
**FSD PHARMA INC.**

**Annual Information Form**
**for the year ended December 31, 2020**

**March 16, 2021**

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## ANNUAL INFORMATION FORM

In this Annual Information Form (this "**AIF**"), unless otherwise noted or the context indicates otherwise, references to "**FSD Pharma**", "**FSD**", the "**Corporation**", "**we**", "**us**" and "**our**" refer, collectively, to FSD Pharma Inc., a corporation formed under the OBCA (as defined herein) and its wholly-owned subsidiaries, including FV Pharma, FSD Biosciences Inc. and Prismic (as such terms are defined herein).

All financial information in this AIF is prepared in Canadian dollars and using International Financial Reporting Standards as issued by the International Accounting Standards Board. The information contained herein is dated as of March 16, 2021, unless otherwise stated.

## MARKET AND INDUSTRY DATA

This AIF includes market and industry data that has been obtained from third party sources, including industry publications. The Corporation believes that its industry data is accurate and that its estimates and assumptions are reasonable, but there is no assurance as to the accuracy or completeness of this data. Third party sources generally state that the information contained therein has been obtained from sources believed to be reliable, but there is no assurance as to the accuracy or completeness of included information. Although the data is believed to be reliable, the Corporation has not independently verified any of the data from third party sources referred to in this AIF or ascertained the underlying economic assumptions relied upon by such sources.

## FORWARD-LOOKING STATEMENTS

The information provided in this AIF, including information incorporated by reference, contains certain "forward-looking information" or "forward-looking statements" within the meaning of Canadian securities laws and United States securities laws (collectively, "**Forward-Looking Statements**"). Forward-Looking Statements relate to future events or future performance, business prospects or opportunities of the Corporation that are based on forecasts of future results, estimates of amounts not yet determined and assumptions of management made in light of management's experience and perception of historical trends, current conditions and expected future developments. All statements other than statements of historical fact may be Forward-Looking Statements.

Any statements that express or involve discussions with respect to predictions, expectations, beliefs, plans, projections, objectives, assumptions or future events or performance are not statements of historical fact and may be Forward-Looking Statements. Forward-Looking Statements are often, but not always, identified by words or phrases such as "seek", "anticipate", "believe", "expect", "plan", "continue", "estimate", "will", "predict", "intend", "forecast", "future", "target", "project", "capacity", "could", "should", "might", "focus", "proposed", "scheduled", "outlook", "potential", "may" or similar expressions and includes suggestions of future outcomes, including, but not limited to statements about: discussions concerning the Corporation's exploration of near-term funding strategies; the progress of the Alfred Hospital Phase 1 Trials (as defined below); the Corporation's plans to advance the research & development of FSD-201 (as defined below) to commercialization through studies and clinical trials, including anticipated timing and associated costs; the status of the FSD-201 COVID-19 Trials (as defined below) for the use of FSD-201 to treat COVID-19 (as defined below) and the review thereof by the FDA (as defined below, including the timing, completion and outcomes of any trials or whether FSD-201 may be effective and feasible in treating COVID-19, the application and the costs associated with such planned trials, and the Corporation's ability to obtain required funding and the terms and timing thereof; the expansion of our product offering(s), our business objectives and the expected impacts of previously announced acquisitions and developments; disposition of other non-core assets in transactions similar to the Pharmadrug Share Sale (as defined below); the investigational new drug FDA application process and any review thereof and its affects on our business objectives; the sale

of substantially all of the assets of FV Pharma (as defined below), including the Facility (as defined below); the anticipated resignation of James A. Datin from the Board and the Audit Committee; or any actions that may or may not be taken at the annual meeting of the shareholders by the Requisitioning Shareholders (as defined below). Readers are cautioned not to place undue reliance on Forward-Looking Statements as the Corporation's actual results may differ materially and adversely from those expressed or implied.

The Corporation has made certain assumptions with respect to the Forward-Looking Statements regarding, among other things: the Corporation's ability to generate sufficient cash flow from operations and obtain financing, if needed, on acceptable terms or at all; the general economic, financial market, regulatory and political conditions in which the Corporation operates; the interest of potential purchasers in the Corporation's products; anticipated and unanticipated costs; the government regulation of the Corporation's activities and products; the timely receipt of any required regulatory approvals; the Corporation's ability to obtain qualified staff, equipment and services in a timely and cost efficient manner; the Corporation's ability to conduct operations in a safe, efficient and effective manner; and the Corporation's expansion plans and timeframe for completion of such plans.

Although the Corporation believes that the expectations and assumptions on which the Forward-Looking Statements are based are reasonable, undue reliance should not be placed on the Forward-Looking Statements, because no assurance can be given that such statements will prove to be correct. Since Forward-Looking Statements addressing future events and conditions, by their very nature they involve inherent risks and uncertainties. Actual results could differ materially and adversely from those currently anticipated due to a number of factors and risks. These include, but are not limited to: the limited operating history of the Corporation and history of losses, and anticipated significant losses for the foreseeable incurred to pursue commercialization of FSD-201; the Corporation's ability to continue as a going concern; the highly speculative nature of pharmaceutical development; the Corporation's ability to generate sufficient revenue to be profitable; the inability to obtain required additional financing on terms favourable to the Corporation; the Corporation's dual class share structure; whether an active trading market for the Corporation's Class B Shares is sustained; risks inherent in an pharmaceutical business and the development and commercialization of pharmaceutical products, including the inability to accurately predict timing or amounts of expenses, requirements of regulatory authorities, and completion of clinical studies (including the FSD-201 COVID-19 Trials) on anticipated timelines, which may encounter substantial delays or may not be able to be completed at all; the Corporation's reliance on only one pharmaceutical candidate, FSD-201; risk related to the sale of the Facility, including whether the Corporation will be able to sell the Facility on terms favourable to the Corporation, or at all; vulnerability to rising or volatile energy costs; the Corporation's reliance on management and key persons; manufacturing problems that could result in delay of the Corporation's development or commercialization programs; the Corporation's compliance with environmental, health and safety laws and regulations; the Corporation's expected minimal environmental impacts; insurance and uninsured risks; interruptions in the supply chain for key inputs; claims from suppliers; risk of conflict related to directors and officers of FSD Pharma who may currently, or in the future, also serve as directors and/or officers of other public companies that may be involved in the same industry as FSD Pharma; demand for skilled labour, specialized knowledge, equipment, parts and components; the Corporation's ability to manage its growth effectively; the Corporation's ability to realize production targets; supply chain interruptions and the ability to maintain required supplies of skilled labour, specialized knowledge, equipment, parts and components; the Corporation's ability to successfully implement and maintain adequate internal controls over financial reporting or disclosure controls and procedures; the Corporation not having been required to certify that it maintains effective internal control over financial reporting or effective disclosure controls and procedures; increased costs as a result of operating as a public company in the United States; risks related to the Corporation's status as a foreign private issuer; the Corporation's ability to identify and execute future acquisitions or dispositions effectively, including the ability to successfully manage the

impacts of such transactions on its operations; the Corporation's international business operations, including expansion to new jurisdictions, could expose it to regulatory risks or factors beyond our control such as currency exchange rates, changes in governmental policy, trade barriers, trade embargoes, investigation of sanctions relating to corruption of foreign public officials or international sanctions and delays in the development of international markets for its products; risks associated with acquisitions and partnerships, including the ability to attract and retain business partners and reliance of the Corporation on the operations of its partners, and the lack of control over such operations associated with investments the Corporation has made in strategic partners; the Corporation taking advantage of reduced disclosure requirements applicable to emerging growth companies; the Corporation's ability to successfully identify and execute future acquisitions or dispositions; expansion of international operations; reliance on the operations of the Corporation's partners; results of litigation; conflicts of interest between the Corporation and its directors and officers; lack of dividends, and reinvestment of retained earnings, if any, into the Corporation's business; the dependence of the Corporation's operations, in part, on the maintenance and protection of its information technology systems, and the information technology systems of its third-party research institution collaborators, contract research organizations or other contractors or consultants, which could face cyber-attacks; tax-related risks, including unforeseen changes to tax and accounting rules, practices or requirements that may be difficult or impossible for the Corporation to implement or comply with, and its classification as a "passive foreign investment company"; changes, whether anticipated or not, in laws, regulations and guidelines that may result in significant compliance costs for the Corporation, including in relation to restrictions on branding and advertising, regulation of provincial distribution and excise taxes; the Corporation's ability to promote and sustain its products, including any restrictions or constraints on marketing practices under the regulatory framework in which the Corporation operates; failure to execute definitive agreements with entities in which the Corporation has entered into letters of intent or memoranda of understanding; changes in government or government policy, or changes in funding for the FDA and other government agencies, which could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions, upon which the Corporation may rely; failure of counterparties to perform contractual obligations; the Corporation's ability to successfully develop new products or find a market for their sale; the Corporation's ability to promote and sustain its brands; the shelf life of inventory, including unexpected write-downs or fair value adjustments of biological assets or recall of products; the ability to provide the capital required for research, product development, operations and marketing; the impact of any future recall of the Corporation's products; reputational risks to third parties with whom the Corporation does business; the Corporation's ability to produce and sell medical products in, and export medical products to, other jurisdictions outside of Canada, which is dependent on compliance with additional regulatory or other requirements; co-investment risks associated with investments the Corporation may make with strategic investors or other third parties through joint ventures or other entities from time to time; failure to comply with laws and regulations; the Corporation's reliance on its own market research and forecasts; competition from other technologies and pharmaceutical products, including from synthetic production, new manufacturing processes and new technologies, and expected significant competition from other companies with similar businesses, and significant competition in an environment of rapid technological and scientific change as competitors have proposed various new product candidates or existing pharmaceutical products or technologies as an effective treatment for COVID-19, which may be safer, more advanced or more effective than the proposed use of FSD-201 as an effective treatment; the Corporation's ability to safely, securely, efficiently and cost-effectively transport our products to consumers; liability arising from any fraudulent or illegal activity, or other misconduct or improper activities that the Corporation's directors, officers, employees, contractors, consultants, commercial partners or vendors may engage in, including noncompliance with regulatory standards and requirements; the Corporation's inability attain the regulatory approvals it needs to

commercialize pharmaceutical products; the Corporation's product candidates being in the preclinical development stage; the Corporation's ability to obtain regulatory approval in jurisdictions for any product candidates; failure to obtain regulatory approval for FSD-201, or to achieve the degree of market acceptance and demand for our products by physicians, patients, healthcare payors, and others in the medical community which are necessary for commercial success, including, in the case of the FSD-201 COVID-19 Trials for the use of FSD-201 to treat COVID-19, due to the possibility that alternative, superior treatments for COVID-19 may be available prior to the approval and commercialization of FSD-201 for the treatment of COVID-19, should such approval be received at all; delays in clinical trials; failure of clinical trials to demonstrate substantial evidence of the safety and/or effectiveness of product candidates, which could prevent, delay or limit the scope of regulatory approval and commercialization, including from difficulties encountered in enrolling patients in clinical trials, and reliance on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, or results from future clinical testing which may demonstrate opposing evidence and draw negative conclusions regarding the effectiveness of FSD-201 as a treatment for COVID-19 or other medical conditions; results of earlier studies or clinical trials not being predictive of future clinical trials and initial studies or clinical trials may not establish an adequate safety or efficacy profile for the Corporation's product candidates to justify proceeding to advanced clinical trials or an application for regulatory approval; difficulties enrolling patients in clinical trials; potential side effects, adverse events, or other properties or safety risks of the Corporation's product candidates, which could delay or halt their clinical development, prevent their regulatory approval, cause suspension or discontinuance of clinical trials, abandonment of a product candidate, limit their commercial potential, if approved, or result in other negative consequences; regulatory regimes of locations for clinical trials outside of the United States; failure to obtain approval to commercialize product candidates outside of the United States; if clinical trials are conducted for product candidates outside of the United States, the FDA and comparable regulatory authorities may not accept data from such trials, or the scope of such approvals from regulatory authorities may be limited; preliminary, interim data obtained from the Corporation's clinical trials that it may announce or publish from time to time may not be indicative of future scientific observations or conclusions as more patient data becomes available, further analyses are conducted, and as the data becomes subject to subsequent audit and verification procedures; manufacturing problems resulting in delays in development or commercialization programs; inability to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for drug candidates; changes in funding for the FDA and other government agencies; unforeseen claims made against the Corporation, including product liability claims or regulatory actions if products are alleged to have caused significant loss or injury; misconduct or other improper activities by employees, independent contractors, consults, commercial partners and vendors; failure to achieve market acceptance in the medical community; inability to establish sales and marketing capabilities, or enter in to agreements with third parties, to sell and market any product candidates that the Corporation may develop; failure to comply with health and data protection laws; reliance on third parties to conduct clinical trials; reliance on single-source suppliers, including single-course suppliers for the acquisition of the drug substance and drug product for FSD-201; reliance on contract manufacturing facilities; inability to obtain or maintain sufficient intellectual property protection for the Corporation's products; uncertainty associated with insurance coverage and reimbursement status for newly-approved pharmaceutical products, which could result in product candidates becoming subject to unfavourable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, including legislative measures aimed at reducing healthcare costs; third-party claims of intellectual property infringement; patent terms being insufficient to protect competitive position on product candidates; risk factors related to the sale of the Facility; inability to obtain patent term extensions or non-patent exclusivity; inability to protect the confidentiality of trade secrets; inability to protect trademarks and trade names; filing of claims challenging the inventorship of the Corporation's patents and other intellectual property; invalidity or unenforceability of patents, including legal challenges to patents

covering FSD-201; claims regarding wrongfully used or disclosed confidential information of third parties; inability to protect property rights around the world; conditions in the global economy and capital markets, including impacts to trade and public health or geopolitical risks, as a result of impacts of COVID-19 or otherwise; that additional issuances of the Corporation's shares could have a significant dilutive effect; and other factors beyond the Corporation's control.

The Corporation cautions that the foregoing list of important risk factors and uncertainties is not exhaustive. Although the Corporation has attempted to identify important factors that could cause actual results to differ materially from those contained in Forward-Looking Statements, there may be other factors that cause results not to be as anticipated, estimated, intended or projected. There is no assurance that such statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on Forward-Looking Statements. You should carefully consider the matters as further discussed under "*Risk Factors*".

The Forward-Looking Statements contained or incorporated by reference in this AIF are made as of the date of this AIF or as otherwise specified. Except as required by applicable securities law, we undertake no obligation to update publicly or otherwise revise any Forward-Looking Statements or the foregoing list of factors affecting those statements, whether as a result of new information, future events or otherwise or the foregoing lists of factors affecting this information.

## GLOSSARY OF TERMS

In addition to terms defined elsewhere in this AIF, the following terms, when used in this AIF, have the following meanings (unless otherwise indicated):

"**ACA**" means, collectively, the U.S. *Patient Protection and Affordable Care Act*, as amended by the U.S. *Health Care and Education Reconciliation Act of 2010*.

"**Acquireco**" means 2620756 Ontario Inc., a wholly-owned subsidiary of the Corporation incorporated under the OBCA for the purpose of carrying out the Amalgamation.

"**AIF**" has the meaning ascribed to herein under "*Annual Information Form*".

"**Amalco**" means the amalgamated entity following the Amalgamation of Acquireco and FV Pharma, which continued under the name "FV Pharma Inc.".

"**Amalgamation**" means the amalgamation of Acquireco and FV Pharma pursuant to the terms of the Amalgamation Agreement.

"**Amalgamation Agreement**" means the business combination agreement dated March 9, 2018, entered into among the Corporation, Acquireco and FV Pharma in respect of the Amalgamation.

"**Articles**" means the articles of amalgamation of the Corpoation.

"**Articles of Amendment**" means the amendment to the Articles providing for the change of name of the Corporation from "Century Financial Capital Group Inc." to "FSD Pharma Inc.", and the concurrent reorganization of the Corporation's share capital, as further described herein.

"**Audit Committee**" means the Audit Committee of the Board.

"**Aura**" means Aura Health Inc.

"**Auxly**" means Auxly Cannabis Group Inc.

"**Board**" means the board of directors of the Corporation.

"**BPCIA**" means the U.S. *Biologics Price Competition and Innovation Act of 2009*.

"**Business Combination**" means the reverse takeover of the Corporation by the shareholders of FV Pharma.

"**Canada House**" means Canada House Wellness Group Inc.

"**Cannabis Act**" means the *Cannabis Act*, S.C. 2018, c.16,.

"**Cannabis Licenses**" means the three licenses received from Health Canada under (or as migrated to, as applicable) the Cannabis Act: (i) a Cultivation License; (ii) a Standard Processing License; and (iii) a Sale

for Medical Purposes License, each of which have been forfeited by the Corporation.

"**Cannara**" means Cannara Biotech Inc.

"**Canntab**" means Canntab Therapeutics Limited.

"**CBD"** means Cannabidiol.

"**Century Shares**" means common shares in the capital of the Corporation prior to the reorganization of the Corporation's share capital as described in the Articles of Amalgamation.

"**Class A Shares**" means the Class A multiple voting shares in the capital of the Corporation.

"**Class B Shares**" means the Class B subordinate voting shares in the capital of the Corporation.

"**Clover**" means Clover Cannastrip Thin Film Technologies Inc.

"**CMO**" means contract manufacturing organization.

"**CMS**" means Centers for Medicare & Medicaid Services.

"**Coattail Agreement**" means the coattail agreement dated May 24, 2018 among the Corporation, Computershare and certain of the Shareholders holding at least 80% of the Class A Shares.

"**Computershare**" means Computershare Trust Company of Canada, the registrar and transfer agent of the Corporation.

"**Corporation**" means FSD Pharma Inc. (formerly Century Financial Capital Group Inc.), a corporation formed under the OBCA.

"**COVID-19**" means the 2019 novel coronavirus (SARS-CoV-2).

"**CRO**" means contract research organization**.**

"**CSA Notice**" means the CSA Staff Notice 51-352 *Issuers with U.S. Marijuana Related Activities.*

"**CSE**" means the Canadian Securities Exchange.

"**EMA**" means European Medicines Agency.

"**Epitech**" means Epitech Group SpA.

"**Facility**" means the facility located at 520 William Street, Cobourg, Ontario, K9A 3A5.

"**FDA**" means the U.S. Food and Drug Administration.

"**FDC Act**" means the U.S. *Federal Food, Drug, and Cosmetic Act*.

"**First Republic**" means First Republic Capital Corporation, a company controlled by Anthony Durkacz.

"**FSD Biosciences**" means FSD Biosciences, Inc., a corporation incorporated under the laws of Delaware

and a wholly-owned subsidiary.

"**FV Pharma**" means FV Pharma Inc., a corporation incorporated under the OBCA and a wholly-owned subsidiary of the Corporation.

"**High Tide**" means High Tide Ventures Inc.

"**HIPAA**" means the U.S. *Health Insurance Portability and Accountability Act* of 1996.

"**JOBS Act**" means the U.S. *Jumpstart Our Business Startups Act*.

"**MCTO**" means management cease trade order.

"**MNP**" means MNP LLP, auditors of the Corporation since November 29, 2019.

"**Nasdaq**" means The Nasdaq Stock Market LLC.

"**NI 52-109**" means National Instrument 52-109 Certification of Disclosure in Issuers' Annual and Interim Filings.

"**NP 46-201**" means National Policy 46-201 – *Escrow for Initial Public Offerings*.

"**OBCA**" means the *Business Corporations Act* (Ontario).

"**OTCQB**" means the OTCQB Venture Market.

"**PEA**" means palmitoylethanolamide.

"**Pharmadrug DE**" means Pharmadrug Production GmbH.

"**Pharmastrip**" means Pharmastrip Corp.

"**Prismic**" means Prismic Pharmaceuticals, Inc., a corporation incorporated under the laws of Arizona and

a wholly-owned subsidiary of the Corporation.

"**SAB**" means the Scientific Advisory Board of the Corporation.

"**Sales Agent**" means A.G.P./Alliance Global Partners.

"**SciCann**" means SciCann Therapeutics Inc.

"**SEDAR**" means System for Electronic Document Analysis and Retrieval.

"**Shareholders**" means shareholders of the Corporation.

"**Solarvest**" means Solarvest BioEnergy Inc.

"**Stock Options**" means incentive stock options of the Corporation.

"**THC**" means tetrahydrocannabinol.

"**USPTO**" means the United States Patent and Trademark Office.

"**U.S. Exchange Act**" means the United States Securities Exchange Act of 1934, as amended.

"**Warrants**" means warrants of the Corporation to purchase Class B Shares.

"**World Class**" means World Class Extractions Inc.

## CORPORATE STRUCTURE

### Name, Address and Incorporation

The Corporation was formed under the OBCA on November 1, 1998 pursuant to the amalgamation of Olympic ROM World Inc., 1305206 Ontario Corporation, 1305207 Ontario Inc., Century Financial Capital Group Inc. and Dunberry Graphic Associates Ltd.

On March 15, 2018, the Shareholders approved the amendments contemplated by the Articles of Amendment at the 2018 annual and special meeting of the Shareholders, pursuant to which, among other things, the Shareholders approved the redesignation of the Century Shares to Class B Shares, the creation of the new class of Class A Shares, and the elimination of the Corporation's existing non-voting Class A Preferred Shares and non-voting Class B Preferred Shares.

On May 24, 2018, FV Pharma completed a reverse takeover of the Corporation by way of a three-cornered amalgamation among the Corporation, FV Pharma and Acquireco, a wholly-owned subsidiary of the Corporation formed solely for the purposes of completing the Amalgamation. In connection with the completion of the Amalgamation, the Corporation: (i) changed its name from "Century Financial Capital Group Inc." to "FSD Pharma Inc."; and (ii) reorganized the capital structure of the Corporation to create a new class of Class A Shares, amended the terms of and re-designated the existing common shares as Class B Shares, and eliminated the existing non-voting Class A Preferred Shares and non-voting Class B Preferred Shares, pursuant to the Articles of Amendment.

On May 29, 2018, the Class B Shares commenced trading on the CSE under the trading symbol "HUGE".

The Corporation's head office is located at First Canadian Place, 100 King Street West, Suite 3400, Toronto, Ontario, Canada M5X 1A4. The Corporation's registered office is located at 1 Rossland Road West, Suite 202, Ajax, Ontario, Canada L1Z 1Z2. As at the date of this AIF, the Corporation is a reporting issuer in each of the provinces of Canada (other than Québec).

On October 16, 2019, the Corporation amended its articles of incorporation to complete a consolidation of all of its issued and outstanding share capital. Pursuant to the amendment, all of the issued and outstanding Class A Shares and Class B Shares were consolidated on the basis of one post-consolidation share for every 201 pre-consolidation shares of the Corporation (the "**Consolidation**"). Unless otherwise noted, presentation in this AIF of the number of Class A Shares, Class B Shares, options, warrants and the issue or exercise prices and any other data related to the foregoing securities are all presented on a post-Consolidation basis.

On January 9, 2020, the Class B Shares commenced trading on the Nasdaq under the trading symbol "HUGE". The Corporation's principal business activity is a clinical-stage biotechnology company that is focused on bioscience, including research and development and clinical development of its lead compound, FSD 201, ultra-micronized Palmitoyl ethylamine (PEA). FSD 201 is known to stabilize mast cells of the human body and down-regulate the pro-inflammatory cytokines to effectuate an anti-inflammatory response.

### Intercorporate Relationships

As at the date of this AIF, the Corporation has two material subsidiaries, FV Pharma and Prismic, which

are both wholly-owned by the Corporation.

**History of FV Pharma**

FV Pharma was incorporated under the OBCA on September 12, 2011 under the name "2298519 Ontario Corp." and changed to its present name, "FV Pharma Inc.", on September 17, 2013. The registered and head office of FV Pharma is located at 1 Rossland Road West, Suite 202, Ajax, Ontario, L1Z 1Z2. FV Pharma's plant and operations are located at 520 William Street, Area 4, Bldg. #3, Cobourg, Ontario, Canada, K9A 3A5.

In March 2020, substantially all of the assets of FV Pharma were classified as being held for sale, and the Corporation is actively exploring a sale of the Facility and/or the Facility Property.

**History of FSD BioSciences, Inc.**

FSD BioSciences, Inc., a wholly-owned subsidiary, is a specialty biotech pharmaceutical R&D company focused on developing over time multiple applications of its lead compound, FSD-201 ultra-micronized palmitoylethanolamide (Ultra-Micro PEA). Ultra-Micro PEA stabilizes mast cells and down-regulates the pro-inflammatory cytokines to effectuate an anti-inflammatory response.

**History of Prismic**

Prismic is incorporated under the laws of the State of Arizona. The registered and head office of Prismic is located at 474 Grove Street, Suite 740, Worcester, Massachusetts, United States, 06105.

Prismic is a U.S.-based specialty pharmaceutical company dedicated to addressing the opioid crisis by developing novel non-addictive prescription drugs for the treatment of pain, inflammation, and neurological disorders, based on formulations utilizing the Corporation's micro-PEA development platform (palmitoylethanolamide with particle sizes of 0.6 – 10 microns).

## GENERAL DEVELOPMENT OF THE BUSINESS

**Three Year History**

***Business Combination with FV Pharma and Concurrent Financing***

Prior to the closing of the Business Combination, the Corporation was engaged in the leasing of operating and manufacturing equipment such as industrial and construction machinery. As of August 31, 2016, all of the Corporation's former leases had been written off and the Corporation was inactive until the completion of the Amalgamation.

On March 9, 2018, the Corporation entered into a definitive Business Combination agreement with FV Pharma, which provided for the reverse takeover of the Corporation by the shareholders of FV Pharma. The Business Combination was carried out by way of a "three-cornered amalgamation" pursuant to the provisions of the OBCA. The three-cornered amalgamation included the following steps:

(i) the Corporation filed Articles of Amendment, providing for the change of name of the Corporation from "Century Financial Capital Group Inc." to "FSD Pharma Inc." and the amendment and re-designation of the Corporation's share capitalization pursuant to which the existing Century Shares were re-designated as "Class B Shares", a new class of "Class A Shares" was created, and the existing classes of non-voting Class A Preferred Shares and non-

voting Class B Preferred Shares were eliminated;

(ii) Acquireco and FV Pharma amalgamated;

(iii) each holder of FV Pharma Class A voting common shares transferred such shares to the Corporation in exchange for an aggregate of 15,000 fully paid and non-assessable Class A Shares on a one-for-one basis, and each holder of FV Pharma Class B non-voting common shares transferred such shares to the Corporation in exchange for an aggregate of 1,305,770,018 fully paid and non-assessable Class B Shares on a one-for-one basis (1,305,770,018 total, on a pre-Consolidation basis);

(iv) the Corporation received one fully paid and non-assessable common share of Amalco for each common share of Acquireco held by the Corporation, following which all such common shares of Acquireco were cancelled;

(v) all FV Pharma shares held by the Corporation as a result of the exchanges described above were cancelled and the Corporation received, for each FV Pharma share, one common share of Amalco and Amalco became a wholly-owned subsidiary of the Corporation; and

(vi) Stock Options and Warrants were issued to the holders of the FV Pharma stock options and warrants, respectively, in exchange and replacement for, on an equivalent basis, such FV Pharma stock options and warrants, which were cancelled.

The Amalgamation resulted in Amalco becoming a wholly-owned subsidiary of the Corporation. Concurrently with the completion of the Amalgamation, the Corporation changed its name to "FSD Pharma Inc." and Amalco continued under the name "FV Pharma Inc.". The Corporation continued the medical cannabis business of FV Pharma.

The valuation ascribed to FV Pharma in the Amalgamation was determined by arm's length negotiations between the Corporation and FV Pharma, and based in part upon FV Pharma's pre-Amalgamation financings. A formal third party valuation was not determined to be necessary.

The Amalgamation was approved by a special resolution of the holders of FV Pharma shares at a shareholder meeting held on May 15, 2018, and by the Corporation, in its capacity as sole shareholder of Acquireco. The Amalgamation was approved, pursuant to the policies of the CSE, by a majority (50% plus one vote) of the votes cast at the meeting of shareholders of FV Pharma.

Concurrently with the completion of the Business Combination, FV Pharma completed a multi-tranche private placement of subscription receipts of FV Pharma (each, a "**Subscription Receipt**") pursuant to the terms of an agency agreement (the "**Agency Agreement**") dated March 9, 2018 between FV Pharma and First Republic, as exclusive agent (the "**Concurrent Financing**"), and each Subscription Receipt converted into one Class B Share in connection with the closing of the Amalgamation. Under the Concurrent Financing, FV Pharma issued an aggregate of 371,159,913 Subscription Receipts at a price of $0.09 per Subscription Receipt (the "**Subscription Price**") for aggregate gross proceeds of $33,404,392.

On the closing of the Business Combination and the satisfaction of certain other escrow release conditions contained in the Agency Agreement and the subscription receipt agreement dated March 9, 2018 among FV Pharma, First Republic and Garfinkle Biderman LLP, as subscription agent, the Subscription Receipts converted into Class B Shares and the net proceeds from the Concurrent Financing ($29,862,645) were

released to the Corporation.

***Investment in SciCann***

On June 6, 2018, the Corporation announced that FV Pharma made an investment into SciCann by executing a term sheet (the "**Term Sheet**") pursuant to which the Corporation invested approximately $2 million and received shares of SciCann representing approximately 10.52% of SciCann's equity. On February 28, 2020, the Term Sheet was amended and certain of FV Pharma's rights thereunder were assigned to the Corporation.

***Partnership Agreement with Cannara***

On June 19, 2018, the Corporation announced the signing of a partnership agreement between FV Pharma and Cannara (the "**Cannara Agreement**"), effective May 31, 2018 concerning the development of Cannara's proposed cannabis cultivation facility outside of Montreal, Québec. In connection with the Cannara Agreement, the Corporation (via FV Pharma) received approximately 75 million shares of Cannara (each, a "**Cannara Share**"). On July 24, 2018, the Corporation announced that Cannara completed a $17.66 million common share equity financing, during which the Corporation made an additional investment of $1 million.

On February 20, 2020, the Corporation announced that it sold all of its direct and indirect equity interests in Cannara to a consortium of buyers for cash proceeds of approximately $7.7 million. The terms of the sale 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 the Corporation's shareholdings in Cannara were subject to a statutory escrow period set to expire in December 2021. Under the terms of the transaction, the buyers agreed to acquire all of the Cannara Shares owned by the Corporation subject to escrow and, as such, assumed all of the associated market risk. The sale represents a 670% return on the Corporation's investment in Cannara.

***Collaboration Agreement with Canntab***

On September 18, 2018, the Corporation announced that it had signed a definitive collaboration agreement dated effective September 17, 2018 with Canntab. Under the terms of the agreement, the Corporation assisted Canntab in obtaining a license to process and sell cannabis products and provided Canntab with up to 10,000 square feet of space at the Facility in exchange for certain royalty and profit-sharing rights in connection with the sale of Canntab-manufactured cannabis-based products. The collaboration agreement with Canntab was terminated in connection with the forfeiture of the Cannabis Licenses.

***Investment in High Tide***

In April 2018 and October 2019, the Corporation completed two investments in High Tide for an aggregate purchase price of $2.2 million. High Tide operates 19 licensed cannabis stores across Canada and holds provincial e-commerce licenses in Saskatchewan and Manitoba. On November 22, 2019, the Corporation sold all of the securities of High Tide it previously acquired to a third party for aggregate cash proceeds of $614,520.

***International Securities Listings***

On August 14, 2018, the Corporation listed its Class B Shares on the Frankfurt exchange and trading under

"WKN: A2JM6M" and the ticker symbol "0K9".

On September 19, 2018, the Corporation announced that the Class B Shares were upgraded to a listing on the OTCQB, trading under the ticker symbol "FSDDF".

On January 9, 2020, the Class B Shares commenced trading on the Nasdaq under the symbol "HUGE".

***Migration of Licenses to the Cannabis Act***

On November 13, 2018, the Corporation announced that its Cultivation License, which was originally granted under the *Access to Cannabis for Medical Purposes Regulations* (Canada), had been migrated to the Cannabis Act, effective November 8, 2018. As of November 7, 2018, FV Pharma also received license amendments approving all of the remaining 30,000 square feet currently built out for additional grow and operations. On June 21, 2019, the Cannabis Licenses were amended to allow the Corporation to sell or provide fresh or dried cannabis or cannabis oil to such other persons who are permitted to purchase medical cannabis products under the Cannabis Act. On July 30, 2020, the Corporation announced that it had notified Health Canada of the Corporation's decision to forfeit all of the Cannabis Licenses, and suspend all activities by FV Pharma.

***Collaboration with World Class Extractions***

On December 6, 2018, the Corporation announced that it had entered into a definitive collaboration and license Agreement with World Class, a company that has developed a unique extraction process designed to produce large-scale, quality, potent cannabis extracts. Under the terms of the agreement and a related lease, the Corporation agreed to (i) provide World Class with 5,000 square feet of space at the Facility, (ii) assist World Class in obtaining an extraction license from Health Canada, and (iii) provide World Class with raw cannabis needed to produce cannabis extracts. The collaboration and license agreement with World Class was terminated in connection with the forfeiture of the Cannabis Licenses.

***Investment in Huge Shops***

Huge Shops operates as a cannabis retailer and offers cannabis products to consumers. Huge Shops has a strategic alliance with Chairman's Brands Corporation, parent company of Coffee Time, a well-established operator of retail coffee shops with more than 75 locations in Canada and other locations worldwide.

On December 20, 2018, the Corporation announced that it had completed the purchase of 17,333,333 shares of Huge Shops (each, a "**Huge Shop Share**") based on the December 2018 subscription price of $0.075 per Huge Shop Share, for a total investment of approximately $1.3 million to acquire approximately 9.9% of the issued and outstanding shares of Huge Shops.

***Solarvest Transactions***

On May 7, 2019, the Corporation announced that it signed a definitive Collaboration and Research Development Agreement with Solarvest (the "**Solarvest Agreement**") to conduct research using its algal expression technology to develop pharma-grade cannabinoids (the "**Solarvest Research Project**"). The Corporation and Solarvest allocated an initial budget of $1 million for the Solarvest Research Project, over a two-year period, and created a joint scientific review committee to assess progress of the project against budgets and timelines.

In connection with the Solarvest Agreement, (i) the Corporation issued 49,751 Class B Shares to Solarvest, at a deemed price of $60.30 per Class B Share, (ii) Solarvest issued 3,000,000 units to the Corporation, at

a deemed price of $0.25 per unit (each, a "**Solarvest Unit**"), with each Solarvest Unit being comprised of one common share in the capital of Solarvest (each, a "**Solarvest Share**") and one common share purchase warrant with an exercise price of $0.25 per Solarvest Share and a term of two years, and (iii) Solarvest issued a convertible debenture to the Corporation 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 Solarvest Shares at a conversion price of $1.00 per Solarvest Share, provided that the Corporation will be required to convert the debenture if Solarvest Shares close at a price of at least $1.20 for a period of 20 consecutive trading days).

On February 4, 2020, the Corporation announced that it agreed to certain amendments to the Solarvest Agreement whereby the Corporation agreed to issue an additional 225,371 Class B Shares to Solarvest in settlement of derivative liability under the Solarvest Agreement. In addition, Solarvest appointed Dr. Edward J. Brennan Jr., the President of the Corporation's BioSciences Division, to the board of directors of Solarvest. The Solarvest Agreement and related agreements were terminated in connection with the forfeiture of the Cannabis Licenses.

***Auxly Joint Venture***

On March 3, 2018, the Corporation entered into a Definitive Strategic Alliance and Streaming Agreement (the "**Auxly Agreement**") with Auxly. On February 6, 2019, the Corporation sent Auxly a Notice of Default, thereby terminating the Agreement effective immediately. Later that same day, Auxly sent a Notice of Default to the Corporation in response. To date, neither party has taken further legal steps.

To fund the development, Auxly purchased 37,313 Class B Shares for the aggregate of $7,500,000 from the treasury by way of private placement, which funds were placed in trust to be spent on construction and development costs in respect of the Facility. The funds were placed in a trust account to be administered by Auxly. Due to the termination of the Auxly Agreement and subsequent negotiations, it is indeterminable at this point as to the amount, if any, of these funds will be released to the Corporation. As a result, the Corporation entered a provision for loss against the funds, which loss has been recognized in the Corporation's consolidated financial statements. Should any funds be released to the Corporation, those amounts will be recognized in future periods as gains on recovery. No other provision has been recorded for this matter as at December 31, 2020.

***Investment in Pharmastrip***

On September 6, 2018, the Corporation invested $1.5 million in Clover. The investment included units comprising 7,500,000 shares and 3,750,000 warrants. In connection with the investment, the Corporation entered into a definitive collaboration and profit sharing agreement with Pharmastrip (the "**Pharmastrip Agreement**"), an entity represented to be an affiliate of Clover, effective January 23, 2019.

FSD was subsequently informed that certain principals of Clover were the subject of Federal Trade Commission proceedings in the U.S., and that the U.S.-based owner of the licensed technology had been placed into receivership. As a result of the foregoing, it may be difficult or impossible for us to realize a return on the investment in Clover and to commercialize the licensed Pharmastrip technology. The Corporation has written down the equity investment to $0 in light of the circumstances.

***Supply Agreement with Canntab and World Class***

On February 12, 2019, the Corporation announced that it had entered into a supply agreement with Canntab and World Class (together, the "**Purchasers**") to purchase hemp flower from a supplier (the "**Supplier**"). Pursuant to this agreement, the Purchasers agreed to buy approximately 1,000 kg of the Supplier's 2018 organic hemp crop, for which the Corporation purchased a quantity with a value of $100,000 prior to

September 30, 2019. Approximately $500,000 was paid by the Purchasers for the 2019 organic hemp crop as a loan to the Supplier in the form of equipment, and paid back in the form of hemp pursuant to a supply and loan agreement (the "**Supply and Loan Agreement**"). Pursuant to the Supply and Loan Agreement, the Supplier granted the Purchasers the right and option to purchase up to $5.0 million of the Supplier's hemp crop for a period of five years commencing in 2019 at a purchase price of $100 per kg per 1% of CBD extracted from the flower. The Supply and Loan Agreement has been terminated in connection with the forfeiture of the Cannabis Licenses.

***Acquisition of Prismic***

On April 23, 2019, the Corporation announced that it entered into a definitive securities exchange agreement with Prismic (the "**Prismic Exchange Agreement**"). Prismic is a U.S.-based specialty research and development pharmaceutical company, developing novel non-addictive prescription drugs with unique safety profiles with the goal of addressing the opioid crisis based on formulations utilizing micro-palmitoylethanolamide's "entourage" effect on certain drugs impacting the endocannabinoid system.

The acquisition of Prismic was completed on June 28, 2019. Pursuant to the terms of the Prismic Exchange Agreement, the Corporation acquired all outstanding securities of Prismic for an aggregate purchase price of US$15,713,448 million (C$20,887,086 million based on an exchange rate of US$1 to CAD$1.3349 calculated based on the average daily exchange rate between April 5, 2019 and April 18, 2019), satisfied by the issuance of an aggregate of 510,940 Class B Shares at a deemed price of $45.7275 (US$34.2504) per Class B Share. The Class B Shares issued to the former Prismic shareholders are subject to an 18-month staggered escrow release pursuant to the terms of the Prismic Exchange Agreement. Additionally, the Corporation assumed approximately US$2.90 million of outstanding Prismic liabilities on closing, some of which may be settled by the issuance of additional Class B Shares.

In accordance with the terms of the Prismic Exchange Agreement, all of the outstanding Prismic stock options and warrants were converted into options and warrants to purchase Class B Shares, with the number and exercise price of such securities having been adjusted in accordance with the exchange ratio under the Prismic Exchange Agreement. The Class B Shares underlying the replacement warrants and options issued to former Prismic securityholders are also subject to an 18-month staggered escrow release pursuant to the terms of the Prismic Exchange Agreement.

***Agreement with Aura Health***

On April 16, 2019, the Corporation entered into a share exchange agreement (the "**Aura Exchange Agreement**") with Aura. Pursuant to the Aura Exchange Agreement, the Corporation acquired common shares in the capital of Aura (each, an "**Aura Share**") valued at approximately $3 million issued from treasury (13,562,386 Aura Shares at a deemed price of $0.221 per Aura Share) in exchange for Class B Shares having an aggregate value of $3 million (being 65,577 Class B Shares at a deemed price of $45.7476 per Class B Share). Subsequent to September 30, 2019, Aura announced a name change to Pharmadrug Inc.

In addition to the Aura Exchange Agreement, Aura, through Pharmadrug DE, a company in which Aura holds an 80% equity interest, and the Corporation entered into a consulting agreement and a supply agreement, each of which is no longer in effect following the forfeiture of the Cannabis Licenses.

In October 2019, FSD issued an additional 61,892 Class B Shares to Aura pursuant to a make whole

provision under the Aura Exchange Agreement.

***Changes to Management, Board of Directors and Advisors***

On July 23, 2018, the Corporation announced the appointment of Mr. Donal Carroll to the role of interim Chief Financial Officer. Mr. Carroll is a finance executive with 20 years of corporate finance leadership and public company experience, as well as deep expertise in syndicate investing, both in equity and debt securities. Mr. Carroll has successfully guided companies for expansion and growth, and has worked with major companies such as Danaher and Unilever (NYSE:UL), where he was instrumental in major restructuring activities, mergers and acquisitions, and the implementations of new internal controls and enterprise resource planning 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. and holds a CPA-CMA designation, as well as a Bachelor of Commerce degree, from University College Dublin.

On August 2, 2018, the Corporation announced the appointment of Dr. Raza Bokhari to its Board. Dr. Bokhari served as the Chairman & Chief Executive Officer of PCL, Inc., 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 and a recipient of Philadelphia Business Journal's "40 under 40" award. A physician-turned-entrepreneur, Dr. Bokhari has, over the past several years, developed expertise in aggregating and accelerating life sciences and healthcare services companies. He has a vast knowledge base of developing creative concepts, implementing programs and forming strategic alliances. An effective "change agent" with several years of experience and expertise in start-up and turn-around businesses, he is adept at turning around struggling companies. Dr. Bokhari recognizes the special role of public offerings, private equity funds, venture capital money, and leveraged debt partners in executing accelerated growth trends in healthcare services and cancer diagnostics and therapeutics.

On October 29, 2018, Dr. Bokhari was appointed as Executive Co-Chairman of the Board and interim Chief Executive Officer of the Corporation. Further, the Corporation announced the appointment of Mr. Zeeshan Saeed as President of the Corporation and Mr. Anthony Durkacz as Executive Co-Chairman of the Board.

On November 14, 2018, the Corporation announced the appointment of Mr. David Urban to the Board. Mr. Urban is an accomplished business and government relations executive. He and his company advise organizations ranging in size from start-ups to the Fortune 100 companies on interactions with government in order to maximize stakeholder and shareholder value. In the field of politics, Mr. Urban has achieved success serving as an advisor to 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 business consultant and political advisor, Mr. Urban is a frequent contributor to CNN as a political commentator.

On November 26, 2018, the Corporation announced the appointment of Mr. Rupert Haynes as Chief Executive Officer of the Corporation. Mr. Haynes was subsequently terminated as Chief Executive Officer on February 6 2019, and Dr. Raza Bokhari was appointed interim (and subsequently permanent) Chief Executive Officer.

On March 13, 2019, the Corporation announced the departure of Mr. Thomas Fairfull as President of FV Pharma and the subsequent appointment of Dr. Sara May as President of FV Pharma. Additionally, the Corporation announced the departure of Mr. Vladimir Klacar, a former Board nominee of Auxly, from the Board.

On May 28, 2019, the Corporation announced the appointment of pharmaceutical industry leader, Dr. Edward J. Brennan, Jr., M.D., FACS, as President of its Biosciences division. Dr. Brennan has more than

25 years' experience in leadership roles at major pharmaceutical companies and clinical research organizations. 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 investigational new drug 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 next founded IndiPharm, a full-service global CRO that was eventually acquired by a private equity company, Velocity Fund Partners. Dr. Brennan received his undergraduate Bachelor of Science Degree in Pharmacy from the Philadelphia College of Pharmacy and Science. He went on to study medicine at the Royal College of Surgeons in Ireland before receiving his medical degree from the Temple University School of Medicine.

On June 3, 2019, the Corporation announced that Dr. Raza Bokhari had been appointed as (permanent) Chief Executive Officer of the Corporation.

On June 12, 2019, the Corporation announced the appointment of Mr. James A. Datin and Mr. Robert J. Ciaruffoli to the Board. Mr. Datin is the current President and Chief Executive Officer of BioAgilytix Labs, LLC, a leading global bioanalytical CRO that supports the development of novel therapeutic biologics. Mr. Datin also has considerable experience managing growing companies throughout the U.S., Europe and Asia, and has completed various corporate transactions including venture investments, buyouts, acquisitions, mergers, initial public offerings, licensing and partnership agreements.

Mr. Ciaruffoli is a CPA and served as the Chairman and CEO of the ParenteBeard/Baker Tilly accounting and advisory firm. During his tenure as Chairman and Chief Executive Officer, 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 ParenteBeard and Baker Tilly Virchow Krause firms to create the 12th largest U.S. accounting and advisory firm. Throughout his career, Mr. Ciaruffoli has served on numerous for-profit and not-for-profit boards.

On October 11, 2019, Mr. Stephen Buyer, a former member of the U.S. House of Representatives, was appointed as a director of the Corporation. 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 long tenure in Congress, he served on the Veterans Affairs, Armed Services, Judiciary, Energy and Commerce Committees, and also served 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 U.S. federal government.

On January 2, 2020, the Corporation announced further changes to its management team. The Corporation appointed Mr. Donal Carroll as the Chief Financial Officer on a permanent basis, Ms. Sandra Lottes as Vice President & Head of Clinical Research for the Corporation's BioSciences Division and Mr. Shahzad Shah as Chief Operating Officer of FV Pharma.

On January 22, 2020, the Corporation appointed Dr. Larry Kaiser to the Board. Dr. Kaiser was formerly the Dean, Lewis Katz School of Medicine at Temple University, President & 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.

On July 29, 2020, the Scientific Advisory Board was dissolved.

On October 20, 2020, Mr. David Urban resigned from the Board due to external contractual obligations.

On January 26, 2021, the Corporation terminated of its former president, Mr. Zeeshan Saeed, for cause. As a result of his termination, in accordance with the terms of his employment agreement, Mr. Saeed resigned from all other positions held with the Corporation and its subsidiaries, including from the Board.

Effective April 30, 2021, Mr. James A. Datin will be resigning from the Board.

Effective March 1, 2021, Randell Mack was appointed as President of FSD BioSciences and Dr. Ed Brennan was named Chief Medical Officer of the Corporation.

***Q4 2019 Private Placement***

The Corporation completed a private placement of Class B Shares in two tranches closed on September 30, 2019 and November 4, 2019 (the "**2019 Private Placement**"). Under the 2019 Private Placement, the Corporation issued an aggregate of 228,670 Class B Shares to the purchasers under the private placement at a price of $20.10 per Class B Share, for aggregate gross proceeds of $4,593,777. Certain of the purchasers of Class B Shares in the 2019 Private Placement included members of senior management and the Board. The Corporation's leadership team, representing founders, directors and members of senior management collectively invested more than $500,000. The net proceeds from the 2019 Private Placement will be used for the expansion of the Corporation's biosciences division, including the research and development of PP-101 micro-PEA plus pregabalin – the Corporation's pre-clinical drug candidate for the treatment of symptoms related to fibromyalgia – and for general corporate purposes, including working capital, potential investments and acquisitions.

***Nasdaq Listing***

On December 16, 2019, the Corporation announced that its Class B shares were approved to be listed on the Nasdaq. The Class B Shares commenced trading on the Nasdaq on January 9, 2020 under the symbol "HUGE".

***Epitech License Agreement***

On January 8, 2020, the Corporation entered into an amended and restated license agreement with Epitech, as further amended in June 2020 (the "**License Agreement**"), which amended and restated the license agreement between Prismic and Epitech through which Prismic secured certain intellectual property rights to PEA from Epitech. The License Agreement grants the Corporation an exclusive, worldwide license (excluding Italy and Spain where the Corporation is not licensed and Epitech remains entitled to commercialize the Licensed Products (as defined herein), directly or indirectly) (the "**Epitech License**") to research, manufacture and commercialize products (the "**Licensed Products**") that are developed using certain proprietary formulations of PEA owned by Epitech and that are to be used to treat chronic kidney disease in humans or, if a prescription drug, any other human condition that is related to pain and chronic pain. The Epitech License also gives the Corporation the right to use the Licensed IP (as defined in the Epitech License) in the development of a prescription drug for the treatment of the cytokine storm associated with COVID-19. In addition, under the terms of the Epitech License, as further amended on July 29, 2020, if Epitech develops or commercializes a prescription drug for the treatment of any other human condition unrelated to pain and chronic pain (a "**Different Prescription Drug**") in its territory, the

Corporation has a first refusal right to use Epitech's patents to develop and commercialize this Different Prescription Drug in its territory (i.e. worldwide excluding Italy and Spain). Should the Corporation exercise this right, but then fail to demonstrate commercially reasonable efforts to develop the Different Prescription Drug in the two years following, Epitech would be free to exploit and/or license to third parties the use of the patents for the Different Prescription Drug. The FSD-201 COVID-19 Trials are subject to such requirements. Finally, the Epitech License provides the Corporation with a non-exclusive license to use Epitech's scientific and technical know-how with respect to ultramicronized-PEA in connection with the development or commercialization of the Licensed Products discussed above. See also "*Risk Factors – Risk Relating to the Development of FSD-201.*"

Under the terms of the License Agreement, the Corporation is required to make payments to Epitech upon the achievement of specified milestones. Upon first notification by the FDA of approval of a New Drug Application, the non-refundable sum of US$700,000 is due and payable to Epitech. Within ten business days of the first notification of approval of a Supplemental New Drug Application by the FDA, the Corporation is required to pay the non-refundable sum of US$1,000,000 to Epitech.

The License Agreement also specifies certain royalty payments. Pursuant to the License Agreement, the Corporation must pay Epitech 25% (in the case of non-prescription drug rights) and 5% (in the case of prescription drug rights) of any one-off lump sum payments it receives as consideration for granting a sub-license to a third-party with respect to a Licensed Product. In addition, the Corporation is required to pay either: (a) 7% of net sales of the Licensed Products in a product regulatory category other than prescription drugs placed on the market by the Corporation; (b) 25% of the royalties received by the Corporation from sub-licensees (such royalties, the "**Net Receipts**") where Licensed Products in a product regulatory category other than prescription drugs are placed on the market by such sub-licensees; or (c) 5% of net sales or Net Receipts of the Licensed Products that are prescription drugs.

Unless otherwise terminated in accordance with its terms, the Epitech License will remain in force until the Corporation is no longer obligated to pay royalties under the License Agreement, which obligation will expire on a country-by-country basis when the last valid claim of the Licensed Patents covering the Licensed Products in a given country expires. The approval of a therapeutically equivalent, generic version of the Licensed Product(s) in a country will conclusively demonstrate that a valid claim does not cover the Licensed Products in that country. If there are no patents covering the Licensed Products in a country, royalties are payable for the license of the scientific and technical know-how under the Epitech License until expiration of the last-to expire Epitech patent that relates to PEA.

***Phase 1 (Australia) Trials***

The Corporation announced on March 9, 2020, that it received approval from the Ethics Committee of the Alfred Hospital, part of the Alfred Health group of hospitals serving the state of Victoria, 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 (the "**Alfred Hospital Phase 1 Trials**"). The principal researcher of this first-in-human safety and tolerability study is the Chief Medical Officer of Nucleus Network, one of Australia's largest and most experienced Phase 1 clinical research organizations.

The Corporation has completed Phase 1 clinical trials accordance with FDA-approved guidelines.

On June 22, 2020, the Corporation announced favourable top-line results from the Alfred Hospital Phase 1 Trials, with no significant safety concerns found up to the highest dose tested of 2400 mg/day. The Alfred Hospital Phase 1 Trials were a single-site study and were conducted at the Alfred Hospital with 48 healthy adult men and women enrolled. The trial sequentially tested single ascending doses ranging from 600 mg

to 2400 mg tablets and multiple ascending doses ranging from 600 mg to 1200 mg tablets administered twice daily for 7 consecutive days. The single ascending dose subjects also were tested for food effect.

The study found FSD-201 to be safe and well-tolerated. Mild and self-limiting side effects were reported and were deemed unlikely to be related to the drug being studied. There were no abnormal laboratory findings or electrocardiograms observed during the study and no serious adverse events were reported. No subjects withdrew due to an adverse event and all eligible subjects completed all doses. The pharmacokinetic profile of FSD-201 utilized in the Alfred Hospital Phase 1 Trials is still being analyzed. The results of the Alfred Hospital Phase 1 Trials are subject to additional audit and verification procedures. See "*Risk Factors – Risks Relating to the Development of FSD-201 – Interim, "top-line," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available or as additional analyses are conducted, and as the data are subject to audit and verification procedures that could result in material changes in the final data.*"

***FSD-201 COVID-19 Trials***

On June 3, 2020, the Corporation announced that the FDA has given the Corporation permission to submit an investigational new drug application to design a Phase 2(a) clinical trial for the use of FSD-201 to treat suspected or confirmed cases of COVID-19, the disease caused by the SARS-CoV-2 virus (the "**FSD-201 COVID-19 Trials**" and, together with the Alfred Hospital Phase 1 Trials, the "**FSD-201 Trials**").

On August 31, 2020, the Corporation announced that it had submitted an investigational new drug application to the FDA in respect of the FSD-201 COVID-19 Trials.

On September 28, 2020, the Corporation announced that the FDA had authorized the initiation of the FSD-201 COVID-19 Trials on 352 patients.

Severe COVID-19 is characterized by an over-exuberant inflammatory response that may lead to a cytokine storm and ultimately death. The Corporation is focused on developing FSD-201 for its anti-inflammatory properties to down-regulate the over-expressed immune response and mitigate the cytokine storm associated with acute lung injury in hospitalized COVID-19 patients.

The FSD-201 COVID-19 Trials consist of randomized, controlled, double-blind, U.S.-multicenter study on 352 patients to assess the efficacy and safety of FSD-201 dosed at 600mg or 1200mg twice-daily, as well as potentially higher dosage levels, together with standard of care compared to standard of care alone in hospitalized patients with COVID-19. Eligible patients will present with symptoms consistent with influenza/coronavirus signs (fever, dry cough, malaise, difficulty breathing) and newly documented positive COVID-19 disease.

The primary objective of the FSD-201 COVID-19 Trials is to determine whether FSD-201 plus standard of care provides a significant improvement in the clinical status of patients (e.g., shorter time to symptom relief). Secondary objectives of the FSD-201 COVID-19 Trials include determining whether FSD-201 plus standard of care demonstrates additional benefit in terms of safety, objective assessments such as length of time to normalization of fever, length of time to improvement of oxygen saturation and length of time to clinical progression, including time to mechanical ventilation or hospitalization, and length of hospital stay. The exploratory endpoint is cytokine clearance as measured by Enzyme Linked Immunosorbent Assay (ELISA). The treatment period of patients in the FSD-201 COVID-19 Trials is expected to be at least 14 days and the primary end point is determined at 28 days. All patients who experience clinical benefit are expected to continue to receive their assigned treatment until study completion.

The duration and cost of clinical trials can vary significantly depending on multiple factors, including the

enrollment rate of volunteers, country in which trials are conducted, and specific trial protocols required. The process of developing pharmaceutical products and receiving the necessary regulatory approvals for commercialization typically takes several years. Accordingly, no near-term revenues from product sales or services are expected from our ultramicronized-PEA candidate(s). The milestones described above represent customary inflection points for financing by clinical-stage biotech companies. However, there is no assurance that the Corporation will be able to achieve these clinical milestones, nor, if successful in doing so, that the Corporation will be able to access additional financing on terms or timing acceptable to the Corporation.

The Corporation's current Phase 2(a) clinical trial is being conducted on hospitalized COVID-19 infected patients. Additional trials, targeting different medical conditions may be undertaken depending on FDA approval and available capital, subject to the requirements of the Epitech License and regulatory approvals as required. See also "*Risk Factors – Risks Relating to the Development of FSD-201*."

***Pharmadrug Share Sale***

On May 21, 2020, the Corporation announced the sale of 5,000,000 common shares ("**Pharmadrug Shares**") of Pharmadrug Inc. (formerly Aura Health) ("**Pharmadrug**") in a privately negotiated transaction at a price of $0.08 per Pharmadrug Share for cash proceeds of $400,000 (the "**Pharmadrug Share Sale**"). Upon completion of the Pharmadrug Share Sale, the Corporation held 8,562,387 Pharmadrug Shares. The Corporation has since sold all of its Pharmadrug Shares.

***June Private Placement***

On June 4, 2020, the Corporation announced that it entered into definitive agreements with certain institutional investors pertaining to the private placement (the "**June Private Placement**") by certain placement agents led by the Sales Agent (collectively, the "**Placement Agents**") of an aggregate of 1,500,000 Class B Shares at a price of $6.75 per Class B Share and warrants (the "**June Warrants**") to purchase an additional 1,500,000 Class B Shares (the "**June Warrant Shares**") for aggregate proceeds to the Corporation of approximately $10,125,000 (before deducting fees payable to the Placement Agents and other estimated offering expenses). The June Warrants have a five-year term and an exercise price of $9.65 per June Warrant Share. The June Private Placement was completed on June 8, 2020, generating net proceeds to the Corporation of $9,185,159. In addition, the Corporation granted the Placement Agents an option to arrange for purchases of up to an additional 1,500,000 Class B Shares and June Warrants to purchase an additional 1,500,000 June Warrant Shares on the same terms as the June Private Placement for a period of 30 days following the initial closing of the June Private Placement.

***2020 Equity Distribution Agreement***

On July 10, 2020, the Corporation entered into an equity distribution agreement with the Sales Agent (the "**2020 Distribution Agreement**") pursuant to which the Corporation was permitted, at its discretion and from time-to-time during the term of the 2020 Distribution Agreement, sell, through the Sales Agent, Class B Shares of the Corporation for aggregate gross proceeds to the Corporation of up to US$20.0 million. The Corporation has completed all sales under the 2020 Distribution Agreement, and entered into new equity distribution agreement. See "*General Development of the Business – Three Year History – 2021 Equity Distribution Agreement*"

***Approval of Issuance of Share Compensation***

On July 24, 2020, the Board authorized the issuance of 1,322,927 Class B Shares in the aggregate as

compensation to its directors, officers and certain of its employees.

On January 21, 2021 and February 10, 2021, the Board authorized the issuance of an aggregate of 1,349,765 Class B Shares as annual share-based awards to certain directors, officers and employees of the Corporation.

***July Offering***

On July 31, 2020, the Corporation announced that it entered into definitive agreements with investors pertaining to the public offering (the "**July Offering**") by the Sales Agent, as sole placement agent, of an aggregate of 2,762,430 Class B Shares (the "**July Shares**") at a price of US$3.62 per Class B Share and warrants (the "**July Warrants**" and together with the July Shares, the "**July Securities**") to purchase an additional 1,381,215 Class B Shares (the "**July Warrant Shares**") for aggregate proceeds to the Corporation of approximately US$10 million (before deducting fees payable to the A.G.P. and other offering expenses). The July Warrants have a five-year term and an exercise price of US$4.26 per July Warrant Share. The July Offering was completed on August 6, 2020, generating net proceeds to the Corporation of US$9,086,648. In addition, the Corporation granted A.G.P. an option to arrange for purchases of up to an additional US$10 million of July Securities on the same terms as the July Offering for a period of 30 days following the initial closing of the July Offering.

***Suspension of FV Pharma Activities***

On July 30, 2020, the Corporation announced that it has notified Health Canada of the Corporation's decision to forfeit the Cannabis Licenses of its wholly owned subsidiary, FV Pharma, and suspend all activities by FV Pharma within 30 days of the notification date. The Corporation is actively exploring the sale all of FV Pharma's assets, including the sale of the its cannabis production facility in Cobourg, Ontario and/or the adjacent real estate.

***October Offering***

On October 16, 2020, the Corporation announced that it entered into definitive agreements with investors pertaining to the public offering (the "**October Offering**") by the Sales Agent, as sole placement agent, of an aggregate of 4,318,179 Class B Shares (the "**October Shares**") at a price of US$2.20 per Class B Share and warrants (the "**October Warrants**" and together with the October Shares, the "**October Securities**") to purchase an additional 3,454,543 Class B Shares (the "**October Warrant Shares**") for aggregate proceeds to the Corporation of approximately US$9.5 million (before deducting fees payable to the A.G.P. and other offering expenses). The October Warrants have a five-year term and an exercise price of US$2.60 per October Warrant Share. The October Offering was completed on October 20, 2020. In addition, the Corporation granted A.G.P. an option to arrange for purchases of up to an additional US$10 million of October Securities on the same terms as the October Offering for a period of 30 days following the initial closing of the October Offering.

***Settlement of Class Action Proceeding***

On October 29, 2020, the Corporation announced that it has entered into a definitive settlement agreement (the "**Settlement Agreement**") with respect to the class action litigation commenced by a plaintiff shareholder in the Ontario Superior Court of Justice in February 2019 relating to the build-out of its facility in Cobourg, Ontario (the "**Settled Action**"). The Settlement Agreement was approved by the Ontario Superior Court of Justice on February 4, 2021. In entering into the Settlement Agreement, the Corporation made no admissions of liability whatsoever. The Settlement Agreement provides for a full and final release of the Corporation, its officers, directors and various other related parties from any and all claims that arose or could have arisen from the claim issued by the plaintiff within the Settled Action. The Settlement

Agreement provides for a settlement amount of $5,500,000, of which $4,571,459 has been funded with the proceeds of insurance and the remaining $928,541 has been funded by the Corporation.

***Matters to be Addressed at Annual Meeting***

On March 16, 2021, the Corporation announced that it will hold its annual meeting of shareholders and special meeting of the shareholders on May 14, 2021, at which, in addition to normal course matters, it will address matters contained in a requisition for a special meeting submitted to the Corporation by certain shareholders of the Corporation (the "**Requisitioning Shareholders**") claiming to hold in excess of 5.1% of the Class B Shares, including Mr. Zeeshan Saeed, the former President of the Corporation and Mr. Anthony Durkacz, who is a director of the Corporation. In addition to the Class B Shares controlled by this group, Mr. Saeed and Mr. Durkacz each hold 24 Class A Shares, with each Class A Share being entitled to 276,660 votes. Dr. Raza Bokhari, the Corporation's Executive Chairman and Chief Executive Officer, holds the remaining 24 Class A Shares. As of the date hereof, the Corporation has 72 Class A Shares and approximately 19,161,602 Class B Shares issued and outstanding. The Requisitioning Shareholders are seeking to reduce the size of the Board to five, and to replace six of the incumbent directors, including Dr. Raza Bokhari, with three directors selected by such shareholders. This annual and special shareholder meeting is in lieu of the June 29, 2021 meeting announced by the corporation on January 22, 2021.

***2021 Equity Distribution Agreement***

The Corporation entered into an Equity Distribution Agreement dated February 11, 2021 (the "**2021 Equity Distribution Agreement**") with the Sales Agent. Under the 2021 Equity Distribution Agreement the Corporation may, at its discretion and from time-to-time during the term of the 2021 Equity Distribution Agreement, sell, through the Sales Agent, Class B Shares. Sales of Class B Shares will be made through "at-the-market distributions" as defined in the Canadian Securities Administrators' National Instrument 44-102-Shelf Distributions, including sales made directly on the Nasdaq, or any other recognized trading market upon which the Class B Shares are listed or quoted in the United States. No offers or sales of Class B Shares will be made in Canada on the CSE or other trading markets in Canada.

***Innovet License Agreement***

In March 2021, the Corporation entered into a license agreement ("**Innovet License Agreement**") with Innovet Italia S.R.L. ("**Innovet**"), under which Innovet granted the Corporation a license to use ultra-micro PEA to develop FDA approved veterinary drugs for the treatment of gastro-intestinal diseases in canines and felines. Under the Innovet License Agreement, the Corporation is required to make payments to Innovet upon the achievement of certain milestones.

## DESCRIPTION OF THE BUSINESS

### Overview

FSD Pharma Inc. ("FSD" or the "Corporation"), through its wholly-owned subsidiary FSD BioSciences, Inc. is a pharmaceutical R&D company focused on developing over time multiple applications of its lead compound, ultra-micro PEA (FSD 201) by down-regulating the cytokines to effectuate an anti-inflammatory response.

The Company filed an IND with the FDA on August 28, 2020 and was approved on September 25, 2020 to initiate a phase 2 clinical trial for the use of FSD201 to treat COVID-19, the disease caused by the SARS-CoV-2 virus. The trial is currently underway and is expected to randomize 352 patients in a controlled,

double-blind multicenter study.

***Epitech License***

As a result of the acquisition of Prismic, the Corporation acquired the Epitech License from Epitech to use, for pharmaceutical purposes, certain patents and other intellectual property rights to PEA. PEA is a naturally occurring substance that is produced within the body in response to inflammation and interacts with endocannabinoid receptors throughout the body, including the central nervous system. The Corporation is currently seeking to advance pharmaceutical development programs centered on PEA that meet one or more selected criteria. All efforts are intended to be founded on a biologic plausibility of an efficacious effect with a high safety profile. See also "*General Description of the Business – Three Year History – Epitech Licsence Agreement*" for additional information regarding the Epitech License.

***FV Pharma and the Facility***

In light of challenging market conditions among Canadian licensed cannabis producers, the Corporation announced on July 30, 2020 that it has notified Health Canada of the Corporation's decision to forfeit the Cannabis Licenses of its wholly owned subsidiary, FV Pharma, and suspend all activities by FV Pharma within 30 days of the notification date. The Corporation is actively exploring the sale of the business and/or the underlying real estate, including the Facility. The Corporation owns the 70-acre property on which the Facility is located (the "**Facility Property**"). In March 2020, substantially all of the assets of FV Pharma were classified as being held for sale, and the Corporation is actively exploring a sale of the Facility and/or the Facility Property.

***Innovet License Agreement***

The Innovet License Agreement, permits the Corporation opportunities to research and devleop veterinary drugs for the treatment of gastro-intestinal diseases in dogs and cats. Under the Innovet License Agreement, the Corporation is required to make payments to Innovet upon the achievement of certain milestones. An initial sum of US$500,000 has been paid to Innovet, and a second sum of US$250,000 will be due and payable on the first anniversary of the Innovet License Agreement. An initial sum of US$500,000 has been paid to Innovet, and a second sum of US$250,000 will be due and payable on the first anniversary of the Innovet License Agreement. The Innovet License Agreement provides that the Corporation shall develop products with a view to submitting an Investigational Animal Drug Application with the FDA within 36 months, and shall submit a New Animal Drug Application within 60 months. The Innovet License Agreement also provides for a 14% fee to Innovet in the event that the Corporation is paid for any sub-license to a third-party, and a 5% fee on the net sales of the products created under the Innovet License Agreement.

**Products and Sales**

The Corporation is focused on pharmaceutical research and development of FDA approved prescription drugs, and is currently focused on developing multiple applications of its lead compound, FSD 201 or ultra-micro PEA over time, by down-regulating the pro-inflammatory cytokines to effectuate an anti-inflammatory response.

The Corporation filed an IND with the FDA on August 28, 2020 and was approved on September 25, 2020 to initiate a Phase 2 clinical trial for the use of FSD 201 to treat COVID-19, the disease caused by the SARS-CoV-2 virus. The trial is currently underway and is expected to randomize 352 patients in a controlled, double-blind multicenter study.

Severe COVID-19 is characterized by an over-exuberant inflammatory response that may lead to a cytokine storm and death. The Corporation is focused on developing ultra-micro PEA for its anti-inflammatory properties to avoid the cytokine storm associated with acute lung injury in hospitalized COVID-19 patients. The Corporation is not making any express or implied claim that its product has the ability to eliminate, cure or contain the COVID-19 (or SARS-2 Coronavirus) infection at this time.

**Specialized Knowledge and Personnel**

The Board and Executive Officers of the Corporation, led by Dr. Raza Bokhari as Executive Chairman and Chief Executive Officer, have a wide combination of skills, knowledge and experience that are necessary for the ongoing success of the Corporation. Our future growth and success depend on our ability to recruit, retain, manage and motivate our qualified employees. The inability to hire or retain experienced personnel in the pharmaceutical field could adversely affect our ability to execute our business plan and harm our operating results. Due to the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the pharmaceutical field is intense. Due to this intense competition, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

**Competitive Conditions**

The pharmaceutical industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Many of these competitors and potential competitors have substantially greater financial, technological, managerial and research and development resources and experience than we have. Some of these competitors and potential competitors have more experience than we have in the development of pharmaceutical products, including validation procedures and regulatory matters. In addition, micro-PEA competes with, and our product candidates, if successfully developed, will compete with, product offerings from large and well-established companies that have greater marketing and sales experience and capabilities than we or our collaboration partners have. Other companies with greater resources than us may announce similar plans in the future. In addition, there are non-FDA approved competitive products and drugs also available in the market.

**Environmental Matters**

The Corporation expects the financial and operational effects of environmental protection requirements on its capital expenditures, profit and competitive position in the current and future financial years to be minimal. For further information, see "*Risk Factors*" in this AIF.

**Employees**

As at December 31, 2020, the Corporation directly employed 9 full-time employees and 11 consultants. The Corporation believes its relationship with its employees, consultants and contractors is good. None of the Corporation's employees are represented by a labour union or subject to a collective bargaining agreement nor are any of Prismic's employees.

**FSD Biosciences Inc., & Industry Overview**

Through the Prismic transaction, the Corporation acquired an exclusive, worldwide license (excluding Italy and Spain) to exploit, for certain specified pharmaceutical purposes, patents and other intellectual property rights to ultramicronized-PEA owned by Epitech. See "*General Description of Business – Three Year*

*History – Epitech License Agreement"* above. PEA is a naturally occurring substance that is produced within the body in response to inflammation and interacts with endocannabinoid receptors throughout the body, including the central nervous system. FSD Pharma is currently seeking to advance pharmaceutical development programs centered on ultramicronized-PEA that meet one or more selected criteria. All efforts are intended to be founded on a biologic plausibility of an efficacious effect with a high safety profile.

FSD BioScience currently has 5 patients enrolled at its 5 clinical trial sites, with 348 patients remaining to be enrolled. FSD BioScience will be initiating additional clinical trial sites in Argentina, Peru, Colombia and Chile.

**Regulatory Environment**

The Corporation is currently focused on obtaining regulatory approvals in the United States for the drug candidates it is developing through FSD Biosciences. In the future, the Corporation may consider seeking approvals for these drug candidates in Canada and elsewhere. The following is a summary of the FDA investigational new drug approval process that the Corporation is undertaking with ultramicronized-PEA in the United States. Assuming the Corporation is successful in obtaining FDA approvals pursuant to the process set out below, it may decide to seek comparable approvals in Canada and elsewhere, which would be subject to different and additional regulatory requirements.

The Corporation will be subject to extensive regulations while it focuses on gaining FDA approvals for treatments it is developing with ultramicronized-PEA. The FDC Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labelling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical product candidates. Failure to comply with applicable U.S. requirements may subject the Corporation to a variety of administrative or judicial sanctions, such as FDA refusals, warning letters, product candidate recalls, product candidate seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product candidate development in the United States typically involves pre-clinical laboratory and animal tests, the submission to the FDA of an investigational new drug, which must be approved before clinical testing is allowed to commence, and adequate, well-controlled clinical trials to establish the safety and effectiveness of the drug for each application for which FDA approval is sought. The satisfaction of FDA pre-market approval requirements typically takes many years. The actual time required may vary substantially based upon the type, complexity and novelty of the product candidate or the diseases a product candidate targets.

Pre-clinical tests generally include laboratory evaluation of product candidate chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product candidate. The conduct of the pre-clinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of pre-clinical testing are submitted to the FDA as part of an investigational new drug along with other information, including information about product candidate chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the investigational new drug is submitted.

A 30-day waiting period after the submission of each investigational new drug is required before commencing clinical testing in humans. If the FDA has not imposed a clinical hold on the investigational new drug or otherwise commented or questioned the investigational new drug within this 30-day period, the clinical trial proposed in the investigational new drug may begin. Clinical trials involve the

administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations, (ii) in compliance with Good Clinical Practice, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the investigational new drug.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board for approval. An institutional review board may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the institutional review board's requirements or may impose other conditions.

If the FSD-201 Trials are successful, the Corporation may pursue additional trials as required and may ultimately pursue a new drug application, which would involve applying to the FDA for the approvals required to market the Corporation's synthetic treatments in the United States. Should the FDA approve the Corporation's new drug application application, the Corporation may seek similar approvals in Canada and elsewhere. There is no assurance that the Corporation will be successful in receiving the required approvals, and the clinical trials are subject to numerous risks.

**Reorganizations**

Other than in connection with the Amalgamation, the Corporation has not completed any material reorganization within the three most recently completed financial years.

## RISK FACTORS

An investment in securities of the Corporation should only be made by persons who can afford a significant or total loss of their investment.

We are exposed to a number of risks through the pursuit of our business objectives. The following risks and uncertainties identified below are those we believe may, individually or in combination with other risks and uncertainties, have a material impact on our business, but these are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us, or risks that we currently deem immaterial, may also impair our business operations. If any of the following risks, or any other risks and uncertainties that we have not yet identified or that we currently consider not to be material, actually occur or become material risks, our business, financial condition, results of operations and cash flows, and consequently the price of the Class B Shares, could be materially and adversely affected. The risks discussed below also include Forward-Looking Statements and our actual results may differ substantially from those discussed in these Forward-Looking Statements. See "*Forward-Looking Statements*" in this AIF.

**Risks Relating to the Development of FSD-201**

*Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have only one pharmaceutical product candidate, FSD-201, and no pharmaceutical product sales, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future*

*viability.*

Pharmaceutical and biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical corporation with a limited operating history. We have no pharmaceutical products approved for commercial sale and have not generated any revenue from pharmaceutical product sales. We are currently focused on developing our only product candidate, FSD-201, which is in early stages of development and will require substantial additional development time, including extensive resources and clinical testing before it would be able to receive regulatory approvals and begin generating revenue from product sales.

We continue to incur significant research and development and other expenses related to ongoing operations and expect to incur losses for the foreseeable future. We anticipate these losses will increase and that we will not generate any revenue from product sales until after we have successfully completed clinical development and received regulatory approval for the commercial sale of FSD-201.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or comparable foreign regulatory authorities to perform nonclinical or preclinical studies or clinical trials in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials. Even if FSD-201 is approved for commercial sale, we anticipate incurring significant costs associated with commercializing FSD-201 and ongoing compliance efforts.

We may never be able to develop or commercialize FSD-201 or achieve profitability. Revenue from the sale of FSD-201, if regulatory approval is obtained, will be dependent, in part, upon the size of the markets in the territories for which we obtain regulatory approval, the accepted price for the product, the ability to obtain reimbursement at any price and whether we own the commercial rights for that territory, as well as the efficiency and availability of any comparable products. Our growth strategy depends on our ability to generate revenue. In addition, if the number of addressable patients is less than anticipated, the indication approved by regulatory authorities is narrower than expected, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of FSD-201, even if approved. Even if we are able to generate revenue from the sale of FSD-201, we may not become profitable and may need to obtain additional funding to continue operations. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to achieve sustained profitability would depress our value and could impair our ability to raise capital, expand our business, diversify our research and development pipeline, market FSD-201 and any other product candidates that we may identify and pursue or continue our operations.

*FSD-201 trials are speculative and may not have conclusive or timely results, which may adversely affect the Corporation's business, financial condition and/or results of operations.*

The Corporation's FSD-201 drug trials are still in early phases and the effectiveness of its products is not yet known. Therefore, the Corporation is subject to a number of financial risks and is unable to predict the timing or amount of expenses that may be required for ongoing trials, including further applications to the FDA. The Corporation may not have the ability to cure, contain or eliminate the COVID-19 infection in its patients at this time, or at all.

*FSD-201 may not receive regulatory approval, which is necessary before it can be commercialized.*

Before obtaining marketing approval from regulatory authorities for the sale of FSD-201, we must conduct

extensive clinical trials to demonstrate its safety and efficacy in humans. We cannot be certain that the FSD-201 Trials will be conducted as planned or completed on schedule, if at all. Our inability to successfully complete clinical development could result in additional costs to us and negatively impact our ability to generate revenue. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize and market FSD-201. We may never be able to develop or successfully commercialize FSD-201.

FSD-201 requires significant additional development; management of clinical and manufacturing activities; and regulatory approval. In addition, we will need to obtain adequate manufacturing supply; build a commercial organization; commence marketing efforts; and obtain reimbursement, or contract for such services, before we generate any significant revenue from commercial product sales, if ever. We cannot be certain that FSD-201 will be successful in clinical trials or receive regulatory approval. Further, FSD-201 may not receive regulatory approval even if it is successful in clinical trials. If we do not receive regulatory approvals for FSD-201 or some other future product candidate that we may identify, we and our subsidiaries may not be able to continue operations, which may result in us out-licensing the technology or pursuing an alternative strategy.

*We rely solely on the Epitech License to use for pharmaceutical purposes certain patents and other intellectual property rights to ultramicronized-PEA that are material to our business and if the Epitech License were to be terminated or if other rights that may be necessary or we deem advisable for commercializing FSD-201 cannot be obtained, it would limit our ability to market FSD-201, which would have a material adverse effect on our business, operating results and financial condition.*

Our principal asset is the Epitech License, which provides us with an exclusive, multi-jurisdictional license to use certain patents and other intellectual property rights to micro-PEA that are owned by Epitech. Under the Epitech License, we are obligated to use commercially reasonable efforts to develop FSD-201, with a view to filing a new drug application with the FDA as soon as practicable. We are also obligated to make milestone payments and royalties to Epitech, which may limit our future profitability and our ability to enter into marketing partnership agreements. If we materially breach any of the terms of the Epitech License (and fail to cure such breach with the specified time, to the extent a cure period is available for such breach), Epitech could terminate the agreement. If we were to lose or otherwise be unable to maintain the Epitech License on acceptable terms, or find that it is necessary or appropriate to secure new licenses from other third parties, we would not be able to market FSD-201, our only product candidate, and our current business model and plan would be impaired, which would have a material adverse effect on our business, operating results and financial condition. See also "*General Description of the Business – Three Year History – Epitech License Agreement*".

*Patent terms may be inadequate to protect our competitive position on FSD-201 for an adequate amount of time.*

Patents have a limited lifespan, and the principal patents relating to our use of ultramicronized-PEA expire in approximately nine years. In the United States, if all maintenance fees are timely paid, 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-201 are extended, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical FSD-201.

*Even if the FSD-201 Trials are successful and FSD-201 receives marketing approval, which may occur much later than anticipated or not at all, FSD-201 may fail to achieve the degree of market acceptance by*

*physicians, patients, healthcare payors, and others in the medical community necessary for commercial success, including, due to the possibility that alternative, superior treatments for COVID-19 may be available prior to the approval and commercialization of FSD-201 for the treatment of COVID-19 or the COVID-19 pandemic will subside and no longer constitute a global health crisis.*

The commercial success of FSD-201, including, specifically, of FSD-201 as a treatment for COVID-19, will depend upon their degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, even if the FSD-201 Trials are successful and FSD-201 receives marketing approval, which may occur much later than anticipated or not at all, FSD-201 may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of FSD-201 to treat COVID-19, if approved for commercial sale, will depend on a number of factors, including:

- the availability of alternative, superior treatments for COVID-19 prior to the approval and commercialization of FSD-201 for the treatment of COVID-19, including the mass production of vaccines that significantly limit and/or ultimately eliminate the market for FSD-201 by drastically reducing COVID-19 infections in the general population;
- the COVID-19 pandemic could subside and no longer constitute a global health crisis;
- the efficacy and safety of FSD-201;
- the ability to offer FSD-201 for sale at competitive prices;
- the ability to manufacture FSD-201 in sufficient quantities and to offer appropriate patient access programs, such as co-pay assistance;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which FSD-201 is approved by FDA, if it approved at all, or comparable regulatory agencies;
- product labeling or product insert requirements of the FDA or other comparable regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labeling;
- restrictions on how FSD-201 is distributed;
- publicity concerning FSD-201 or competing products and treatments;
- the strength of marketing and distribution support;
- favorable third-party coverage and sufficient reimbursement; and
- the prevalence and severity of any side effects or adverse effects.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations,

hospitals, other healthcare providers, government agencies or private insurers will determine that FSD-201 is safe, therapeutically effective and cost effective as compared with competing treatments. If FSD-201 does not achieve an adequate level of acceptance, we may not generate significant product revenue, and we may not become profitable.

*We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval for an effective COVID-19 treatment before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize FSD-201 and ultimately harm our financial condition.*

The development and commercialization of new drug products is highly competitive. We face competition with respect to FSD-201 from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Significant competition exists in the treatment of COVID-19. We will need to compete with all current and future treatments within the indications where our development is focused. As of the date of this AIF, there are several viable vaccines being mass produced and deployed globally. Additionally, there are a significant number of COVID-19 antibody treatments in various stages of development, including certain monoclonal antibody treatments made to treat and possibly prevent COVID-19 that are currently in Phase 3 trials. Any current or future treatments that are successfully developed and fully-approved for marketing could represent significant competition for FSD-201 as a treatment of COVID-19 and/or eliminate the market for FSD-201 as such a treatment altogether.

Most of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of FSD-201 relating to our competitors' products and our competitors may allege that FSD-201 infringes, misappropriates or otherwise violates their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

*If we are unable to obtain regulatory approval in one or more jurisdictions for FSD-201, our business will be substantially harmed.*

We cannot commercialize FSD-201 until the appropriate regulatory authorities have reviewed and approved the it. Approval by the FDA and comparable other regulatory authorities is a lengthy and unpredictable process, and depends upon numerous factors, including substantial discretion of the regulatory authorities. Approval policies, regulations, or the type and amount of nonclinical or clinical data necessary to gain approval may change during the course of FSD-201's development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We cannot be certain that FSD-201 will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

Obtaining marketing approval is an extensive, lengthy, expensive and inherently uncertain process, and regulatory authorities may delay, limit or deny approval of FSD-201 for many reasons, including but not

limited to:

- the inability to demonstrate to the satisfaction of the FDA or comparable other regulatory authorities that FSD-201 is safe and effective as a treatment for our targeted indications;

- the FDA or comparable other regulatory authorities may disagree with the design, endpoints or implementation of our clinical trials;

- the population studied in the clinical program may not be sufficiently broad or representative to assure safety or efficacy in the full population for which we seek approval;

- the FDA or comparable other regulatory authorities may require additional preclinical studies or clinical trials beyond those that we currently anticipate;

- the FDA or comparable other regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;

- the data collected from clinical trials of FSD-201 may not be sufficient to support the submission of an new drug application, biologics license application, or other submission for regulatory approval in the United States or elsewhere;

- we may be unable to demonstrate to the FDA or comparable other regulatory authorities that FSD-201's risk-benefit ratio for its proposed indication is acceptable;

- the FDA or comparable other regulatory authorities may identify deficiencies in the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable other regulatory authorities may change in a manner that renders the clinical trial design or data insufficient for approval.

The lengthy approval process, as well as the unpredictability of the results of clinical trials and evolving regulatory requirements, may result in our failure to obtain regulatory approval to market FSD-201, which would significantly harm our business, results of operations, financial condition and prospects.

*We may encounter substantial delays in the FSD-201 Trials or may not be able to conduct or complete clinical trials on the expected timelines, if at all.*

Clinical testing is expensive, time consuming, and subject to significant uncertainty. We cannot guarantee that our ongoing and planned FSD-201 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. A failure of one or more clinical trials can occur at any stage of testing, and the FSD-201 Trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to obtain the additional financing required to conduct the clinical trials;

- delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical studies;

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support

the initiation or continuation of clinical trials;

- delays in confirming target engagement, patient selection or other relevant biomarkers to be utilized in preclinical and clinical product candidate development;

- delays in reaching agreement on acceptable terms with prospective contract research organizations ("**CROs**"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;

- delays in identifying, recruiting and training suitable clinical investigators;

- delays in obtaining required Institutional Review Board approval at each clinical trial site;

- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of a new drug application or amendment, clinical trial application or amendment, or equivalent application or amendment, as a result of a new safety finding that presents unreasonable risk to clinical trial participants;

- a negative finding from an inspection of the FSD-201 Trials operations or study sites;

- developments in trials for other product candidates with the same targets or related modalities as our product candidates conducted by competitors that raise regulatory or safety concerns about risk to patients of the treatment;

- if the FDA or other regulatory authorities find that the investigational protocol or plan is clearly deficient to meet stated objectives;

- difficulties in securing access to materials for the comparator arm of certain of the FSD-201 Trials;

- delays in identifying, recruiting and enrolling suitable patients to participate in the FSD-201 Trials, and delays caused by patients withdrawing from the FSD-201 Trials or failing to return for post-treatment follow-up;

- difficulty collaborating with patient groups and investigators;

- failure by CROs, other third parties, or us to adhere to clinical trial requirements;

- failure to perform in accordance with the FDA's or any other regulatory authority's current good clinical practice, requirements, or regulatory guidelines in other countries;

- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;

- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- the cost of clinical trials of any product candidates that we may identify and pursue being greater

than we anticipate;

- clinical trials of any product candidates that we may identify and pursue producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;

- transfer of manufacturing processes to larger-scale facilities operated by a CMO, or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and

- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of product candidates that we may identify for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to FSD-201, we may be required to or we may elect to conduct additional nonclinical studies or clinical trials to bridge data obtained from the modified product candidate to data obtained from nonclinical and clinical research conducted using earlier versions. Clinical trial delays could also shorten any periods during which FSD-201 has patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize product candidates and may harm our business, results of operations, financial condition and prospects.

We could also encounter delays if a clinical trial is suspended or terminated by us or by the data safety monitoring board or similar regulatory authority. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable other regulatory authorities. The FDA or comparable other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of FSD-201.

Delays in the initiation, conduct or completion of any clinical trial of FSD-201 will increase our costs, slow down the product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of FSD-201. Any of these events could have a material adverse effect on our business, results of operations, financial condition and prospects.

*The FSD-201 Trials may fail to demonstrate substantial evidence of the safety and/or effectiveness of FSD-*

*201, which would prevent, delay or limit the scope of regulatory approval and commercialization.*

Before obtaining regulatory approvals for the commercial sale of FSD-201, we must demonstrate through lengthy, complex and expensive nonclinical studies, preclinical studies and clinical trials that FSD-201 is both safe and effective for use in each target indication. FSD-201 must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many months or years to complete, and its outcome is inherently uncertain. Failure may occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We cannot be certain that the FSD-201 Trials will be successful. Additionally, any safety concerns observed in the FSD-201 Trials in our targeted indications could limit the prospects for regulatory approval of FSD-201, which could have a material adverse effect on our business, results of operations, financial condition and prospects. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or comparable other regulatory authorities will interpret the results as we do, and more trials could be required before we submit FSD-201 for approval. 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. To the extent that the results of the trials are not satisfactory to the FDA or comparable other regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of FSD-201. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of FSD-201, which may also limit its commercial potential.

*Results from future clinical research may draw opposing or negative conclusions regarding the potential of FSD-201 as a treatment for COVID-19, which could have a material adverse effect on our development plans, business, financial condition and results of operations.*

Our rationale for pursuing development of FSD-201 for COVID-19 is derived from data from various studies and clinical trials of the anti-inflammatory potential of PEA conducted over the last 50 years (the "**Historical PEA Studies**"). However, we could have misinterpreted or performed a flawed analysis of such data. Factors that could have affected our interpretation and analysis of the Historical PEA Studies include:

- none of the Historical PEA Studies directly evaluate the safety or efficacy profile of PEA with respect to COVID-19;
- the Historical PEA Studies evaluated variable formulations, dosages, and patient populations; and
- some of the Historical PEA Studies were conducted decades ago across several international jurisdictions and, as such, may have used clinical trial procedures and statistical analysis methods that differ significantly from currently accepted best practices.

Given such factors, among others, investors should not place undue reliance on the Historical PEA Studies. Future research studies and clinical trials may draw opposing or negative conclusions regarding the potential of FSD-201 as a treatment for COVID-19, which could have a material adverse effect on our development plans business, financial condition and results of operations.

*Results of earlier studies or clinical trials may not be predictive of future clinical trial results, and initial studies or clinical trials may not establish an adequate safety or efficacy profile for FSD-201 to justify proceeding to advanced clinical trials or an application for regulatory approval.*

The results of nonclinical and preclinical studies and clinical trials, including the Historical PEA Studies,

may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. The results of preclinical studies and clinical trials in one set of patients or disease indications, or from preclinical studies or clinical trials that we did not lead, may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if early-stage clinical trials are successful, we may need to conduct additional clinical trials of FSD-201 in additional patient populations or under different treatment conditions before we are able to seek approvals from the FDA and regulatory authorities outside the United States to market and sell this product candidate. Our failure to obtain marketing approval for FSD-201 would substantially harm our business, results of operations, financial condition and prospects.

*Interim, "top-line," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available or as additional analyses are conducted, and as the data are subject to audit and verification procedures that could result in material changes in the final data.*

From time to time, we may publish interim, "top-line," or preliminary data from our clinical studies. For example, on June 22, 2020, we published "top-line" results from our Phase 1 randomized, double-blind, placebo-controlled study of FSD-201. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Material adverse changes between preliminary, "top-line," or interim data and final data could significantly harm our business prospects. See "*General Description of the Business – Three Year History – Phase 1 (Australia) Trials*".

*Issued patents covering FSD-201 could be found invalid or unenforceable if challenged in court.*

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering FSD-201, the defendant could counterclaim that the patent covering FSD-201 is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent eligibility, novelty, non-obviousness, written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in other jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover FSD-201. The outcome following legal assertions of invalidity and

unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on FSD-201. Such a loss of patent protection would have a material adverse impact on our business.

*The drug substance and drug product for FSD-201 are currently acquired from single-source suppliers. The loss of these suppliers, or their failure to supply us with the drug substance or drug product, could materially and adversely affect our business.*

The drug substance and drug product for FSD-201 are grown or manufactured by single- source suppliers or CMOs under development and manufacturing contracts and services and quality agreements and purchase orders. We do not currently have any other suppliers for the drug substance or drug product of FSD-201 and, although we believe that there are alternate sources of supply that could satisfy our clinical and commercial requirements, we cannot assure you that identifying alternate sources and establishing relationships with such sources would not result in significant delay in the development of FSD-201. Furthermore, under the Epitech License, we must source any PEA used in FSD-201 that is sold outside of the United States or Canada from Epitech, except in certain limited circumstances described by the agreement.

Our dependence on single-source suppliers exposes us to certain risks, including the following:

- our suppliers may cease or reduce production or deliveries, raise prices or renegotiate terms;
- delays caused by supply issues may harm our reputation; and
- our ability to progress our business could be materially and adversely impacted if our single-source suppliers upon which we rely were to experience significant business challenges, disruption or failures due to issues such as financial difficulties or bankruptcy, issues relating to regulatory or quality compliance issues, or other legal or reputational issues.

Additionally, we may not be able to enter into supply arrangements with alternative suppliers on commercially reasonable terms, or at all. A delay in the development of FSD-201 or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers could have a material adverse impact upon on our business.

*We expect to rely on third parties to conduct the FSD-201 Trials and aspects of our 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.*

We currently rely and expect 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 with us or be unable to fulfill their contractual obligations. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. If we need to enter into alternative arrangements, it would delay FSD-201 development activities.

Our reliance on these third parties for research and development activities reduces control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that the FSD-201 Trials is conducted in accordance with the general investigational plan and protocols for the trial and applicable legal, regulatory, and scientific standards, and our reliance on third parties does not

relieve us of our regulatory responsibilities. In addition, the FDA and comparable other regulatory authorities require compliance with good clinical practices for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these good clinical practices through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable good clinical practice regulations, some or all of the clinical data generated in the FSD-201 Trials may be deemed unreliable and the FDA or comparable other regulatory authorities may require us to perform additional nonclinical or clinical trials or to enroll additional patients before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of the FSD-201 Trials complies with the good clinical practice regulations. For any violations of laws and regulations during the conduct of clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

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 our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for FSD-201 and will not be able to, or may be delayed in our efforts to, successfully commercialize FSD-201. Our failure or the failure of these third parties to comply applicable regulatory requirements or our stated protocols could also subject us to enforcement action.

We also expect to rely on other third parties to store and distribute drug supplies for the FSD-201 Trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

**Risks Related to the Pharmaceutical Business**

*We may encounter difficulties enrolling patients in clinical trials, and clinical development activities could thereby be delayed or otherwise adversely affected.*

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion and we may not be able to identify and enroll a sufficient number of patients, or those with required or desired characteristics and criteria, in a timely manner.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of a patient population;
- patient eligibility criteria defined in the applicable clinical trial protocols, which may limit the patient populations eligible for clinical trials to a greater extent than competing clinical trials for

the same indication;

- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to a trial site;
- the design of the trial;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the approval or concurrent enrollment of clinical trials involving competing product candidates currently under development, or competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
- the ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete such trials, for any reason.

If we have difficulty enrolling sufficient numbers of patients to conduct clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

*Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or halt their clinical development, prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit their commercial potential, if approved, or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.*

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our product candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable other regulatory authorities. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate if approved. We may also be required to modify or terminate our study plans based on findings in our preclinical studies or clinical trials. Many product candidates that initially show promise in early-stage testing may later be found to cause side effects that prevent further development. As we work to advance existing product candidates and to identify new product candidates, we cannot be certain that later testing or trials of product candidates that initially showed promise in early testing will not be found to cause similar or different

unacceptable side effects that prevent their further development. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as the use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.

Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or to change the requirements for approval of any of our product candidates.

In addition to side effects caused by the product candidate, the administration process or related procedures also can cause adverse side effects. If any such adverse events occur, our clinical trials could be suspended or terminated. If we are unable to demonstrate that any adverse events were caused by the administration process or related procedures, the FDA, Health Canada, the European Commission, the EMA, or other regulatory authorities could order us to cease further development of, or deny approval of, a product candidate for any or all targeted indications. Even if we can demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

Additionally, if any of our product candidates receives marketing approval, the FDA could impose a boxed warning in the labeling of our product and could require us to adopt a risk evaluation and mitigation strategy, and could apply elements to assure safe use to ensure that the benefits of the product outweigh its risks, which may include, among other things, a Medication Guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by our product candidates once approved, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required by the FDA to implement a risk evaluation and mitigation strategy;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these occurrences could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and may harm our business, financial condition and prospects

significantly.

*We may in the future conduct clinical trials for product candidates outside the United States, and the FDA and comparable other regulatory authorities may not accept data from such trials.*

We may in the future choose to conduct one or more clinical trials outside the United States, including in Canada, Europe or Asia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable other regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from non-U.S. clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of non-U.S. data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many non-U.S. regulatory authorities have similar approval requirements. In addition, such non-U.S. trials would be subject to the applicable local laws of the other jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable other regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable other regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval or clearance for commercialization in the applicable jurisdiction.

*Even if we obtain FDA approval for product candidates that we may identify and pursue in the United States, we may never obtain approval to commercialize any product candidates outside of the United States, which would limit our ability to realize their full market potential.*

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking non-U.S. regulatory approval could result in difficulties and costs and require additional nonclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval, as well as additional risks. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize

the full market potential of our products will be harmed.

*We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business.*

Our CMOs must employ multiple steps to control the manufacturing process to assure that the process is reproducible and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory to conduct clinical trials or supply commercial markets. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet the FDA, the EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

In addition, the FDA, the EMA and other regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, results of operations, financial condition and prospects.

Our CMOs also may encounter problems hiring and retaining the experienced scientific, quality assurance, quality-control and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our CMOs' manufacturing process or facilities could result in delays in planned clinical trials and increased costs, and could make us a less attractive collaborator for potential partners, including larger biotechnology companies and academic research institutions, which could limit access to additional attractive development programs. Problems in our manufacturing process could restrict our ability to meet potential future market demand for products.

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

In connection with the clinical development of our drug candidates for certain indications, we 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 our drug candidates. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable other regulatory authorities regulate *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we may develop, which we expect will require separate regulatory

clearance or approval prior to commercialization.

We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic drug candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic drug candidates, or experience 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 we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic corporation with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic corporation may otherwise terminate. We may not be able to enter into arrangements with another diagnostic corporation to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic candidates.

*If approved, our investigational products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.*

The ACA includes a subtitle called the BPCIA which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another corporation may still market a competing version of the reference product if the FDA approves a biologics license application for the competing product containing the sponsor's own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity, and potency of the other corporation's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a biologics license application should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover,

the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

*Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.*

The ability of the FDA to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved, or for other actions to be taken, by relevant government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown could prevent the timely review of our patent applications by the USPTO, which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, in our operations as a public corporation, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

*Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop.*

We face an inherent risk of product liability exposure related to the testing of product candidates in human clinical trials and will face an even greater risk if we commercially sell any medicines that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or medicines caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome,

liability claims may result in:

- decreased demand for any product candidates or medicines that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize our product candidates.

Although we intend to maintain product liability insurance, including coverage for clinical trials that we plan to sponsor, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we commence additional clinical trials and if we successfully commercialize any product candidates. The market for insurance coverage is increasingly expensive, and the costs of insurance coverage will increase as our clinical programs increase in size. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

*Our employees, directors, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.*

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, directors, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and comparable other regulatory authorities; provide true, complete and accurate information to the FDA and comparable other regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar other fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities. If we obtain FDA approval of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other 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 pricing, discounting, educating, marketing and promotion, sales and commission, 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, which could result in regulatory sanctions and cause serious harm to our reputation. We intend to adopt a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees, directors and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our

business, including the imposition of significant fines or other sanctions.

*Even if we obtain regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.*

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post- marketing studies, and submission of safety, efficacy, and other post-market information, including both U.S. federal and state requirements in the United States and requirements of comparable other regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA and comparable other regulatory authorities, including ensuring that quality control and manufacturing procedures conform to good manufacturing practices, regulations. As such, we and our CMOs will be subject to continual review and inspections to assess compliance with good manufacturing practices and adherence to commitments made in any new drug application, biologics license application or marketing authorization application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we may receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable other regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance.

The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing, labeling, advertising and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved label. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval.

The holder of an approved new drug application, biologics license application or marketing authorization application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose

restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our CMOs' facilities;
- seize or detain products; or
- require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our corporation and our operating results will be adversely affected.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

*The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses.*

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion

of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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

We do not have a sales or marketing infrastructure and have little experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to market and sell our product candidates, if and when they are approved. We may also elect to enter into collaborations or strategic partnerships with third parties to engage in commercialization activities with respect to selected product candidates, indications or geographic territories, including territories outside the United States, although there is no guarantee we will be able to enter into these arrangements even if the intent is to do so.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- the inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;

- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;

- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;

- the inability to price products at a sufficient price point to ensure an adequate and attractive level of profitability;

- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent commercialization

organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop internally. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us or them. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively or may expose us to legal and regulatory risk by not adhering to regulatory requirements and restrictions governing the sale and promotion of prescription drug products, including those restricting off-label promotion. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates, if approved.

*The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our 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 United States, 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, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our 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, 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 we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our 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, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to

realize a sufficient return on our investment.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control corporation profits. Additional price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable other regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain

reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Additionally, we may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which we receive approval. Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the companion diagnostic tests that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, results of operations, financial condition and prospects.

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

The United States and many other jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

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 us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely

affect:

- the demand for our product candidates, if approved;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the amount of taxes that we are required to pay; and
- the availability of capital.

We expect that the 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 we receive 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 us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

*If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected.*

Healthcare providers, physicians and third-party payors in the United States 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 our 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. Additionally, FDA or other regulators may not agree that we have mitigated any risk of bias in our clinical trials due to payments or equity interests provided to investigators or institutions which could limit a regulator's acceptance of those clinical trial data in support of a marketing application. Moreover, efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, exclusion from participation in

Medicare, Medicaid and other U.S. federal healthcare programs, integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to international equivalents of the healthcare laws mentioned above, among other local laws.

*Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.*

We and any potential collaborators may be subject to U.S. federal, state, and international data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous U.S. federal and state laws and regulations, including U.S. federal health information privacy laws, state data breach notification laws, state health information privacy laws, and U.S. federal and state consumer protection laws (e.g., Section 5 of the U.S. Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by the U.S. *Health Information Technology for Economic and Clinical Health Act*. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

*We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.*

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish

collaborative arrangements for research, development, manufacturing, and commercialization.

If any of these competitors or competitors for our other product candidates receive FDA approval before we do, our product candidates would not be the first treatment on the market, and our market share may be limited.

In addition to competition from other companies targeting our target indications, any products we may develop may also face competition from other types of therapies.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of our targeted disease indications or similar indications, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications that we are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

*If the contract manufacturing facilities on which we rely do not continue to meet regulatory requirements or are unable to meet our supply demands, our business will be harmed.*

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including our existing CMOs for all of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with good manufacturing practices, or similar regulatory requirements outside the United States. These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates. Our failure, or the failure of third-party manufacturers,

to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production, seizures or recalls of product candidates or marketed drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect clinical or commercial supplies of our product candidates.

We or our CMOs must supply all necessary documentation in support of a new drug application, biologics license application or marketing authorization application on a timely basis and must adhere to regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our CMOs have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the CMOs, we cannot control the manufacturing process of, and are completely dependent on, our 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.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through a new drug application, biologics license application supplement or marketing authorization application variation, or equivalent other regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

**Risks Related to our Intellectual Property**

*If we are unable to obtain and maintain sufficient intellectual property protection for our products, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully*

*commercialize our products may be impaired.*

As is the case with other pharmaceutical and biopharmaceutical companies, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others, particularly patents, in the United States and other countries with respect to our product candidates and technology. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to micro-PEA or other product candidates that we may identify.

Obtaining and enforcing pharmaceutical and biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

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 our rights to the same extent as the laws of the United States, or vice versa. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our analysis of these issues, including interpreting the relevance or the scope of claims in a patent or a pending application, determining applicability of such claims to our proprietary technologies or product candidates, predicting whether a third party's pending patent application will issue with claims of relevant scope, and determining the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner.

Our ability to enforce patent rights also depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims,

such proceedings would be expensive and would divert the attention of our management and technical personnel. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates to ours, or limit the duration of the patent protection of our product candidates. 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, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

*Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.*

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes re-examination proceedings before the USPTO, and corresponding patent offices in other countries. Numerous U.S. and international issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products may be subject to claims of infringement of the patent rights of third parties.

Other third parties may assert that we are employing their proprietary technology without authorization. There may be other third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of micro-PEA. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that micro-PEA or other product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of micro-PEA or other product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we

obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all, or it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize micro-PEA or other product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Parties making claims against us, may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, 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 our business, results of operations, financial condition and prospects.

*Patent terms may be inadequate to protect our competitive position on product candidates for an adequate amount of time.*

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, 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 our product candidates are obtained, once the patent life has expired, we 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, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

*If we are not able to obtain patent term extension or non-patent exclusivity in the United States under the Hatch- Waxman Act and in other countries under similar legislation, thereby potentially extending the marketing exclusivity term of our product candidates, our business may be materially harmed.*

Depending upon the timing, duration and specifics of FDA marketing approval of our 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. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended.

Patent term extension also may be available in certain other countries upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any other country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration sooner, and our revenue could be reduced, possibly materially.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering a product candidate even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for certain of our licensed patents, we do not have the right to control prosecution, including filing with the USPTO, a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch- Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

*If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.*

We seek to protect our confidential proprietary information, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose proprietary information, including trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. We may not be able to obtain adequate remedies in the event of such unauthorized use. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Trade secrets will also over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from corporation to corporation or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights.

In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position, business, results of operations, financial conditions, and prospects would be harmed.

*If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.*

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, results of operations, financial condition and prospects.

*We may be subject to claims challenging the inventorship of our patents and other intellectual property.*

Our agreements with employees and our personnel policies provide that any inventions conceived by an individual in the course of rendering services to us shall be our exclusive property. Although our policy is to have all such individuals complete these agreements, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property may not be automatic upon the creation of an invention and despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or licensed patents, trade secrets, or other intellectual property as an inventor or co- inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may

lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Any of the foregoing could have a material adverse effect on our competitive position, business, results of operations, financial condition and prospects.

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

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

*We may not be able to protect our intellectual property rights throughout the world.*

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. 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 United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in other jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that

we develop or license.

**General Corporate Risks**

*Public health crises, including the ongoing novel coronavirus (COVID-19) pandemic, could have significant economic and geopolitical impacts that may adversely affect the Corporation's business, financial condition and/or results of operations.*

The Corporation's financial and/or operating performance could be materially adversely affected by the public health crisis resulting from the ongoing COVID-19 pandemic and other similar public health crises. Such public health crises, including the ongoing COVID-19 pandemic, and economic and geopolitical impacts caused as a result of such public health crises, can result in volatility and disruption to global supply chains, trade and market sentiment, mobility of people, and global financial markets, which could affect interest rates, credit ratings, credit risk, inflation, business, liquidity and volatility of capital markets, financing opportunities, financial conditions and results of operations, and other factors relevant to the Corporation. In addition, such public health crises may subject the Corporation to risks related to employee health and safety, slowdowns or temporary suspensions of operations in impacted locations, temporary or indefinite delays in the completion of our clinical trials, additional non-compensable costs, and/or the cancellation of contracts, all of which could negatively impact the Corporation's business, financial condition and/or results of operations.

*The Corporation's limited operating history makes it difficult to evaluate its current business and future prospects and may increase the risk that it will not be successful. We have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future.*

The Corporation is therefore subject to many of the risks common to early-stage enterprises, including undercapitalization, cash shortages, limitations with respect to personnel, financial, and other resources and lack of revenues. The Corporation's limited operating history makes it difficult to evaluate its current business and future prospects. There is no assurance that the Corporation will be successful in achieving a return on shareholders' investment and the likelihood of success must be considered in light of the early stage of operations.

Future transfers by holders of Class A Shares to arm's length parties or other than to permitted holders will generally result in those shares converting to Class B Shares, which will have the effect, over time, of increasing the relative voting power of those holders of Class A Shares who retain their shares. Such holders could, in the future, control a significant percentage of the combined voting power of Class A Shares and Class B Shares.

Each of the Corporation's directors and officers owes a fiduciary duty to the Corporation and must act honestly and in good faith with a view to the best interests of Corporation. However, any director and/or officer that is a shareholder, even a controlling shareholder, is entitled to vote its shares in its own interests, which may not always be in the interests of the Corporation's shareholders generally. The inability of the Class B Shares to control the matters affecting the Corporation, combined with the ability of holders of Class A Shares to control matters affecting the Corporation and to take actions that the holders of Class B Shares may not view as beneficial, may adversely affect the market price of the Class B Shares.

*The Corporation is vulnerable to rising energy costs.*

Rising or volatile energy costs may adversely impact the business of the Corporation and its ability to

operate profitably.

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

Our 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 non- hazardous 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. We may be required to compensate those suffering loss or damage due to our operations and may have civil or criminal fines or penalties imposed for violations of applicable laws or regulations. In particular, the Corporation may face liabilities arising from environmental issues related to the former use of the Facility and the former owner of the Facility has no obligation to indemnify the Corporation in respect of any such liabilities. The Corporation is also subject to zoning and other local regulations that may interfere with the Corporation's activities. For example, several buildings on the Corporation's property have been designated by the Town of Cobourg as buildings of cultural heritage value under the *Ontario Heritage Act* and the Corporation is obligated to preserve, and in some cases to repair, such buildings. Changes in environmental, employee health and safety or other laws, more vigorous enforcement thereof or other unanticipated events could require extensive changes to our operations or give rise to material liabilities. If any of the foregoing matters were to occur it could have a material adverse effect on our business, results of operations, financial condition and prospects.

*The Corporation is subject to insurance risks.*

The Corporation's business is subject to a number of risks and hazards generally, including adverse environmental conditions, cybersecurity and other IT systems risks, accidents, labour disputes, product liability and changes in the regulatory environment. Such occurrences could result in damage to assets, personal injury or death, environmental damage, delays in operations, monetary losses and possible legal liability.

Although the Corporation maintains and intends to continue to maintain insurance to protect against certain risks in such amounts as it considers to be reasonable, its insurance will not cover all the potential risks associated with its operations. The Corporation may also be unable to maintain insurance to cover these risks at economically feasible premiums. Insurance coverage may not continue to be available or may not be adequate to cover any resulting liability. Moreover, insurance against risks such as environmental pollution or other hazards encountered in the operations of the Corporation is not generally available on acceptable terms. The Corporation might also become subject to liability for pollution or other hazards which may not be insured against or which the Corporation may elect not to insure against because of premium costs or other reasons. Losses from these events may cause the Corporation to incur significant costs that could have a material adverse effect upon its business, results of operations, financial condition and prospects.

*Any significant interruption in the supply chain for key inputs could materially impact the Corporation's business.*

Our business is dependent on a number of key inputs and their related costs including raw materials and supplies, as well as electricity, water and other local utilities. Any significant interruption or negative change in the availability or economics of the supply chain for key inputs could materially impact our business, financial condition and operating results. Any inability to secure required supplies and services

or to do so on appropriate terms could have a material adverse impact on our business, financial condition and operating results.

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

The ability of the Corporation to research and develop pharmaceutical products will be dependent on it having access to, at a reasonable cost and in a timely manner, skilled labour, individuals with specialized knowledge, equipment, parts and components. No assurances can be given that the Corporation will be successful in maintaining its required supply of skilled labour, individuals with specialized knowledge, equipment, parts and components. It is also possible that the final costs of the major equipment contemplated by the Corporation may be significantly greater than anticipated by management, and may be greater than funds available, in which circumstance the Corporation may curtail, or extend the timeframes for completing, its capital expenditure plans. This could have an adverse effect on the operations and financial results of the Corporation.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our qualified employees. The inability to hire or retain experienced personnel in the pharmaceutical field could adversely affect our ability to execute our business plan and harm our operating results. Due to the specialized scientific and managerial nature of our business, the Corporation relies heavily on its ability to attract and retain qualified scientific, technical and managerial personnel.In addition, competition for highly qualified personnel may be intense and there can be no assurance that we will be successful in identifying, attracting, hiring and retaining such personnel in the future. In particular, specialized knowledge with respect to research and clinical development is important to the pharmaceutical industry. If we are unable to identify, attract, hire and retain qualified personnel in the future, such inability could have a material adverse effect on our business, operating results and financial condition.

*A potential sale of the Facility is subject to various potential problems and uncertainties and may be delayed or adversely affected by a number of factors beyond the Corporation's control.*

Three buildings that are part of the Facility have been designated by the Town of Cobourg as heritage buildings. The buildings must be retained, and the Corporation must follow the Town of Cobourg's by-laws and official plan regulations with respect to upkeep.

There are risks that may have a material adverse effect on our business, operating results and financial condition, if the Corporation cannot sell the Facility and/or the Facility Property on terms favourable to the Corporation.

*Changes in laws, regulations and guidelines may result in significant compliance costs for our business..*

The Corporation's operations are subject not only to a variety of laws, regulations and guidelines relating to the pharmaceutical industry, but also to regulations relating to health and safety, privacy, the conduct of operations and the protection of the environment in the jurisdictions in which they operate. Changes to such laws, regulations and guidelines, including changes related to government taxes and levies, may materially and adversely affect the Corporation's businesses, financial

*The shelf life of inventory could unexpectedly change and write-down of inventory may be required.*

Management regularly reviews the amount of inventory on hand, reviews the remaining shelf life and estimates the time required to manufacture and sell such inventory; however, write-down of inventory may still be required due to extraneous factors such as lower prices in the market. Any such write-down

of inventory could have a material adverse effect on our business, financial condition, and results of operations.

*The Corporation's products may be subject to recalls for a variety of reasons, which could require the Corporation to expend significant management and capital resources.*

Manufacturers and distributors of products are sometimes subject to the recall or return of their products for a variety of reasons, including product defects, such as contamination, unintended harmful side effects or interactions with other substances, packaging safety and inadequate or inaccurate labeling disclosure. If any of the Corporation's products are recalled due to an alleged product defect or for any other reason, the Corporation could be required to incur the unexpected expense of the recall and any legal proceedings that might arise in connection with the recall. The Corporation may lose a significant amount of sales and may not be able to replace those sales at an acceptable margin or at all. In addition, a product recall may require significant management attention. Although the Corporation has detailed procedures in place for testing its products, there can be no assurance that any quality, potency or contamination problems will be detected in time to avoid unforeseen product recalls, regulatory action or lawsuits. Additionally, if one of the Corporation's significant brands were subject to recall, the image of that brand and the Corporation could be harmed. A recall for any of the foregoing reasons could lead to decreased demand for the Corporation's products and could have a material adverse effect on the results of the operations and financial condition of the Corporation. Additionally, product recalls may lead to increased scrutiny of the Corporation's operations by Health Canada or other regulatory agencies, requiring further management attention and potential legal fees and other expenses.

*The Corporation may decide to invest with certain strategic investors and/or other third parties through joint ventures or other entities from time to time, thereby subjecting it to co-investment risks.*

The Corporation has, and may decide in the future to invest with certain strategic investors and/or other third parties through joint ventures or other entities. These parties may have different interests or superior rights to those of the Corporation. Although it is the general intent of the Corporation to retain control and superior rights associated with its investments, all of our current investments involve non-controlling stakes, and in respect of future acquisitions, under certain circumstances, it may be possible that the Corporation relinquishes such rights over certain of its investments and, therefore, may have a limited ability to protect its position therein. In those cases where the Corporation does maintain a control position with respect to its investments, the Corporation's investments may be subject to typical risks associated with third-party involvement, including the possibility that a third-party may have financial difficulties resulting in a negative impact on such investment, may have economic or business interests or goals that are inconsistent with those of the Corporation, or may be in a position to take (or block) action in a manner contrary to the Corporation's objectives. The Corporation may also, in certain circumstances, be liable for the actions of its third party partners or co-investors.

*Failure to comply with laws and regulations could subject the Corporation to regulatory or agency proceedings which could divert management's attention and resources and have a material adverse impact on the Corporation's business, financial condition and results of operation.*

The Corporation's business requires compliance with many laws and regulations. Failure to comply with these laws and regulations could subject the Corporation to regulatory or agency proceedings or investigations and could also lead to damage awards, fines and penalties. The Corporation may become involved in a number of government or agency proceedings, investigations and audits. The outcome of any regulatory or agency proceedings, investigations, audits, and other contingencies could harm the Corporation's reputation, require the Corporation to take, or refrain from taking, actions that could harm its operations or require the Corporation to pay substantial amounts of money, harming its financial

condition. There can be no assurance that any pending or future regulatory or agency proceedings, investigations and audits will not result in substantial costs or a diversion of management's attention and resources or have a material adverse impact on the Corporation's business, financial condition and results of operation.

*There is substantial doubt about the Corporation's ability to continue as a going concern and if the Corporation 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.*

The Corporation's auditor has indicated in the Corporation's audited annual financial statements that there is substantial doubt about the Corporation's ability to continue as a going concern. The Corporation is in the preliminary stages of its planned operations and has not yet determined whether its processes and business plans are economically viable. The continued operations of the Corporation and the recoverability of amounts shown for property, plant and equipment in the Corporation's audited annual financial statements are dependent upon the ability of the Corporation to obtain sufficient financing to complete the development of its facilities and extraction processes, and if they are proven successful, the existence of future profitable production, or alternatively, upon the Corporation's ability to dispose of its interest on an advantageous basis, all of which are uncertain. Importantly, the inclusion in the Corporation's financial statements of a going concern opinion may negatively impact the Corporation's ability to raise future financing and achieve future revenue. If the Corporation is unable to obtain additional financing from outside sources and/or eventually generate enough revenues, the Corporation may be forced to sell a portion or all of the Corporation's assets or curtail or discontinue its operations. If any of these events happens, a prospective purchaser could lose all or part of its investment. In addition, the Corporation's financial statements do not include any adjustments to the Corporation's recorded assets or liabilities that might be necessary if the Corporation becomes unable to continue as a going concern.

*The Corporation has a history of losses and may not be able to generate sufficient revenue to be profitable or to generate positive cash flow on a sustained basis.*

The Corporation has incurred losses since its inception in 2011. The Corporation may not be able to generate revenue, achieve or maintain profitability and may continue to incur significant losses in the future. In addition, the Corporation expects to continue to increase operating expenses as it implements initiatives to continue to grow its business. If the Corporation's revenues do not increase to offset these expected increases in costs and operating expenses, it will not be profitable.

Additionally, our costs are expected to increase in future periods, which could negatively affect our future operating results and ability to achieve and sustain profitability. We expect to continue to expend substantial financial and other resources on expanding our processing capability and production capacity and to pursue the commercialization of pharmaceutical products. These investments may not result in increased revenue or growth in the business. If we cannot successfully earn revenue at a rate that exceeds the costs associated with our business, we will not be able to achieve or sustain profitability or generate positive cash flow on a sustained basis and our revenue growth rate may decline. If we fail to continue to grow our revenue and overall business, our business, results of operations, financial condition and prospects could be materially adversely affected.

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

There is no guarantee that the Corporation will be able to execute on its strategy. Developing

biopharmaceutical products is expensive and time-consuming, and we expect to require substantial additional capital to conduct research, preclinical testing and human studies, to potentially establish pilot scale and commercial scale manufacturing processes and facilities, and to establish and develop quality control, regulatory, marketing, sales and administrative capabilities to support our existing programs and pursue potential additional programs. We are or may in the future also be responsible for the payments to third parties of expenses that may include milestone payments, license maintenance fees and royalties, including in the case of certain of our agreements with academic institutions or other companies from whom intellectual property rights underlying their respective programs have been licensed or acquired. Because the outcome of any preclinical or clinical development and regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of any product candidates we may identify.

Our future funding requirements for the development of pharmaceutical products will depend on many factors, including, but not limited to:

- time and cost necessary to complete ongoing and planned clinical trials;
- the time and cost necessary to pursue regulatory approvals for our product candidates, and the costs of post-marketing studies that could be required by regulatory authorities;
- the progress, timing, scope and costs of our nonclinical studies, preclinical studies, clinical trials and other related activities, including the ability to enroll patients in a timely manner, for the ongoing and planned clinical trials set forth above, and potential future clinical trials;
- the costs of obtaining clinical and commercial supplies of raw materials and drug products for our product candidates;
- our ability to successfully identify and negotiate acceptable terms for third-party supply and contract manufacturing agreements with CMOs;
- our ability to successfully commercialize product candidates;
- the manufacturing, selling and marketing costs associated with our product candidates, including the cost and timing of expanding our internal sales and marketing capabilities or entering into strategic collaborations with third parties to leverage or access these capabilities;
- the amount and timing of sales and other revenues from our product candidates, if any are approved, including the sales price and the availability of adequate third-party reimbursement;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the time and cost necessary to respond to technological and market developments;
- the costs of acquiring, licensing or investing in intellectual property rights, products, product

candidates and businesses;

- our ability to attract, hire and retain qualified personnel; and
- the costs of maintaining, expanding and protecting our intellectual property.

Additional funds may not be available when we need them, on terms that are acceptable, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit or terminate one or more research or development programs or the commercialization of any product candidates or be unable to expand operations or otherwise capitalize on business opportunities, as desired, which could materially affect our business, results of operations, financial condition and prospects.

In addition, the continued development of the Corporation's pharmaceutical operations will require significant additional financing over several years. The failure to raise such capital could result in the delay or indefinite postponement of current business strategy or the Corporation ceasing to carry on business. There can be no assurance that additional capital or other types of financing will be available if needed or that, if available, the terms of such financing will be favorable to the Corporation, at times for reasons beyond the Corporation's control. For example, economic downturns or uncertain market conditions, whether affecting the economy in general or the pharmaceutical industry in particular, could adversely impact the Corporation's ability to raise capital through equity or debt financing. In addition, any further issuances of equity securities could have a significant dilutive effect on the holders of Class B Shares.

In addition, from time to time, the Corporation may enter into transactions to acquire assets or the shares of other companies. These transactions may be financed wholly or partially with debt, which may temporarily increase the Corporation's debt levels above industry standards. Any debt financing secured in the future could involve restrictive covenants relating to capital raising activities and other financial and operational matters, which may make it more difficult for the Corporation to obtain additional capital and to pursue business opportunities, including potential acquisitions.

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

Another risk associated with the production and sale of pharmaceutical products is the loss of important staff members. The success of the Corporation will be dependent upon the ability, expertise, judgment, discretion and good faith of its senior management and key personnel. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. For example, during the 2019 fiscal year the Corporation 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 Corporation. On March 13, 2019, the Corporation announced the departure of Thomas Fairfull as President of FV Pharma and the subsequent appointment of Dr. Sara May as President of FV Pharma. On June 3, 2019, the Corporation announced that Dr. Raza Bokhari was appointed as permanent Chief Executive Officer. The Board has also engaged a consulting firm and has commenced the process of finding a permanent Chief Financial Officer to replace the Corporation's interim Chief Financial Officer. In addition, in connection with the closing of the Prismic acquisition, Prismic founders Zachary Dutton and Peter Moriarty have joined FSD in the roles of Chief Executive Officer of Prismic and Chairman of the Biosciences/Pharmaceuticals Industry Advisory Board, respectively. On January 26, 2021, Mr. Zeeshan Saeed was terminated, for cause, as President. The Corporation may not be able to find appropriate replacements for key personnel on a timely basis.

Furthermore, each of our executive officers may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees. Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our drug pipeline toward scaling up for commercialization, sales and marketing personnel, will also be critical to our success. 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 Corporation's business, operating results or financial condition.

In addition, the Corporation's future success depends on its continuing ability to attract, develop, motivate and retain highly qualified and skilled employees. Qualified individuals are in high demand, and the Corporation may incur significant costs to attract and retain them, if it is able to hire them at all.

*The Corporation'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.*

The Corporation's dual class structure has the effect of concentrating voting control and the ability to influence corporate matters with those shareholders. Currently, all 72 outstanding Class A Shares are held by the Corporation's founders. 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 51% of the voting power of the Corporation's outstanding voting shares and therefore have significant influence over management and affairs of the Corporation and over all matters requiring shareholder approval.

In addition, because of the voting ratio between Class A Shares and Class B Shares, the holders of Class A Shares collectively continue to control a majority of the combined voting power of the voting shares even where the Class A Shares represent a substantially reduced percentage of the total outstanding shares. The different voting rights could diminish the value of the Class B Shares to the extent that investors or any potential future purchasers of the Class B Shares attribute value to the superior voting or other rights of the Class A Shares. Holders of the Class B Shares will only have a right to vote, as a class, in limited circumstances as described in its constating documents.

The concentrated voting control of holders of Class A Shares limits the ability of Class B Shareholders to influence corporate matters and all matters requiring shareholder approval, including the election of directors as well as with respect to decisions regarding amendment of the Corporation's share capital, creating and issuing additional classes of shares, making significant acquisitions, selling significant assets or parts of our business, merging with other companies and undertaking other significant transactions.

As a result, holders of Class A Shares have the ability to control substantially all matters affecting us and actions may be taken that our holders of Class B Shares may not view as beneficial. The market price of the Class B Shares could be adversely affected due to the significant influence and voting power of the holders of Class A Shares. Additionally, the significant voting interest of holders of Class A Shares may discourage transactions involving a change of control, including transactions in which an investor, as a holder of the Class B Shares, might otherwise receive a premium for the Class B Shares over the then-current market price, or discourage competing proposals if a going private transaction is proposed by one or more holders of Class A Shares.

*There are upcoming matters at the Corporation's annual meeting of shareholders that could alter the Board.*

At the Corporation's annual meeting of shareholders on May 14, 2021, a requisition for a special meeting has been submitted to the Corporation by the Requisitioning Shareholders, claiming to hold in excess of 5.1% of the Class B Shares, including Mr. Zeeshan Saeed, the former President of the Corporation and Mr.

Anthony Durkacz, who is a director of the Corporation. In addition to the Class B Shares controlled by this group, Mr. Saeed and Mr. Durkacz each hold 24 Class A Shares, with each Class A Share being entitled to 276,660 votes. Dr. Raza Bokhari, the Corporation's Executive Chairman and Chief Executive Officer, holds the remaining 24 Class A Shares. As of the date hereof, the Corporation has 72 Class A Shares and approximately 35,114,998 Class B Shares issued and outstanding. The Requisitioning Shareholders are seeking to reduce the size of the Board to five, and to replace six of the incumbent directors, including Dr. Raza Bokhari, with three directors selected by such shareholders.

*The Corporation may be unable to manage its growth, including capacity constraints and pressure on our internal systems and controls, which may have a material adverse effect on the Corporation's business, results of operations, financial conditions and prospects.*

The Corporation may be subject to growth-related risks including capacity constraints and pressure on its internal systems and controls. The ability of the Corporation to manage growth effectively will require it to continue to implement and improve its operational and financial systems and to expand, train and manage its employee base. The inability of the Corporation to deal with this growth may have a material adverse effect on the Corporation's business, results of operations, financial condition and prospects.

*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 Corporation to provide reliable financial reports and to help prevent fraud. Although the Corporation has undertaken a number of procedures and has implemented a number of safeguards, in each case, in order to help ensure the reliability of its financial reports, including those imposed on the Corporation under Canadian securities law, the Corporation cannot be certain that such measures will ensure that the Corporation 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 Corporation's results of operations or cause it to fail to meet its reporting obligations.

Effective systems of internal control over financial reporting and disclosure are critical to the operation of a public corporation. However, we do not expect that our disclosure controls and procedures or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of such controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Due to the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected in a timely manner or at all. If we cannot provide reliable financial reports or prevent fraud, our reputation and operating results could be materially adversely affected, which could cause investors to lose confidence in us and our reported financial information, which in turn could result in a reduction in the value of the Class B Shares.

*To date, the Corporation has not been required to certify in connection with its reports under applicable Canadian securities legislation that it maintains effective internal control over financial reporting or effective disclosure controls and procedures.*

In contrast to the certificates that are now required of the Corporation pursuant to Rule 15d-14(a) under the U.S. Exchange Act, as a public corporation in the United States and the certificates required under NI 52-109, the Corporation utilizes the Venture Issuer Basic Certificate which does not include

representations relating to the establishment and maintenance of disclosure controls and procedures and internal control over financial reporting. In particular, the certifying officers who have filed the Corporation's certificates have not previously made any representations relating to the establishment and maintenance of: (a) controls and other procedures designed to provide reasonable assurance that information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and (b) a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS.

*We will incur increased costs as a result of operating as a public corporation in the United States and our management will be required to devote substantial time to new compliance initiatives.*

As a public corporation in the United States, we will incur significant legal, accounting, insurance and other expenses that we did not incur prior to being listed in the United States. In addition, the U.S. *Sarbanes-Oxley Act* (2002) and rules implemented by the U.S. Securities and Exchange Commission and the Nasdaq, impose various other requirements on public companies, and we will need to spend time and resources to ensure compliance with our reporting obligations under Canadian securities laws, as well as our obligations in the United States.

Being a public corporation in the United States and complying with applicable rules and regulations have made and will continue to make it more expensive for us to obtain director and officer liability insurance, and we may continue to be required to incur substantially higher costs to obtain and maintain the same or similar coverage that is currently in place in Canada. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our Board.

*Risks related to our status as a foreign private issuer.*

As a foreign private issuer, in reliance on Nasdaq rules that permit a foreign private issuer to follow the corporate governance practices of its home country, the Corporation is permitted to follow certain Canadian corporate governance practices instead of those otherwise required under the corporate governance standards for U.S. domestic issuers.

Further, as a foreign private issuer, the Corporation is exempt from a number of requirements under U.S. securities laws that apply to public companies that are not foreign private issuers. In particular, the Corporation is exempt from the rules and regulations under the U.S. Exchange Act related to the furnishing and content of proxy statements, and its officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the U.S. Exchange Act. The Corporation is exempt from the provisions of Regulation FD, which prohibits the selective disclosure of material non-public information to, among others, broker-dealers and holders of a company's securities under circumstances in which it is reasonably foreseeable that the holder will trade in the company's securities on the basis of the information. Even though Canadian securities law requirements regarding the disclosure of material and non-public information by public companies are similar to U.S. securities law requirements and the Corporation voluntarily complies with Regulation FD, these exemptions and leniencies will reduce the frequency and scope of information and protections to which purchasers are entitled as investors.

*We are an emerging growth corporation and intend to take advantage of reduced disclosure requirements applicable to emerging growth companies, which could make the Class B Shares less attractive to*

*investors.*

We are an "emerging growth corporation" as defined in the JOBS Act and anticipate remaining an emerging growth corporation for the foreseeable future. For so long as we remain an emerging growth corporation, we are permitted to and intend to rely upon exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the JOBS Act.

We may take advantage of some, but not all, of the available exemptions available to emerging growth companies. We cannot predict whether investors will find the Class B Shares less attractive if we rely on these exemptions. If some investors find the Class B Shares less attractive as a result, there may be a less active trading market for the Class B Shares and our share price may be more volatile.

*We may not be able to successfully identify and execute future acquisitions or dispositions or to successfully manage the impacts of such transactions on our operations.*

The Corporation has made and may continue to pursue acquisition opportunities to advance its strategic plan. The successful integration of an acquired business typically requires the management of the pre-acquisition business strategy, including the retention and addition of senior management, customers, realization of identified synergies, retention of key staff and the development of a common corporate culture. Achieving the benefits of acquisitions depends in part on successfully consolidating functions and integrating operations and procedures in a timely and efficient manner, as well as the ability to realize anticipated growth opportunities and synergies from newly formed partnerships. Any failure to integrate an acquired business or realize the anticipated benefits of new partnerships may have a material adverse effect on the Corporation's business, results of operations, financial condition and prospects, including its future prospects for acquisitions or partnerships. There is no assurance that the Corporation will be able to successfully integrate an acquired business in order to maximize or realize the benefits associated with an acquisition.

In addition, from time to time the Corporation enters into letters of intent and memoranda of understanding with respect to which definitive agreements have not yet been, but are expected to be, executed. The Corporation may not be able to perform under these contracts as a result of operational or other breaches or due to events beyond its control, and the Corporation may not be able to ultimately execute a definitive agreement in cases where one does not currently exist.

*Any expansion of our international operations will result in increased operational, regulatory and other risks.*

We may in the future expand into other geographic areas, which could increase our operational, regulatory, compliance, reputational and foreign exchange rate risks. The failure of our operating infrastructure to support such expansion could result in operational failures and regulatory fines or sanctions.

*The Corporation is reliant on the operations of its partners and has little or no control over such operations.*

The Corporation has made investments in strategic partners and relies on such partners to execute on their business plans. Other than with respect to certain contractual arrangements, the Corporation has little or no control in or influence over the operations of its partners. Further, the interests of the Corporation and its partners may not always be aligned. As a result, the Corporation's projected cash flows that are dependent upon the operation of its partners are subject to the risk that its partners may: (i) have business

interests or targets that are inconsistent with those of the Corporation; (ii) take action contrary to the Corporation's policies or objectives; (iii) be unable or unwilling to fulfill their obligations under their agreements with the Corporation; or (iv) experience financial, operational or other difficulties, including insolvency, which could limit or suspend a partner's ability to perform its obligations. In addition, payments may flow through the Corporation's partners and there is a risk of delay and additional expense in receiving such revenues. Failure to receive payments in a timely fashion, or at all, under the agreements to which the Corporation is entitled may have a material adverse effect on the Corporation. In addition, the Corporation must rely, in part, on the accuracy and timeliness of the information it receives from its partners and uses such information in its analyses, forecasts and assessments relating to its own business. If the information provided to the Corporation by its partners contains material inaccuracies or omissions, the Corporation's ability to accurately forecast or achieve its stated objectives, or satisfy its reporting obligations, may be materially impaired.

*The Corporation may become party to litigation from time to time which could adversely affect its business.*

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

*Settlement Agreement.*

On October 29, 2020, the Corporation announced that it has entered into the Settlement Agreement with respect to the class action litigation commenced by a plaintiff shareholder in the Ontario Superior Court of Justice in February 2019 relating to the build-out of its facility in Cobourg, Ontario. The Settlement Agreement was approved by the Ontario Superior Court of Justice on February 4, 2021. In entering into the Settlement Agreement, the Corporation made no admissions of liability whatsoever. The Settlement Agreement provides for a full and final release of the Corporation, its officers, directors and various other related parties from any and all claims that arose or could have arisen from the claim issued by the plaintiff within the Settled Action. The Settlement Agreement provides for a settlement amount of $5,500,000, of which $4,571,459 has been funded with the proceeds of insurance and the remaining $928,541 has been funded by the Corporation.

*Claims from suppliers.*

A dismissed contractor commenced a lien action combined with a breach of contract action in Ontario Superior Court of Justice (Cobourg) (the "Cobourg Superior Court") in early 2019 claiming approximately $1.7 million in various purported damages, with a claim for lien component of $188,309 which claim was registered November 26, 2018. The Corporation is defending the action and has taken steps to obtain particulars and inspect documents of the plaintiff which remain unaddressed to date. The Corporation has paid monies into court totalling $235,387 to vacate the lien from title which funds stand as security for the lien claim and its costs in Cobourg Superior Court of Justice file no. CV-19-0002. As such, full provision for the lien claim and security for costs has been made; however, the 2019 breach of contract claim has not been provisioned as the Corporation intends to defend itself from this claim.

*Conflicts of interest may arise between the Corporation and its directors and officers as a result of other*

*business activities undertaken by such individuals.*

Certain directors and officers of the Corporation 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 Corporation. In particular, certain directors and officers of the Corporation serve as directors or officers of entities that may compete with or have conflicting interests with the Corporation.

In addition, the Corporation's directors and the officers are required to act honestly and in good faith with a view to its best interests. However, in conflict of interest situations, the Corporation's directors and officers may owe the same duty to another corporation and will need to balance their competing interests with their duties to the Corporation. Circumstances (including with respect to future corporate opportunities) may arise that may be resolved in a manner that is unfavorable to the Corporation. These business interests could require the investment of significant time and attention by our executive officers and directors. In some cases our executive officers and directors may have fiduciary obligations associated with business interests that interfere with their ability to devote time to our business and affairs, which could adversely affect our operations.

*The Corporation has not paid dividends in the past and does not anticipate paying dividends in the near future.*

The Corporation has not paid dividends in the past and does not anticipate paying dividends in the near future. The Corporation expects to retain earnings to finance the development and enhancement of its products and to otherwise reinvest in the Corporation's businesses. Any decision to declare and pay dividends in the future will be made at the discretion of the Board and will depend on, among other things, financial results, cash requirements, contractual restrictions and other factors that the Board may deem relevant. As a result, investors may not receive any return on investment in Class B Shares unless they sell them for a share price that is greater than that at which such investors purchased them.

*The Corporation's operations depend, in part, on the maintenance and protection of its information technology systems and the information technology systems of its third-party research institution collaborators, CRO or other contractors or consultants, which could face cyber-attacks that cause material losses to our business.*

We have entered into agreements with third parties for hardware, software, telecommunications and other IT services in connection with our operations. Our operations depend, in part, on how well we, our future CROs, other contractors, consultants and our suppliers protect networks, equipment, IT systems and software against damage from a number of threats, including, but not limited to, cable cuts, damage to physical plants, natural disasters, terrorism, fire, power loss, hacking, computer viruses, vandalism and theft. Our operations also depend on the timely maintenance, upgrade and replacement of networks, equipment, IT systems and software, as well as pre-emptive expenses to mitigate the risks of failures. Any of these and other events could result in information system failures, delays and/or increase in capital expenses. The failure of information systems or a component of information systems could, depending on the nature of any such failure, adversely impact our reputation and results of operations.

For example, the loss of, or damage to, clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely or expect to rely on third parties for research and development, the manufacture and supply of drug product and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate

disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Certain data breaches must also be reported to affected individuals and the certain regulatory bodies, and in some cases may be required to be publicly disclosed, under provisions of HIPAA, as amended, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including federal and provincial data protection legislation in Canada, European Union Data Protection Directive, and financial or other penalties may also apply.

Cyber incidents can result from deliberate attacks or unintentional events. Cyber-attacks could result in any person gaining unauthorized access to digital systems for purposes of misappropriating assets or sensitive information, including personally identifiable information, corrupting data, or causing operational disruption. Cyber- attacks could also result in important remediation costs, increased cyber security costs, lost revenues due to a disruption of activities, litigation and reputational harm affecting customer and investor confidence, which could materially adversely affect our business and financial results.

We have not experienced any material losses to date relating to cyber-attacks or other information security breaches, but there can be no assurance that we will not incur such losses in the future, which could be in excess of any available insurance and could materially adversely affect our business and financial results. Our risk and exposure to these matters cannot be fully mitigated because of, among other things, the evolving nature of these threats. As a result, cyber security and the continued development and enhancement of controls, processes and practices designed to protect systems, computers, software, data and networks from attack, damage or unauthorized access is a priority. As cyber threats continue to evolve, we may be required to expend additional resources to continue to modify or enhance protective measures or to investigate and remediate any security vulnerabilities.

*Tax and accounting requirements may change in ways that are unforeseen to us and we may face difficulty or be unable to implement or comply with any such changes.*

We are subject to numerous tax and accounting requirements, and changes in existing accounting or taxation rules or practices, or varying interpretations of current rules or practices, could have a significant adverse effect on our financial results, the manner in which we conduct our business or the marketability of any of our products. We currently have international operations and plans to expand such operations in the future. These operations, and any expansion thereto, will require us to comply with the tax laws and regulations of multiple jurisdictions, which may vary substantially. Complying with the tax laws of these jurisdictions can be time consuming and expensive and could potentially subject us to penalties and fees in the future if we were to fail to comply.

*Tax risks related to our status as a "passive foreign investment corporation", or "PFIC".*

Under the Internal Revenue Code of 1986, we will be a PFIC for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as holding and receiving directly its proportionate share of assets and income of such corporation. If we are a PFIC for any taxable year during which a U.S. holder holds our shares, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including

ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred and additional reporting requirements.

Based on our analysis of our income, assets, activities and market capitalization, we believe that we were a PFIC in the 2019 taxable year. We have not yet determined our PFIC status for the current taxable year, but we expect to be a PFIC. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. As a result, there can be no assurance regarding whether we will be treated as a PFIC for the current year, or may be treated as a PFIC in the future. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our Class B Shares from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how we spend the cash we raise in any offering.

## DIVIDENDS AND DISTRIBUTIONS

The future payment of dividends will be dependent upon the financial requirements of the Corporation to fund further growth, the financial condition of the Corporation and other factors which the Board may consider in the circumstances. It is not contemplated that any dividends will be paid in the immediate or foreseeable future, if at all.

## DESCRIPTION OF CAPITAL STRUCTURE

The Corporation's authorized share capital consists of an unlimited number of Class A Shares and an unlimited number of Class B Shares. As of the date of this AIF, there were 72 Class A Shares issued and outstanding and 35,114,998 Class B Shares issued and outstanding. As of the date of this AIF, the Class B Shares represented approximately 49% of the voting rights attached to outstanding voting securities of the Corporation. The following is a summary of the rights, privileges, restrictions and conditions attached to the Class B Shares.

### *Voting Rights*

Except as otherwise prescribed by the OBCA, at a meeting of the Shareholders, each Class B Share entitles the holder thereof to one vote and each Class A Share entitles the holder thereof to 276,660 votes on all matters.

### *Rank*

The Class A Shares and Class B Shares rank pari passu with respect to the payment of dividends, return of capital and distribution of assets in the event of the liquidation, dissolution or winding up of the Corporation. In the event of the liquidation, dissolution or winding-up of the Corporation or any other distribution of its assets among its shareholders for the purpose of winding-up its affairs, whether voluntarily or involuntarily, the holders of Class A Shares and the holders of Class B Shares are entitled to participate equally, share for share, subject always to the rights of the holders of any class of shares ranking senior to the Class A Shares and the Class B Shares, in the remaining property and assets of the Corporation available for distribution to shareholders, without preference or distinction among or between the Class A

Shares and the Class B Shares.

***Dividends***

Holders of Class A Shares and Class B Shares are entitled to receive, subject always to the rights of the holders of any class of shares ranking senior to the Class A Shares and Class B Shares, dividends out of the assets of the Corporation legally available for the payment of dividends at such times and in such amount and form as the Board may from time to time determine and the Corporation will pay dividends thereon on a pari passu basis, if, as and when declared by the Board.

***Conversion***

The Class B Shares are not convertible into any other class of shares. Each outstanding Class A Share may, at any time at the option of the holder, be converted into one Class B Share. Upon the first date that any Class A Share is held other than by a permitted holder, the permitted holder which held such Class A Share until such date, without any further action, shall automatically be deemed to have exercised his, her or its rights to convert such Class A Share into a fully paid and non-assessable Class B Share.

***Subdivision or Consolidation***

No subdivision or consolidation of the Class A Shares or the Class B Shares may be carried out unless, at the same time, the Class A Shares or the Class B Shares, as the case may be, are subdivided or consolidated in the same manner and on the same basis.

On October 16, 2019, the Corporation completed the Consolidation of all of its issued and outstanding Class A Shares and Class B Shares. Pursuant to the Consolidation of all of the issued and outstanding Class A Shares and Class B Shares on the basis of one post-Consolidation share for every 201 pre-Consolidation shares of each class.

***Change of Control Transactions***

The holders of Class B Shares are entitled to participate on an equal basis with holders of Class A Shares in the event of a "Change of Control Transaction" requiring approval of the holders of Class A Shares and Class B Shares under the OBCA, unless different treatment of the shares of each such class is approved by a majority of the votes cast by the holders of outstanding Class A Shares and by a majority of the votes cast by the holders of outstanding Class B Shares each voting separately as a class.

***Proposals to Amend the Articles of Amendment***

Neither the holders of the Class A Shares nor the holders of the Class B Shares are entitled to vote separately as a class upon a proposal to amend the Articles of Amendment in the case of an amendment referred to in paragraph (a) or (e) of subsection 170(1) of the OBCA.

Neither the holders of the Class A Shares nor the holders of the Class B Shares shall be entitled to vote separately as a class upon a proposal to amend the Articles of Amendment in the case of an amendment referred to in paragraph (b) of subsection 170(1) of the OBCA unless such exchange, reclassification or cancellation: (a) affects only the holders of that class; or (b) affects the holders of Class A Shares and Class B Shares differently, on a per share basis, and such holders are not otherwise entitled to vote separately as

a class under any applicable law in respect of such exchange, reclassification or cancellation.

***Take-Over Bid Protection***

Under applicable Canadian law, an offer to purchase Class A Shares would not necessarily require that an offer be made to purchase Class B Shares. In accordance with the rules of the CSE designed to ensure that, in the event of a take-over bid, the holders of Class B Shares will be entitled to participate on an equal footing with holders of Class A Shares, the holders of not less than 80% of the outstanding Class A Shares have entered into the Coattail Agreement. The Coattail Agreement contains provisions customary for dual class, publicly-traded corporations designed to prevent transactions that otherwise would deprive the holders of Class B Shares of rights under the take-over bid provisions of applicable Canadian securities legislation to which they would have been entitled if the Class A Shares had been Class B Shares.

The undertakings in the Coattail Agreement do not apply to prevent a sale of Class A Shares by a holder of Class A Shares party to the Coattail Agreement if concurrently an offer is made to purchase Class B Shares that:

(a) offers a price per Class B Share at least as high as the highest price per share paid or required to be paid pursuant to the take-over bid for the Class A Shares;

(b) provides that the percentage of outstanding Class B Shares to be taken up (exclusive of shares owned immediately prior to the offer by the offeror or persons acting jointly or in concert with the offeror) is at least as high as the percentage of outstanding Class A Shares to be sold (exclusive of Class A Shares owned immediately prior to the offer by the offeror and persons acting jointly or in concert with the offeror);

(c) has no condition attached other than the right not to take up and pay for Class B Shares tendered if no shares are purchased pursuant to the offer for Class A Shares; and

(d) is in all other material respects identical to the offer for Class A Shares.

In addition, the Coattail Agreement does not prevent the sale of Class A Shares by a holder thereof to a permitted holder, provided such sale does not or would not constitute a take-over bid or, if so, is exempt or would be exempt from the formal bid requirements (as defined in applicable securities legislation). The conversion of Class A Shares into Class B Shares, shall not, in of itself constitute a sale of Class A Shares for the purposes of the Coattail Agreement.

Under the Coattail Agreement, any sale of Class A Shares (including a transfer to a pledgee as security) by a holder of Class A Shares party to the Coattail Agreement is conditional upon the transferee or pledgee becoming a party to the Coattail Agreement, to the extent such transferred Class A Shares are not automatically converted into Class B Shares in accordance with the Articles of Amendment.

The Coattail Agreement contains provisions for authorizing action by the trustee to enforce the rights under the Coattail Agreement on behalf of the holders of the Class B Shares. The obligation of the trustee to take such action will be conditional on the Corporation or holders of the Class B Shares providing such funds and indemnity as the trustee may require. No holder of Class B Shares has the right, other than through the trustee, to institute any action or proceeding or to exercise any other remedy to enforce any rights arising under the Coattail Agreement unless the trustee fails to act on a request authorized by holders of not less than 10% of the outstanding Class B Shares and reasonable funds and indemnity have been provided to the

trustee.

The Coattail Agreement may not be amended, and no provision thereof may be waived, unless, prior to giving effect to such amendment or waiver, the following have been obtained: (a) the consent of the CSE and any other applicable securities regulatory authority in Canada and (b) the approval of at least 66⅔% of the votes cast by holders of Class B Shares represented at a meeting duly called for the purpose of considering such amendment or waiver, excluding votes attached to Class B Shares held directly or indirectly by holders of Class A Shares, their affiliates and related parties and any persons who have an agreement to purchase Class A Shares on terms which would constitute a sale for purposes of the Coattail Agreement other than as permitted thereby.

No provision of the Coattail Agreement limits the rights of any holders of Class B Shares under applicable law.

At the annual and special meeting of Shareholders of the Corporation held December 16, 2019, the Shareholders approved an amendment to the Articles to authorize certain transfers of Class A Shares. The Shareholders approved an amendment to permit the holders of Class A Shares to complete transfers of Class A Shares to a director, executive officer or Founder of the Corporation, such that a Founder who is no longer actively involved in the business and affairs of the Corporation could transfer that Founder's Class A Shares to those individuals who remain active.

## MARKETS FOR SECURITIES

### Trading Price and Volume

The Class B Shares commenced trading on the CSE on May 29, 2018 under the symbol "HUGE". Prior to the CSE listing, there was no public trading in any securities of the Corporation. The following table sets out the high and low prices and aggregate volume of the Class B Shares traded through the CSE on a monthly basis for the most recent financial year ended December 31, 2020.

| Month | High (C$) | Low (C$) | Total Volume |
|---|---|---|---|
| January 2020 | 15.10 | 7.14 | 1,390,028 |
| February 2020 | 8.28 | 4.90 | 410,199 |
| March 2020 | 7.15 | 3.51 | 755,243 |
| April 2020 | 5.13 | 4.08 | 278,739 |
| May 2020 | 4.65 | 3.60 | 189,782 |
| June 2020 | 14.74 | 3.95 | 1,997,668 |
| July 2020 | 9.09 | 4.78 | 1,375,554 |
| August 2020 | 4.80 | 3.60 | 782,720 |
| September 2020 | 4.01 | 3.33 | 293,301 |
| October 2020 | 3.58 | 1.84 | 426,835 |
| November 2020 | 3.00 | 1.70 | 1,089,453 |
| December 2020 | 2.70 | 1.97 | 862,091 |

The Class B Shares are also listed on the Nasdaq in the United States under the symbol "HUGE". The price range and trading volume of the Class B Shares for the prior 12 month period, as reported by the Nasdaq,

are set out below:

| Month | High (US$) | Low (US$) | Total Volume |
|---|---|---|---|
| January 2020 | 10.39 | 5.67 | 66,694 |
| February 2020 | 6.75 | 3.88 | 60,861 |
| March 2020 | 5.50 | 2.39 | 74,919 |
| April 2020 | 3.85 | 2.75 | 41,330 |
| May 2020 | 3.39 | 2.55 | 42,495 |
| June 2020 | 14.00 | 2.92 | 5,003,735 |
| July 2020 | 6.87 | 3.56 | 25,215,300 |
| August 2020 | 3.61 | 2.69 | 18,548,000 |
| September 2020 | 3.08 | 2.50 | 518,021 |
| October 2020 | 2.75 | 1.39 | 640,687 |
| November 2020 | 2.37 | 1.28 | 4,483,612 |
| December 2020 | 2.07 | 1.55 | 2,389,322 |

Our outstanding Class B Shares are also listed and posted for trading on the Börse Frankfurt or Frankfurt Stock Exchange under "WKN: A2JM6M" and the trading symbol "0K9A".

**Prior Sales**

The following table sets forth details regarding all issuances of securities by the Corporation, including all convertible securities, during the most recently completed financial year ended December 31, 2020. All

figures are shown on a post-Consolidation basis.

| Date of Issuance | Securities | Number of Securities | Exercise or Weighted Average Issue Price per Security |
|---|---|---|---|
| October 20, 2020 | Warrants[(1)] | 3,454,543 | US$2.60 |
| October 20, 2020 | Class B Shares[(1)] | 4,318,179 | US$2.20 |
| July 30 to October 15, 2020 | Class B Shares[(3)] | 5,531 | US$2.67 |
| August 6, 2020 | Warrants[(2)] | 1,381,215 | US$4.26 |
| August 6, 2020 | Class B Shares[(2)] | 2,762,430 | US$3.62 |
| July 15 to 29, 2020 | Class B Shares[(3)] | 48,317 | US$3.81 |
| June 22, 2020 | Class B Shares[(2)] | 22,382 | $2.61 |
| June 8, 2020 | Warrants[(3)] | 1,500,000 | $9.65 |
| June 8, 2020 | Class B Shares[(3)] | 1,500,000 | $6.75 |
| April 14, 2020 | Options[(4)] | 110,000 | $4.75 |
| March 27, 2020 | Class B Shares[(5)] | 7,485 | $3.50 |
| March 24, 2020 | Options[(4)] | 872,139 | $3.86 |
| March 23, 2020 | Class B Shares[(5)] | 56,229 | $2.57 |
| March 16, 2020 | Class B Shares[(6)(7)] | 474,995 | $4.35 |
| March 13, 2020 | Class B Shares[(8)] | 399,483 | $4.57 |
| March 6, 2020 | Options[(4)] | 20,000 | $6.16 |
| February 4, 2020 | Class B Shares[(9)] | 225,371 | $8.00 |
| January 21, 2020 | Options[(4)] | 15,000 | $9.54 |
| January 2, 2020 | Class B Shares[(10)] | 27,580 | $7.31 |

**Notes:**

(1) Represents the Class B Shares and associated Warrants issued pursuant to the October Offering.
(2) Represents the Class B Shares and associated Warrants issued pursuant to the July Offering.
(3) Represents Class B shares issued pursuant to the Corporation's previous at-the-market equity distribution program.
(4) Represents Class B Shares issued upon the exercise of Options held by a former securityholder of Prismic.
(5) Represents the Class B Shares and associated Warrants issued pursuant to the June Private Placement.
(6) Represents the issuance of Options issued to a director, officer, employee, or consultant of the Corporation (or any of its subsidiaries) under the Stock Option Plan.
(7) Represents Class B Shares issued to certain holders of Prismic debt assumed by the Corporation in connection with the acquisition. For further information see "*General Development of the Business – Three Year History – Acquisition of Prismic"* in the 2019 AIF.
(8) Represents Class B Shares issued as part of share-based bonus to certain employees for performance related to the year ended December 31, 2019.
(9) Represents Class B Shares issued as part of share-based compensation to the Board for their annual compensation for the year ended December 31, 2019 in lieu of cash.
(10) Represents Class B Shares issued to certain officers of the Corporation as a bonus for services provided to the Corporation during the year ended December 31, 2019.

## ESCROWED SECURITIES AND SECURITIES

## SUBJECT TO CONTRACTUAL RESTRICTION ON TRANSFER

As of the date of this AIF, no securities are being held in escrow or subject to contractual restrictions on transfer.

## DIRECTORS AND EXECUTIVE OFFICERS

### Name, Occupation and Security Holding

The following table sets out certain information regarding the directors and executive officers of the Corporation as at the date of this AIF. Each of the directors is elected to hold office until the next annual meeting of the shareholders of the Corporation or until a successor is duly elected or appointed. All figures are shown on a post-Consolidation basis.

As of December 31, 2020, all of the Corporation's directors and executive officers, as a group, beneficially owned or exercised control or direction over, directly or indirectly, 72 Class A Shares, or approximately 100 percent of the number of Class A Shares and 19,161,620 Class B Shares or approximately 49 percent of the number of Class B Shares that were outstanding as of such date. As of March 12, 2021 all of the Corporation's directors and executive officers, as a group, beneficially owned or exercised control or direction over, directly or indirectly, 72 Class A Shares, or approximately 100 percent of the number of Class A Shares and 24,283,865 Class B Shares or approximately 69% percent of the number of Class B Shares that were outstanding as of such date.

| Name, Position and Province of Residence | Principal Occupation During Last Five Years | Date Became Director or Executive Officer | Class A Shares Owned or Controlled[1] | Class B Shares Owned or Controlled[1] |
|---|---|---|---|---|
| Dr. Raza Bokhari, Chief Executive Officer, Executive Chairman and Director[12][30]<br>*Pennsylvania, United States* | Managing Partner, RBx Capital LP; Chairman, Parkway Clinical Laboratories Inc. | July 17, 2018 | 24[26] | 2,428,386[5] |
| Dr. Edward Brennan, Chief Medical Officer<br>*Pennsylvania, United States* | Medical Director, Wyeth-Ayerst Research and GlaxoSmithKline; Founder, IndiPharm | May 28, 2019 | Nil | 112,920[18] |
| Stephen Buyer, Director[9][10][29]<br>*Indiana, United States* | Managing Partner, 10-Square Solution, LLC; former Congressman, United States House of Representatives | October 11, 2019 | Nil | 163,726[14] |
| Donal Caroll, Chief Financial Officer, Former Director<br>*Ontario, Canada* | Chief Financial Officer, FSD Pharma | July 23, 2018 | Nil | 85,357[16] |
| Robert J. Ciaruffoli, Director[7][8][10][13][27][29]<br>*Pennsylvania, United States* | Co-Founder and Vice-Chairman, Broad Street Angels; Former | June 12, 2019 | Nil | 156,453[19] |

| | | | | |
|---|---|---|---|---|
| | Chairman and CEO, Parente Beard/Baker Tilly | | | |
| James A. Datin, Director[11][17][29]<br>*North Carolina, United States* | President & Chief Executive Officer, BioAgilytix | June 12, 2019 | Nil | 98,961[20] |
| Anthony Durkacz, Director<br>*Ontario, Canada* | Director and Executive Vice-President, First Republic Capital Corporation; Director and Chief Financial Officer, Snipp Interactive Inc. | June 18, 2018 | 24[2][26] | 450,058[3][4] |
| Gerald Goldberg, Director[6][12][27][29]<br>*Ontario, Canada* | Executive Chairman, Osoyoos Cannabis Inc.; Interim CEO, Canada House Wellness Group Inc.; CEO and President, Leo Acquisitions Corp.; Senior Partner, Schwartz, Levitsky, Feldman LLP; President, Victory Capital Corp. | May 24, 2018 | Nil | 60,211[21] |
| Dr. Larry Kaiser, Director[6][8][28][29]<br>*Pennsylvania, United States* | Managing Director, Healthcare Industry Group, Alvarez and Marsal; formerly President and CEO, Temple University Health System; formerly Dean, Lewis Katz School of Medicine, Temple University; Senior Executive Vice President, Health Science, Temple University | January 22, 2020 | Nil | 93,466[15] |
| Dr. Sara May, President, FV Pharma<br>*Ontario, Canada* | President, FV Pharma; formerly Quality Assurance, FV Pharma; formerly Ecologist and GIS Manager, Beacon Environmental | March 13, 2019 | Nil | 14,755[22] |
| Zeeshan Saeed, Former President and Director[23]<br>*Ontario, Canada* | Director and Executive Vice President, FV Pharma;<br>CEO, Platinum | May 24, 2018 | 24 [24][26] | 504,476[25] |

| | | | | |
|---|---|---|---|---|
| | Telecommunications Inc. | | | |

**Notes:**

(1) The information as to the number of Class A Shares and/or Class B Shares beneficially owned or over which control or direction is exercised has been furnished by the respective nominee and has not been independently verified by the Corporation. Presented as of March 12, 2021.
(2) Fortius Research and Trading Corp., a corporation controlled by Anthony Durkacz, is the registered owner of the Class A Shares.
(3) Fortius Research and Trading Corp., a corporation controlled by Anthony Durkacz, is the registered owner of 106,043 Class B Shares and First Republic Capital Corporation, a corporation majority owned by Anthony Durkacz, is the registered owner of 170,418 Class B Shares.
(4) Anthony Durkacz also holds 199,004 warrants and 99,502 Stock Options.
(5) Dr. Bokhari also holds 412,932 Stock Options.
(6) Member of Audit and Risk Committee.
(7) Chairman of the Audit and Risk Committee.
(8) Member of the Governance Committee.
(9) Chairman of the Governance Committee.
(10) Member of the Compensation Committee.
(11) Chairman of the Compensation Committee.
(12) Member of the Corporate Disclosure Committee.
(13) Chairman of the Corporate Disclosure Committee.
(14) Mr. Buyer also holds 45,000 Stock Options.
(15) Dr. Kaiser also holds 64,900 Stock Options.
(16) Mr. Carroll also holds 104,774 Stock Options.
(17) Mr. Datin will be resigning from the Board of Directors effective April 30, 2021.
(18) Mr. Brennan also holds 127,115 Stock Options.
(19) Mr. Ciaruffoli also holds 82,313 Stock Options.
(20) Mr. Datin also holds 39,876 Stock Options.
(21) Mr. Goldberg also holds 39,875 Stock Options.
(22) Dr. May also holds 12,438 Stock Options.
(23) Mr. Saeed was terminated for cause from his positions of President and Director effective January 26, 2021.
(24) Xorax Family Trust, a trust of which Zeeshan Saeed is a beneficiary, is the registered owner of the Class A Shares.
(25) Xorax Family Trust, a trust of which Zeeshan Saeed is a beneficiary, is the registered owner of 317,543 Class B Shares. Mr. Saeed also holds 199,004 Stock Options.
(26) In March 2020, Dr. Bokhari entered into private agreements with Mr. Durkacz (as to 12 Class A Shares) and Mr. Saeed (as to 12 Class A Shares) in connection with the acquisition of 24 Class A Shares now currently held by Dr. Bokhari.
(27) Member of Nominating Committee.
(28) Chairman of Nominating Committee.
(29) Member of Executive Committee.
(30) Chairman of Executive Committee.

## Cease Trade Orders, Bankruptcies, Penalties or Sanctions

### *Corporate Cease Trade Orders*

To the best of management's knowledge, other than set out below, no director or executive officer of the Corporation is, or within the ten years before the date of this AIF has been, a director, chief executive officer

or chief financial officer of any Corporation that:

(a) was subject to a cease trade order, an order similar to a cease trade order, or an order that denied the relevant corporation access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer; or

(b) was subject to a cease trade order, an order similar to a cease trade order, or an order that denied the relevant corporation access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days that was issued after the director or executive officer ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

Gerry Goldberg was the Interim Chief Executive Officer of Canada House when a MCTO was issued by the Ontario Securities Commission on September 13, 2017. The MCTO was issued in respect of Canada House's failure to file its audited financial statements and management discussion and analysis for the year ended April 30, 2017 before the August 28, 2017 filing deadline. The MCTO was lifted effective November 22, 2017.

***Bankruptcies***

To the best of management's knowledge, no director or executive officer of the Corporation has: (i) within ten years before the date of this AIF, been a director or officer of any corporation that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or was subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold its assets; or (ii) within ten years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver manager or trustee appointed to hold the assets of the director or executive officer.

***Penalties and Sanctions***

To the best of management's knowledge, no director or executive officer of the Corporation has been subject to: (a) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with any securities regulatory authority; or (b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable security holder in deciding whether to vote for a director or executive officer.

**Conflicts of Interest**

Conflicts of interest may arise as a result of the directors, officers and promoters of the Corporation also holding positions as directors or officers of other companies. Some of the individuals who will be directors and officers of the Corporation have been and will continue to be engaged in the identification and evaluation of assets, businesses and companies on their own behalf and on behalf of other companies, and situations may arise where the directors and officers of the Corporation will be in direct competition with

the Corporation. Conflicts, if any, will be subject to the procedures and remedies provided under the OBCA.

## PROMOTERS

There are currently no individuals who would be considered promoters of the Corporation.

## LEGAL PROCEEDINGS AND REGULATORY ACTIONS

### Shareholder Settlement

The Corporation was the defendant in a proposed class action lawsuit filed at the Ontario Superior Court of Justice in Toronto on February 22, 2019 (the "**Settled Action**"). The plaintiff shareholder alleged that the Corporation misrepresented information with respect to the progress of the build-out of the first phase the Facility by the Corporation and Auxly. The plaintiff further alleges that when the Corporation subsequently announced that the Auxly Agreement had been terminated, the price of the Class B Shares on the CSE decreased causing losses to her and the other shareholders of the Corporation.

On October 29, 2020 the Corporation announced that it had entered into a definitive settlement agreement the "**Settlement Agreement**") before the Ontario Superior Court of Justice with respect to the Settled Action, pursuant to which the Corporation will pay $5,500,000, of which $4,571,459 has been funded with the proceeds of insurance and the remaining $928,541 has been funded by the Corporation. The Settlement Agreement provides for a full and final release of the Corporation, its officers, directors and various other related parties from any and all claims that arose or could have arisen from the claim issued by the plaintiff within the Settled Action. The Settlement Agreement was approved by the Ontario Superior Court of Justice on February 4, 2021.

### Dismissed Supplier

A dismissed contractor commenced a lien action combined with a breach of contract action in the Cobourg Superior Court in early 2019 claiming approximately $1,700,000 in various purported damages, with a claim for lien component of $188,309 which claim was registered November 26, 2018. We are defending the action and have taken steps to obtain particulars and inspect documents of the plaintiff which remain unaddressed to date. The Corporation has paid monies into court totalling $235,387 to vacate the lien from title, which funds stand as security for the lien claim and its costs in Cobourg Superior Court file no. CV-19-0002. On October 7, 2020, FSD signed a settlement agreement of $198,000. The settlement will be paid from the funds held by the Cobourg Superior Court with the remaining funds being paid back to FSD. See "*Risk Factors – General Corporate Risks – Claims from suppliers*".

Other than stated above, there are no material legal proceedings or regulatory actions that the Corporation is or was a party to, or that any of its property is or was the subject of, during the years ended December 31, 2020, and no such proceedings are known by the Corporation to be contemplated. From time to time, however, the Corporation may be subject to various claims and legal actions arising in the course of its business.

Other than stated above, the Corporation is not aware of any settlement agreements, penalties or sanctions the Corporation has entered into before a court relating to securities legislation or with a securities regulatory authority or that would be material to a reasonable investor in making an investment decision.

### Former Employee

FSD hired an individual (the "**Claimant**") whose employment was subsequently terminated in the

probationary period due to non-performance/cause in February 2019. The individual retained legal counsel in or around February 15, 2019 demanding that he be provided (i) unpaid wages; (ii) unpaid holiday pay, (iii) payment for wrongful dismissal (one week) and (iv) breach of contract.

The Corporation has a provision of $105,180 (£59,748) in relation to the claimed amounts for unpaid wages and unpaid holiday pay. On July 29, 2020, a judgment was issued ordering the Corporation to pay unpaid wages and unpaid holiday pay in the amount of £59,748. On August 6, 2020, the Corporation filed an application for reconsideration for that decision, as key evidence was not considered in determining the judgment. The ruling on the application for reconsideration is outstanding. On August 26, 2020, the Claimant filed a separate cost order against the Corporation. The ultimate outcome of the matter cannot be reliably determined at this time and no additional provision has been recorded for this matter as at December 31, 2020.

**2021 Special and General Meeting of Shareholders**

At the Corporation's annual meeting of shareholders on May 14, 2021, a requisition for a special meeting has been submitted to the Corporation by the Requisitioning Shareholders claiming to hold in excess of 5.1% of the Class B Shares, including Mr. Zeeshan Saeed, the former President of the Corporation and Mr. Anthony Durkacz, who is a director of the Corporation. In addition to the Class B Shares controlled by this group, Mr. Saeed and Mr. Durkacz each hold 24 Class A Shares, with each Class A Share being entitled to 276,660 votes. Dr. Raza Bokhari, the Corporation's Executive Chairman and Chief Executive Officer, holds the remaining 24 Class A Shares. As of the date hereof, the Corporation has 72 Class A Shares and approximately 19,161,620 Class B Shares issued and outstanding. The Requisitioning Shareholders are seeking to reduce the size of the Board to five, and to replace six of the incumbent directors, including Dr. Raza Bokhari, with three directors selected by such shareholders.

## INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Except as disclosed elsewhere in this AIF, no: (a) director or executive officer of the Corporation; (b) person or Corporation who beneficially owns, or controls or directs, directly or indirectly, more than 10% of any class or series of the Corporation's outstanding securities; or (c) any associate or affiliate of any of the foregoing, has had any material interest, direct or indirect, in any transaction within the three most recently completed financial years or during the current financial year that has materially affected or is reasonably expected to materially affect the Corporation, other than an interest arising solely from the ownership of shares where such person received no extra or special benefit or advantage not shared on a pro rata basis by all shareholders.

## TRANSFER AGENT AND REGISTRAR

The transfer agent and registrar of the Corporation is Computershare at its office located at 100 University Avenue, 8th Floor, Toronto, Ontario, Canada M5J 2Y1.

## MATERIAL CONTRACTS

Other than those listed below, elsewhere in this AIF, and those entered into in the ordinary course of the Corporation's business, there are no material contracts of the Corporation which were entered into in the most recently completed financial year or which were entered into before the most recently completed

financial year but are still in effect as of the date of this AIF:

(a) the Amalgamation Agreement;

(b) License Agreement;

(c) the Escrow Agreement; and

(d) the Coattail Agreement.

## AUDIT COMMITTEE INFORMATION

The Audit Committee is governed by an Audit Committee charter, a copy of which is attached as Schedule "A".

### Composition of the Audit and Risk Committee

As of the date of this AIF, the following are the members of the Audit Committee:

| Name | Independent | Financially Literate |
|---|---|---|
| Robert J. Ciaruffoli (Chair) | Yes | Yes |
| Larry Kaiser | Yes | Yes |
| Gerald Goldberg | Yes | Yes |

The Audit Committee's function include, but are not limited to: reviewing the integrity of the Corporation's financial statements, financial disclosures and internal controls over financial reporting; monitoring the Corporation's ongoing compliance with legal and regulatory requirements; selecting the external auditor for shareholder approval; and reviewing the qualifications, independence and performance of the external auditor. Information concerning the relevant education and experience of the Audit Committee members is set forth below.

### Relevant Education and Experience

The Board believes that the composition of the Audit Committee reflects financial literacy and expertise. Currently, all members of the Audit Committee have been determined by the Board to be "independent" and "financially literate" as such terms are defined under National Instrument 52-110 – *Audit Committees*. The Board has made these determinations based on the education as well as breadth and depth of experience of each member of the Audit Committee.

All the members of the Audit Committee have the education and/or practical experience required to understand and evaluate financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the Corporation's financial statements. The following is a brief summary of the education and experience of each member of the Committee that is relevant to the performance of his or her responsibilities as an Audit Committee member:

***Robert Ciaruffoli (Chair)***

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 holds a Bachelor of Science in Accounting from Kings College, Wilkes-Barre, Pennsylvania. He holds the CPA designation and served as the Chairman and CEO of the ParenteBeard/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 ParenteBeard 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.

***Larry Kaiser***

Dr. Kaiser was formerly President and Chief Executive Officer of the Temple University Health System and Senior Executive Vice-President for Health Affiars and the Lewis Katz Dean of the Lewis Katz School of Medicine at Temple University. He serves on multiple editorial boards including the Annals of Surgery, the American Journal of Surgery and the European Journal of Cardiothoracic Surgery.

Dr. Kaiser graduated from the Tulane University School of Medicine in 1977 and completed his residency in general surgery as well as a fellowship in surgical oncology at the University of Califonia, Los Angeles. He then completed a residency in cardiovascular and thoracic surgery at the University of Toronto. Following that, he held positions as attending thoracic surgeon at Memorial Sloan-Kettering Cancer Center and Assistant Professor of Surgery at Cornell University Medical College (New York) and subsequently as Associate Professor (with tenure) at the Washington University School of Medicine (St. Louis). At the University of Pennsylvania, Dr. Kaiser held a variety of positions, including chief of general thoracic surgery, founder and director of the university's lung transplantation program, director of its Center for Lung Cancers and Related Disorders, and co-director of the Thoracic Oncology Laboratory. In 1996 he was named as the first Eldridge Eliason Professor of Surgery and, in 2001 following a national search, was named the John Rhea Barton Professor and Chair of the Department of Surgery as well as Surgeon in Chief for the University of Pennsylvania Health System. He has been a director of both the American Board of Srugery and the American Board of Thoracic Surgery, and was elected to the National Academy of Medicine in 2005. He is the author or co-author of 17 books and more than 300 original papers.

***Gerald Goldberg***

Mr. Goldberg the President at Leo Acquisitions Corp. since October 2009 and serves as its Chief Executive Officer. 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 Chief Executive Officer, President and Chief Financial Officer of Victory Capital Corp. until March 2017. Mr. Goldberg served as the Chief Executive Officer, President of Prime City One Capital Corp. until July 2016.

Mr. Goldberg also 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. He was Interim Chief Executive Officer of Canada House Wellness Group Inc. from April 2016 to December 2017.

**Pre-Approval Policies and Procedures**

The Audit Committee will pre-approve all non-audit services to be provided to the Corporation by its external auditors. The Audit Committee may delegate to one or more of its members the authority to pre-approve non-audit services but preapproval by such member or members so delegated shall be presented to the full Audit Committee at its first scheduled meeting following such pre-approval.

**Reliance on Certain Exemptions**

At no time since the commencement of the most recently completed financial year of the Corporation has the Corporation relied on the exemption in section 2.4 of NI 52-110 (De Minimis Non-Audit Services), or an exemption from the application of NI 52-110, in whole or in part, granted under Part 8 of NI 52-110 (Exemptions). The Corporation is relying upon the exemption in section 6.1 of NI 52-110.

**Auditors' Fees**

The following table sets forth the fees paid by the Corporation to its auditor for services rendered during the years ended December 31, 2020 and December 31, 2019:

| Fee | For the year ended December 31, 2019 | For the year ended December 31, 2020 |
|---|---|---|
| Audit Fees[(1)] | $199,135 | $460,000 |
| Audit-Related Fees[(2)] | Nil | $2,000 |
| Tax Fees[(3)] | Nil | $18,800 |
| All Other Fees[(4)] | Nil | Nil |
| **Total** | **$199,135** | **$480,800** |

**Notes:**

(1) "Audit Fees" include fees necessary to perform the annual audit and quarterly reviews of the Corporation's consolidated financial statements. Audit Fees include fees for review of tax provisions and for accounting consultations on matters reflected in the financial statements. Audit Fees also include audit or other attest services required by legislation or regulation, such as comfort letters, consents, reviews of securities filings and statutory audits.

(2) "Audit-Related Fees" include services that are traditionally performed by the auditor. These audit-related services include employee benefit audits, due diligence assistance, accounting consultations on proposed transactions, internal control reviews and audit or attest services not required by legislation or regulation.

(3) "Tax Fees" include fees for all tax services other than those included in "Audit Fees" and "Audit-Related Fees". This category includes fees for tax compliance, tax planning and tax advice. Tax planning and tax advice includes assistance with tax audits and appeals, tax advice related to mergers

and acquisitions, and requests for rulings or technical advice from tax authorities.

(4) "All Other Fees" include all other non-audit services.

All permissible categories of non-audit services require pre-approval by the Audit Committee, subject to certain statutory exemptions.

## INTERESTS OF EXPERTS

The Corporation's auditors are MNP (the "**Auditor**"), who have prepared an independent auditor's report dated March 16, 2021, in respect of the Corporation's audited consolidated annual financial statements for the two most recent fiscal years ended December 31, 2020, and December 31, 2019. The Auditor has advised that they are independent with respect to the Corporation in accordance with the rules of professional conduct of the Institute of Chartered Professional Accountants of Ontario and within the meaning of the applicable rules and regulations adopted by the U.S. Securities Exchange Commission and the Public Company Accounting Oversight Board (United States).

As of the date of this AIF, to the best of our knowledge, MNP and the partners and associates of MNP, beneficially own, directly or indirectly, in their respective groups, less than 1% of our outstanding securities.

No person or corporation whose profession or business gives authority to a statement made by the person or corporation and who is named as having prepared or certified a part of this AIF or as having prepared or certified a report or valuation described or included in this AIF holds any beneficial interest, direct or indirect, in any securities or property of the Corporation or of any associate or affiliate of the Corporation and no such person is expected to be elected, appointed or employed as a director, senior officer or employee of the Corporation or of any associate or affiliate of the Corporation and no such person is a promoter of the Corporation or any associate or affiliate of the Corporation.

## ADDITIONAL INFORMATION

Additional information relating to the Corporation may be found on SEDAR at www.sedar.com. Additional information including directors' and officers' remuneration and indebtedness, principal holders of the Corporation's securities and securities authorized for issuance under equity compensation plans are contained in the Corporation's management information circular dated November 14, 2019, in respect of the annual and special meeting of Shareholders held on December 16, 2019, which is available on SEDAR at www.sedar.com. Additional financial information is provided in the Corporation's audited consolidated financial statements and management's discussion and analysis thereon for the years ended December 31, 2020 and 2019, which are also available under the Corporation's SEDAR profile.

**SCHEDULE "A"**

**AUDIT COMMITTEE CHARTER**

(*See attached*)

**FSD PHARMA INC.**
**AUDIT COMMITTEE**
**CHARTER**

## PURPOSE AND AUTHORITY

The Audit Committee (the "Committee") of the Board of Directors (the "Board") of FSD Pharma Inc. (the "Company") assists the Board in fulfilling its responsibility for oversight of: (a) the integrity of the Company's financial statements (b) the qualifications, independence and performance of the Company's independent auditors, (c) the Company's compliance with legal and regulatory requirements, and ( d) the quality and integrity of the accounting, auditing and reporting practices of the Company and such other duties as directed by the Company's Board.

The Committee shall maintain free and open communication with the independent accountants and the management of the Company. In discharging this oversight role, the Committee is empowered to investigate any matter brought to its attention. In discharging its responsibilities, the Committee, in its sole discretion, has the authority to appoint, compensate and provide oversight of, and retain or obtain the advice of, external auditors, outside counsel or other experts or advisors. The Company shall at all times make adequate provisions for the payment of all fees and other compensation approved by the Committee for such auditors, counsel, experts or advisors. The Committee also has the authority to obtain advice and assistance from internal accounting or other advisers or employees. The Committee shall perform its Committee functions for all FSD Pharma Inc. subsidiaries.

While the Committee has the authority, duties and responsibilities set forth in this Charter, the Committee's function is one of oversight. The Company's management is responsible for preparing the Company's financial statements and for developing and maintaining systems of internal accounting and financial controls, while the independent accountants will assist the Committee and the Board in fulfilling their responsibilities for their review of these financial statements and internal controls.

The Committee expects the independent accountants to call to the Committee's attention any accounting, auditing, internal accounting control, regulatory or other related matters that the independent accountants believe warrant consideration or action. The Committee recognizes that the Company's management and the internal and outside accountants have more knowledge and information about the Company than do Committee members. Further, the Company's management is responsible for business risk management processes including the identification, assessment, mitigation and monitoring of risks on a Company-wide basis. Consequently, in carrying out its oversight responsibilities, the Committee does not provide any expert or special assurance as to the Company's financial statements, business risk management processes, or internal controls or any professional certification as to the independent accountants' work.

## COMPOSITION AND MEETINGS

The Committee shall be composed of three or more directors as determined by the Board, each of whom shall satisfy, as determined by the Board: (i) the independence requirements of National Instrument 52-110 - Audit Committees, and (ii) meet the other applicable requirements of any stock exchange on which the Company's securities are listed from time to time, and

(iii) the Company's Policy Regarding Nominations of Directors. At least one member of the Committee shall: (a) qualify as an "audit committee financial expert" within the meaning of the rules of the U.S. Securities Exchange Commission ("SEC"), and (b) meet the experience requirements within applicable securities and stock exchange rules. Committee members shall not simultaneously serve on the audit committees of more than two additional audit committees of other public companies, unless the Board determines that service by any member of the Committee on more than two additional audit committees of other public companies (other than controlled companies of FSD Pharma Inc.) would not impair the ability of such member to effectively serve on the Company's Audit Committee. Directors' fees (including fees for attendance at meetings of committees of the Board) are the only compensation that a Committee member may receive from the Company.

The Board shall appoint the Chair and the other members of the Committee annually and as vacancies or newly created positions occur, considering the recommendation of the Nominating and Corporate Governance Committee, and the Board may remove members of the Committee at any time. The members of the Committee shall serve until their successors are appointed and qualified to serve on the Committee. The Chair shall be responsible for leadership of the Committee, including overseeing the agenda, presiding over the meetings and reporting to the Board. The Committee may invite to its meetings any member of Company management and such other persons as it deems appropriate to carry out its responsibilities.

The Committee shall meet at least quarterly each calendar year ( or more frequently if circumstances require) and hold such other meetings from time to time as may be called by its Chair, or requested by the Chief Executive Officer ("CEO") of the Company or any two members of the Committee. Meetings may be held in person, by video conference or by telephone. Committee actions may be taken by unanimous written consent of the members. A majority of the members of the Committee shall constitute a quorum of the Committee. The vote of a majority of the members of the full Committee shall be the act of the Committee.

Except as expressly provided in this Charter or the By-Laws of the company or as required by law, regulations or stock exchange listing standards, the Committee shall fix its own rules of procedures.

DUTIES AND RESPONSIBILITIES

In addition to any other responsibilities which may be assigned from time to time by the Board, the Committee shall be responsible for the following matters:

1. The Committee is directly responsible for the appointment, pre-approval of compensation, retention and oversight of the work of the independent accountants employed by the Company (including resolution of disagreements between management and the accountants regarding financial reporting) for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Company. The independent accountants shall report directly to the Committee.

2. The Committee shall have the sole authority to appoint or replace the independent accountants who audit the financial statements of the Company. The Committee shall have the ultimate authority and responsibility to evaluate the performance of the independent accountants

and, where appropriate, replace the independent accountants. In the process, the Committee will discuss and consider the accountants' written affirmation that the accountants are in fact independent, will discuss the nature and rigor of the audit process, receive and review all reports and will provide to the independent accountants full access to the Committee (and the Board) to report on any and all appropriate matters.

3. The Committee shall ensure that the independent accountants submit on at least a quarterly basis to the Committee a statement delineating all relationships between the independent accountants (or any of their affiliates) and the Company and actively engage in a dialogue with the independent accountants with respect to any disclosed relationships or services that may impact the accountants' objectivity and independence; and, if deemed appropriate by the Committee, recommend that the Board take appropriate action to ensure the independence of the accountants.

4. The Committee shall review with the independent accountants the independent accountants' responsibilities under generally accepted auditing standards, the proposed scope and timing of the annual audit (including planning, staffing, budget, locations and reliance upon management), past audit experience and other matters bearing upon the scope of the audit.

5. The Committee shall pre-approve all audit and audit-related engagement fees and terms and other significant compensation to be paid to the independent accountants as well as pre-approve all non-audit engagements with the independent accountants. The Committee shall consult with management but shall not delegate these responsibilities.

6. The Committee shall review and discuss with management and the independent accountants the Company's annual audited financial statements, including: (a) the related "Management's Discussion and Analysis of Financial Condition and Results of Operations," (b) matters regarding accounting and auditing principles as well as internal controls that could have a significant effect on the Company's financial statements, and (c) any other matters required to be discussed by the Public Company Accounting Oversight Board ("PCAOB") Auditing Standard No. 16, as modified or supplemented, relating to the conduct of the audit, prior to the filing of the Company's annual audited financial statements. The Committee shall also recommend to the Board that the Company's annual financial statements, together with the report of their independent accountants as to their examination, be approved.

7. The Committee shall review and discuss with management and the independent accountants the Company's quarterly financial statements, including the related "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the matters required to be discussed pursuant to PCAOB Auditing Standard No. 16 and AU Section 722, as modified or supplemented, prior to the filing of the Company's interim financial statements, including the results of the independent accountants' reviews of the quarterly financial statements to the extent applicable.

8. The Committee shall review and discuss with the independent accountants any other matters required to be discussed by PCAOB Auditing Standard No. 16, as modified or supplemented.

9. The Committee shall review and discuss with management and the independent accountants, as applicable:

(a) major issues regarding accounting principles and financial statement presentations, including any significant changes in the Company's selection or application of accounting principles, and reports from management and the independent accountants as to the Company's internal controls over financial reporting and any special audit steps adopted in light of material control deficiencies;

(b) analyses prepared by management or the independent accountants setting forth significant financial reporting issues and judgments made in connection with the preparation of the financial statements, including analyses of the effects of alternative GAAP methods on the financial statements;

(c) any management letter provided by the independent accountants and management's response to that letter;

(d) the effect of regulatory and accounting initiatives, as well as off-balance sheet structures, derivatives and liquidity exposures, on the financial statements of the Company;

(e) the critical accounting policies and practices of the Company;

(f) earnings press releases (paying particular attention to any use of "pro forma," or "adjusted" non-GAAP, information);

(g) financial information and earnings guidance, if any, that are given to analysts and rating agencies, provided that such review and discussion may address the general types of information disclosed and types of presentations made and need not take place in advance of each instance in which the Company may provide such information or earnings guidance; and

(h) suggestions or recommendations of the independent accountants or the internal auditors regarding any of the foregoing items.

10. The Committee shall review and discuss with the independent accountants any audit problems, difficulties or differences encountered and management's responses thereto, such as:

(a) any restrictions on the scope of the independent accountants' activities or on access to requested information;

(b) any accounting adjustments that were noted or proposed by the auditor but were "passed" (as immaterial or otherwise);

(c) any communications between the audit team and the audit firm's national office respecting auditing or accounting issues presented by the engagement;

(d) any management or internal control letter issued, or proposed to be issued, by the independent accountants; and

(e) any significant disagreements between management and the independent accountants.

11. The Committee shall, in conjunction with the CEO and Chief Financial Officer ("CFO") of the Company, review the Company's disclosure controls and procedures and internal controls over financial reporting. The review of internal controls over financial reporting shall include whether there are any significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to affect the Company's ability to record, process, summarize and report financial information and any fraud involving management or other employees with a significant role in internal controls over financial reporting.

12. The Committee shall evaluate the qualifications, performance and independence of the independent accountants, including a review and evaluation of the lead partner of the independent accountant and taking into account the opinions of management and the Company's internal auditors, and shall present its conclusions with respect to the independence of the independent accountants to the full Board on at least an annual basis. The Committee shall obtain and review a report from the independent accountants at least annually regarding: (a) the independent accountants' internal quality control procedures, (b) any material issues raised by the most recent internal quality control review, peer review of the independent accountants or PCAOB review or inspection of the firm, or by any other inquiry or investigation by governmental or professional authorities within the preceding five years respecting one or more independent audits carried out by the firm, (c) any steps taken to deal with any such issues, and (d) all relationships between the independent accountants and the Company consistent with applicable requirements of the PCAOB regarding the independent accountant's communications with the audit committee concerning independence.

13. The Committee shall ensure that the lead audit partner of the independent accountants and the concurring audit partner responsible for reviewing the audit are rotated at least every five years, and further consider rotation of the independent accountant firm itself.

14. The Committee shall recommend to the Board policies for the Company's hiring of employees or former employees of the independent accountants who were engaged on the Company's account.

15. The Committee shall obtain and review disclosures made by the Company's principal executive officer and principal financial officer regarding compliance with their certification obligations as required under National Instrument 52-109 - Certification of Disclosure in Issuers Annual and Interim Filings, including the Company's disclosure controls and procedures and internal controls for financial reporting and evaluations thereof.

16. The Committee shall review the independent accountants' assessment of the Company's internal controls.

17. The Committee shall maintain and review annually procedures for: (a) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and (b) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters.

18. The Committee shall meet on a regular basis with members of management to review business risk management processes, which include the identification, assessment, mitigation and monitoring of risks on a Company-wide basis.

19. The Committee shall coordinate its oversight of business risk management processes with other committees of the Board having primary oversight responsibility for specific risks and annually review for the Board which committees maintain such oversight responsibilities and the overall effectiveness of business risk management processes. The Committee shall oversee an annual audit of the political contributions of the Company.

20. The Committee shall review policies and procedures related to officers' expense accounts and perquisites, including use of corporate assets.

21. The Committee shall review legal and regulatory matters that may have a material effect on financial statements, related Company compliance policies, and reports to regulators.

22. The Committee shall regularly report to the Board. This report shall include a review of any issues that arise with respect to the quality or integrity of the Company's financial statements, the Company's compliance with legal or regulatory requirements, the independence and performance of the Company's independent accountants, the Company's internal controls over financial reporting, and any other matters that the Committee deems appropriate or is requested to include by the Board, including reporting all important matters relating to managing significant business risks.

23. The Committee shall prepare a report for inclusion in the Company's annual proxy and information statements as required by securities laws and stock exchange regulations and submit it to the Board for approval.

24. The Committee shall annually conduct a self-assessment of its activities under the terms of its charter and report any conclusions and/or recommendations to the Board.

25. The Committee shall annually review and assess the adequacy of this Charter and submit any recommended changes to the Board for approval.

Dated: November 8, 2019