methadone—are a driving factor in the increase in opioid overdose deaths, with the number of opioid prescriptions filled moving in tandem with opioid overdose deaths. The amount of prescription opioids sold in the U.S. has more than tripled from 1999 to 2017, without an overall change in the amount of pain people reported, with more than 523,000 opioid prescriptions dispensed daily in 2017 (Source: CDC National Center for Injury Prevention and Control's *Annual Surveillance Report of Drug-Related Risks and Outcomes,* 2018).

Medical Cannabis Role in the Opioids Crisis

There is growing evidence to support the use of medical cannabis as an adjunct to or substitute for prescription opiates in treating chronic pain. To date, over 28 randomized clinical trials have documented that cannabinoid agents are effective analgesics for chronic pain. An Expert Review Committee assembled by the National Academy of Sciences (NAS) in 2017 concluded that there is substantial evidence that cannabis is an effective treatment for chronic pain in adults (Source: University of Washington's Alcohol and Drug Abuse Institute [ADAI]: *Role of Medicinal Cannabis as Substitute for Opioids in Control of Chronic Pain: Separating Popular Myth from Science and Medicine*).

Research shows that opiates and cannabinoids use overlapping signaling systems in the body, which has to do with drug tolerance, pain, and dependence. This common mechanism would support the fact that when used in conjunction with opiates, cannabinoids lead to a greater cumulative relief of pain, resulting in a reduction in the use of opiates (and associated side-effects) by patients in a clinical setting (Source: *Journal of Psychoactive Drugs*, Vol. 44(2):125-33, 2012).

Further research indicates the use of medical cannabis as a substitute for opioids. In an online questionnaire of 1,248 cannabis users, 46% reported using cannabis as a substitute for prescription drugs; the most frequent substitution was narcotics/opioids (35.8%). In another survey of 2,897 cannabis patients, approximately 30% (n=841) reported using an opioid-based pain medication currently or in the past six months; of these, 61% were also using cannabis. The majority of these patients (97%) reported using less opioids when using cannabis and experienced more tolerable side effects with cannabis than with opioid medications alone (92%). They also reported preferring cannabis to opioids to treating their condition and would consider choosing only cannabis if it was more readily available (93%) (Source: University of Washington's Alcohol and Drug Abuse Institute [ADAI]: *Role of Medicinal Cannabis as Substitute for Opioids in Control of Chronic Pain: Separating Popular Myth from Science and Medicine*).

Studies also measured the effect of cannabis on the number of opioid prescriptions. A longitudinal analysis of the number of opioid prescriptions filled under Medicare Part D showed that when medical marijuana laws went into effect in a given state, opioid prescriptions fell by 2.21 million daily doses filled per year. When medical marijuana dispensaries opened, prescriptions for opioids fell by 3.74 million daily doses per year. These reductions in daily opioid doses were particularly notable for hydrocodone (Vicodin) and morphine prescriptions. Another study analyzed Medicaid prescription data from 2011 to 2016, and showed that states with implemented medical marijuana laws have seen a 5.88% lower rate of opioid prescribing; when they implemented adult-use (i.e., recreational use) marijuana laws, there was a 6.38% reduction in opiate prescribing (Source: Harvard Medical School's *Access to medical marijuana reduces opioid prescriptions*, May 2018).

Fewer prescriptions and lower usage of opioids due to medical cannabis availability and use has a direct effect on opioid overdose deaths. An association between medical marijuana laws and decreased opioid-related mortality has been documented in a well conducted study published in 2014. The authors compared opioid analgesic overdose mortality from 1999 to 2010 in 50 U.S. states with and without legal access to medical cannabis. They found that states with medical cannabis laws had a 24.8% lower annual opioid overdose mortality rate compared to states without medical cannabis laws. Furthermore, this decrease generally strengthened over time, with mortality rates decreasing in each year after medical cannabis law implementation, reaching a 33% reduction in the six years after medical marijuana was legalized (Source*: JAMA Internal Medicine*, Vol. 174(10):1668-1673, 2014).

Synthetic Cannabinoids

Accumulating evidence suggests that the endocannabinoid system (ECS) is a promising target for treating a variety of health conditions through the development of novel therapeutics. Accordingly, two paths of cannabinoid drug development have emerged. One approach is focused on developing medications that are derived directly from the cannabis plant, while the other focuses on a single molecule approach, where individual or novel cannabinoids with therapeutic potential are identified and synthesized for pharmaceutical development. The later approach provides significant advantages. Though approximately 120 naturally occurring cannabinoids have been identified, they are finite and somewhat limited with respect to their pharmacological effect. On the other hand, hundreds of cannabinoids have been synthesized and characterized, including substances that are chemically identical to the cannabinoids found naturally in the cannabis, in addition to novel molecules not found in nature. Medicinal chemists are therefore able to modify known cannabinoid molecules in order to target specific pharmacological effects, resulting in medications that have a very specific mechanisms of action.

Synthetic cannabinoids can provide further advantages in the manufacturing of a pharmaceutical-grade therapeutic agent. Quality control for synthetically derived, single molecule medications is much easier, and is the standard for the pharmaceutical industry, as these pharmaceutical products are free from impurities associated with plants like mold, pesticides, and heavy metals. This also results in advantages in clinical testing, as synthetic molecules offer a consistent and pure product, avoiding the variations of naturally occurring cannabinoids in terms of strength and purity, and eliminating variables that could complicate the clinical trial process. That being said, identification of target molecules, especially novel synthetic molecules, requires a rigorous and lengthy pre-clinical screening process that is entirely different than what is required for botanical cannabis products and the route to which FSD Pharma, through its BioSciences division, is pursuing in seeking to address the opioid crisis.

FSD PHARMA, INC.

FSD Pharma Inc. ("FSD" or "the Company") is a specialty biotech pharmaceutical company focused on developing high-quality, indoor-grown, pharmaceutical-grade cannabis, with particular attention being placed on creating a pipeline of FDA-approved synthetic compounds that target the endocannabinoid system (ECS) of the human body. The Company is specifically targeting certain diseases of the central nervous system, as well as autoimmune disorders of the skin, gastrointestinal (GI) tract, and musculoskeletal system.

The Company operates two subsidiaries: (1) FSD BioSciences, focused on developing a robust pipeline to deliver highly effective products to safely address pain, inflammation, and neurological disorders (with a goal of improving patient outcomes with FDA approval prescription medications); and (2) FV Pharma, focused on producing and extracting high-quality, hydroponic, pharmaceutical-grade cannabis leaf. The common thread between the two subsidiaries is the ultimate impact on the ECS via its derivative cannabinoids.

FSD's BioSciences subsidiary is targeting the rapidly growing synthetic pharmaceutical cannabinoid market. The cannabis plant has been shown to be chemically rich, with 565 known constituents belonging to 23 classes of compounds, with the most recognized class of compounds in cannabis being the cannabinoids, with 120 different cannabinoids, plant-derived molecules unique to cannabis. These cannabinoids, along with many other elements may have their own therapeutic value, where the components bind to and/or interact with receptors throughout the body to produce wide-ranging physiologic effects. While the mechanisms of action from the various cannabinoids is not yet fully understood, it is believed that they work by mimicking the effects of the body's own cannabinoids, or endocannabinoids. FSD seeks to target diseases/syndromes where cannabinoids may prove more effective than alternative treatments and is concentrated on the high-value pharmaceutical-grade cannabis market.

FV Pharma is a Licensed Producer under Canada's Cannabis Act and Regulations, receiving its cultivation license on October 13, 2017 and its full Sale for Medical Purposes license on June 21, 2019. The Company is licensed to cultivate cannabis in its Cobourg, Ontario facility (the former Kraft Foods Company plant) and has achieved roughly C$260,000 in sales from medical cannabis during its most recent quarter (4Q 2019).

FSD BioSciences, Inc.

In June 2019, FSD acquired U.S.-based specialty pharmaceutical company Prismic Pharmaceuticals, Inc., which now forms a part of FSD's BioSciences subsidiary, dedicated to developing novel non-addictive prescription drugs to treat pain and inflammation. Patient populations with chronic pain continue to grow and are underserved, with current treatment costs approaching $650 billion per year. Led by Peter Moriarty, a founder of Shire Pharmaceuticals, Prismic has built a solid foundation for a specialty pharmaceutical company, where FSD is now working towards advancing proprietary drug candidates through the various development and regulatory stages.

Prismic's goal is to address the opioid crisis with formulations utilizing ultramicronized palmitoylethanolamide's (PEA) "entourage" effect on certain drugs that impact the ECS. PEA is an endogenous fatty acid amide that has demonstrated to bind to a receptor in the cell nucleus and exert a variety of biological functions related to chronic pain and inflammation. The entourage effect proposes that PEA can produce *indirect* receptor-mediated effects as well as activate transient intracellular signaling channels.

Prismic holds exclusive licensing rights to a type of PEA, which forms a base for the Company's lead development platform to formulate its lead candidate, a 600mg ultramicronized PEA tablet. PEA interacts with endocannabinoid receptors throughout the body, including the central nervous system, and is a naturally occurring anti-inflammatory in response to inflammation. Micronization is a process of reducing the average diameter of a solid material's particles to allow it to be orally bioavailable. Invented by Epitech of Italy, the micronization technique is protected by patents until 2030.

FSD seeks to conduct a pharmaceutical R&D program with ultramicronized PEA initially through the Prismic drug asset with the goal of advancing additional pharmaceutical development programs. These efforts are based on a biologic plausibility of an efficacious cannabinoid effect with a high safety profile. On March 9, 2020, the Company announced receipt of approval from the Ethics Committee of the Alfred Hospital, part of the Alfred Health group of hospitals serving the state of Victoria in Australia, to initiate a Phase 1, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, and pharmacokinetics of single and multiple ascending doses of ultramicronized-PEA in normal healthy volunteers. This study is expected to total nearly C$2 million, plus another C$1 to run toxicology studies to satisfy some FDA requirements. FSD expects the safety and tolerability to come back with positive datapoints since ultramicronized-PEA has been used for years as a prescription-based medical food supplement in Italy and Spain and other parts of Europe. While there are restrictions in the U.S. for using plant-based phytocannabinoid molecules in R&D, it is worth noting that GW Pharmaceuticals, which is the leader in this space, has brought one cannabis-derived drug to market, called Epidiolex®, with a market cap of $5 billion. Greater details on GW's efforts are provided on page 41. While GW's R&D is plant-based, FSD BioSciences is a synthetic cannabinoid platform.

PEA Overview

One approach to overcome the problem created by prolonged opioid use (hyperalgesia, tolerance, and abuse) may be the addition of another agent that effectively either reduces the development of tolerance or potentiates the drug efficacy, thus allowing the use of lower doses of opioids, especially if the agent has its own inherent anti-inflammatory and pain relieving effects. Resolution of inflammation is driven in part by the secretion of soluble products, including lipid-mediated signaling molecules. 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 demonstrates 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 endoneural 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).

PEA and Opioid Interaction

A key differentiator between classical steroidal and non-steroidal anti-inflammatory drugs and PEA is the fact that PEA's ability to act as anti-inflammatory and pain-relieving agent is modulated by its direct effect on the inflammation process as well as its indirect mechanisms. The later relies on PEA's interactions with the ECS, which in turn influences the response to opioids through the opioid system since opiates and cannabinoids use overlapping signaling systems in the body having to do with drug tolerance, pain, and dependence. 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 cannabinoid 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).

The most compelling experimental evidence to date to support the use of PEA and opioids in a single therapy is the demonstration of delayed development of tolerance to the anti-nociceptive effects of morphine with the repeated administration of both compounds. In the study, 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, whereas control animals needed 31 days for full recovery. PEA's ability to strengthen the efficacy and potency of morphine analgesia, allowing prolonged and effective pain relief with low doses, suggest the use of PEA in association with morphine for chronic pain therapies may be beneficial (Source: *Frontiers in Pharmacology*, Vol. 9:473, 2018).

However, the lipophilic nature and large particle size of PEA in the native state may limit 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, limiting its effectiveness and bioavailabilty 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. A study designed to evaluate the oral anti-inflammatory efficacy of micronized/ultramicronized (particle size 0.6µm - 10µm) versus nonmicronized PEA formulations (particle size 100µm - 2000µm) demonstrated ultramicronized PEA to display a superior oral efficacy compared to naïve (non-micronized) PEA. In an inflammation model in rats, accumulation of infiltrating inflammatory cells and increased myeloperoxidase activity were significantly decreased by orally given ultramicronized PEA, but not nonmicronized PEA. In addition, edema and thermal hyperalgesia were markedly and significantly reduced by oral treatment with ultramicronized PEA compared to nonmicronized PEA. However, when given by the **intraperitoneal** route, all PEA formulations proved effective. These findings illustrate the superior anti-inflammatory action exerted by orally administered ultramicronized PEA, versus that of nonmicronized PEA (Source: *Journal of Neuroinflammation*, Vol.11:136, 2014).

Summary of Select PEA Papers

The accompanying section provides a summary of select PEA review and opioid sparing papers as well as provides a summary of select PEA efficacy and bioavailability papers, as published to date.

PEA Review

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 ultra-micronized 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 ultra-micronized). Preclinical and human studies indicate that micronized or ultra-micronized 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

Ultramicronized 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 ultramicronized 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 ultramicronized PEA treatment on 35 patients with Burning Mouth Syndrome. During the study, a statistically significant reduction of burning mouth sensation was registered in the ultramicronized 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 ultramicronized 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 ultramicronized -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.

Palmitoylethanolamide, a Special Food for Medical Purposes, in the Treatment of Chronic Pain: A Pooled Data Meta-analysis.
(Source: *Pain Physician*, Vol. 19(2):11-24, 2016).

The study performed a pooled meta-analysis of 12 studies to evaluate the efficacy of micronized and ultramicronized PEA on pain intensity in patients with chronic and/or neuropathic pain. Results showed that PEA elicits a significant progressive reduction of pain intensity. Noteworthy, serious adverse events were not reported in any of the studies. These results confirm that PEA represents a new therapeutic strategy to manage chronic and neuropathic pain associated with neuroinflammation.

Bioavailability

Oral Ultramicronized Palmitoylethanolamide: Plasma and Tissue Levels and Spinal Antihyperalgesic Effect.
(Source: *Frontiers in Pharmacology,* Vol. 9:249, 2018).

The study evaluated oral ultramicronized PEA bioavailability compared to naïve PEA. The study showed that, in both healthy rats and those subjected to an inflammatory stimulus, orally administered ultramicronized PEA had a more favorable absorption profile compared to naïve PEA, resulting in higher PEA plasma levels. Notably, ultramicronized PEA down-regulated distinct spinal inflammatory and oxidative pathways, providing deeper understanding of the mechanisms involved in the anti-hyperalgesic effect of ultramicronized PEA.

Micronized/ultramicronized palmitoylethanolamide displays superior oral efficacy compared to nonmicronized palmitoylethanolamide in a rat model of inflammatory pain.
(Source: *Journal of Neuroinflammation,* Vol. 11:136, 2014).

The present study evaluates the oral anti-inflammatory efficacy of ultramicronized PEA versus nonmicronized PEA formulations. In an inflammation model in rats, accumulation of infiltrating inflammatory cells and increased myeloperoxidase activity were significantly decreased by ultramicronized PEA, but not nonmicronized PEA. In addition, edema and thermal hyperalgesia were significantly reduced with ultramicronized PEA compared to nonmicronized PEA. However, when given by the intraperitoneal route, all PEA formulations proved effective.

FV PHARMA

FV Pharma, FSD's wholly owned subsidiary, is a Licensed Producer under Canada's Cannabis Act and Regulations, receiving its cultivation license on October 13, 2017 and its full Sale for Medical Purposes license on June 21, 2019. The Company is licensed to cultivate cannabis at its facility and intends to cover all aspects of the cannabis industry, including cultivation, legal, processing, manufacturing, extracts, and R&D. The facility has an electrical sub-station on site, natural gas lines, multiple water-intakes, rail lines directly into the facility, and 26 loading docks. On August 21, 2019, FSD announced that its online ordering system for the direct fulfillment of prescriptions of dried medicinal cannabis was operative through www.fvpharma.com, noting that sales are limited to Canadian prescription base consumers. Individuals are required to have a prescription from a medical practitioner or a registration number with Health Canada in order to place an order. During the fourth quarter, FV Pharma reported approximately C$260,000 from the sale of medical cannabis. FV Pharma has applied to expand its license to sell CBD oil via a partnership with Canntab, hoping to bring to market in Canada gel caps and extended release CBD tablets.

Production Facility (Former Kraft Food Facility)

FSD's cannabis production facility, which is the former Kraft Foods facility, is located in Cobourg, Ontario, one-hour east of Toronto, where it is easily accessible. The facility is supported by sufficient infrastructure to conduct its operations (over 70-acres, with 40 acres primed for development) and received its standard processing and full sales licenses from Health Canada in 2019.

Specialized Knowledge and Personnel

Expertise and knowledge on the subject of cultivating and growing medical cannabis is vital to the industry. The nature of growing cannabis is not so different than growing other agricultural products. Variables such as temperature, humidity, lighting, air flow, watering, and feeding cycles are defined and controlled to produce consistent product and avoid contamination. The product is cut, sorted, and dried under specified conditions that are established to protect the activity and purity of the product. Once the processing is complete, each batch is tested to quality specifications that are set for activity and purity.

President and a director of FV Pharma, Dr. Sara May (biography on page 10), is a Ph.D. graduate with a multidisciplinary background in plant breeding and crop genetics. She has over ten years of experience designing, implementing, and managing large-scale projects in the field, lab, and greenhouse. She has deep expertise in the medical cannabis industry, having previously worked in Santa Cruz, California for large scale growers with medical licenses. Dr. May's experience includes managing large scale operations, developing, and implementing quality control and quality assurance methods, as well as standard operating procedures. She has co-authored ten peer-reviewed published manuscripts and is an active peer reviewer for national and international scientific journals.

STRATEGIC PARTNERSHIPS

FSD has formed strategic alliances and collaborative agreements. These relationships are with Canntab Therapeutics Ltd., SciCann Therapeutics, Solarvest BioEnergy Inc., Huge Shops, and Aura Health Inc. FSD is also pursuing alternative production methods of cannabinoids through a collaborative effort with Solarvest. These partnerships are summarized in Figure 15 and detailed in the accompanying section.

Figure 15
STRATEGIC PARTNERSHIPS

Source: FSD Pharma Inc.

Canntab Therapeutics Ltd. Collaboration

On July 10, 2018, FSD announced that it had entered into a non-binding LOI with Canntab. Subsequently, on September 18, 2018, the Company announced that it had entered into a definitive collaboration agreement dated effective September 17, 2018. Under the terms of the Canntab Agreement, the Company will assist Canntab in obtaining a license to process and sell cannabis products pursuant to the Cannabis Act and will provide Canntab with up to 10,000 square feet of space at the Company's facility. Canntab will build and install, at its expense, its own manufacturing facility within the facility that will operate in accordance with GMP, intended to produce a suite of novel cannabis oral dose delivery platforms, including gel capsules and tablets, and other types of cannabis-based products, including sleep aids and pain relievers. The Canntab products are expected to be produced initially as samples, which Canntab will submit to Health Canada for approval prior to launching production and sales. Canntab expects to begin manufacturing at FSD's facility in the fourth quarter of 2019.

Along with this agreement, Canntab has granted the Company certain royalty and profit-sharing rights in connection with the sale of the Canntab products, where Canntab will provide FSD with 50% of the profits that Canntab receives on any retail sales of Canntab products through channels that are established by the Company, and the Company will be entitled to retain 50% of the profits from the sales of Canntab products effected by the Company. In addition, for any Canntab products not sold, Canntab will pay the Company a royalty of 3.5% of Canntab's sale price for all Canntab products that are manufactured and sold from the Canntab area of the facility. As part of the agreement, Canntab also agreed to purchase certain quantities of cannabis oils from the Company at cost, plus a mark-up, until such time that Canntab receives its license. Founded on April 20, 2016 by pharmaceutical industry professionals, Canntab is a Canadian cannabis oral dosage formulation company based in Markham, Ontario, engaged in the R&D of advanced pharmaceutical-grade formulations of cannabinoids. The company developed a unique, patent pending technology that resulted in the creation of a range of oral dosage products to effectively treat different ailments by delivering a consistent dose of medicinal cannabis extract.

SciCann Therapeutics Strategic Partnership

SciCann Therapeutics is a Canadian-Israeli specialty pharmaceutical company dedicated to developing and commercializing novel and disruptive pharmaceutical products that target and modulate the endocannabinoid system. The company is active in the fields of oncology, pain management, neurodegenerative diseases, and inflammatory disorders, and is developing a line of proprietary products to treat life-threatening conditions that present a high level of unmet need. On June 6, 2018, the Company announced that FV Pharma had made an investment into SciCann Therapeutics under which the Company invested C$2 million and owns 10.52% of SciCann.

Solarvest BioEnergy Collaborative Research Agreement

On May 7, 2019, FSD announced the signing of a LOI with Solarvest BioEnergy Inc. to develop and test pharmaceutical-grade cannabinoids out of algae. The process could reduce the production time for targeted cannabinoid molecules by up to 95%. Solarvest is an algae technology company whose production platform provides it with an extremely flexible system capable of being adapted to produce numerous products. The Company and Solarvest have allocated an initial budget of $1 million for the research project over a two-year period and created a joint scientific review committee to assess progress of the project against budgets and timelines. The company has completed a feasibility study for the expression of CBD and THC as a way to produce cannabinoids in sterile GMP facilities. If development of proof of concept that algae can express the Project Cannabinoids is achieved, Solarvest and FSD intend to enter into a license agreement under which Solarvest will grant the Company an exclusive, worldwide license over any use of prescription drugs that can treat diseases affecting the central nervous system using a subset of the Project Cannabinoids.

In consideration for the license, the Company will be required to pay Solarvest a royalty equal to 5% of the net profits from the sale of such products as well as reimburse Solarvest for the cost of production. In addition to the licensing agreement, Solarvest will pay a royalty fee to FSD on the sale or licensing of any products that result from the project, other than the Company's licensed indications, equal to 5% of the net sales or net license fees. Once Solarvest has paid an aggregate of $3 million in royalty fees, the royalty percentage will be reduced to 3%. If the Project Cannabinoids are found to develop successfully in algae, then it may allow for the Company to manufacture pharmaceutical grade cannabinoid molecules at a fraction of the cost and time required to develop cannabinoids by standard cultivation and processing methods.

In connection with this agreement, (1) the Company issued 49,751 Class B Shares to Solarvest, at a deemed price of $60.30 per Class B Share, (2) Solarvest issued 3,000,000 units to the Company, at a deemed price of $0.25 per unit, with each unit being comprised of one common share in the capital of Solarvest and one share purchase warrant with an exercise price of $0.25 and a term of two years, and (3) Solarvest issued a convertible debenture to the Company in the principal amount of $2.4 million (the debenture has a five-year term, bears interest of 3% per annum, and is convertible into shares at a conversion price of $1.00 per share, provided that the Company will be required to convert the debenture should Solarvest shares close at a price of at least $1.20 for a period of 20 consecutive trading days). The Company determined (at period ended September 30, 2019) the value of Solarvest's shares in FSD has fallen below the minimum value, therefore a derivative liability of $2.2 million was recorded. The two companies announced in February 2020 that they have agreed to amendments to the Research Agreement, where FSD has agreed to issue additional Class B subordinate voting shares to Solarvest, which will enable Solarvest to fund the CBD Research Project. In addition, effective February 4, 2020, Solarvest appointed Dr. Edward J. Brennan, Jr., M.D., FACS (President of FSD Pharma's BioSciences Subsidiary, biography on page 10) to the board of directors of Solarvest.

Huge Shops

FSD has a strategic investment in Huge Shops, a Toronto-based cannabis retailer. Huge Shops has a strategic alliance with Chairman's Brands, parent company of Coffee Time, a well-established operator of retail coffee shops with more than 75 locations in Canada and other locations worldwide. As part of the investment, Huge Shops has the option to acquire a minimum of 10 retail locations under Chairman's umbrella of properties, and, subject to availability and further negotiation, purchase additional Coffee Time sites. FSD's investment in Huge Shops is projected to facilitate creating a network with a well-established consumer base of 14 million consumers in key demographic areas throughout Ontario.

Pharmadrug Inc. (Aura Health Inc.)

In April 2019, FSD completed a share exchange transaction with Aura Health (now called Pharmadrug Inc.), a Toronto-based medical cannabis company that is building a global network of vertically integrated businesses. FSD acquired 13.56 million shares valued at $3 million from Aura Health. In addition to the share exchange agreement, Aura, through Pharmadrug Production GmbH (Pharmadrug), entered into: (1) a consulting agreement, whereby Pharmadrug will assist the Company with obtaining euGMP certification at the facility; and (2) a supply agreement, whereby Pharmadrug committed to purchasing Canadian produced cannabis product from the Company, provided that such product is saleable in the German market. Pharmadrug is one of the few cannabis distribution license holders in Germany. Strategically this opens another channel for the Company to distribute cannabis products in the German market where prices for cannabis are often higher than in Canada. Subsequent to September 30, 2019, Aura announced a name change to Pharmadrug Inc.

Milestones

Recently Achieved Milestones

The Company has recently achieved the following key milestones:

- ***Signed an agreement in 2Q19 to acquire U.S.-based specialty R&D pharmaceutical company, Prismic Pharmaceuticals***. Prismic is focused on developing non-addictive prescription drugs to treat pain and inflammation and address the opioid crisis. Its efforts are based on formulations employing ultramicronized palmitoylethanolamide (PEA).

- ***Approval to initiate Phase I study.*** On March 9, 2020, the Company announced receipt of approval from the Ethics Committee of the Alfred Hospital, part of the Alfred Health group of hospitals serving the state of Victoria in Australia, to initiate a Phase 1, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, and pharmacokinetics of single and multiple ascending doses of ultramicronized-PEA in normal healthy volunteers.

- ***Raised C$4.5 million in December 2019.***

- ***Obtained the following licenses***

    - Sale for Medical Purposes License from Health Canada

    - Access to Cannabis for Medical Purposes Regulations (ACMPR) Cultivation License in the Province of Ontario

    - Standard Processing License in the Province of Ontario

    - Secured from Epitech, worldwide license (except Italy and Spain) to research, develop, and commercialize ultramicronized PEA formulations, including FDA approved prescription medications.

- ***Under FV Pharma, FSD launched an online ordering system to fulfill orders under FVPharma.com.***

- ***Formed strategic alliances with:***

    - ***Huge Shops***: Option to acquire at least 10 retail locations

    - ***Aura Health***: Sourcing medical cannabis for Germany/Eurozone pharmaceutical and synthetic cannabinoids for a variety of clinical applications

    - ***Canntab Therapeutics***: Oral dosages of medical-grade cannabinoids

    - ***SciCann Therapeutic***: Help develop cannabinoid-based drugs for inflammatory disorders; robust cannabinoid research network in Israel

    - ***Solarvest BioEnergy***: R&D for proof of concept that pharmaceutical-grade cannabinoids can be created by algal expression technology

- ***Continued to strengthen its management team, Board of Directors, and Scientific Advisory Board.*** CEO, Dr. Raza Bokhari, officially became the Company's CEO in June 2019 after serving as the Company's interim CEO. The Company recently added Dr. Larry Kaiser to its Board of Directors, a renowned cardiovascular surgeon and veteran healthcare executive, having recently been President and Chief Executive Officer of Temple Health System. For its BioSciences subsidiary, the Company recently hired Dr. Sandra Lottes as Vice President of Clinical Research. Dr. Lottes is a Doctor of Pharmacology, with 30-plus years in drug development.

Recent Conferences and Attended Forums

- Bio CEO Investor Conference in New York (February 10, 2020)
- 11th Annual Biotech Showcase in San Francisco (January 7, 2019)
- Arcview Cannabis Investor Forum in Vancouver (April 25, 2019)
- 2019 BIO International Convention in Philadelphia (June 4, 2019)
- MJ Link Micro Investor Conference in New York City (June 25, 2019)
- 10th Global Family Office Investment Summit in Dubai (November 24, 2019)
- Swiss Cannabis Institute Investment Conference in Zurich & Geneva (November 26-27 2019)
- 12th Annual LD Micro Investor Conference in Los Angeles (December 11, 2019)

Potential Milestones in 2020

In the coming months, FSD expects to report progress on its internal initiatives as well as its external partnerships, as described in the accompanying section. Some of the milestones that could be forthcoming include:

FSD Pharma BioSciences

- Report clinical trial results for human safety and tolerability for lead candidate, FSD201
- Conduct clinical trials for animal safety and pharmacology of ultramicronized-PEA.
- Secure an IND from the FDA to begin Phase II trials looking into applications of ultramicronized-PEA, specifically for early-stage osteoarthritis and endometriosis.
- Continue to bolster R&D platform, focused on cannabinoids and their potential for widespread clinical applications, developing FDA-approved medications that could be commercialized internationally.
- Augment $50 million cash on balance sheet by monetizing non-cash assets and raising new capital through a PIPE and registered offering.

Partnerships

- ***Solarvest.*** Develop proof-of-concept that algae can express pharmaceutical-grade cannabinoids through biosynthesis.
- ***Canntab Therapeutics.*** Begin manufacturing commercial batches of oil-filled gel capsules at Cobourg facility.
- ***Canntab Therapeutics.*** Receive approval by Health Canada of XR tablet.
- ***Continue to pursue acquisition targets***. There are between 30 to 40+ companies focused on synthetic cannabinoid research with promising results that have come up through Phase 2 or Phase 2A/2B, though some may be running out of money. FSD believes it may be able to provide a better platform joining with these companies.

Investment Highlights

- ***FSD Pharma Inc. is a specialty biotech pharmaceutical company focused on developing a pipeline of synthetic compounds targeting the endocannabinoid system (ECS) of the human body.*** The Company is seeking to bring to market commercial FDA approved cannabinoid-based and endocannabinoid system (ECS)-targeting pharmaceuticals to treat certain diseases of the central nervous system and other autoimmune diseases.

- ***FSD recently acquired U.S.-based specialty research and development (R&D) pharma company, Prismic Pharmaceuticals.*** With the goal of developing non-addictive prescription drugs to treat pain and inflammation to address the opioid crisis, Prismic is developing an ultramicronized formulation of palmitolylethonalamide (PEA) or ultramicronized-PEA. PEA is a naturally occurring anti-inflammatory agent that is expected to be effective for many inflammatory ailments, including chronic pain, arthritis, and fibromyalgia, among others. Micronization of PEA improves its oral bioavailability, with this technique protected by patents until 2030.

    - On March 9, 2020, FSD announced that it had received approval from the Ethics Committee of the Alfred Hospital, part of the Alfred Health group of hospitals serving the state of Victoria in Australia, to initiate a Phase 1, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, and pharmacokinetics of single and multiple ascending doses of ultramicronized-PEA in normal healthy volunteers.

    - Patient populations with chronic pain continue to grow though remain underserved, with current treatment costs approaching $650 billion per year (Source: American Physical Therapy Association).

- ***The Company has a diversified business model, which helps lessen risk.*** FSD seeks to de-risk investment by securing therapeutic assets that target large markets with significant unmet need.

- ***In addition to its Prismic acquisition, FSD has formed strategic alliances and collaborative agreements.*** These relationships are with Canntab Therapeutics Ltd., SciCann Therapeutics, Solarvest BioEnergy Inc., Huge Shops, and Aura Health Inc. FSD is also pursuing alternative production methods of cannabinoids through a collaborative effort with Solarvest.

- ***FSD has begun medical sales under the Sales for Medical Purposes License as of August 2019, achieving approximately C$260,000 during the most recent quarter.*** The Company is now waiting for the additional amendments to be able to sell the dried flower as well as a license for the sale of oil-based products. This ties in with partner Canntab Therapeutics such that FSD can begin selling their sustained-release tablets being produced through their patent pending technology.

- ***Drug development is led by industry veterans and backed by industry leaders.*** Edward Brennan, MD, FACS, President of BioSciences Subsidiary, has three decades of experience coming from Johnson & Johnson and Glaxo SmithKline, where he was successful in identifying and developing promising clinical candidates. Dr. Charles Pollack Jr., chairman of the Scientific Advisory Board, is an expert in synthetic cannabinoid research, having been the founder of The Lambert Center for the Study of Medicinal Cannabis and Hemp at Thomas Jefferson University, in Philadelphia.

- ***Worldwide patents protected for ten more years.*** The Company's intellectual property (IP) portfolio covers ultra-micronized composition-of-matter and use features U.S. patent expiration dates ranging from 2029 to 2034.

- ***FSD is well positioned financially.*** As of December 31, 2019, FSD had C$7.9 million in cash.

Competition

Companies developing cannabis-based therapeutic compounds face substantial competition. As FSD continues to develop and commercialize its cannabis-based products, it may encounter competition from other specialty (cannabis-specific) pharmaceutical companies, as well as large pharmaceutical companies and biotechnology companies worldwide that enter the cannabis space. Potential competitors 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.

As evidence of cannabis' effectiveness and the public perception and acceptance increases, the medical marijuana market will expand, resulting from increased legalization of cannabis products and relaxed legislation regarding research and development (R&D) of cannabis-based therapeutic options, both prescription and over-the-counter (OTC). This could lead to an increase in levels of competition within the overall cannabis market in two fronts. As more countries pass laws that allow for the production and distribution of medical cannabis, it increases import and export competition from international cannabis producers. Furthermore, as evidence of cannabis' many benefits increases, so does the interest from the global pharmaceutical industry. The entrance of the large pharmaceutical companies into the cannabis market will transform the cannabis industry. This could lead to an increase in patents, partnerships, and sponsored clinical trials of cannabis-based technologies as big pharmaceutical companies ink deals with cannabis firms, or even make their own forays into the space. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Accordingly, the list of companies presented in this Competition section is not in any way an exhaustive collection of the Company's competitors. However, it is believed to be a sample of the type of competition that FSD may face as it strives to commercialize its technologies and product candidates.

Arena Pharmaceuticals, Inc. (ARNA-NASDAQ)

Arena Pharmaceuticals is a biopharmaceutical company that focuses on providing novel medicines with pharmacology and pharmacokinetics to patients worldwide. Arena is a clear example of a major pharmaceutical company entering the cannabis-based therapeutic market. Its pipeline includes Olorinab (APD371), the company's first cannabinoid-related product candidate, which is an oral, peripherally acting, highly selective, full agonist of the cannabinoid receptor 2 (CB2) in Phase II for the treatment of gastrointestinal pain. Arena was founded in 1997 and is based in San Diego, California.

Botanix Pharmaceuticals Limited (BXPHF-OTC)

Botanix Pharmaceuticals is a cannabinoid therapeutics company leveraging the unique anti-inflammatory, immune-modulating, and antimicrobial properties of synthetic cannabidiol for the development of therapeutics for serious skin diseases. Botanix's product pipeline includes five programs focused on safe and effective topical treatments for serious skin diseases: BTX 1503, a transdermal gel formulation for the treatment of serious acne in adults and teenagers; BTX 1308, a transdermal gel formulation for the treatment of plaque psoriasis; BTX 1204, a transdermal gel formation for the treatment of atopic dermatitis; BTX 1701, a novel product for mild acne; and BTX 1801, a novel antimicrobial. The company has an exclusive license to use a proprietary drug delivery system, called Permetrex™, for direct skin delivery of active pharmaceuticals, a delivery technology it uses in all its product candidates. The company is based in North Perth, Australia.

Cara Therapeutics, Inc. (CARA-NASDAQ)

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors (KORs). Cara is developing a novel and proprietary class of product candidates, led by KORSUVA™ (CR845/difelikefalin), a first-in-class KOR agonist that targets the body's peripheral nervous system, as well as certain immune cells. In Phase 2 and Phase 3 trials, KORSUVA injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in hemodialysis patients with moderate-to-severe chronic

kidney disease-associated pruritus (CKD-aP), and is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Additionally, it is being studied orally in Phase 2 trials for chronic kidney disease associated pruritus stage 3-5, chronic liver disease associated pruritus, and atopic dermatitis associated pruritus. Cara Therapeutics was founded in 2004 and is headquartered in Stamford, Connecticut.

Corbus Pharmaceuticals Holdings, Inc. (CRBP-NASDAQ)

Corbus Pharmaceuticals is a clinical-stage pharmaceutical company that leverages its pipeline of endocannabinoid system-targeting drug candidates for the development and commercialization of various therapeutics to treat rare, chronic, and serious inflammatory and fibrotic diseases. Its lead product candidate is lenabasum, a synthetic oral endocannabinoid drug designed to resolve chronic inflammation and fibrotic processes. The compound is in Phase 3 clinical trial for the treatment of systemic sclerosis and dermatomyositis, and in Phase 2 clinical trial to treat systemic lupus erythematosus and cystic fibrosis. The company also has a license to develop, manufacture, and market CRB-4001, a 2nd generation peripherally restricted CB1 inverse agonist, which is in a preclinical stage to treat liver, lung, heart, and kidney fibrotic diseases. In addition, it has a strategic collaboration with Kaken Pharmaceutical Co., Ltd. for the development and commercialization of lenabasum in Japan. Corbus is headquartered in Norwood, Massachusetts.

Emerald Bioscience, Inc. (EMBI-OTC)

Emerald Bioscience is a biopharmaceutical company focused on the discovery, development, and commercialization of new chemical entities and bioengineered cannabinoid-based therapeutics for unmet medical needs. With proprietary technology licensed from the University of Mississippi, Emerald is developing novel ways to deliver cannabinoid-based drugs for specific indications with the aim of optimizing the clinical effects of such drugs while limiting potential adverse events. Emerald's strategy is to clinically develop a number of proprietary biosynthetic compounds, alone or in combination with corporate partners. The company's lead product candidate is NB1111 for the treatment of glaucoma. Its product pipeline also comprises NB2222 for the treatment of dry eye syndrome, macular degeneration, and diabetic retinopathy; and NB3000 for the treatment of methicillin-resistant Staphylococcus aureus (MRSA). The company was formerly known as Nemus Bioscience, Inc. and changed its name to Emerald Bioscience, Inc. in March 2019. Emerald Bioscience was founded in 2012 and is headquartered in Long Beach, California.

GW Pharmaceuticals, plc (GWPH-NASDAQ)

GW Pharmaceuticals is a biopharmaceutical company focused on discovering, developing, and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. Its lead product is EPIDIOLEX® (cannabidiol), an oral formulation of purified cannabidiol for the treatment of refractory childhood epilepsies, as well as for the treatment of Dravet syndrome, Lennox-Gastaut syndrome, tuberous sclerosis complex, and infantile spasms. This is the first cannabis plant-derived medicine ever approved by the FDA. The company also develops and markets Sativex—the world's first prescription medicine derived from the cannabis plant—an oromucosal spray for the treatment of spasticity due to multiple sclerosis (MS), which is now approved in over 25 countries outside of the U.S., and is preparing to file an NDA in the U.S. The company has a deep pipeline of additional clinical stage cannabinoid product candidates under development for both orphan and non-orphan indications, for which the company is advancing multiple late-stage clinical programs, with a particular focus on the treatment of PTSD and other neurological conditions. GW has other cannabinoid product candidates in Phase 2 trials for autism and schizophrenia. The company was founded in 1998 and is headquartered in Cambridge, the UK, with operations in Europe, the U.S. (through its subsidiary Greenwich Biosciences), Canada, and Asia.

Kalytera Therapeutics, Inc. (KLY-TSX)

Kalytera Therapeutics is a clinical-stage pharmaceutical company developing cannabidiol and next-generation cannabinoid therapeutics for the treatment of serious and life-threatening human disease. The company's lead program involves the use of cannabidiol formulations to prevent and treat acute on **graft versus host disease (GVHD)**. The program is in late stage clinical testing with an ongoing Phase 2 clinical study and a scheduled Phase 2-3 pivotal registration study. In addition to its lead program, Kalytera initiated a preclinical program to develop a novel, proprietary cannabinoid compound for the treatment of acute and chronic pain that eliminates the risks of addiction or respiratory suppression that exist with opioid analgesics. The compound consists of a next-generation cannabinoid conjugated with naproxen, a generic, non-steroidal, anti-inflammatory drug that is already approved for the treatment of pain. The company is further developing K-1032, a prodrug for the treatment of chronic inflammatory skin diseases, such as acne vulgaris; K-1012, a prodrug for the treatment of adult respiratory distress syndrome; K-1022, a prodrug to treat ulcerative colitis; and K-1052, a prodrug for the treatment of sepsis-induced acute renal failure and traumatic brain injury. Kalytera Therapeutics was founded in 2014 and is headquartered in San Rafael, California.

Tetra Bio-Pharma Inc. (TBP-TSX)

Tetra Bio-Pharma is a biopharmaceutical company engaged in cannabinoid-based drug discovery and development with a Health Canada approved, and FDA reviewed, clinical program aimed at bringing novel prescription drugs and treatments to patients and their healthcare providers. The company has several subsidiaries engaged in the development of an advanced and growing pipeline of bio pharmaceuticals, natural health, and veterinary products containing cannabis and other medicinal plant-based elements. On the pharmaceutical front, the company focuses on the ophthalmic, chronic pain, and oncology drug formulations. Its lead product is PPP001, a dried cannabis prescription drug for advanced cancer pain. Tetra Bio-Pharma is also developing other cannabis-based drugs for pain management; a series of natural health products, including a topical product for pain management; an oral product line for cardiovascular disease prevention, athletic performance, and well-being; a topical product for skin care; a topical product for women; and Munchies B Gone gum. The company was formerly known as GrowPros Cannabis Ventures Inc. and changed its name to Tetra Bio-Pharma Inc. in September 2016. Tetra Bio-Pharma is headquartered in Orleans, Canada.

Zynerba Pharmaceuticals, Inc. (ZYNE-NASDAQ)

Zynerba Pharmaceuticals operates as a clinical stage specialty pharmaceutical company. It engages in the development and commercialization of transdermal pharmaceutically-produced cannabinoid treatments for rare and near-rare neurological and psychiatric, or neuropsychiatric disorders in patients with high unmet medical needs. The company is developing Zygel (CBD gel), a transdermal cannabidiol gel, which is in Phase II clinical trial for treating children and adolescent patients with developmental and epileptic encephalopathies; is in Phase II/III clinical trial to treat children and adolescent patients with fragile X syndrome; and is in Phase II clinical trial for treating children and adolescent patients with autism spectrum disorder. Zygel is the first and only pharmaceutically manufactured CBD formulated as a patent-protected permeation-enhanced clear gel, designed to provide controlled drug delivery into the bloodstream transdermally (i.e. through the skin). It is also developing ZYN001, a pro-drug of tetrahydrocannabinol. Founded in 2007 and formerly known as AllTranz, Inc., the company changed its name to Zynerba Pharmaceuticals, Inc. in August 2014. Zynerba is headquartered in Devon, Pennsylvania.

Additional Potential Competitors

FSD will also face competition from established medical marijuana growers and distributors, both Canadian and those with international operations, including but not limited to Aphria, Inc. (APH-TSX), Aurora Cannabis, Inc. (ACB-NYSE), Canopy Growth Corporations (CGC-NASDAQ), the Cronos Group (CRON-NASDAQ), Hexo Corp. (HEXO-NYSE), and Tilray, Inc. (TLRY-NASDAQ), among others.

Historical Financial Results

Figures 16, 17, and 18 provide FSD's consolidated statements of loss and comprehensive loss, its consolidated statements of financial position, and its consolidated statements of cash flows as of December 31, 2019 as filed in its most recent SEC Form 40-F on March 4, 2020.

Figure 16
CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS
For the years ended December 31, 2019 and 2018
[expressed in Canadian dollars, except share and per share amounts]

	2,019	2,018
	$	$
Revenue	**257,099**	—
Cost of revenue	**1,959,111**	—
Gross loss before fair value adjustments	**(1,702,012)**	—
Fair value adjustments on inventory sold	**22,249**	—
Unrealized loss on changes in fair value of biological assets	**682,739**	—
Gross loss	**(2,407,000)**	—
Expenses		
General and administrative	**14,811,529**	18,740,360
Share-based payments	**16,061,319**	6,440,406
Depreciation and amortization	**3,146,680**	183,194
Allowance for impairment of Auxly funds	**—**	7,499,977
Impairment of property, plant and equipment and right-of-use asset	**243,468**	—
Total operating expenses	**34,262,996**	32,863,937
Loss from operations	**(36,669,996)**	(32,863,937)
Other income	**(125,536)**	(88,763)
Finance expense	**206,454**	—
Loss on settlement of financial liability	**24,810**	—
Loss on change in fair value of derivative liability	**3,568,305**	—
Loss (gain) on changes in fair value of other investments	**11,669,157**	(10,064,550)
Net loss	**(52,013,186)**	(22,710,624)
Other comprehensive loss		
Items that may be subsequently reclassified to income:		
Exchange loss on translation of foreign operations	**(112,690)**	—
Comprehensive loss	**(52,125,876)**	(22,710,624)
Net loss per share – basic and diluted	**(7.37)**	(3.85)
Weighted average number of shares outstanding – basic and diluted	**7,056,245**	5,905,252

Source: FSD Pharma Inc.

Figure 17

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

As at December 31, 2019 and 2018

[expressed in Canadian dollars]

	2019	2018
	$	$
ASSETS		
Current assets		
Cash	**7,932,737**	21,134,930
Trade and other receivables	**2,070,055**	990,988
Prepaid expenses and deposits	**430,381**	444,099
Inventory	**942,939**	—
Biological assets	**—**	—
	11,376,112	22,570,017
Non-current assets		
Other investments	**11,780,864**	18,064,541
Right-of-use asset, net	**127,410**	—
Property, plant and equipment, net	**11,804,145**	12,141,676
Intangible assets, net	**22,358,932**	—
	57,447,463	52,776,234
LIABILITIES		
Current liabilities		
Trade and other payables	**4,467,826**	1,743,806
Lease obligations	**56,207**	—
Derivative liability	**2,646,269**	—
Notes payable	**1,908,412**	—
	9,078,714	1,743,806
Non-current liabilities		
Lease obligations	**146,662**	—
	9,225,376	1,743,806
SHAREHOLDER'S EQUITY		
Class A share capital	**201,500**	201,500
Class B share capital	**97,815,149**	67,916,302
Warrant reserve	**5,745,034**	4,442,145
Contributed surplus	**23,091,099**	4,977,300
Foreign exchange translation reserve	**(112,690)**	—
Accumulated deficit	**(78,518,005)**	(26,504,819)
	48,222,087	51,032,428
	57,447,463	52,776,234

Source: FSD Pharma Inc.

Figure 18
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended December 31, 2019 and 2018
[expressed in Canadian dollars]

	2,019	2,018
	$	$
Operating activities		
Net loss	**(52,013,186)**	(22,710,624)
Add (deduct) items not affecting cash		
Depreciation and amortization	**3,146,680**	183,194
Impairment of property, plant and equipment and right-of-use asset	**243,468**	—
Listing expense	—	7,991,791
Interest expense	**206,454**	—
Share-based payments	**16,061,319**	6,440,406
Change in fair value of other investments	**11,669,157**	(17,564,529)
Change in fair value of derivative liability	**3,568,305**	—
Change in fair value adjustments on inventory sold	**22,249**	—
Change in fair value of biological assets	**682,739**	—
Loss on settlement of financial liability	**24,810**	—
Allowance for impairment of Auxly funds	—	7,499,977
Changes in non-cash working capital balances		
Trade and other receivables	**(1,079,067)**	(664,610)
Prepaid expenses and deposits	**39,892**	(99,264)
Inventories	**(942,939)**	—
Biological assets	**(682,739)**	—
Trade and other payables	**825,120**	433,754
Cash used in operating activities	**(18,227,738)**	(18,489,905)
Investing activities		
Cash acquired from acquisition Prismic Pharmaceuticals Inc.	**2,329**	—
Reverse Takeover Transaction	—	2,041,501
Proceeds from sale of investments	**614,520**	—
Purchase of other investments	—	(7,999,991)
Purchase of property, plant and equipment	**(534,118)**	(4,032,832)
Additions to intangible assets	**(389,640)**	—
Cash used in investing activities	**(306,909)**	(9,991,322)
Financing activities		
Repayment of lease obligation	**(56,207)**	—
Proceeds from issuance of shares	**4,593,777**	44,987,422
Share issue costs	**(32,705)**	(3,768,381)
Proceeds from exercise of share options	**732,598**	2,857,050
Proceeds from warrants exercised	**94,991**	800,078
Cash provided by financing activities	**5,332,454**	44,876,169
Net (decrease) increase in cash during the year	**(13,202,193)**	16,394,942
Cash, beginning of year	**21,134,930**	4,739,988
Cash, end of year	**7,932,737**	21,134,930

Source: FSD Pharma Inc.

Recent Events

03/09/2020— FSD Pharma Inc. ("FSD" or "the Company") announced receipt of approval from the Ethics Committee of the Alfred Hospital, part of the Alfred Health group of hospitals serving the state of Victoria in Australia, to initiate a Phase 1, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics of single and multiple ascending doses of ultramicronized-PEA in normal healthy volunteers.

03/04/2020—FSD announced that Executive Co-Chairman and CEO, Raza Bokhari, MD will be joined by the Company's founders, Anthony Durkacz and Zeeshan Saeed, members of its Board of Directors, and leadership team to ring the opening bell at the Canadian Securities Exchange (CSE) on Friday, March 6, 2020 at 9:30 a.m. Eastern time.

02/20/2020—FSD announced the sale of its 12% equity interest in Cannara Biotech Inc. (LOVE-CSE) to a consortium of buyers for cash proceeds of more than $7.7 million. The terms of the Share Sale Transaction were negotiated at arm's length with a group of buyers that included entities controlled by members of the Cannara board and senior management. A substantial portion of FSD's shareholdings in Cannara were subject to a statutory escrow expiring December 2021. Under the terms of the Share Sale Transaction, the buyers agreed to acquire FSD's interest subject to escrow and, as such, assumed all of the associated market risk. The Share Sale Transaction represents a 670% return on the Company's stake in Cannara.

02/05/2020—FSD announced that Raza Bokhari, MD, Executive Co-Chairman and Chief Executive Officer, accompanied by FSD's leadership, will be participating in the 22nd Annual BIO CEO & Investor conference, including presenting a Company overview on Monday, February 10, 2020.

02/04/2020—FSD and Solarvest BioEnergy Inc. announced that the companies have agreed to amendments to the Collaborative Research and Development Agreement announced in their May 7, 2019 press release. Under the amended Agreement, FSD has agreed to issue additional Class B subordinate voting shares to Solarvest, which will enable Solarvest to fund the CBD Research Project. Solarvest has also appointed Dr. Edward J. Brennan, Jr., M.D., FACS, currently the President of FSD Pharma's BioSciences Subsidiary, to the board of directors of Solarvest.

01/22/2020—Announced that it has appointed Larry Kaiser, MD, FACS to its Board of Directors, effective immediately. Dr. Kaiser will also continue to serve as the Chairman of FSD's Scientific Advisory Board (SAB).

01/17/2020—Announce that Dr. Raza Bokhari, along with the founders, members of the Company's Board of Directors, members of the leadership team, early investors, advisors, and other stakeholders, rang the NASDAQ Stock Market opening bell on Wednesday, January 22, 2020 at NASDAQ'S MarketSite in New York City.

01/09/2020—Announced that its Class B Subordinate Voting Shares will commence trading on the NASDAQ Capital Market under the symbol 'HUGE' on January 9, 2020. The Company's Class B Subordinate Voting Shares will continue to trade on the Canadian Securities Exchange under the symbol 'HUGE'.

01/06/2020—Announced that its Class B Subordinate Voting Shares have been approved for listing on the NASDAQ Capital Market under the symbol 'HUGE.' Trading on the NASDAQ is expected to commence at market open on Thursday, January 9, 2020.

01/02/2020—Announced the appointments of three key executives: Donal Carroll, Chief Financial Officer (Mr. Carroll previously served as interim CFO); Sandra Lottes, Pharm D, Vice President and Head of Clinical Research of FSD's BioSciences Subsidiary; and Shahzad Shah, Chief Operating Officer of FV Pharma.

12/16/2019—Announced that NASDAQ has approved FSD's application to have its Class B Subordinate Voting Shares listed on the NASDAQ Capital Market.

12/13/2019—Announced that Raza Bokhari, MD, was scheduled to present an overview of the Company at the Investor Summit conference on Tuesday, December 17, 2019 at the Kimpton Hotel Monaco in Philadelphia.

12/05/2019—Announced that Edward Brennan, MD, is scheduled present an overview of the Company at the 12th Annual LD Micro Main Event Investor conference on Wednesday, December 11, 2019 at the Luxe Sunset Boulevard Hotel in Los Angeles.

11/29/2019—Reported financial and operational results for the three and nine months ended September 30, 2019. These filings are available for review on the Company's SEDAR profile at www.sedar.com. During this period, FSD continued to focus on developing a robust pipeline of FDA approved synthetic compounds to treat diseases of the central nervous system, and autoimmune disorders of the skin, GI tract, and the musculoskeletal system. The Company intends to initiate Phase 1 first-in-human safety and tolerability trials for its lead candidate during 1Q20. In addition, the Company accelerated set-up activities to commence medical cannabis sales in August from its Cobourg facility. FSD also raised more than C$4.5 million in additional capital through a private placement in which the management, founders, and board members contributed in excess of C$2.5 million.

11/04/2019—Announced that it closed a second tranche of its previously announced private placement and has now raised total gross proceeds of C$4,596,285 from investors, including members of senior management and the Board of Directors.

10/23/2019—Announced that an amended and restated management's discussion and analysis for the year ended December 31, 2018 was filed to address comments received from Ontario Securities Commission (OSC) staff and in order to improve the Company's disclosure.

10/17/2019—Announced that the Company's Class B Shares are trading on the OTCQB under the ticker symbol FSDDD for 20 business days, effective as of October 16, 2019. On November 13, 2019, the OTCQB symbol will revert to FSDDF. The temporary change is protocol for exchange stocks that undergo structural events, such as the 1:201 share consolidation announced by FSD on October 11, 2019.

10/11/2019—Announced the appointment of former U.S. congressman Stephen Buyer to the Company's Board of Directors. The Company also announced that it will complete a consolidation of its Class A multiple voting shares and its Class B subordinate voting, each on a 1 to 201 basis.

10/01/2019—Provided an update on its previously announced private placement of its Class B subordinate voting shares at a price of C$0.10 per Share. On September 30, 2019, the Company closed an initial tranche of the private placement, raising gross proceeds of C$4,583,085 from investors, including members of senior management and board of directors, and issuing an aggregate of 45,830,850 Shares.

09/25/2019—Announced the signing of a letter of intent to establish a joint venture with the Company's wholly-owned subsidiary, FV Pharma Inc. and World-Class Extractions Inc. to develop, manage, and operate a cannabis extraction and processing facility in Cobourg, Ontario. The joint venture, which supersedes and replaces the Collaboration and License Agreement between both parties entered in November 23, 2018, aims to extract various cannabidiol and other valuable elements from cannabis and hemp plants.

08/30/2019—Launched a private placement of up to C$5 million of its Class B subordinate voting shares at a price of C$0.10 per Share. The Company expects to close the Private Placement by September 30, 2019. To date, C$1,314,000 million of proceeds have been committed and received. The CEO has personally invested $500,000 and the FSD leadership team, representing founders, directors, and members of the senior management team have collectively invested more than C$500,000.

08/21/2019—Announced the launch of its online ordering system for the direct fulfillment of medicinal cannabis orders. Through its wholly-owned subsidiary, FV Pharma Inc., clients with a prescription from a medical practitioner or a registration number with Health Canada can now place an order online for dried cannabis on FVPharma.com.

07/30/2019—Announced the appointment of Larry Kaiser, MD, FACS, Dean, Lewis Katz School of Medicine at Temple University and President & CEO of Temple Health System as Chairman of its Scientific Advisory Board (SAB). The Company also announced the appointment of Adam Friedman, MD, FAAD, Ken Mackie, MD and Sara Jane Ward, PhD to its SAB—three renowned cannabis researchers and scientists who bring the total SAB membership to nine.

07/02/2019—Announced the completed the acquisition by FSD of Prismic Pharmaceuticals Inc. Pursuant to the terms of the agreement, FSD acquired all outstanding shares of Prismic for an aggregate purchase price of approximately $17.5 million (C$23.4 million), satisfied by the issuance of approximately 102.7 million Class B subordinate voting shares in the capital of FSD. In addition, FSD has agreed to assume approximately $3.05 million of outstanding Prismic liabilities.

06/24/2019—Announced its wholly-owned subsidiary FV Pharma received its Full Sale for Medical Purposes license to sell cannabis under the Cannabis Act (Canada). The license is effective as of June 21, 2019. The latest amendment to the license, originally granted on April 18, 2019, allows the FSD facility in Cobourg, Ontario to supply and sell cannabis products, including dried and fresh cannabis to the medicinal use marketplace.

06/12/2019—Announced the appointment biotech industry veterans James A. Datin and Robert J. Ciaruffoli, CPA to the Company's Board of Directors.

06/06/2019—Announced the addition of two distinguished cannabis researchers, Ziva Cooper, Ph.D. and Mallory Loflin, Ph.D., to the company's Scientific Advisory Board.

06/03/2019—The Board of Directors unanimously voted Raza Bokhari, M.D., Executive Co-Chairman of the Board, as permanent Chief Executive Officer (CEO). Dr. Bokhari has served as interim CEO of the Company since February. On May 30, the Company also reported its financial results for the three months ended March 31, 2019. These filings are available for review on the Company's SEDAR profile at www.sedar.com.

05/31/2019—Announced that Dr. Raza Bokhari will be featured in the 2019 BIO International Convention's panel presentation, "Building a Winning Team for Biotech Business Success–Lessons You Can Learn from Industry Veterans and Former NFL Player Turned Broadcaster Solomon Wilcots," on June 4 in Philadelphia, PA.

05/31/2019—Congratulated High Tide Inc. on the recent announcement from Alberta Gaming, Liquor and Cannabis lifting the moratorium on issuing cannabis licenses and accepting license applications. The announcement is an encouraging sign of steadily improving cannabis supply levels in Alberta and is a positive step for companies like High Tide that have numerous stores ready and waiting to sell retail cannabis products. As a strategic investor in High Tide, FSD is pleased to see changes that will support the continued growth and success of the cannabis industry as well as the companies in which it is invested.

05/28/2019—Announced the appointment of pharmaceutical industry leader, Edward J. Brennan, Jr., M.D., FACS, as President of its BioSciences subsidiary. Dr. Brennan has more than 25 years of experience in leadership roles at major pharmaceutical companies and clinical research organizations.

05/21/2019—Announced that three eminent cannabis researchers have joined the company's Scientific Advisory Board: Daniele Piomelli, Ph.D., Ryan Vandrey, Ph.D., and David Casarett, MD, MA.

05/07/2019—Announced a collaborative R&D agreement with Solarvest BioEnergy, a technology company that developed an algal-based flexible production platform capable of producing health products. Under the agreement, Solarvest will conduct research using its algal expression technology to develop pharmaceutical-grade cannabinoids

05/06/2019—Reported financial and operational results for the fourth quarter and fiscal year-ended December 31, 2018. These filings are available for review on the Company's SEDAR profile at www.sedar.com.

04/26/2019—Announced that in celebration of its wholly-owned subsidiary FV Pharma having been awarded a sales license by Health Canada, the Company is hosting a media event at its headquarters in Cobourg.

04/24/2019—Announced that it has entered into a share exchange transaction with Aura Health Inc., in which the Company acquired $3 million worth of Aura shares in exchange for FSD shares. Aura Health is a Toronto-based cannabis company building an international network of vertically integrated businesses in the medical cannabis industry. The transaction positions FSD to establish distribution channel in Germany and Eurozone

04/23/2019—Announced an agreement dated April 22, 2019 pursuant to which FSD has agreed to acquire Prismic Pharmaceuticals Inc. Prismic is developing novel non-addictive prescription drugs with unique safety profiles with the goal of addressing the opioid crisis based on formulations impacting the endocannabinoid system. This transaction positions FSD to help contribute to addressing the opioid crisis through use of synthetic cannabinoids.

04/22/2019—Announced that its wholly-owned subsidiary, FV Pharma Inc., received its Sale for Medical Purposes license to sell cannabis under the Cannabis Act (Canada). The license went into effect on April 18, 2019. The license allows the current FSD facility to supply and sell cannabis products. The Company anticipates receiving the amended sales license that will include the sale of dried and fresh cannabis flower in the near future.

04/17/2019—Announced that Dr. Raza Bokhari will participate in the Arcview Investor Forum being held April 23-25, 2019, in Vancouver.

04/04/2019—Announced the appointment of Charles V. Pollack, Jr., M.A., M.D., FACEP, FAAEM, FAHA, FACC, FESC, FCPP, as Chairman of its Scientific Advisory Board. In this capacity Dr. Pollack will serve as a strategic guide and resource to the Company as it develops disruptive, science-based, cannabinoid therapeutics.

03/28/2019—Announced the signing of a consulting agreement with Joseph L. Romano, a lawyer with a strong track-record in personal injury law. Mr. Romano has been working with medical cannabis since 2006, assisting people coping with chronic pain to have access to medical cannabis, a viable alternative to opioid based medications.

03/13/2019—Announced that Sara May, Ph.D., has been appointed President of FV Pharma, a wholly-owned subsidiary of FSD, effective immediately. Dr. May replaces Thomas Fairfull, former President of FV Pharma.

02/28/2019—Announced that it has entered into a supply and loan agreement with Canntab Therapeutics Ltd. and World Class Extractions Inc. to purchase hemp flower from Thomas Elcome. Pursuant to the Agreement, Canntab Therapeutics and World Class Extractions obtain the right and option to purchase up to C$5.0 million of hemp crop for a period of five years commencing in 2019 at a purchase price of C$100.0 per kg per 1% of CBD extracted from the flower. This follows the February 12, 2019 supply agreement between the same parties to purchase up to 1,000 kg of Thomas Elcome's 2018 organic hemp crop.

02/19/2019—Announced that FSD's wholly-owned subsidiary, FV Pharma, received its Standard Processing License. According to Health Canada's new Cannabis Act regulations, the Processing License is required for any facility that is processing more than the equivalent of 600 kg of dried flowers per year.

02/14/2019—Provided a corporate update on operations, strategy, and leadership changes.

02/12/2019—Announced that it entered into a supply agreement with Canntab Therapeutics Ltd. and World Class Extractions Inc. to purchase hemp flower from Thomas Elcome. Pursuant to the agreement, Canntab and World Class Extractions have agreed to buy approximately 1,000 kg of Thomas Elcome's 2018 hemp crop at a purchase price of C$100.00 per kg per 1% of CBD extracted from the flower. Working alongside Canntab and World Class, FSD will extract CBD from the organic hemp obtained in the purchase order. The Purchasers will process the hemp flower into gel capsules and tablets at the FSD Facility.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by FSD Pharma Inc. ("FSD" 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's statements on its financial and other reports filed from time to time.

The content of this report with respect to FSD has been compiled primarily from information available to the public released by the Company through news releases, presentations, Annual Reports, and other filings. FSD 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 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 thousand U.S. dollars for its services in creating this report and for updates.

Investors should carefully consider the risks and information about FSD'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 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'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, as well as copies of this report, can be obtained in either a paper or electronic format by calling (647) 864-7969.

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'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'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'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 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 Company may be unable to raise the capital necessary for it to execute its strategy on favorable terms or at all.

The continued development of the Company's cannabis operations will require significant additional financing over several years. To achieve its ultimate objective of 3,800,000 square feet dedicated to cannabis cultivation and related ancillary business all under one roof, multiple rounds of additional funding will be required. The failure to raise such capital could result in the delay or indefinite postponement of current business strategy or the Company ceasing to carry on business. There can be no assurance that additional capital or other types of financing will be available if needed or, if available, the terms of such financing will be favorable to the Company.

The Company's dual class structure has the effect of concentrating voting control and the ability to influence corporate matters with a limited number of holders of Class A Shares.

FSD's dual class share structure has the effect of concentrating voting control and the ability to influence corporate matters with limited shareholders. Currently, all 15,000 outstanding Class A Shares are held by the Company's founders, Thomas Fairfull, Zeeshan Saeed, and Anthony Durkacz. Class A Shares have 276,660 votes per share and Class B Shares have one vote per share. Shareholders who hold Class A Shares together hold approximately 79% of the voting power of the Company's outstanding voting shares and therefore have significant influence over management and affairs of FSD and over all matters requiring shareholder approval.

The success of FSD 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. During the 2019 fiscal year, the Company experienced significant turnover of its senior management: Rupert Haynes was terminated as Chief Executive Officer on February 6, 2019, less than three months after his appointment, and Dr. Raza Bokhari was re-appointed interim Chief Executive Officer of the Company (a position that became permanent on June 3, 2019). On March 13, 2019, the Company announced the departure of Thomas Fairfull as President of FV Pharma and the subsequent appointment of Sara May as President of FV Pharma. The Company may not be able to find appropriate replacements for key personnel on a timely basis. Furthermore, each of FSD's executive officers may terminate their employment with the Company at any time. FSD 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 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 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 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 is reliant on the operations of its partners and has little or no control over such operations.

The Company has made investments in strategic partners and relies on such partners to execute on their business plans and produce cannabis products. Other than with respect to certain contractual arrangements, the Company has little or no control in or influence over the operations of its partners. Furthermore, the interests of FSD and its partners may not always be aligned. As a result, the Company's projected cash flows that are dependent upon the operation of its partners are subject to the risk that its partners may have business interests or targets that are inconsistent with those of the Company or may be unable or unwilling to fulfill their obligations under their agreements with FSD.

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 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's ability to continue operating and the market price for Company's Class B Shares and could result in the use of significant resources. Even if FSD 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. In particular: FSD's executive co-chairman of the Board of Directors and chief executive officer, Dr. Raza Bokhari, is also the chairman and chief executive officer of PCL, Inc., a provider of addiction screening and opioid prescription medication monitoring; the managing partner of RBx Capital, LP; and a board member of Akers Biosciences and World Class; the Company's interim chief financial officer, Donal Carroll, is also a director of World Class and Bird River Resources Inc.; and the Company's executive co-chairman of the board, Anthony Durkacz, is currently a director and executive vice president at First Republic Capital Company, which has acted as the exclusive agent of the Company and has raised approximately $53 million of equity capital for the Company to date. Mr. Durkacz is also a director of World Class and of iWallet Company. Sara May, president of FV Pharma, is a director of Cannara. Gerry Goldberg, a director of the Company, is also a director of Capicorn Business Acquisition Inc., Baymount Incorporated, Leo Acquisitions Corp., and Osoyoos Cannabis Inc. David Urban, a director of the Company, is also a director of Virtu Financial, Inc. Consequently, there is a risk that such officers or directors will be in a position of conflict.

Risks Related to the Cannabis Production Business

Failure to comply with the requirements of Health Canada's Cannabis License or any failure to maintain the License would have a material adverse impact on the business, financial condition, and operating results of the Company.

The continuation and development of the Company's business is dependent on the good standing of the License and any other permits or approvals required to engage in such activities. Failure to comply with the requirements of the License or any failure to maintain the License would have a material adverse impact on the business, financial condition, and operating results of the Company. Although FSD believes it will meet the requirements of the Cannabis Act and Cannabis Regulations for future extensions or renewals of its License, there can be no guarantee that Health Canada will extend or renew the License or that, if extended or renewed, the License will be extended or renewed on the same or similar terms. Should Health Canada not extend or renew the License, or should it renew the License on different terms, the business, financial condition, and results of the operation of the Company would be materially and adversely affected.

The Company is required to comply with environmental, health, and safety laws and regulations.

The Company's business involves the growing of cannabis, an agricultural product. FSD's operations are subject to environmental and safety laws and regulations concerning, among other things, zoning, emissions, and discharges to water, air, and land, the handling and disposal of hazardous and nonhazardous materials and wastes, and employee health and safety. Failure to comply with applicable environmental laws, regulations, and permitting requirements may result in enforcement actions thereunder, including orders issued by regulatory or judicial authorities causing operations to cease or be curtailed, and may include corrective measures requiring capital expenditures, installation of additional equipment, or remedial actions.

No assurances can be given that the Company will be successful in maintaining its required supply of skilled labor, specialized knowledge, equipment, parts, and components.

The ability of the Company to compete and grow cannabis will be dependent on it having access to, at a reasonable cost and in a timely manner, skilled labor, individuals with specialized knowledge, equipment, parts, and components. No assurances can be given that the Company will be successful in maintaining its required supply of skilled labor. In particular, specialized knowledge with respect to cultivating and growing medical cannabis and processing such materials into THC and CBD concentrates and derivative products is important to the industry. If the Company is unable to identify, attract, hire, and retain qualified personnel in the future, such inability could have a material adverse effect on the Company's business, operating results, and financial condition.

The Company is reliant on its production facility as its only property for cannabis cultivation and related ancillary businesses, and adverse changes or developments affecting the Facility could have an adverse impact on FSD.

The proposed activities and resources of the Company's production division are primarily focused within the Facility. The Company's operations and the conditions of the Facility is, and will be, subject to hazards inherent in the cannabis industry. A significant failure of the Facility could have an impact on FSD's ability to continue operating under its existing Health Canada licenses.

Adverse changes affecting the development or construction of the Facility and commencement of production could have a material and adverse effect on the Company's business, financial condition, and prospects.

Any adverse changes affecting the development or construction of the Facility and expansion of production could have a material and adverse effect on the Company's business, financial condition, and prospects. There is a risk that these changes or developments could adversely affect the Facility due to a variety of factors. In addition, any potential expansion of the Facility is subject to Health Canada regulatory approvals. While management currently holds the requisite approvals for the expansion of 30,000 square feet of the Facility, the delay or denial of approvals of additional expansion may have a material adverse impact on the business and may result in the Company not meeting anticipated or future demand when it arises.

Risks Related to the Medical Cannabis Industry

Failure of the Company to comply with licensing requirements under the Cannabis Act could have a material adverse impact on its business, financial condition, and results of operations.

The market for cannabis (including medical and recreational cannabis) in Canada is regulated by the Cannabis Act, the Narcotic Control Regulations, and other applicable law. Health Canada is the primary regulator. The Cannabis Act aims to treat cannabis like any other narcotic used for medical purposes by creating conditions for a new commercial industry that is responsible for its production and distribution. The Cannabis Act will subject the Company to stringent ongoing compliance and reporting requirements. Failure to comply with the requirements of its License or any failure to maintain the License could have a material adverse impact on the business, financial condition, and operating results of the Company. Furthermore, the License has an expiry date of October 13, 2020. Upon expiration of the License, the Company will be required to apply for renewal to Health Canada containing information prescribed under the Cannabis Act and any such renewal cannot be assured.

The Company faces regulatory risks, including delays in obtaining, or failure to obtain regulatory approvals. Changes in regulation and violation of regulations could have a material adverse effect on its business, results of operations, and financial condition.

FSD operates in a new industry which is highly regulated and is in a market that is very competitive and evolving rapidly. The Company's operations are subject to various laws, regulations, and guidelines by governmental authorities, particularly Health Canada, relating to the manufacture, marketing, management, transportation, storage, sale, and disposal of medical marijuana, and also including laws and regulations relating to health and safety, the conduct of operations, and the protection of the environment. Laws and regulations, applied generally, grant government agencies and self-regulatory bodies broad administrative discretion over the activities of the Company, including the power to limit or restrict business activities as well as impose additional disclosure requirements on the Company's products and services.

Changes in laws, regulations, and guidelines may result in significant compliance costs for FSD's business, including in relation to restrictions on branding and advertising, regulation of provincial distribution, and excise taxes.

The Cannabis Act came into effect on October 17, 2018 to create a regulated adult-use recreational market for cannabis in Canada. The Cannabis Act and Cannabis Regulations prohibit testimonials, lifestyle branding and packaging, as well as certain other promotional activity that is appealing to youth and set out broad prohibitions on the promotion of cannabis at the federal level. In addition, the governments of every Canadian province and territory have enacted and implemented their respective regulatory regimes for the distribution and sale of cannabis for adult-use purposes within those jurisdictions. The provincial or territorial legislation and regulatory regimes may change in ways that impact the Company's ability to continue its business as currently conducted or proposed to be conducted.

There is no guarantee that provincial or territorial regulatory regimes governing the distribution and sale of cannabis for adult-use recreational purposes in each jurisdiction will remain as currently enacted or that any such legislation and regulation will create the growth opportunities that FSD currently anticipates. Although the operations of the Company are currently carried out in accordance with all applicable rules and regulations, no assurance can be given that new rules and regulations will not be enacted or that existing rules and regulations will not be applied in a manner which could limit or curtail the Company's ability to produce or sell medical or recreational cannabis, should it decide to apply for a license to sell recreational cannabis in the future.

The current medical and recreational cannabis industry is relatively undeveloped and there is no certainty that the market of patients or recreational users will expand as sufficiently as industry analysts predict.

The current medical and recreational cannabis industry is relatively undeveloped, with no certainty that the market of patients or recreational users will expand as sufficiently as industry analysts predict. In particular, the federal legalization of the recreational use of cannabis, effective on October 17, 2018, will have a significant impact on operations in terms of the competition that FSD will face from the recreational cannabis industry. It is unclear at this point what the form of such a market for cannabis generally will be and how the Company's participation in it will be permitted or restricted by any of the as-yet unidentified federal, provincial, and municipal rules, by-laws, and regulations.

The Company must rely largely on its own market research to forecast future projected sales as detailed forecasts are not generally obtainable from other sources and prices for FSD's products may vary considerably from the Company's forecasts at this early stage of the cannabis industry in Canada.

A failure in the demand for its products to materialize as a result of competition, technological change, or other factors could have a material adverse effect on the business, results of operations, and financial condition of the Company.

Certain key employees are subject to security clearance from Health Canada, and there can be no assurance that such personnel will be able to obtain or renew security clearances in the future.

As a Licensed Producer under the Cannabis Act, certain key employees are subject to a security clearance by Health Canada. Under the Cannabis Act a security clearance cannot be valid for more than five years and must be renewed before the expiry of a current security clearance. There is no assurance that any of FSD's existing personnel who presently or may in the future require a security clearance will be able to obtain or renew such clearances, or that new personnel who require a security clearance will be able to obtain one. Failure by a key employee to maintain or renew his or her security clearance could result in a material adverse effect on the Company's business, financial condition, and results of operations.

The Company's employees or shareholders could be prevented from entering the U.S. or become subject to a lifetime ban on entry into the U.S.

U.S. Customs and Border Protection (CBP) has confirmed that border agents may seek to permanently ban any foreign visitor who admits to working or investing in the cannabis industry, or admits to have used cannabis, even legal use, but generally only if such foreign visitor is travelling to the U.S. for reasons related to the cannabis industry. CBP confirmed that investing even in publicly traded cannabis companies is considered facilitation of illicit drug trade under CBP policy. This policy is limited to citizens of foreign countries and not citizens of the U.S. Therefore, any of the Company's shareholders who are a not citizens of the U.S., particularly if travelling to the U.S. for reason related to the cannabis industry, could be prevented from entering the U.S. or could become subject to a lifetime ban on entry into the U.S.

The Company may be subject to product liability claims or regulatory action if its products are alleged to have caused significant loss or injury. This risk is exacerbated by the fact that cannabis use may increase the risk of serious adverse side effects.

If licensed as a distributor of products designed to be ingested by humans, the Company faces an inherent risk of exposure to product liability claims, regulatory action, and litigation if its products are alleged to have caused significant loss or injury. In addition, the sale of the Company's products would involve the risk of injury to consumers due to tampering by unauthorized third parties or product contamination. There can be no assurances that the Company will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities. Such insurance is expensive and may not be available in the future on acceptable terms, or at all. The inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of the Company's products.

Unfavorable publicity regarding the cannabis industry could have a material adverse effect on FSD, the demand for the Company's proposed products, and its results of operations, financial condition, and cash flows.

Management believes the medical cannabis industry is highly dependent upon consumer perception regarding the safety, efficacy, and quality of the medical cannabis produced. Consumer perception of the Company's proposed products may be significantly influenced by scientific research or findings, regulatory investigations, litigation, media attention, and other publicity regarding the consumption of medical cannabis products. There can be no assurance that future scientific research, findings, regulatory proceedings, litigation, media attention, or other research findings or publicity will be favorable to the medical cannabis market or any particular product, or consistent with earlier publicity.

Results from future clinical research may draw opposing or negative conclusions regarding the facts and perceptions related to cannabis, which could have a material adverse effect on the Company's business, financial condition, and results of operations.

Research regarding the medical benefits, viability, safety, efficacy, dosing, and social acceptance of cannabis or isolated cannabinoids (such as CBD and THC) remains in early stages. There have been relatively few clinical trials on the benefits of CBD and THC. Although the Company believes that the articles, reports, and studies support its beliefs regarding the therapeutic benefits, viability, safety, efficacy, dosing, and social acceptance of cannabis, future research studies and clinical trials may draw opposing or negative conclusions regarding the facts and perceptions related to cannabis, which could have a material adverse effect on the demand for FSD's products with the potential to lead to a material adverse effect on the Company's business, results of operations, financial condition, or prospects.

Third parties with whom the Company does business may perceive that they are exposed to reputational risk as a result of FSD's cannabis-related business activities and may ultimately elect not to do business with the Company.

The parties with whom FSD does business may perceive that they are exposed to reputational risk as a result of its cannabis business activities. Failure to establish or maintain business relationships as a result of such perceived reputational risk could have a material adverse effect on the Company's business.

The Company's ability to produce and sell its medical products in, and export its medical products to, other jurisdictions outside of Canada is dependent on compliance with additional regulatory and other requirements.

FSD would be required to obtain and maintain certain permits, licenses, or other approvals from regulatory agencies in countries and markets outside of Canada in which it proposes to operate or to export, in order to sell its medical products in these countries, including, in the case of certain countries, the ability to demonstrate compliance with good manufacturing practices (GMPs). There can be no assurance that FSD would be able to comply with these standards. In addition, any expansion into international operations would depend on the Company's ability to secure the necessary permits, licenses, or other approvals. In addition, Canada is a signatory to the Single Convention on Narcotic Drugs, 1961 as amended by the 1972 Protocol, the Convention on Psychotropic Substances, 1971, and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. These drug control conventions establish a framework whereby trade in cannabis between countries is strictly limited to medical and scientific purposes and is subject to country-by-country quotas, which could limit the amount of medical cannabis FSD can export to any particular country.

Competition from synthetic production, the introduction of new products embodying new technologies, including new manufacturing processes, and the emergence of new industry standards may render the Company's products obsolete, less competitive, or less marketable.

The pharmaceutical industry may attempt to dominate the cannabis industry through the development and distribution of synthetic products which emulate the effects and treatment of organic cannabis. If they are successful, the widespread popularity of such synthetic products could change the demand, volume, and profitability of the cannabis industry. This could adversely affect the ability of the Company to secure long-term profitability and success through the sustainable and profitable operation of its business.

The Company may not be able to transport its products to consumers in a safe, secure, and efficient manner.

Due to the perishable nature of its proposed products, the Company will depend on fast and efficient third-party transportation services to distribute its product. Any prolonged disruption of third-party transportation services could have an adverse effect on the financial condition and results of operations of the Company. Due to the nature of FSD's products, security of the product during transportation to and from its facilities is of the utmost concern. A breach of security during transport or delivery could have a material and adverse effect on FSD's business, financial condition, and prospects.

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 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'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 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.

The Company's involvement in the cannabis industry may delay or materially impair its ability to complete any clinical trials and attain the regulatory approvals it requires to commercialize pharmaceutical products, which may have a material adverse effect on the Company's business and results of operations.

The Company was founded as a medical cannabis company, and the growth and sale of cannabis remains a central part of its business. While all pharmaceutical companies face risks in developing and bringing pharmaceutical products to market successfully, the Company's involvement in the cannabis industry may increase the risks that any pharmaceutical company would face. For example, while some U.S. states have legalized cannabis growth and possession, U.S. federal law continues to ban the possession, sale, or import of cannabis into the U.S. and prohibits the financing of activities outside the U.S. that are unlawful under Canadian or other foreign laws. As a U.S. federal agency, the FDA may review the Company's activities, clinical trials, if any, and applications for approval with heightened scrutiny because of the Company's involvement in the Canadian cannabis industry. Finally, third parties, especially those in the U.S., may avoid doing business with the Company due to its involvement in the cannabis industry or may only provide their services and products to FSD at a premium to account for increased counter-party risks.

FSD'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 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 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 is unable to successfully validate, develop, and obtain regulatory approval for companion diagnostic tests for its drug candidates that require or would commercially benefit from such tests, or experience significant delays in doing so, the Company may not realize the full commercial potential of these drug candidates.

In connection with the clinical development of FSD's drug candidates for certain indications, the Company may work with collaborators to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from its drug candidates. Such companion diagnostics would be used during the Company's clinical trials as well as in connection with the commercialization of its product candidates. If FSD is unable to successfully develop companion diagnostics for these

therapeutic drug candidates, or experiences delays in doing so, the development of these therapeutic drug candidates may be adversely affected, these therapeutic drug candidates may not obtain marketing approval, and FSD may not realize the full commercial potential of any of these therapeutics that obtain marketing approval.

If FSD 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 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'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'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 vary 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 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'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, such as gene therapy products.

Sales of these or other product candidates that FSD 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 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 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'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'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 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 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 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 and prescription of 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 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 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 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'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 with the drug substance or drug product, could materially and adversely affect its business.

The drug substance, and drug product for certain of FSD's product candidates, are grown or manufactured by single-source suppliers or CMOs. FSD 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 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 GMP, or similar regulatory requirements outside the U.S. Although FSD 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'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.

Risks Related to the Company's Intellectual Property

If FSD 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'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 ultramicronized-PEA 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'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 with any meaningful protection, prevent competitors from competing with the Company, or otherwise provide FSD with any competitive advantage. The Company's competitors may be able to circumvent FSD'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's development and commercialization efforts.

FSD'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 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'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'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 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'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 is 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 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 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 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 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 may not be able to protect its rights to these trademarks and trade names. Over the long term, if FSD 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 may be subject to claims challenging the inventorship of its patents and other intellectual property.

FSD's agreements with employees provide that any inventions conceived by an individual in the course of rendering services to the Company shall be FSD'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 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's competitive position, business, results of operations, financial condition, and prospects.

FSD 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 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 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'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'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 has patent protection, but enforcement is not as strong as in the U.S. Proceedings to enforce FSD'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'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

Access to Cannabis for Medical Purposes Regulations (ACMPR)—A set of regulations concerning the production, distribution, and use of medical cannabis across Canada and created in 2016. Health Canada administers the rules, which include information about who qualifies to use medical cannabis, recommendations, how to authorize it, who can produce it, and more. The Access to Cannabis for Medical Purposes Regulations (ACMPR) replaced the Marihuana for Medical Purposes Regulations (MMPR), which came into effect in 2014.

Canada's Cannabis Act and Regulations—The Cannabis Act (also known as Bill C-45) is a law which legalized recreational cannabis use nationwide in Canada. The law, which was approved on June 2018, made Canada the second country in the world to legalize recreational cannabis nationwide after Uruguay.

Cannabidiol (CBD)—A non-intoxicating cannabinoid found in cannabis and hemp that is sometimes used medicinally due to its analgesic, anti-inflammatory, antineoplastic, and chemopreventive activities. Cannabidiol, which is devoid of psychoactive activity, is the second most prevalent cannabinoid in cannabis, after THC.

Cannabinoids—Plant derived chemical compounds unique to the cannabis plant. There are over 120 cannabinoids, with THC and CBD the most well-known. Cannabinoids affect the body by binding with specific receptors located throughout the body. Different cannabinoids have different effects depending on which receptors they bind to.

Cannabis—Also referred to as marijuana**,** cannabis is a tall plant or herb with a stiff upright stem and divided serrated leaves that are used to produce hemp fiber and as a drug. Cannabis also refers to the psychoactive dried flower buds, leaves, or preparations (such as hashish) or chemicals (such as THC) that are derived from the Cannabis sativa (a species of the cannabis herb family) and used as a drug.

Cannabis Tracking and Licensing System (CTLS)—Health Canada's Cannabis Tracking and Licensing System, or CTLS, is a public facing web application that enables the submission of new license applications, request for amendments, and license renewals in addition to submission of monthly tracking reports.

CB1—Cannabinoid receptor type 1, also known as cannabinoid receptor 1, is an essential component of the body's *endocannabinoid system (ECS)*. The human CB1 receptor is expressed in the peripheral nervous system and central nervous system. The primary endogenous agonist (activator) of the human CB1 receptor is anandamide, with the cannabinoid THC also binding to CB1, resulting in cannabis' psychoactive effect.

CB2—Cannabinoid receptor type 2, also known as cannabinoid receptor2, is an essential component of the body's *endocannabinoid system (ECS)*. CB2 is expressed primarily in the immune system and immune cells that travel throughout the body and plays an important role in fighting inflammation. CB2 is a strong target of the endocannabinoid 2-arachidonoylglycerol (2-AG), as well as the plant derived cannabinoid CBD.

Clinical eCB deficiency syndromes (CEDS)—Clinical endocannabinoid deficiency (CECD) is a medical theory that proposes that a deficiency of endocannabinoids is the underlying pathophysiology of migraines, fibromyalgia, and irritable bowel syndrome (IBS), and may also be involved in depression, schizophrenia, Huntington's disease, Parkinson's Disease, and multiple sclerosis (MS).

Dravet Syndrome—Previously known as severe myoclonic epilepsy of infancy (SMEI), Dravet syndrome is a catastrophic type of epilepsy with prolonged seizures that are often triggered by hot temperatures or fever. It is intractable, and hard to treat with anticonvulsant medications. It often begins before one year of age.

Endocannabinoids—Substances produced from within the body that activate cannabinoid receptors. Two of the most studied endocannabinoids are anandamide (N-arachidonoylethanolamide, AEA), which has a pharmacology similar to THC and binds to the central (CB1) and, to a lesser extent, peripheral (CB2); and 2-arachidonoylglycerol (2-AG), which binds to both the CB1 and CB2 receptors with similar affinity, acting as a full agonist at both.

Endocannabinoid System (ECS)—A complex cell-signaling biological system identified in the early 1990s and composed of three core components: endocannabinoids, receptors, and enzymes. The endocannabinoid system remains under preliminary research, but studies revealed it may be involved in regulating a broad range of physiological and cognitive processes, including pain, stress, appetite, energy, metabolism, inflammation, cardiovascular function, learning and memory, reproduction and fertility, muscle formation, bone remodeling and growth, liver function, and sleep. These functions all contribute to homeostasis, which refers to stability of the body's internal environment.

Fentanyl—A powerful opioid drug used in the treatment of severe pain. Fentanyl displays a high risk for addiction and dependence and can cause respiratory distress and death when taken in high doses or when combined with other substances, especially alcohol.

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.

Graft versus host disease (GVHD)—An immune condition that occurs after transplant procedures when immune cells from the donor (known as the graft or graft cells) attack the recipient patient host's tissues; the disease is a side effect that is common after an allogeneic bone marrow transplant (stem cell transplant).

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 patient litigation involving generic pharmaceuticals.

Homeostasis—The tendency toward a relatively stable equilibrium between interdependent elements, especially as maintained by physiological processes.

Hyperalgesia—Abnormally increased sensitivity to pain. It can result from either injury to part of the body or from use of opioid painkillers. When a person becomes more sensitive to pain as a result of taking opioid medication, it's called opioid-induced hyperalgesia.

Intraperitoneal—Administered through the peritoneum, 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.

Lennox-Gastaut Syndrome—A complex, rare, and severe childhood-onset epilepsy. It is characterized by multiple and concurrent seizure types, cognitive dysfunction, and slow spike waves on electroencephalogram (EEG). Typically, it presents in children aged 3 to 5 years and can persist into adulthood.

Neuroinflammation—Inflammation of the nervous tissue normally cause by an inflammatory response within the brain or spine. It may be initiated in response to a variety of cues, including infection, traumatic brain injury, toxic metabolites, or autoimmunity.

Opioid Tolerance—A decrease in pharmacologic response following repeated or prolonged use of opioids. Since the effect of the same amount of the drug on the body becomes less over time, opioid tolerance leads to increase opioid dosage in order to maintain the analgesic benefit.

Oromucosal—Relating to or directed towards the mucous surfaces of the mouth.

Palmitolylethonalamide (**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".

Pro-nociceptive—Nociception is the perception of a painful or injurious stimulus. Nociception triggers a variety of physiological and behavioral responses and usually results in a subjective experience of pain. While an antinociceptive blocks the detection of a painful or injurious stimulus or pain, a pro-nociceptive agent facilitates or enhances the ability of a person to feel pain.

Sale for Medical Purposes License—A license issued by Health Canada under Canada's Cannabis Act that allows for the sale of cannabis products to the medicinal use marketplace, including to patients who hold prescriptions from authorized healthcare providers.

Synthetic—A compound or substance made artificially by chemical reactions, especially to imitate a natural product.

Tetrahydrocannabinol (**THC**)—A crystalline compound that is the most prevalent cannabinoid in cannabis and the principal psychoactive constituent of the plant. THC binds with the cannabinoid 1 (CB1) receptors in the brain and produces a high or sense of euphoria. Its anti-emetic properties (inhibits vomiting) are particularly useful in the treatment of cancer patients who are taking chemotherapy. Also, as THC increases the appetite and reduces the vomit response, it is useful in treating anorexia and other eating disorders.

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.

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