

## FORM 7

### **MONTHLY PROGRESS REPORT**

Name of Listed Issuer: FSD Pharma Inc. (the "Issuer", "Company" or "FSD")

Trading Symbol: HUGE

Number of Outstanding Listed Securities: 14,835,510 Class B Subordinate Voting Shares ("Class B Shares") (as of the last business day of the month for which this report is filed)

Date: October 6, 2020

This Monthly Progress Report must be posted before the opening of trading on the fifth trading day of each month. This report is not intended to replace the Issuer's obligation to separately report material information forthwith upon the information becoming known to management or to post the forms required by Exchange Policies. If material information became known and was reported during the preceding month to which this report relates, this report should refer to the material information, the news release date and the posting date on the Exchange website.

This report is intended to keep investors and the market informed of the Issuer's ongoing business and management activities that occurred during the preceding month. Do not discuss goals or future plans unless they have crystallized to the point that they are "material information" as defined in the Policies. The discussion in this report must be factual, balanced and non-promotional.

#### **General Instructions**

- (a) Prepare this Monthly Progress Report using the format set out below. The sequence of questions must not be altered nor should questions be omitted or left unanswered. The answers to the items must be in narrative form. State when the answer to any item is negative or not applicable to the Issuer. The title to each item must precede the answer.
- (b) The term "Issuer" includes the Issuer and any of its subsidiaries.
- (c) Terms used and not defined in this form are defined or interpreted in Policy 1 – Interpretation and General Provisions.

#### **Report on Business**

**1. Provide a general overview and discussion of the development of the Issuer's business and operations over the previous month. Where the Issuer was inactive disclose this fact.**

On or about September 16, 2020, the Company issued an aggregate of 80,850 Class B Shares as compensation to a director of the Company as described in a press release disseminated on July 31, 2020.

On or about September 23, 2020, the Company issued an aggregate of 32,232 Class B Shares as compensation to a director of the Company as described in a press release disseminated on July 31, 2020.

On September 28, 2020, the Company announced that the U.S. Food and Drug Administration ("**FDA**") has authorized the initiation of a Phase 2 study for the use of FSD-201 (ultramicrosized palmitoylethanolamide, or ultramicrosized PEA) to treat COVID-19, the disease caused by the SARS-CoV-2 virus (the "**FSD-201 COVID-19 Trial**"). The company is expected to start dosing patients in October 2020. Management of the Company believes that FSD-201 may have the potential to address the over-exuberant inflammatory response characterized by COVID-19 infection that may lead to a cytokine storm and ultimately death.

**2. Provide a general overview and discussion of the activities of management.**

See Item 1 above.

**3. Describe and provide details of any new products or services developed or offered. For resource companies, provide details of new drilling, exploration or production programs and acquisitions of any new properties and attach any mineral or oil and gas or other reports required under Ontario securities law.**

See Item 1 above.

**4. Describe and provide details of any products or services that were discontinued. For resource companies, provide details of any drilling, exploration or production programs that have been amended or abandoned.**

Not applicable.

**5. Describe any new business relationships entered into between the Issuer, the Issuer's affiliates or third parties including contracts to supply products or services, joint venture agreements and licensing agreements etc. State whether the relationship is with a Related Person of the Issuer and provide details of the relationship.**

Not applicable.

**6. Describe the expiry or termination of any contracts or agreements between the Issuer, the Issuer's affiliates or third parties or cancellation of any financing arrangements that have been previously announced.**

Not applicable.

7. **Describe any acquisitions by the Issuer or dispositions of the Issuer's assets that occurred during the preceding month. Provide details of the nature of the assets acquired or disposed of and provide details of the consideration paid or payable together with a schedule of payments if applicable, and of any valuation. State how the consideration was determined and whether the acquisition was from or the disposition was to a Related Person of the Issuer and provide details of the relationship.**

Not applicable.

8. **Describe the acquisition of new customers or loss of customers.**

Not applicable.

9. **Describe any new developments or effects on intangible products such as brand names, circulation lists, copyrights, franchises, licenses, patents, software, subscription lists and trade-marks.**

Not applicable.

10. **Report on any employee hirings, terminations or lay-offs with details of anticipated length of lay-offs.**

Not applicable.

11. **Report on any labour disputes and resolutions of those disputes if applicable.**

Not applicable.

12. **Describe and provide details of legal proceedings to which the Issuer became a party, including the name of the court or agency, the date instituted, the principal parties to the proceedings, the nature of the claim, the amount claimed, if any, if the proceedings are being contested, and the present status of the proceedings.**

From time to time, the Company is named as a party to claims or involved in proceedings, including legal, regulatory and tax related, in the ordinary course of its business. While the outcome of these matters may not be estimable at period end, the Company makes provisions, where possible, for the estimated outcome of such claims or proceedings. Should a loss result from the resolution of any claims or proceedings that differs from these estimates, the difference will be accounted for as a charge to profit or loss in that period.

*Environmental*

Management believes that there are no probable environmental related liabilities that will have a material adverse effect on the financial position or operating results of the Company.

*Claims from suppliers*

A dismissed contractor commenced a lien action combined with a breach of contract action in 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 Company will defend the action and has taken steps to obtain particulars and inspect documents of the plaintiff which remain unaddressed to date. The Company 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 Company intends to defend itself from this claim.

#### Former employee

FSD hired an individual by way of employment agreement dated November 11, 2018. The individual's employment was subsequently terminated in the probationary period due to non-performance/cause on February 5 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.

On July 28, 2020, a labour tribunal in the United Kingdom decided in favour of the former employee and ordered an award of GBP 59,747 to be paid by the Corporation. However, the Issuer believes there are grounds to challenge the findings and order due to administrative and/or judicial error. The Issuer has filed an application for reconsideration, which has yet to be adjudicated.

#### Class Action

On February 22 2019, a shareholder in FSD commenced a proposed class proceeding against the Company by issuing a statement of claim in the Ontario Superior Court. Amongst other causes of action, the individual seeks leave to bring a claim pursuant to s.138 of the Ontario Securities Act.

On July 21, 2020, the Ontario Superior Court of Justice granted leave to the plaintiff to proceed with a claim for damages on the theory that certain disclosure of the Issuer for the three and nine months ended September 30, 2018 contained a misrepresentation. The decision permits the plaintiff to proceed with her case; however, a final decision has not yet been rendered in the action. Further, the decision narrowed the cause of action for which the plaintiff may claim damages to a period shorter than that originally contained in the plaintiff's pleadings. Although the decision permits the plaintiff to proceed to the certification of the proposed class, the Issuer has not received any indication from the plaintiff of when a certification motion may be brought. The Issuer is considering its response to this decision.

#### Auxly Cannabis Group Inc.

On March 3 2018, FSD entered into a Definitive Strategic Alliance and Streaming Agreement (the "Auxly Agreement") with Auxly Cannabis Group Inc. ("Auxly"). On February 6 2019, the Company sent Auxly a Notice of Default, thereby terminating the Auxly Agreement effective immediately. Later that same day,

Auxly sent a Notice of Default to the Company in response. To date, neither party has taken further steps.

To fund the development of the buildout of the Company's growing operations, Auxly purchased 7,500,000 Class B shares for the aggregate of \$7,500,000 from the Company's treasury by way of private placement, which funds were placed in trust to be spent on construction and development costs. The funds were placed in a trust account to be administered by Auxly. Due to the termination and subsequent negotiations, it is indeterminable at this point as to the amount, if any, of these funds will be released to the Company. As a result, the Company entered a provision for loss against the funds and should any funds be released to the Company, those amounts will be recognized in future periods as gains on recovery.

**13. Provide details of any indebtedness incurred or repaid by the Issuer together with the terms of such indebtedness.**

Not applicable.

**14. Provide details of any securities issued and options or warrants granted.**

<b>Security</b>	<b>Number Issued</b>	<b>Details of Issuance</b>	<b>Use of Proceeds<sup>(1)</sup></b>
Class B Shares	113,082	Issued as compensation to directors of the Company	N/A

*(1) State aggregate proceeds and intended allocation of proceeds.*

**15. Provide details of any loans to or by Related Persons.**

Not applicable.

**16. Provide details of any changes in directors, officers or committee members.**

Not applicable.

**17. Discuss any trends which are likely to impact the Issuer including trends in the Issuer's market(s) or political/regulatory trends.**

See attached Schedule A. The information in Schedule A is a summary only of certain risk factors and is qualified in its entirety by reference to, and should be read in conjunction with detailed information appearing elsewhere. These risks and uncertainties are not the only ones the Company is facing. Additional risks and uncertainties not presently known to the Company, or that it currently deems immaterial, may also impair its operations. If any such risks actually occur, the business, financial condition, liquidity and results of the Company's operations could be materially adversely affected. The risk factors described in Schedule A should be carefully considered by readers, including investors considering a purchase of securities of the Company, along with all other information set forth elsewhere. An investment in securities of the Company should only be made by persons who can afford a significant or total loss of their investment.

## Certificate Of Compliance

The undersigned hereby certifies that:

1. The undersigned is a director and/or senior officer of the Issuer and has been duly authorized by a resolution of the board of directors of the Issuer to sign this Certificate of Compliance.
2. As of the date hereof there were is no material information concerning the Issuer which has not been publicly disclosed.
3. The undersigned hereby certifies to the Exchange that the Issuer is in compliance with the requirements of applicable securities legislation (as such term is defined in National Instrument 14-101) and all Exchange Requirements (as defined in CNSX Policy 1).
4. All of the information in this Form 7 Monthly Progress Report is true.

Dated October 6, 2020.

Donal Carroll  
Name of Director or Senior  
Officer

(signed) "Donal Carroll"  
Signature

Chief Financial Officer  
Official Capacity

<b>Issuer Details</b> Name of Issuer FSD Pharma Inc.	For Month End September	Date of Report YY/MM/D 20/10/7
Issuer Address PO Box 696		
City/Province/Postal Code Cobourg, Ontario K9A 4R5	Issuer Fax No. (905) 373-0303	Issuer Telephone No. (289) 677-0806
Contact Name Donal Carroll	Contact Position CFO	Contact Telephone No. (289) 677-0806
Contact Email Address info@fvpharma.com	Web Site Address www.fsdpharma.com	

## SCHEDULE A RISK FACTORS

### **Risks Relating to Pharmaceutical Businesses and the Development of FSD-201**

*Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future. 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, ultramicrosized-palmitoylethanolamide ("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 R&D 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 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 ultramicro-nized-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 license of certain intellectual property rights related to FSD-201 acquired from Epitech Group SpA ("**Epitech**") pursuant to an amended and restated license agreement (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 an NDA 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 within 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.

***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 ultramicro-nized-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 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, including the possible development and mass production of a vaccine that significantly limits and/or ultimately eliminates 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 Prospectus Supplement, there are several vaccine candidates in Phase 1-3 trials, as well as numerous major candidates in pre-clinical stages of development and research. 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 NDA, 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 an NDA 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 practices ("GCP"), requirements, or regulatory guidelines in other countries;
- occurrence of adverse events ("AEs") 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 contract manufacturing organization ("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.

***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 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 GCPs 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 GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable GCP 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 GCP 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.

## **General Risks**

***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 contract manufacturing organizations (“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 cannabis operations will require significant additional financing over several years.

In addition, any further issuances of equity securities could have a significant dilutive effect on the holders of Class B Shares. See “— *Additional issuances of Class B Shares, Class A Shares or securities convertible into Class B Shares or Class A Shares could have a significant dilutive effect on the Offered 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 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 15,000 outstanding Class A Shares are held by the Corporation’s founders, Thomas Fairfull, Zeeshan Saeed and Anthony Durkacz. See “*Principal Shareholders*”. Class A Multiple Voting Shares (“**Class A Shares**”) have 276,660 votes per Class A Share and Class B Subordinate Voting Shares (“**Class B Shares**”) have one vote per Class B Share. Shareholders who hold Class A Shares together hold approximately 67% 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.

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 may not view as beneficial, may adversely affect the market price of the Class B Shares.

***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 medical cannabis 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 has experienced and continues to experience 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 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. 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 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 information technology ("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 related to our growing operations, 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 compete and grow cannabis 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. 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.

***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. The Corporation filed its financial statements and management's discussion and analysis for the year ended December 31, 2018 later than the filing deadline required by Canadian securities laws. If the Corporation or its auditors discover a material weakness, the disclosure of that fact, even if quickly remedied, could reduce the market's confidence in the Corporation's consolidated financial statements and materially adversely affect the trading price of the Class B Shares.

Effective systems of internal control over financial reporting ("ICFR") and disclosure are critical to the operation of a public company. However, we do not expect that our disclosure controls and procedures ("DCP") or ICFR 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.

***We incur additional costs as a result of operating as a public company in the United States and our management is required to devote substantial time and attention to new compliance initiatives.***

As a public company in the United States, we will incur significant legal, accounting and other expenses that we did not incur prior to being listed in the United States. In addition, the Sarbanes-Oxley Act (2002) (the “**Sarbanes-Oxley Act**”), and rules implemented by the SEC, and the NYSE American, 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.

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

***We are an emerging growth company 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 company” as defined in the JOBS Act and anticipate remaining an emerging growth company for the foreseeable future. For so long as we remain an emerging growth company, 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 and produce cannabis products. 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.

On February 6, 2019, the Corporation terminated the Definitive Strategic Alliance and Streaming Agreement with Auxly Cannabis Group Inc. ("**Auxly**") dated March 3, 2018 (the "**Auxly Agreement**") by sending a Notice of Default to Auxly. Later that same day, Auxly sent a Notice of Default to the Corporation in response. Pursuant to the Auxly Agreement, Auxly purchased 7,500,000 Class B Shares and deposited \$7,500,000, the purchase price therefor, into trust to be spent on construction of the Facility. Due to the termination of the Auxly Agreement, it is indeterminable whether any of the funds will be released to the Corporation. To date, neither party has taken any steps to commence litigation with respect to the termination of the Auxly Agreement.

The Corporation is currently a defendant to a proposed class action lawsuit launched on February 22, 2019. The plaintiff shareholder alleges 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. When the Corporation subsequently announced that the Auxly Agreement had been terminated, the price of the Class B Shares on the CSE decreased. The claim alleges that the plaintiff and other shareholders suffered losses and damages as a result of acquiring the Corporation's securities at artificially inflated prices. To advance a class action under the *Securities Act* (Ontario), the plaintiff must seek leave from the court. As of the date of this Prospectus, the plaintiff has not taken any further steps to advance the litigation or certify the class.

A former contractor commenced a lien action combined with a breach of contract action in the first quarter of 2019 claiming approximately \$1.7 million from the Corporation in various purported damages. The Corporation intends to defend the breach of contract action and has taken steps to obtain particulars and inspect documents of the plaintiff.

The Corporation may not be able to predict the outcomes of each of the foregoing instances of litigation and expects to expend significant capital resources in the defense of these claims.

***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: the Corporation's executive co-chairman of the board of directors and chief executive officer, Dr. Raza Bokhari, is also the chairman and chief executive officer of PCL, Inc., a global diagnostic provider of addiction screening and opioid prescription medication monitoring, including designer drugs and synthetic cannabinoids, the managing partner of RBx Capital, LP and a board member of Akers Biosciences, a Nasdaq listed company, and World Class; the Corporation's interim chief financial officer, Donal Carroll, currently is also a director of World Class and Bird River Resources Inc.; and the Corporation's executive co-chairman of the board, Anthony Durkacz, is currently a director and executive vice president at First Republic Capital Corporation, which has acted as the exclusive agent of the Corporation and has raised approximately \$53 million of equity capital for the Corporation to date in such capacity with First Republic Capital Corporation. Mr. Durkacz is also a director of World Class and of iWallet Corporation. Sara May, President of FV Pharma, is a director of Cannara. Gerry Goldberg, a director of the Corporation, is also a director of Capicorn Business Acquisition Inc., Baymount Incorporated, Leo Acquisitions Corp. and Osoyoos Cannabis Inc. David Urban, a director of the Corporation, is also a director of Virtu Financial, Inc. See "*Management's Discussion and Analysis— Transactions with Related Parties*". Consequently, there is a risk that such officers or directors will be in a position of conflict. Conflicts, if any, will be subject to the procedures and remedies available under the OBCA.

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 company 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, contract research organizations ("CROs") 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 U.S. federal Health Insurance Portability and Accountability Act of 1996 (“**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 company”, or “PFIC”.***

Under the Code, 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 2018 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.

For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see the section of this Prospectus entitled “Certain U.S. Federal Income Tax Considerations For U.S. Holders.”

***The Corporation may not succeed in promoting and sustaining its brands, which could have an adverse effect on its future growth and business.***

A critical component of our future growth is our ability to promote and sustain our brands, which we believe can be achieved by providing a high-quality user experience. An important element of our brand promotion strategy is establishing a relationship of trust with our consumers. In order to provide a high-quality user experience, we have invested and will continue to invest substantial amounts of resources in the development products, infrastructure, fulfilment and customer service operations. If our consumers are dissatisfied with the quality of the products sold to them or the customer service they receive and their overall customer experience, our consumers may stop purchasing products from us.

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

If licensed as a distributor of products designed to be ingested by humans, the Corporation faces an inherent risk of exposure to product liability claims, regulatory action and litigation if its products are alleged to have caused significant loss or injury. In addition, the sale of the Corporation’s products would involve the risk of injury to consumers due to tampering by unauthorized third parties or product contamination.

Previously unknown adverse reactions resulting from human consumption of the Corporation’s products alone or in combination with other medications or substances could occur. The Corporation may be subject to various product liability claims, including, among others, that the Corporation’s products caused injury or illness, include inadequate instructions for use or include inadequate warnings concerning possible side effects or interactions with other substances. A product liability claim or regulatory action against the Corporation could result in increased costs, could adversely affect the Corporation’s reputation with its clients and consumers generally, and could have a material adverse effect on the results of operations and financial condition of the Corporation. There can be no assurances that the Corporation will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities. Such insurance is expensive and may not be available in the future on acceptable terms, or at all. The inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of the Corporation’s potential products.

***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.

***Third parties with whom we do business may perceive that they are exposed to reputational risk as a result of our previous cannabis-related business activities and may ultimately elect not to do business with us.***

The parties with whom we do business may perceive that they are exposed to reputational risk as a result of our previous cannabis business activities. Failure to establish or maintain business relationships as a result of such perceived reputational risk could have a material adverse effect on our business.

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

We would be required to obtain and maintain certain permits, licenses or other approvals from regulatory agencies in countries and markets outside of Canada in which we propose to operate or to export, in order to produce or export to, and sell our medical products in, these countries, including, in the case of certain countries, the ability to demonstrate compliance with GMP. There can be no assurance that we would be able to comply with these standards.

Any expansion into international operations would depend on our ability to secure the necessary permits, licenses or other approvals. An agency's denial of or delay in issuing or renewing a permit, license or other approval, or revocation or substantial modification of an existing permit or approval, could prevent us exporting our products internationally. In addition, Canada is a signatory to the *Single Convention on Narcotic Drugs, 1961* as amended by the *1972 Protocol*, the *Convention on Psychotropic Substances, 1971*, and the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988*. These drug control conventions establish a framework whereby trade in cannabis between countries is strictly limited to medical and scientific purposes and is subject to country-by-country quotas, which could limit the amount of medical cannabis we can export to any particular country.

In addition, any expansion into international operations could subject our business to certain risks relating to fluctuating exchange rates or require a number of up-front expenses, including those associated with obtaining regulatory approvals, as well as additional ongoing expenses, including those associated with infrastructure, staff and regulatory compliance. Due to the complexity and nature of cannabis operations and the dependence on various international regulatory requirements, we would be subject to a wide variety of laws and regulations domestically and internationally with respect to the flow of funds and product across international borders, including those related to money laundering, financial recordkeeping and proceeds of crime, including the *Proceeds of Crime (Money Laundering) and Terrorist Financing Act* (Canada), as amended and the rules and regulations thereunder, the *Criminal Code* (Canada) and any related or similar rules, regulations or guidelines, issued, administered or enforced by governmental authorities internationally.

***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.

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

The pharmaceutical industry may attempt to dominate the cannabis industry through the development and distribution of synthetic products which emulate the effects and treatment of organic cannabis. If they are successful, the widespread popularity of such synthetic products could change the demand, volume and profitability of the cannabis industry. This could adversely affect the ability of the Corporation to secure long-term profitability and success through the sustainable and profitable operation of its business. There may be unknown additional regulatory fees and taxes that may be assessed in the future.

In addition, rapidly changing markets, technology, emerging industry standards and frequent introduction of new products characterize our business. The process of developing our products is complex and requires significant continuing costs, development efforts and third-party commitments. Our failure to develop new technologies and products and the obsolescence of existing technologies could adversely affect our business, financial condition and operating results. We may be unable to anticipate changes in our potential customer requirements that could make our existing technology obsolete. Our success will depend, in part, on our ability to continue to enhance our existing technologies, develop new technology that addresses the increasing sophistication and varied needs of the market, and respond to technological advances and emerging industry standards and practices on a timely and cost-effective basis. The development of our proprietary technology entails significant technical and business risks. We may not be successful in using our new technologies or exploiting our niche markets effectively or adapting our businesses to evolving customer or medical requirements or preferences or emerging industry standards.

***We may become subject to liability arising from any fraudulent or illegal activity by our employees, contractors, consultants and others.***

We are exposed to the risk that our employees, independent contractors, consultants, service providers and licensors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional undertakings of unauthorized activities, or reckless or negligent undertakings of authorized activities, in each case on our behalf or in our service that violate: (i) government regulations, specifically Health Canada regulations; (ii) manufacturing standards; (iii) Canadian federal and provincial healthcare laws and regulations; (iv) laws that require the true, complete and accurate reporting of financial information or data; (v) U.S. federal laws banning the possession, sale or import of cannabis into the United States and prohibiting the financing of activities outside the United States that are unlawful under Canadian or other foreign laws; (vi) laws of the European Union, including money laundering

laws, extending their reach to proceeds from cannabis sales even if legal in the country in which the activity takes place or (vii) the terms of our agreements with insurers. In particular, we could be exposed to class action and other litigation, increased Health Canada inspections and related sanctions, the inability to obtain future GMP compliance certifications, lost sales and revenue or reputational damage as a result of prohibited activities that are undertaken in the growing or production process of our products without our knowledge or permission and contrary to our internal policies, procedures and operating requirements.

We cannot always identify and prevent misconduct by our employees and other third parties, including service providers and licensors, and the precautions taken by us to detect and prevent this activity may not be effective in controlling unknown, unanticipated or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from such misconduct. If any such actions are instituted against us, and we are not successful in defending our self or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal or administrative penalties, damages, monetary fines and contractual damages, reputational harm, diminished profits and future earnings or curtailment of our operations.

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