FSD PHARMA INC.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF
FINANCIAL CONDITION AND RESULTS OF OPERATIONS
FOR THE SIX MONTH PERIOD ENDED JUNE 30, 2019

INTRODUCTION

The following Management Discussion and Analysis ("**MD&A**") of FSD Pharma Inc. ("**FSD**" or the "**Company**") is prepared with information as at August 29, 2019 and provides an analysis of the Company's performance and financial condition as at and for the six month period ended June 30 2019 as well as an analysis of future prospects. The Board of Directors of the Company (the "**Board of Directors**") carries out its responsibility for review of this disclosure principally through its audit committee, comprised of independent directors. The audit committee reviews this disclosure and recommends its approval by the Board of Directors.

Prior to the Reverse Takeover Transaction (as defined in "*General Overview - Acquisition of FV Pharma Inc.*") the Company (as Century Financial Capital Group Inc.) had a fiscal year end of August 31st. As the Reverse Takeover Transaction with FV Pharma Inc. ("**FV Pharma**") resulted in a reverse takeover of the Company, FV Pharma is now deemed to be the reporting company and financial results will be reported on a consolidated basis in future periods using FV Pharma's fiscal year end of December 31st.

This MD&A has been prepared in compliance with the requirements of National Instrument 51-102 – Continuous Disclosure Obligations. This discussion should be read in conjunction with the unaudited consolidated interim financial statements of the Company for the six month period ended June 30 2019 together with the notes thereto, as well as the audited consolidated financial statements of the Company for the year ended December 31 2018 together with the notes thereto. All amounts are in Canadian dollars unless otherwise specified. The financial statements of the Company, along with Certifications of Annual and Interim Filings, the Company' s annual information form dated May 13, 2019 for the year ended December 31, 2018, news releases and other information are available on the Canadian System for Electronic Document Analysis and Retrieval (SEDAR) under FSD Pharma Inc. at www.sedar.com.

In this MD&A, unless otherwise specified or the context otherwise requires, reference to "we", "us", "our", "its", or "the Company" means, collectively, FSD Pharma Inc., subsidiaries of, and partnership interests held by, FSD Pharma Inc. and its subsidiaries.

For the purposes of preparing this MD&A, management, in conjunction with the Board of Directors, considers the materiality of information. Information is considered material if: (i) there is a substantial likelihood that a reasonable investor would consider it important in making an investment decision; or (ii) it would significantly alter the total mix of information available to investors. Management, in conjunction with the Board of Directors, evaluates materiality with reference to all relevant circumstances, including potential market sensitivity.

FORWARD-LOOKING STATEMENTS

The information provided in this MD&A, including information incorporated by reference, may contain certain forward-looking statements and forward-looking information (collectively referred to as "forward-looking statements") within the meaning of applicable securities legislation about our current expectations, estimates and projections about the future, based on certain assumptions made by us in light of the Company's experience and perception of historical trends. Although we believe that the expectations represented by such forward-looking statements are reasonable, there can be no assurance that such expectations will prove to be correct.

This forward-looking information is identified by words such as "anticipate", "believe", "expect", "plan", "forecast", "future", "target", "project", "capacity", "could", "should", "focus", "proposed", "scheduled", "outlook", "potential", "may" or similar expressions and includes suggestions of future outcomes, including statements about the Company's intention to increase its production through its proposed expansion of the cannabis cultivation facility located in Cobourg, Ontario and owned by the Company's wholly owned subsidiary FV Pharma Inc. and the

expected costs and timing thereof; the Company's proposed partnership and joint ventures with, and investments in, other entities; the Company's expected production capacity; the estimated costs of the Company's proposed capital projects and future investments; potential proceeds from the exercise of the Company's outstanding share purchase warrants; actions taken by the Company, or that the Company may take in the future, to adjust its capital structure; improvements to the Company's cultivation, manufacturing and standardization processes; potential future supply agreements; potential effects of regulations under the *Cannabis Act* (Canada) (together with the regulations thereunder (the "**Cannabis Regulations**"), the "**Cannabis Act**") and related legislation introduced by provincial governments; the undertaking of clinical research to study the effects of the Company's products on client health; the Company's strategy of becoming a leading provider of quality products for the medical cannabis market; and future sales opportunities in other emerging medical markets. Readers are cautioned not to place undue reliance on forward-looking information as the Company's actual results may differ materially from those expressed or implied.

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

Although the Company believes that the expectations and assumptions on which the forward-looking statements are based are reasonable, undue reliance should not be placed on the forward-looking statements because no assurance can be given that they will prove to be correct. Since forward-looking statements address future events and conditions, by their very nature they involve inherent risks and uncertainties. Actual results could differ materially from those currently anticipated due to a number of factors and risks. These include, but are not limited to: reliance on the license issued by Health Canada designating that, pursuant to the Cannabis Act, FV Pharma is authorized to cultivate, process cannabis and sell cannabis to other holders of licenses under the Cannabis Act pursuant to its Cultivation License, Processing License and Sale for Medical Purposes License; the limited operating history of the Company; the Company's ability to continue as a going concern; the highly speculative nature of drug development; the Company's ability to generate sufficient revenue to be profitable; the Company's ability to raise the capital necessary for it to execute its strategy; the Company's dual class structure; risks inherent in an agricultural business; rising energy costs; the Company's reliance on key persons; the Company's compliance with environmental, health and safety laws and regulations; insurance risks; failure of the Company to realize its cannabis production targets; interruptions in the supply chain for key inputs; demand for skilled labour, specialized knowledge, equipment, parts and components; the Company's reliance on the Facility (as defined herein) as its only property for cannabis cultivation and related ancillary business; the expansion of the Facility; the Company's ability to manage its growth; the Company's ability to successfully implement and maintain adequate internal controls over financial reporting or disclosure controls and procedures; the Company not having been required to certify that it maintains effective internal control over financial reporting or effective disclosure controls and procedures; increased costs as a result of operating as a public company in the United States; the Company taking advantage of reduced disclosure requirements applicable to emerging growth companies; the Company's ability to successfully identify and execute future acquisitions or dispositions; expansion of international operations; reliance on the operations of the Company's partners; results of litigation; conflicts of interest between the Company and its directors and officers; payment of dividends; the partial dependence of the Company's operations on the maintenance and protection of its information technology systems; unforeseen tax and accounting requirements; tax risks related to the Company's status as a "passive foreign investment company"; regulatory risks relating to the Company's compliance with the Cannabis Act; changes in laws, regulations and guidelines; the Company's ability to maintain the License; changes to the market price of cannabis; the ability of the Company to produce and sell cannabis supply; failure to execute definitive agreements with entities in which the Company has entered into letters of intent or memoranda of understanding; changes in government; changes in government policy; failure of counterparties to perform contractual obligations; the Company's ability to successfully develop new products or find a market for their sale; lack of certainty regarding the expansion of the cannabis market; ability of key employees of the Company to obtain

or renew security clearances in the future; the ability of the Company's employees or shareholders to enter the United States; unfavorable publicity or consumer perception of the Company and the cannabis industry; the Company's ability to promote and sustain its brands; marketing constraints in the cannabis industry; product liability claims or regulatory actions; the shelf life of inventory; fair value adjustments to the Company's biological assets; impact of any future recall of the Company's products; increased competition in the cannabis market in Canada and internationally; the impact of any negative scientific studies on the effects of cannabis; reputational risks to third parties with whom the Company does business; the Company's ability to produce and sell its medical products outside of Canada; co-investment risks; failure to comply with laws and regulations; the Company's reliance on its own market research and forecasts; competition from synthetic production and new technologies; the Company's ability to transport its products; liability arising from any fraudulent or illegal activity; the existence and growth of the cannabis industry; the Company's inability to complete clinical trials and attain the regulatory approvals it needs to commercialize pharmaceutical products; the Company's product candidates being in the preclinical development stage; the Company's ability to obtain regulatory approval in jurisdictions for any product candidates; delays in clinical trials; failure of clinical trials to demonstrate substantial evidence of the safety and/or effectiveness of product candidates; results of earlier studies or clinical trials not being predictive of future clinical trials; difficulties enrolling patients in clinical trials; side effects, adverse events or other properties or safety risks of product candidates; regulatory regimes of locations for clinical trials outside of the United States; failure to obtain approval to commercialize product candidates outside of the United States; published clinical trial data may change in future trials; manufacturing problems resulting in delays in development or commercialization programs; inability to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for drug candidates; changes in funding for the U.S. Food and Drug Administration ("**FDA**") and other government agencies; product liability lawsuits; misconduct or other improper activities by employees, independent contractors, consults, commercial partners and vendors; failure to achieve market acceptance in the medical community; inability to establish sales and marketing capabilities; failure to comply with health and data protection laws; reliance on third parties to conduct clinical trials; loss of single-source suppliers; reliance on contract manufacturing facilities; inability to obtain or maintain sufficient intellectual property protection for the Company's products; third-party claims of intellectual property infringement; patent terms being insufficient to protect competitive position on product candidates; inability to obtain patent term extensions or non-patent exclusivity; inability to protect the confidentiality of trade secrets; inability to protect trademarks and trade names; filing of claims challenging the inventorship of the Company's patents and other intellectual property; invalidity or unenforceability of patents; claims regarding wrongfully use or disclosed confidential information of third parties; inability to protect property rights around the world; that additional issuances of the Company's shares could have a significant dilutive effect; and other factors beyond the Company's control.

The Company cautions that the foregoing list of important factors is not exhaustive. Although the Company has attempted to identify important factors that could cause actual results to differ materially from those contained in forward-looking statements, there may be other factors that cause results not to be as anticipated, estimated or intended. There is no assurance that such statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements. You should carefully consider the matters discussed under "*Risks and Uncertainties*" in this MD&A.

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

Market and Industry Data

This MD&A includes market and industry data that has been obtained from third party sources, including industry publications. The Company believes that its industry data is accurate and that its estimates and assumptions are reasonable, but there is no assurance as to the accuracy or completeness of this data. Third party sources generally state that the information contained therein has been obtained from sources believed to be reliable, but there is no assurance as to the accuracy or completeness of included information. Although the data is believed to

be reliable, the Company has not independently verified any of the data from third party sources referred to or ascertained the underlying economic assumptions relied upon by such sources.

DESCRIPTION OF THE BUSINESS

In connection with a continuous disclosure review by the Ontario Securities Commission, this narrative description of the Company's business clarifies and supersedes certain disclosure previously made by FSD regarding developments in its business.

General Overview

The Company was formed under the provisions of the *Business Corporations Act* (Ontario) ("**OBCA**") on November 1, 1998 pursuant to the amalgamation of Olympic ROM World Inc., 1305206 Ontario Company, 1305207 Ontario Inc., Century Financial Capital Group Inc. and Dunberry Graphic Associates Ltd. On May 24, 2018 pursuant to Articles of Amendment, the Company changed its name to "FSD Pharma Inc.". The head office of the Company is located at 520 William Street, Cobourg, Ontario, K9A 3A5.

FV Pharma, a wholly-owned subsidiary of the Company, was incorporated under the OBCA on September 12, 2011 as 2298519 Ontario Corp. and changed to its present name, "FV Pharma Inc. " on September 17 2013. The registered and head office of FV Pharma is located at 520 William Street, Cobourg, Ontario, K9A 3A5.

Currently, the Class B Subordinate Voting Shares ("**Class B Shares**") of the Company are posted for trading in Canada on the Canadian Securities Exchange under the trading symbol "HUGE"; in the United States of America on the OTC under the trading symbol "FSDDF"; and on the Frankfurt Exchange under "WKN: A2JM6M" and the ticker symbol "0K9".

The Company is a licensed producer of cannabis in Canada under the Cannabis Act and Regulations. The Company operates two business divisions: one division is focused on bioscience, including research and development ("**R&D**") and clinical development of synthetic cannabinoid based treatments of certain disease conditions with an aim to improve patient outcomes. Our goal is for these compounds to ultimately be approved by the FDA and other international regulatory agencies as prescription medications. The other division is focused on producing and extracting high-quality, hydroponic, pharmaceutical-grade cannabis leaf. The common denominator between the two divisions is the medicinal-grade cannabis plant and its derivative cannabinoids.

The Company's bioscience division intends to leverage the early but burgeoning pharmaceutical synthetic cannabinoid market with a focus on pharmaceutical development through review and approval by the FDA and other international regulatory agencies. The cannabis plant contains more than 110 cannabinoids (e.g., tetrahydrocannabinol ("**THC**"), cannabidiol ("**CBD**"), cannabinol, cannabigerol, and tetrahydrocannabivarin) that activate over 60 known molecular pathways in the human body, along with many other constituents, not unique to the cannabis plant, such as terpenes and flavonoids that may have their own therapeutic value. These components bind to or interact with receptors throughout the human body to produce wide-ranging physiologic effects. The specific mechanisms of action of the various cannabinoids is not yet fully understood, but it is likely that they work by mimicking the effects of the body's own cannabinoids, or endocannabinoids. The discovery of endocannabinoids – neurotransmitters, neuromodulators, and specialized receptors that the body produces autonomously and naturally – and of cannabinoid receptors in the brain and central nervous system, the peripheral nervous system, the body's immune system, and the gastrointestinal and genitourinary tracts, provided the basis for the belief that cannabinoids may play an important medical role in impacting inflammation and disordered homeostasis in humans. Endocannabinoids and their receptors play pivotal roles in the body's health and in many disease processes. In recent years, there has been considerable interest in cannabinoids for the treatment of human disease, through modulation of the endocannabinoid system. Scientific research since the 1960s shows that the endocannabinoid system may play a role in the management of many medical conditions and chronic diseases.

The Company's goal is to launch our prospective lead asset, which we acquired on June 28, 2019 when we acquired Prismic Pharmaceuticals, Inc. ("**Prismic**"): micro-palmitoylethanolamide ("**PEA**"). Upon receipt of regulatory approval, we expect to launch micro-PEA plus pregabalin for treatment of fibromyalgia. PEA is a naturally occurring

substance that is produced within the body in response to inflammation and interacts with endocannabinoid receptors throughout the body, including the central nervous system.

We intend to conduct our pharmaceutical R&D program initially through Prismic, our recently acquired subsidiary. We are seeking to advance pharmaceutical development programs centered on micro-PEA that meet one or more selected criteria. All efforts are intended to be founded on a biologic plausibility of an efficacious cannabinoid effect with a high safety profile. Within that range, we anticipate targeting:

- diseases/syndromes in which current primary therapy is an immunosuppressive biologic, where cannabinoids may prove to be a more effective alternative;
- diseases/syndromes in which current primary therapy is a single drug, which affords only 50% of patients satisfactory symptom control; and
- indications where the beneficial effects of cannabinoids have been previously demonstrated, such as a recently FDA-approved cannabinoid product used to treat Dravet Syndrome, and Lennox-Gastaut Syndrome.

Transaction with FV Pharma

On March 9, 2018, the Company executed an agreement (the "**Definitive Agreement**") providing for the reverse takeover of the Company by the shareholders of FV Pharma.

The Transaction was completed by way of a “three-cornered amalgamation” pursuant to the provisions of the OBCA, whereby 2620756 Ontario Inc., a wholly-owned subsidiary of the Company amalgamated with FV Pharma, and the amalgamated entity became a wholly-owned subsidiary of the Company.

The Definitive Agreement included a number of conditions customary to transactions of this type, all of which were satisfied. Following the completion of the Transaction, the Company continued the medical cannabis business of FV Pharma and changed its name to “FSD Pharma Inc.”.

On May 29 2018, the Class B Shares commenced trading on the CSE under the trading symbol “HUGE”. As a result of the completion of the Transaction, the Company’s principal business activity became that of FV Pharma.

FV Pharma License and Facility Overview

The License

The Company holds the following licences from Health Canada:

i) a Cultivation License;

ii) a Processing License; and

iii) a Sale for Medical Purposes License,

(collectively, the "**License**").

FV Pharma received its initial License under section 22(2) of the Access to Cannabis for Medical Purposes Regulations (“**ACMPR**”) on October 13, 2017, authorizing FV Pharma to cultivate and process cannabis. In addition, the License permitted FV Pharma to acquire cannabis plants and/or seeds for the purpose of initiating plant growth and for conducting analytical testing.

On February 19, 2019, FV Pharma obtained the Processing License from Health Canada.

On April 22, 2019, FV Pharma received the Sale for Medical Purposes License to supply and sell certain cannabis products under the Cannabis Act, which was limited to cannabis plants and cannabis plant seed. On June 24, 2019, FV Pharma received an amendment to the Sale for Medical Purposes License which permits FV Pharma to sell or provide fresh or dried cannabis to such persons who are permitted to purchase medical cannabis products under

the Cannabis Act. A further sales license amendment to permit the sale of cannabis oil has been submitted to Health Canada and is pending.

The Company is not currently licensed to sell cannabis for recreational use, and has no immediate plans to apply for a license that would allow it to do so, although the Company has made investments in recreational cannabis retailers in Canada, as further described below.

The Facility

FV Pharma's plant and operations are located at its facility (the "**Facility**") 520 William Street, Cobourg, Ontario, K9A 3A5. FV Pharma acquired the Facility in November 2017 and expanded operations into the Facility in 2018, following approval from Health Canada and the completion of financing to complete its proposed capital improvements.

The License permits the cultivation of cannabis in approximately 11,000 square feet of the Facility, and permits the processing of cannabis in approximately 4,000 square feet of the Facility. The Company is currently cultivating cannabis in 9,500 square feet and regularly uses the processing area when required. In total, the Facility hosts an existing 620,000 square feet of building space. The Facility is situated only one hour east of Toronto in Cobourg, Ontario, off the 401 highway and has access by car or rail to Toronto, Ottawa and Montreal.

The Company was previously party to a joint venture with Auxly Cannabis Group Inc. ("**Auxly**"), whereby the parties entered into an agreement (the "**Auxly Agreement**") to combine their respective capabilities to develop and expand certain portions of the Facility in mutually agreed upon phases on identified areas within the Facility. Under the Auxly Agreement, Auxly assumed primary carriage through the implementation of each project phase at the Facility, including, but not limited to: the design of each phase of development at the Facility and the management and supervision of all professional services performed in connection therewith, including architectural services, engineering services, construction services and security services; assisting in the hiring, training and oversight of professional and operational staff; and assisting with the regulatory licensing process including facilitating interaction between the Company and Health Canada. The Auxly Agreement also provided that Auxly had primary responsibility for financing and/or sourcing the funds required for the capital expenditures for each project phase at the Facility, to be comprised of both equity and debt financing provided directly by Auxly or by a third party lender arranged for and designated by Auxly.

It had been anticipated by the Company and Auxly that the first phase of construction would be completed and ready for Health Canada approval by the end of December 2018, but this did not materialize. On February 6, 2019, the Company terminated the Auxly Agreement. Auxly claims that it identified contractual breaches relating to the Company's management and staffing obligations of the Facility, as well as significant concerns regarding certain aspects of the Facility's infrastructure. The Company maintains that it terminated the Auxly Agreement in response to Auxly's failure to perform its obligations under the Auxly Agreement to develop all aspects of the Facility in mutually agreed upon staged phases.

The Company has retained Matheson Constructors Limited to continue the expansion of the Facility, however, as a result of the termination of the Auxly Agreement, the phase of the expansion of the Facility to create an approximately 30,000 square foot self-contained cultivation facility, including Good Manufacturing Practices processing spaces, is not expected to be completed until the end of the first quarter of 2020**.** FSD will require an amendment to its License from Health Canada to be able to cultivate and process cannabis in the expanded space of the Facility.

The Company owns the 70-acre property on which the Facility is located. 32 acres of the property are utilized for the Facility's current building, with the remaining 38 acres available for additional development. Assuming we are able to acquire or raise the significant amount of capital that would be required to complete the property's development, and assuming adequate demand for our products, the Company believes it has the ability to ultimately achieve a total of approximately 3,800,000 square feet dedicated to cannabis cultivation and related ancillary businesses all under one roof, which would make it one of the largest indoor cannabis cultivation facilities in the world.

Products and Sales

To date, the Company has not commenced commercial sales under the License and has not generated any revenue from the sale of cannabis products. The Company is canvassing, and as indicated below with respect to the agreement with Canntab and World Class has entered into, potential opportunities with respect to the commercial sale of its products.

Competition

The Company expects to compete with other licensed producers in Canada and, as it moves forward with execution of its international business plan, expects to compete with other exporting Canadian licensed producers as well as local foreign producers. See "*Risk Factors—Risks Related to the Business—Companies existing in the markets for the medical and recreational cannabis products face substantial competition and in particular the legalization of recreational cannabis may result in increased levels of competition in the overall cannabis market*".

While the Company believes it is well positioned to deliver high-quality, consistent product to the market, its main competitive drawback is its size relative to the larger players in the industry. That being said, the Company is proceeding with aggressive capacity expansion plans and, with its new management team and financial resources, it expects to be competitive in the cannabis industry.

Specialized Knowledge and Personnel

Knowledge with respect to cultivating and growing medical cannabis is important to the industry. The nature of growing cannabis is not substantially different from the nature of growing other agricultural products. Variables such as temperature, humidity, lighting, air flow, watering and feeding cycles are defined and controlled to produce consistent product and to avoid contamination. The product is cut, sorted and dried under defined conditions that are established to protect the activity and purity of the product. Once processing is complete, each processing batch is subjected to testing against quality specifications set for activity and purity.

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

Environmental Matters

The Company's growing operations are, by their nature, highly contained and have no material environmental impact. All growing and processing is conducted indoors in controlled rooms. All by-products and waste are disposed of and handled in strict compliance with the requirements of the Cannabis Act. The Company expects the financial and operational effects of environmental protection requirements on its capital expenditures, profit and competitive position in the current and future financial years to be minimal; however, the Company may be subject to significant financial and operational effects of environmental protection requirements. See "*Risk Factors—Risks Related to the Business—The Company is required to comply with environmental, health and safety laws and regulations*".

Employees

As at June 30, 2019, the Company directly employed 19 full-time employees and 3 consultants. The Company believes its relationship with its employees is good. None of the Company's employees are represented by a labour union or subject to a collective bargaining agreement nor are any FV Pharma's employees.

Licenses, Permits and Authorizations

The Cannabis Regulations establish six classes of licenses:

- cultivation licenses (standard cultivation, micro-cultivation and nursery cultivation);
- processing licenses (standard processing and micro-processing);
- analytical testing licenses;
- sales for medical purposes licenses;
- research licenses; and
- cannabis drug licenses.

The Cannabis Regulations also create subclasses for cultivation licenses (standard cultivation, micro-cultivation and nursery) and processing licenses (standard processing and micro-processing). Different licenses and each sub-class therein have different rules and requirements that are intended to be proportional to the public health and safety risks posed by each license category and each sub-class. Producers holding production and sale licenses under the ACMPR were transferred to similar licenses under the Cannabis Act pursuant to a two-stage process. Licenses issued pursuant to the Cannabis Regulations are valid for a period of no more than five years.

The Cannabis Regulations permit cultivation license holders to conduct both outdoor and indoor cultivation of cannabis. A holder of a license must only conduct authorized activities (except for destruction, antimicrobial treatment and distribution) at the location set out in the license. The implications of the proposal to allow outdoor cultivation are not yet known, but such a development could be significant as it may reduce start-up capital required for new entrants in the cannabis industry. It may also ultimately lower prices as capital expenditure requirements related to growing outside are typically lower than those associated with indoor growing.

Cannabis for Medical Purposes

Part 14 of the Cannabis Regulations entitled "Access to Cannabis for Medical Purposes" sets out the regime for medical cannabis following legalization, which remains substantively the same as that which previously existed under the CDSA and the ACMPR, with adjustments to create consistency with rules for recreational use, improve patient access, and reduce the risk of abuse within the medical access system. The sale of medical cannabis remains federally regulated and, in each case, sales can only be made by an entity that holds a licence to sell under the Cannabis Regulations to patients that have a medical document and have registered with the licenced entity. Just as with the medical cannabis regime under the ACMPR, under the Cannabis Regulations, customers (patients) need to obtain a medical document from their doctor and then register as a client with a cannabis company that has a licence to sell (the registration is only good for up to a year). The client can then order from the cannabis company online or via telephone and the cannabis will be shipped directly to the client (to a maximum 150 grams per month).

Under the ACMPR regime, medical cannabis was sold online by licensed producers only. This did not change on October 17, 2018, with the introduction of the Cannabis Act, however users of medical cannabis may elect to purchase cannabis from retailers of recreational cannabis. The Federal Government intends to review the medical cannabis system in five years to determine if the introduction of retail cannabis sales has had an impact on the demand for medical cannabis.

Security Clearances

Certain people associated with cannabis licensees, including individuals occupying a "key position" such as directors, officers, large shareholders and individuals identified by the Minister of Health (the "**Minister**"), must hold a valid security clearance issued by the Minister. Under the Cannabis Regulations, the Minister may refuse to grant security clearances to individuals with associations to organized crime or with past convictions for, or in association with, drug trafficking, corruption or violent offences. This was largely the approach in place previously under the ACMPR and other related regulations governing the licensed production of cannabis for medical purposes. Individuals who have histories of nonviolent, lower-risk criminal activity (for example, simple possession of cannabis, or small-scale cultivation of cannabis plants) are not precluded by legislation from participating in the legal cannabis

industry. The grant of security clearance to such individuals is at the discretion of the Minister and such applications will be reviewed on a case-by-case basis. See "Risk Factors–Risks Related to the Medical and Recreational Cannabis Industry–Certain key employees are subject to security clearance from Health Canada, and there can be no assurance that such personnel will be able to obtain or renew security clearances in the future".

In addition, the Cannabis Regulations expand the ACMPR security clearance requirements to include:

- any "responsible person", "head of security", "master grower", "quality assurance person", or alternates for these positions;
- any partners of a partnership that hold a license; and
- any individuals who exercise, or are in a position to exercise, direct control over a corporate or cooperative license-holder, including all:
    - directors and officers of the individual, if a corporation;
    - partners of the individual, if a partnership; and,
    - directors and officers of the individual if it is a corporate partner in a partnership.

Cannabis Tracking and Licensing System

Under the Cannabis Act, the Minister is authorized to establish and maintain a national cannabis tracking system. The purpose of this system is to track cannabis throughout the supply chain to help prevent the diversion of cannabis into, and out of, the illicit market. The Cannabis Regulations provide the Minister with the authority to make a ministerial order that would require certain persons named in such order to report specific information about their authorized activities with cannabis, in the form and manner specified by the Minister. Accordingly, the Minister has introduced the Cannabis Tracking and Licensing System (the "**CTLS**"). License-holders are required to use the CTLS to submit monthly reports to the Minister, among other things, pursuant to the Cannabis Tracking System Order, SOR/2018-178.

Cannabis Products

At the retail level, the Cannabis Regulations permit the sale to the public of dried cannabis, cannabis oil, fresh cannabis, cannabis plants, and cannabis seeds. The sale of edible cannabis products and concentrates (such as hashish, wax and vaping products) is currently prohibited but is expected to be permitted by October 2019. The Company is not currently licensed to sell Cannabis for retail use.

The Cannabis Regulations acknowledge that a range of product forms should be enabled to help the legal industry displace the illegal market. Additional product forms that are mentioned under the Cannabis Regulations include vaporization cartridges manufactured with dried cannabis. Specific details related to these new products are to be set out in a subsequent regulatory proposal.

Packaging and Labelling

The Cannabis Regulations require plain packaging for cannabis products, including strict requirements for logos, colours and branding. The Cannabis Regulations further require mandatory health warnings, a standardized cannabis symbol and specific product information.

Advertising

The Cannabis Act places a general ban on the promotion of cannabis, cannabis accessories or any service related to cannabis, unless the promotional activity is specifically authorized under the Cannabis Act. Cannabis products may be promoted at their point of sale if the promotion indicates only its availability and/or price. Further, brand preference and informational promotion are permitted if such promotion is:

- in a communication that is addressed and sent to an individual who is 18 years of age or older and is identified by name;
- in a place where young persons are not permitted; or

- communicated by means of a telecommunication, where the person responsible for the content of the promotion has taken reasonable steps to ensure that the promotion cannot be accessed by a young person.

Health Products and Cosmetics Containing Cannabis

Health Canada has taken a scientific, evidence-based approach for the oversight of health products containing cannabis, including prescription and non-prescription drugs, natural health products, veterinary drugs and veterinary health products, and medical devices. Under the Cannabis Regulations, the use of cannabis-derived ingredients (other than certain hemp seed derivatives containing no more than 10 parts per million THC in cosmetics) is permitted, subject to the provisions of the Cannabis Act.

Provincial and Territorial Regulatory Regimes

While the Cannabis Act provides for the regulation of the commercial production of cannabis for adult-use purposes and related matters by the Canadian federal government, it also provides that provinces and territories of Canada have authority to regulate other aspects of recreational cannabis (similar to what is currently the case for liquor and tobacco products), such as sale and distribution, minimum age requirements, places where cannabis can be consumed, and a range of other matters.
Each Canadian jurisdiction has established a minimum age of 19 years for cannabis use, except for Québec and Alberta, where the minimum age is 18. A summary of the adult use regimes, by province, is as follows:

British Columbia*:* British Columbia passed the *Cannabis Control and Licensing Act* (British Columbia) and the *Cannabis Distribution Act* (British Columbia), and issued the *Private Retail Licensing Guide* to regulate the recreational cannabis industry in the province. British Columbia's Liquor Distribution Branch is the only wholesale distributor of recreational cannabis. It operates cannabis retail stores and is responsible for licensing and monitoring private, recreational cannabis stores.

Ontario: Ontario introduced a regulated private retail model for cannabis in Ontario by way of the *Cannabis Statute Law Amendment Act, 2018* (Bill 36) ("**CSLAA**"). It emphasizes three public policy objectives: to implement a safe, legal system for cannabis that will protect consumers, to undermine the illegal market, and to protect public safety. The CSLAA does the following: (i) it amends the *Cannabis Act, 2017*, the *Ontario Cannabis Retail Company Act, 2017*, the *Liquor Control Act*, the *Smoke-Free Ontario Act, 2017*, the *Highway Traffic Act*, and other related statutes; and (ii) it enacts the *Cannabis License Act, 2018*, which establishes the licensing system for Ontario's private retail stores, which is administered by the Alcohol and Gaming Commission of Ontario ("**AGCO**"). The Ontario government announced that, until December 13, 2019, the AGCO would only grant 25 retail operator licenses and retail sale authorizations to prospective retailers across five regions, with the intention of having private retail stores open and operational by April 1, 2019. The 25 permitted retailers, as well as the prospective retailers placed on the waiting list, were selected by lottery on January 11, 2019, and 25 winners were announced. Until April 1, 2019, when private retail locations began to open, the Ontario Cannabis Retail Company was the only authorized vendor of recreational cannabis in Ontario, and such sales could only be completed online through the Ontario Cannabis Store website.

Alberta: Alberta has a cannabis framework providing for the purchase of cannabis products from private retailers, which receive their products from a government-regulated distributor. Under the *Gaming, Liquor and Cannabis Act*, only licensed retail outlets are permitted to sell cannabis, with online sales run by the Alberta Gaming and Liquor Commission.

Saskatchewan: In Saskatchewan, recreational cannabis is sold by private retailers. Under the *Cannabis Control (Saskatchewan) Act* (Bill 121), the Saskatchewan Liquor and Gaming Authority has committed to issuing up to 60 retail permits to private retailers in approximately 40 municipalities and First Nation communities across the province.

Manitoba: Manitoba has a hybrid model for cannabis distribution. The supply of cannabis in Manitoba is secured and tracked by the Manitoba Liquor & Lotteries Company; however, licensed private retail stores are permitted to sell recreational cannabis.

Québec: Québec passed its Cannabis law, Bill 157. In Québec, the sale of all recreational cannabis is managed and conducted through the stores of the Société québécoise du cannabis, a subsidiary of Société des alcools du Québec, and its online website.

Newfoundland and Labrador: In Newfoundland and Labrador, pursuant to the *Cannabis Control Act,* recreational cannabis is sold through licensed private stores, with the crown-owned liquor corporation, the Newfoundland and Labrador Liquor Corp. ("**NLC**"), overseeing the distribution to private sellers. The NLC controls the possession, sale and delivery of cannabis, and sets prices. It is also the initial online retailer, although licenses may later be issued to private retailers.

Nova Scotia: The *Cannabis Control Act* establishes the licensing system for the retail sale of recreational cannabis in Nova Scotia. The Nova Scotia Liquor Company is responsible for the regulation of cannabis in the province, and recreational cannabis is only sold publicly through government-operated storefronts and online sales.

New Brunswick: Under the *Cannabis Control Act,* the Cannabis Management Company controls and oversees the sale of recreational cannabis in New Brunswick. Retail sales, whether in stores or online, are exclusively through Cannabis NB, a subsidiary of the New Brunswick Liquor Company.

Prince Edward Island: Under the *Cannabis Management Company Act*, the sale of recreational cannabis in Prince Edward Island is controlled and supervised by the Cannabis Management Company, which operates retail stores and online sales.

Yukon: Under the *Cannabis Control and Regulation Act*, the distribution and sale of recreational cannabis in the Yukon is limited to government outlets and government-run online stores, however it does contemplate the later licensing of private retailers.

Nunavut: Pursuant to the *Nunavut Cannabis Act*, the Nunavut Liquor and Cannabis Commission ("**NULC**") controls the distribution and sale of cannabis, online and in physical stores. The NULC also has the authority to contract with agents for the sale of cannabis.

Northwest Territories: The *Cannabis Legalization and Regulation Implementation Act* governs the distribution and sale of recreational cannabis. The N.W.T. Liquor and Cannabis Commission controls the importation, distribution, sale and pricing of cannabis products, however it is allowing private retailers to apply for retail licenses. Communities in the Northwest Territories will be able to hold a plebiscite to prohibit cannabis, similar to the options currently available to restrict alcohol.

The Company is not currently licensed to sell cannabis for recreational use, and has no immediate plans to apply for a license that would allow it to do so.

CSA Staff Notice 51-352 (Revised) Regarding Issuers with U.S. Marijuana-Related Activities

On February 8, 2018, the Canadian Securities Administrators revised their previously released CSA Staff Notice 51-352 *Issuers with U.S. Marijuana Related Activities* (the "**CSA Notice**"), setting out disclosure expectations on the risks faced by issuers with cannabis-related activities in the United States. In particular, the CSA Notice confirmed that a disclosure-based approach remains appropriate, and provided guidance on disclosure expectations for issuers with direct and indirect involvement in the cultivation and distribution of cannabis, as well as issuers that provide goods and services to third parties, in the United States.

Health Canada Statement on Changes to Cannabis Licensing Process

On May 8, 2019, Health Canada introduced changes to the cannabis licensing process to align the approach with other regulated sectors, such as pharmaceuticals.

Under the new approach, Health Canada will require new applicants for licenses to cultivate cannabis, process cannabis, or sell cannabis for medical purposes to have a fully built site that meets all the requirements of the Cannabis Regulation*s* at the time of their application, as well as satisfying other application criteria.

With respect to existing applications, Health Canada will complete a high-level review of applications currently in the queue. If the application passes this review, Health Canada will provide a status update letter to the applicant, indicating that it has no concerns with what is proposed in the application. Once the applicant has a completed site that meets the regulatory requirements, Health Canada will review the application in detail, in priority based on the original application date.

Health Canada is implementing these adjustments following a review of its current licensing process, which identified that a significant amount of resources are being used to review applications from entities that are not ready to begin operations, contributing to wait times for more mature applications and an inefficient allocation of resources. To support applicants, Health Canada has made available additional guidance on the license application process and on the regulatory requirements regarding Good Production Practices and physical security measures. Health Canada is also working to establish service standards for the review of applications, which will increase predictability for applicants.

The Company believes that the changes introduced by Health Canada will benefit the Company as the number of new licenses for competitors will be limited.

Narrative Description of the Company's Business

Business Objectives

The Company's principal business is the production and sale of medical cannabis in Canada, through FV Pharma. On October 13, 2017, Health Canada issued FV Pharma its License under the Cannabis Act, authorizing it to cultivate and process cannabis. The License subsequently migrated to the Cannabis Act, and expanded to allow FV Pharma to sell cannabis to other licensed producers in accordance with subsection 11(5) of the Cannabis Regulations. On June 24, 2019, the Company received an amendment to the License allowing it to sell fresh or dried cannabis or cannabis oil to such other persons who are permitted to purchase medical cannabis products under the Cannabis Act (see "*Risk Factors – Risks Related to the Medical Industry – Failure of the Company to comply with licensing requirements under the Cannabis Act could have a material adverse impact on its business, results of operations, financial condition and prospects*").

The Company's primary focus is to launch its prospective lead asset, which it acquired on June 28, 2019 when it acquired Prismic: micro-PEA. Upon receipt of regulatory approval, the Company expects to launch micro-PEA plus pregabalin for the treatment of fibromyalgia.

Recent Developments: 2018 and 2019 to Date

Acquisition of Prismic Pharmaceuticals

On June 28, 2019, the Company closed the acquisition of Prismic, a U.S.-based specialty research and development pharmaceutical company that is developing novel non-addictive prescription drugs with innovative safety profiles. Prismic's goal was to address the opioid crisis based on formulations utilizing micro-PEA's complimentary, or "entourage" effect on certain drugs used to impact the body's endocannabinoid system. When micro-PEA is administered simultaneously or in combination with other drugs such as opiates, certain anticonvulsants and cannabinoids (such as THC and CBD), at least one study has shown that the desired therapeutic effect may be achieved at a lower than normal dose of the opiate.

Pursuant to the terms of a securities exchange agreement, the Company acquired all outstanding common and preferred shares of Prismic for an aggregate purchase price of US$17.5 million ($23.4 million based on an exchange rate of US$1 to CAD$1.3349 calculated based on the average daily exchange rate between April 5, 2019 and April 18, 2019), satisfied by the issuance of an aggregate of 102.7 million Class B Shares at a deemed price of $0.2275 (US$0.1704) per Class B Share. The Class B Shares issued to the Prismic shareholders were deposited into escrow at the closing of the transaction, and will be subject to an 18-month staggered escrow release.

In addition, the Company agreed to assume up to US$4.0 million of outstanding Prismic liabilities, some of which may be settled by the issuance of additional Class B Shares.

Partnership Agreement with Cannara

The Company has also made an investment in Cannara Biotech Inc. ("**Cannara**"), which is developing its own cannabis production facility. Under a partnership agreement with Cannara, a previously held subsidiary of the Company, FV Pharma Québec Inc. ("**FV Québec**"), applied for a second site license for cultivation at the Cannara facility which is currently being considered by Health Canada. In exchange for: (i) FV Québec applying for the second site license; and (ii) the transfer of all of the outstanding common shares of FV Québec effective June 4, 2019, Cannara issued 75,003,750 Class B shares in the capital of Cannara to the Company.

Under the terms of the partnership agreement, the Company will assist Cannara with cannabis licensing requirements to operate a lower cost indoor cannabis cultivation and processing center. Cannara's facility is less than one hour from Canada's second largest city, Montreal. Cannara's new premises, once fully licensed and built out, is expected to be used for the operation of licensed cannabis cultivation and/or the sale of products, namely dried cannabis, fresh cannabis, cannabis oil, saleable cannabis and other cannabis-derived products for medical purposes and, when formally legalized for recreational purposes, Cannara's facility is expected to be one of the largest indoor cannabis production facilities in Québec. Cannara's facility is under construction and, according to Cannara, 105,000 square feet of the Cannara facility is expected to be completed in the third quarter of 2019. The Company does not intend to occupy any portion of Cannara's facility.

The Company currently owns 85,003,750 Class B shares in the capital of Cannara, approximately 12.8%. The Company believes that the market opportunity for cannabis and cannabis-derived products in Québec is significant, as it is the second largest province by population in Canada, only behind Ontario. The Company and Cannara intend to collaborate on many upcoming projects including obtaining cannabis strains, exchanging indoor grow technologies and assisting each other in the sale and distribution of indoor cannabis products in their respective provinces.

Dr. Sara May, President of FV Pharma, is a director of Cannara. See "*Transactions with Related Parties*".

Agreement with Aura Health Inc.

On April 16, 2019, the Company entered into a share exchange agreement with Aura Health Inc. ("**Aura**"). Pursuant to this agreement, the Company acquired common shares in the capital of Aura having an aggregate value of $3 million (13,562,386 common shares at price of $0.2212 per share) in exchange for Class B Shares having an aggregate value of $3 million (13,181,019 Class B Shares at price of $0.2276 per Class B Share).

In addition to the share exchange agreement, Aura, through Pharmadrug Production GmbH ("**Pharmadrug**"), a company in which Aura holds an 80% equity interest, and the Company entered into: (i) a consulting agreement, whereby Pharmadrug will assist the Company with obtaining euGMP certification at the Facility; and (ii) a supply agreement, whereby Pharmadrug committed to purchasing Canadian produced cannabis product from the Company, provided that such product is saleable in the German market. Pharmadrug is one of the few cannabis distribution license holders in Germany. Strategically this opens another channel for the Company to distribute cannabis products in the German market where prices for cannabis are often higher than in Canada.

Solarvest Transaction

On May 7, 2019, the Company announced the signing of a definitive Collaborative Research and Development Agreement (the "**Research Agreement**") with Solarvest BioEnergy Inc. ("**Solarvest**"). Pursuant to the Research Agreement, Solarvest will conduct research using its algal expression technology to develop pharma-grade cannabinoids (the "**Project Cannabinoids**"). The Company and Solarvest have allocated an initial budget of $1,000,000 for the research project, over a two-year period, and created a joint scientific review committee to assess progress of the project against budgets and timelines.

If development of proof of concept that algae can express the Project Cannabinoids is achieved, Solarvest and the Company intend to enter into a license agreement under which Solarvest will grant the Company an exclusive, worldwide license over any use of prescription drugs that can treat diseases affecting the central nervous system using a subset of the Project Cannabinoids. In consideration for the license, the Company will be required to pay Solarvest a royalty equal to 5% of the net profits from the sale of such products as well as reimburse Solarvest for the cost of production.

In addition to the licensing agreement, Solarvest will pay a royalty fee to the Company on the sale or licensing of any products that result from the project, other than the Company's licensed indications described above, equal to 5% of the net sales or net license fees. Once Solarvest has paid an aggregate of $3,000,000 in royalty fees, the royalty percentage will be reduced to 3%.

If the Project Cannabinoids are found to develop successfully in algae, then it may allow for the Company to manufacture pharmaceutical grade cannabinoid molecules at a fraction of the cost and time required to develop cannabinoids by standard cultivation and processing methods.

In connection with the Research Agreement, (i) the Company issued 10,000,000 Class B Shares to Solarvest, at a deemed price of $0.30 per Class B Share, (ii) Solarvest issued 3,000,000 units to the Company, at a deemed price of $0.25 per unit, with each unit being comprised of one common share in the capital of Solarvest and one share purchase warrant with an exercise price of $0.25 and a term of two years, and (iii) Solarvest issued a convertible debenture to the Company in the principal amount of $2,400,000 (the debenture has a five-year term, bears interest of 3% per annum, and is convertible into shares at a conversion price of $1.00 per share, provided that the Company will be required to convert the debenture should Solarvest shares close at a price of at least $1.20 for a period of 20 consecutive trading days).

Supply Agreement with Canntab and World Class

On February 12, 2019, the Company announced that it had entered into a supply agreement with Canntab Therapeutics Limited ("**Canntab**") and World Class Extractions Inc. ("**World Class**") to purchase hemp flower from hemp supplier Thomas Elcome (the "**Supplier**"). Pursuant to the agreement, the Purchasers have agreed to buy approximately 1,000 kg of the Supplier's 2018 hemp crop at a purchase price of $10,000 per kg of finished, full spectrum (100%) CBD ($100 per kg for each 1% CBD), extracted from the flower. Subsequently on February 28, 2019, the Purchasers announced that they had entered into a supply and loan agreement with the Supplier. Pursuant to the supply and loan agreement, the Supplier granted the Purchasers the right and option to purchase up to $5.0 million of the Supplier's hemp crop for a period of five years commencing in 2019 at a purchase price of $10,000 per kg of finished, full spectrum (100%) CBD ($100 per kg for each 1% of CBD) extracted from the flower. The Purchasers provided a loan to the Supplier in the amount of $500,000 to purchase equipment, which the Supplier has agreed to pay back in hemp product from its 2019 crop. The Company and the Purchasers intend to extract CBD from the Supplier's 2019-2024 hemp crops and process the oil into gel capsules and tablets at the Facility.

Termination of Agreement with Auxly

On February 6, 2019, the Company announced the termination of the Auxly Agreement dated March 5, 2018 with Auxly, pursuant to which the parties had agreed to combine their respective capabilities to develop certain portions of the Facility in mutually agreed upon phases on identified areas within the Facility.

Investment in Huge Shops

On December 20, 2018, the Company announced that it had completed an investment of $1,300,000 to acquire approximately 9.9% of the issued and outstanding shares of Huge Shops, Inc. ("**Huge Shops**"), a Toronto-based cannabis retailer. Huge Shops has the option to acquire a minimum of ten retail locations under the umbrella of properties owned or operated by Chairman's Brands' subsidiary Coffee Time.

Collaboration with World Class

On December 6, 2018, the Company announced that it had entered into a definitive Collaboration and License Agreement with World Class, a company that has developed an innovative extraction process designed to produce large-scale, quality, potent cannabis and hemp extracts. Under the terms of the Collaboration and License Agreement and a related lease, the Company will provide World Class with 5,000 square feet of space at the Facility, assist it in obtaining an extraction license from Health Canada, and provide World Class with the raw cannabis needed to produce cannabis extracts. Cannabis extracts is a rapidly growing segment of the cannabis consumer market. The Company's relationship with World Class, a company holding proprietary and novel extraction technology, is strategic in terms of low cost and efficient access to extracts.

In addition, World Class will use its specialized knowledge and procedures to produce cannabis extract for the Company. The Company will compensate World Class for such services by providing 7% of all cannabis extracts produced by World Class for the Company at the Facility to World Class, either in cash or cannabis extract, at World Class's option. In addition, World Class has granted the Company a 3% royalty right over the gross profits, as defined in the Collaboration and License Agreement, derived from World Class's sale of any cannabis extracts provided to World Class by the Company.

Anthony Durkacz, Executive Co-Chairman of the Company, is the chairman of the board of directors of World Class. Each of Raza Bohkari, Executive Co-Chairman & Chief Executive Officer and Donal Carroll, interim Chief Financial Officer of the Company, is a director of World Class. See "*Management's Discussion and Analysis– Transactions with Related Parties*".

Migration of License to the Cannabis Act

On November 13, 2018, the Company announced that the License, which was originally granted under the ACMPR, had been migrated to the Cannabis Act, effective November 8, 2018. The issuance of the new cannabis cultivation license includes the ability to sell certain cannabis products (excluding dried or fresh cannabis flower) to other licensed producers in accordance with subsection 11(5) of the Cannabis Regulations. As of November 7, 2018, FV Pharma also received license amendments approving all of the remaining 30,000 square feet currently being built out for additional grow and operations. On June 24, 2019, the License was amended to allow the Company to sell or provide fresh or dried cannabis or cannabis oil to such other persons who are permitted to purchase medical cannabis products under the Cannabis Act.

Investment in Pharmastrip

On September 6, 2018, the Company invested $1.5 million in Clover Cannastrip Thin Film Technologies Inc. ("**Clover**"). The Company's investment includes units comprising 7,500,000 shares and 3,750,000 warrants.

In connection with the investment, the Company entered into a definitive collaboration and profit sharing agreement with Pharmastrip Corp. ("**Pharmastrip**"), an entity represented to be an affiliate of Clover, effective January 23, 2019. Under the terms of the agreement, the Company agreed to install Pharmastrip proprietary equipment at the Facility. The Company intends to use the equipment to manufacture and sell organic medical cannabis infused in oral thin film strips, subject to the receipt of all necessary approvals and licenses from Health Canada. Pharmastrip agreed to grant the Company an exclusive, perpetual license to manufacture and sell the oral thin film strips in Canada, and profits from the sale of any such products will be shared equally by the Company and Pharmastrip. Oral thin film strips are another way for consumers to effectively consume cannabis based products. As of the date of this MD&A, Pharmastrip has not yet delivered equipment to the Facility so manufacturing has not commenced.

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

Expansion into Jamaican Market

On September 13, 2018, the Company announced that it had entered into a letter of intent with JJAMACANN Inc. to form a joint venture operating as FSD Jamaica with a view to expanding into the Jamaican cannabis market.

Subsequent to the announcement, no material agreements were entered into with JJAMACANN Inc. and FSD does not presently intend to pursue the expansion further.

Collaboration Agreement with Canntab

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

In consideration of the Company's services, Canntab has granted the Company certain royalty and profit sharing rights in connection with the sale of the Canntab Products. Canntab will provide the Company with 50% of the profits that Canntab receives on any retail sales of Canntab Products through channels that are established by the Company, and the Company will be entitled to retain 50% of the profits from the sales of the Canntab Products effected by the Company. In addition, for any Canntab Products not sold in accordance with the foregoing sentence, Canntab will pay the Company a royalty of 3.5% of Canntab's sale price for all Canntab Products that are manufactured and sold from the Canntab area of the Facility. As part of the Canntab agreement Canntab also agreed to purchase certain quantities of cannabis oils from the Company at cost, plus a mark-up, until such time that Canntab receives its license.

Investment in SciCann

On June 6, 2018, the Company announced that FV Pharma had made an investment into SciCann Therapeutics Inc. ("**SciCann**") by executing a term sheet (the "**Term Sheet**") pursuant to which the Company invested the amount of $2 million and owns 10.52% of SciCann.

During the term of the Term Sheet, FV Pharma has the exclusive license in Canada for the manufacture and distribution of a line of proprietary (patent pending) cannabinoid-based and indication-specific products developed by SciCann until May 27, 2038, subject to certain conditions. Under the Term Sheet, FV Pharma is required to make certain royalty payments to SciCann with respect to any Scicann products it sells, but is under no obligation to manufacture and distribute such products. Finally, FV Pharma shall also receive premium access to the cannabinoid scientific research platform developed by SciCann in Israel, which includes a network of leading researchers, academic institutions and medical centers.

Investment in High Tide

In April 2018 the Company made an investment into High Tide Ventures Inc. ("**High Tide**") of $200,000 at a price of $0.36 per common share of High Tide. In October 2018, the Company made a further investment in High Tide of $2,000,000 at $0.50 per unit. The Company owns approximately 2.22% of High Tide, including a total of 4,551,999 common shares and 2,000,000 common share purchase warrants, each exercisable at a price of $0.75 per share, expiring on December 17, 2020.

High Tide currently operates 14 licensed cannabis stores across Canada and holds provincial e-commerce licenses in Saskatchewan and Manitoba. High Tide expects to operate a total of 22 locations across Canada by the end of August 2019.

Other Corporate Activities

Changes to Management, Board of Directors and Auditors

On July 30, 2019, the Company announced the appointment of Dr. Larry Kaiser as Chairman of the Company's Scientific Advisory Board ("**SAB**"). In this capacity on the SAB, Dr. Kaiser will serve as a strategic guide and resource to the Company as it develops disruptive, science-based, cannabinoid therapeutics. Dr. Kaiser is the Dean, Lewis Katz School of Medicine at Temple University, President & CEO of Temple Health System and Senior Executive Vice President for Health Affairs at Temple University in Philadelphia, and was named one of the "50 Most Influential Clinical Executives" for 2019 by *Modern Healthcare*. Before joining Temple University in 2011, Dr. Kaiser served as the President of the University of Texas Health Science Center at Houston. He graduated from Tulane University School of Medicine and completed a residency in general surgery as well as a fellowship in surgical oncology at UCLA. Dr. Kaiser then completed a residency in cardiovascular and thoracic surgery at the University of Toronto. Following faculty appointments at Memorial Sloan-Kettering Cancer Center and the Washington University School of Medicine, Dr. Kaiser joined the University of Pennsylvania in 1991, where he held positions including Associate Professor of Surgery, Chief of General Thoracic Surgery, Founder and Director of Penn's Lung Transplantation Program, and Director of its Center for Lung Cancers and Related Disorders. In 2001 he was named the John Rhea Barton Professor and Chairman of the Department of Surgery and the University Health System's Surgeon-in-Chief.

Dr. Kaiser is the author or co-author of 16 books and more than 300 peer-reviewed papers, and is a member of every major surgical society. In 2005 he was elected to the National Academy of Medicine (formerly the Institute of Medicine of the National Academy of Sciences). His recent honors include citations in Castle Connolly's *America's Top Doctors for Cancer*, *Who's Who in the World* and *Philadelphia* magazine's "Top Doctors," among others. Dr. Kaiser maintains time in his schedule at Temple for a limited surgical practice.

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

Mr. Ciaruffoli is a Certified Professional Accountant and served as the Chairman and Chief Executive Officer of the Parente Beard/Baker Tilly accounting and advisory firm. During his tenure as Chairman and Chief Executive Officer, he and his team transitioned the firm from a Pennsylvania practice to a multi-state super-regional firm. In 2014, he orchestrated a merger of the Parente Beard and Baker Tilly Virchow Krause firms to create the 12th largest US accounting and advisory firm. Throughout his career, Mr. Ciaruffoli has served on numerous for-profit and not-for-profit boards.

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

As of June 2019, the Board has engaged a consulting firm and has commenced the process of finding a permanent Chief Financial Officer to replace the Company's interim Chief Financial Officer.

On March 28, 2019, the Company entered into a consulting agreement (the "**Romano Agreement**") with Joseph L. Romano, a lawyer in the Toronto area who has been working within the medical cannabis field since 2006, assisting people coping with chronic pain to obtain access to medical cannabis. Under the terms of the Romano Agreement, Mr. Romano is expected to provide consulting on the inner workings of third party actions, Workplace Safety and Insurance Board claim handling, first party coverage and no fault benefits across Canada. Mr. Romano is also expected to assist in creating strategic distribution channels for the Company's cannabis products and identify acquisition opportunities for the Company. In consideration for his services, Mr. Romano will receive consulting fees as well as periodic distributions of Class B Shares and warrants to acquire Class B Shares.

Effective April 8, 2019, the Company changed its auditors from Dale Matheson Carr-Hilton Labonte LLP to McGovern Hurley LLP.

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

On November 26, 2018, the Company announced the appointment of Rupert Haynes as Chief Executive Officer of the Company. Mr. Haynes was subsequently terminated as Chief Executive Officer on February 6, 2019, and Dr. Raza Bokhari was re-appointed Interim Chief Executive Officer. On June 3, 2019, the Company announced that Dr. Bokhari was appointed Chief Executive Officer.

On November 14, 2018, the Company announced the appointment of David Urban to the Board of Directors. Mr. Urban is an accomplished business and government relations executive. He and his company advise organizations ranging in size from start-ups to the Fortune 100 on interaction with government in order to maximize stakeholder and shareholder value. In the field of politics, Mr. Urban has achieved success serving as an advisor to campaigns at the highest levels, including the President of the United States, the United States Senate and United States House of Representatives. In addition to his role as a business consultant and political advisor, Mr. Urban is a frequent contributor to CNN as a political commentator.

On October 29, 2018, Dr. Bokhari was appointed as Executive Co-Chairman of the Board of Directors and interim Chief Executive Officer of the Company. Further, the Company announced the appointment of Zeeshan Saeed as President of the Company and Anthony Durkacz as Executive Co-Chairman of the Board of Directors. Mr. Saeed is an entrepreneur who has been involved with FV Pharma for over four years. Mr. Saeed provided consulting advice to FV Pharma and was instrumental for raising the initial seed capital. He played a key role in bringing together a team of professionals in the development of FV Pharma's business plan. Mr. Saeed has experience in international capital markets and has helped various startups with the process of raising initial funding and getting listed on various stock exchanges. Mr. Saeed is an engineer by qualification and is currently the President and a director of the Company. Before entering capital markets, Mr. Saeed was the founder and CEO of Platinum Telecommunications Inc. Mr. Saeed grew Platinum Telecommunications Inc. to a stage at which it was taken over by BankEngine Technologies, which in turn was taken over by a larger public entity. Mr. Durkacz is a director and Executive Vice President at FRCC. Mr. Durkacz holds an Honours Bachelor of Business Administration from Brock University with a major in both Accounting and Finance. Mr. Durkacz was previously a director and Chief Financial Officer of Snipp Interactive Inc.

August 2, 2018, the Company announced the appointment of Dr. Raza Bokhari to the Board of Directors. Dr. Bokhari currently serves as the Chairman of the Board of PCL, Inc., a global diagnostic provider of addiction screening and opioid prescription medication monitoring, including designer drugs and synthetic cannabinoids. He is also the managing partner of RBx Capital, LP and a recipient of Philadelphia Business Journal's "40 under 40" award. A physician-turned-entrepreneur, Dr. Bokhari has, over the past several years, developed outstanding expertise in aggregating and accelerating life sciences and healthcare services companies. He has a vast knowledge base of developing creative concepts, implementing programs and forming strategic alliances. An effective "change agent" with several years of experience and expertise in start-up and turn-around businesses, he is adept at turning around struggling companies. Dr. Bokhari recognizes the special role of public offering, private equity funds, venture capital money, and leveraged debt partners in executing accelerated growth trends in healthcare services and cancer diagnostics and therapeutics.

On July 23, 2018, the Company announced the appointment of Mr. Donal Carroll to the role of interim Chief Financial Officer. Mr. Carroll is a finance executive with 20 years of corporate finance leadership and public company experience, as well as deep expertise in syndicate investing, both in equity and debt securities. Mr. Carroll has successfully guided companies for expansion and growth, and has worked with major corporations such as Danaher Company and Unilever, where he was instrumental in major restructuring activities, mergers and acquisitions and the implementation of new internal controls and enterprise resource planning systems resulting in significant efficiencies through periods of substantial change and company growth. Mr. Carroll has been an independent director of Bird River Resources Inc. and holds a CPA-CMA designation, as well as a Bachelor of Commerce degree, from University College Dublin.

RESULTS OF OPERATIONS

The following table outlines our condensed consolidated statements of loss and comprehensive loss for the three and six months ended June 30, 2019 and 2018:

	Three months ended			Six months ended		
	June 30 2019	June 30 2018	Change	June 30 2019	June 30 2018	Change
Revenue						
Rental income	$ 18,501	$ 28,340	$ (9,839)	$ 37,001	$ 68,323	$ (31,322)
Other income	-	1,032	(1,032)	-	1,032	(1,032)
	18,501	29,372	(10,871)	37,001	69,355	(32,354)
Expenses						
General and administrative	1,512,107	28,021	1,484,086	2,705,794	334,343	2,371,451
Consulting fees	752,313	707,599	44,714	1,181,869	931,270	250,599
Depreciation	179,588	-	179,588	226,275	56,711	169,564
Loss on change in fair value of biological assets	321,375	-	321,375	175,524	-	175,524
Insurance	60,584	-	60,584	127,065	74,682	52,383
Interest expense	7,242	-	7,242	7,242	-	7,242
Listing expense	-	7,885,144	(7,885,144)	-	7,885,144	(7,885,144)
Occupancy costs	88,104	248,529	(160,425)	776,077	526,508	249,569
Production and growing expenses	-	-	-	37,440	64,727	(27,287)
Professional fees	531,591	573,700	(42,109)	884,858	631,579	253,279
Salaries, wages and benefits	916,523	516,032	400,491	1,445,927	647,826	798,101
Shareholder and public company costs	50,671	-	50,671	105,002	10,000	95,002
Share based payments	5,383,199	1,390,900	3,992,299	5,686,057	2,076,296	3,609,761
	9,803,297	11,349,925	(1,546,628)	13,359,130	13,239,086	120,044
Loss before the undernoted	(9,784,796)	(11,320,553)	1,535,757	(13,322,129)	(13,169,731)	(152,398)
Changes in fair value of investments	(4,460,724)	7,500,000	(11,960,724)	(3,220,677)	7,500,000	(10,720,677)
Net (loss) and comprehensive (loss) for the period	**$ (14,245,520)**	**$ (3,820,553)**	**$ (10,424,967)**	**$ (16,542,806)**	**$ (5,669,731)**	**$ (10,873,075)**
(Loss) per Class B share:						
Basic and diluted	$ (0.010)	$ (0.004)	$ (0.007)	$ (0.012)	$ (0.005)	$ (0.007)
Weighted average number of Class B shares outstanding						
Basic and diluted	1,408,883,160	1,077,343,360	331,539,800	1,398,100,551	1,077,343,360	320,757,191

Revenue

The Company currently does not derive revenues from sale of cannabis products. The only revenue it generates is from subleasing an unused portion of its Cobourg facility to unrelated third parties.

Expenses

General and administrative

General and administrative expenses are comprised of:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
	$	$	$	$
Stock promotion, investor relations and media	991,807	3,187	2,058,294	268,510
Travel, lodging and meals	157,118	-	270,850	-
General office	105,173	24,834	108,164	65,833
IT related expenditure	46,981	-	57,458	-
Other	211,028	-	211,028	-
Total	1,512,107	28,021	2,705,794	334,343

General and administrative expenses increased from $28,021 to $1,512,107 for the three months ended June 30, 2019 as compared to the equivalent period in the prior year and increased from $334,343 to $2,705,794 for the six months ended June 30, 2019 as compared to the equivalent period in the prior year. The increase is primarily due to stock promotion, investor relations and media expenses from becoming a public reporting issuer in May 2018. The increase is also due to higher general office and administrative expenses including travel, lodging and meals and IT related expenditures and other to support the Company's growing operations.

Consulting fees

Consulting fees increased from $707,599 to $752,313 for the three months ended June 30, 2019 as compared to the equivalent period in the prior year and increased from $931,270 to $1,181,869 for the six months ended June 30, 2019 as compared to the equivalent period in the prior year. The increase is primarily due to the development and the growth of the business.

Depreciation expense

Depreciation expense was $179,588 and $226,275 respectively for the three- and six-month periods ended June 30, 2019 compared to nil and $56,711 for the comparable periods in 2018. The increase in depreciation expense is primarily due to the commencement of depreciation on building and building improvements during the three months ended June 30, 2019.

Loss on change in fair value of biological assets

The Company capitalizes all the direct and indirect costs as incurred related to the biological transformation of the biological assets between the point of initial recognition and the point of harvest including labour related costs, grow consumables, utilities, facilities costs including an allocation of overhead costs related to production facility and production related depreciation. Capitalized costs are subsequently recorded within cost of sales in the consolidated statements of loss in the period that the related product is sold. From inception to June 30, 2019, the Company has not sold any cannabis.

At each reporting period and at the point of harvest, the Company measures biological assets, at fair value less cost to sell up to the point of harvest. Unrealized gains or losses arising from the changes in fair value less cost to sell during the period are separately recorded in the consolidated statement of loss for the related period.

Loss on change in fair value for the three and six months ended June 30, 2019 was $321,375 and $175,524, respectively. There were no biological assets for the three and six months ended June 30, 2018.

Insurance

Insurance expense increased from nil to $60,584 for the three months ended June 30, 2019 as compared to the equivalent period in the prior year and increased from $74,682 million to $127,065 for the six months ended June 30, 2019 as compared to the equivalent period in the prior year. The increase is primarily due to higher insurance costs on increased value of Company's assets along with public reporting issuer directors and officer's insurance.

Interest expense

Interest expense represents interest expense on lease obligations resulting from adoption of IFRS 16.

Listing expense

The Company recognized listing expense from its reverse takeover transaction in 2018.

Occupancy costs

Occupancy costs decreased from $248,529 to $88,104 for the three months ended June 30, 2019 as compared to the equivalent period in the prior year and increased from $526,508 to $776,077 for the six months ended June 30, 2019 as compared to the equivalent period in the prior year. The decrease for the three months ended June 30, 2019 was due to the allocation of occupancy costs to biological assets and inventory production which were capitalized. For the six months ended June 30, 2019, the increase in costs was due to increased repairs and maintenance on the facility.

Production and growing expenses

Production and growing expenses for the three months ended June 30, 2019 and 2018 were nil. For the six ended June 30, 2019, production and growing costs decreased from $64,727 to $37,440 as compared to the equivalent period in the prior year. The decrease for the six months ended June 30, 2019 was due to the allocation of production and growing expenses to biological assets and inventory production which were capitalized.

Professional fees

Professional fees decreased from $573,700 to $531,591 for the three months ended June 30, 2019 as compared to the equivalent period in the prior year and increased from $631,579 to $884,858 for the six months ended June 30, 2019 as compared to the equivalent period in the prior year. Professional fees primarily include legal and audit fees. Professional fees are dependent on the number and the nature of the transactions the Company undertakes at any given time and will fluctuate from time to time as the Company grows.

Salaries and wages

Salaries and wages increased from $516,032 to $916,523 for the three months ended June 30, 2019 as compared to the equivalent period in the prior year and increased from $647,826 to $1,445,927 for the six months ended June 30, 2019 as compared to the equivalent period in the prior year. The increase is primarily related to the additional hires in late 2018 and 2019 to support the setup and start of the production along with developing a team for the future and addressing human resource gaps. This was partly offset by production related salaries and wages being capitalized to biological assets and inventory.

Shareholder and public company costs

Shareholder and public company costs increased from nil to $50,671 for the three months ended June 30, 2019 as compared to the equivalent period in the prior year and increased from $10,000 to $105,002 for the six months ended June 30, 2019 as compared to the equivalent period in the prior year. The increase is primary due to the Company becoming a public reporting issuer in May 2018.

Share based payments

Share based payments expense increased from $1,390,900 to $5,383,199 for the three months ended June 30, 2019 as compared to the equivalent period in the prior year and increased from $2,076,296 to $5,686,057 for the six months ended June 30, 2019 as compared to the equivalent period in the prior year. The increase is primary due to the significantly higher number of stock options granted during the three months ended June 30, 2019.

Change in fair value of investments

The Company has various investments in other entities that are measured at fair value through profit or loss. The change in fair value of investments during the three months ended June 30, 2019 and 2018 was a loss of $4,460,724 and a gain of $7,500,000, respectively. For the six months ended June 30, 2019 and 2018, the change in fair value was a loss of $3,220,677 and a gain of $7,500,000, respectively. The change in fair value of investments will fluctuate as the fair value of the underlying investments change.

SELECTED QUARTERLY INFORMATION

The following table sets forth selected unaudited quarterly statements of operations data for each of the six quarters commencing January 1, 2018 and ending June 30, 2019. The information for each of these quarters has been prepared on the same basis as the audited annual financial statements for the year ended December 31, 2018 and the unaudited condensed consolidated interim financial statements for the period ended June 30, 2019. This data should be read in conjunction with our audited annual financial statements for the year ended December 31, 2018 and the unaudited condensed consolidated interim financial statements for the period ended June 30, 2019. These quarterly operating results are not necessarily indicative of our operating results for a full year or any future period.

		Net (Loss)		
Quarter Ended	Total Revenue ($)	Total ($)	Per Share ($)	Total Assets ($)
June 30 2019	18,501	(14,245,520)	(0.01)	71,493,830
March 31 2019	18,500	(2,297,286)	(0.00)	51,001,559
December 31 2018	5,575	(12,751,632)	(0.02)	52,776,234
September 30 2018	13,833	(3,018,819)	(0.00)	66,576,844
June 30 2018	29,372	(3,435,409)	(0.00)	52,800,119
March 31 2018	39,983	(3,504,764)	(0.00)	15,331,960

At this point in the Company's development, it does not as yet derive revenues from the sale of cannabis products; the only revenue it generates is from subleasing an unused portion of its Cobourg facility to unrelated third parties.

The Company continues to expend considerable amounts of capital on the development of its business, the continued renovation and build-out of its Cobourg facility, salaries and wages for employees and ongoing operating expenses relating to the management of a public reporting issuer. Net loss for the Company fluctuates significantly as the Company grows along with the fluctuations in fair value of the investments held.

The Company became a public reporting issuer in Q2 of 2018 resulting in recognition of $7.9 million listing expense for the completion of reverse take-over transaction.

Financial position

	As at June 30 2019	As at December 31 2018	Change
ASSETS			
Current			
Cash and cash equivalents	$ 9,843,824	$ 21,134,930	$ (11,291,106)
Sales taxes recoverable	1,589,244	982,663	606,581
Prepaid and other assets	1,322,643	452,424	870,219
Inventory	955,048	-	955,048
Biological assets	229,950	-	229,950
Total current assets	13,940,709	22,570,017	(8,629,308)
Non-current			
Other investments	20,343,864	18,064,541	2,279,323
Property, plant and equipment	12,419,843	12,141,676	278,167
Intangible assets	24,789,414	-	24,789,414
Total non-current assets	57,553,121	30,206,217	27,346,904
Total assets	**$ 71,493,830**	**$ 52,776,234**	**$ 18,717,596**
LIABILITIES			
Current			
Trade payables	$ 2,399,380	$ 1,743,806	$ 655,574
Current portion of lease liability	40,937	-	40,937
Convertible notes	1,727,484	-	1,727,484
Short term notes	195,475	-	195,475
Total current liabilities	4,363,276	1,743,806	2,619,470
Non-current			
Non-current portion of lease liability	182,019	-	182,019
Total liabilities	4,545,295	1,743,806	2,801,489
SHAREHOLDERS' EQUITY			
Class A share capital	201,500	201,500	-
Class B share capital	91,478,775	67,916,302	23,562,473
Warrants	6,327,748	4,442,145	1,885,603
Contributed surplus	12,231,955	4,977,300	7,254,655
Deficit	(43,291,443)	(26,504,819)	(16,786,624)
Total shareholders' equity	66,948,535	51,032,428	15,916,107
Total liabilities and shareholders' equity	**$ 71,493,830**	**$ 52,776,234**	**$ 18,717,596**

Assets

Current assets

Current assets decreased by $8,629,308 primarily due to the decrease in cash and cash equivalents of $11,291,106 which was offset by increase in:

- sales taxes recoverable of $606,581 due to timing of the sales tax eligible expenditures and timing of the filing of the sales tax returns;
- Prepaid and other assets of $870,219 due to deposits on purchases of inventory; and
- Inventory and biological assets of $1,184,998 due to fair value measurement of plants as at June 30, 2019 and harvesting of plants during the six months ended June 30, 2019 which are included in inventory along with purchases of inventory from third parties

Non-current assets

Other investments increased by $2,279,323 primarily due to investments in Aura Health of $3,000,000 million and Solarvest of $2,500,000 offset by recognition of loss on change in fair value of $3,220,677 for the six months ended June 30, 2019.

Property, plant and equipment increased by $278,167 primarily due to the additions of $555,614 offset by depreciation of $277,447.

Intangible assets increased by $24,789,414 from the recognition of intangible assets acquired on acquisition of Prismic on June 28, 2019.

Liabilities

Current liabilities

Current liabilities increased by $2,619,470 primarily due to the liabilities assumed on acquisition of Prismic. This was partly offset by decrease in trade payables (excluding Prismic) due to timing.

Non-current liabilities

Non-current portion of lease liability represents obligations increased by $182,019 due to adoption of IFRS 16 during the period.

Shareholders' equity

Shareholder's equity increased by $15,916,107 primarily due to the consideration issued for acquisition of Prismic and investment in Solarvest. This was partly offset by the net loss of $16,542,806 and recognition of $243,818 through deficit on adoption of IFRS 16.

Liquidity, Capital Resources and Financing

As at June 30, 2019 the Company had cash and cash equivalents of $9,843,824 representing a decrease of $11,291,106 from December 31, 2018. This decrease was primarily due to cash used in operating activities of $11,367,285 for the six months ended June 30, 2019.

For the six months ended June 30, 2019, the Company incurred net loss and comprehensive loss of $16,542,806 and financed its operations and met its capital requirements primarily through equity raises from fiscal 2018.

The Company believes it has sufficient liquidity to support continued operations and to meet its short-term liabilities and commitments as they become due. The Company manages its liquidity risk by monitoring its operating requirements. The Company prepares budget and cash forecasts to ensure it has sufficient funds to fulfill obligations. In managing working capital, the Company may, where necessary, limit or control the amount of working capital used for operations or other initiatives, pursue additional financing, manage the timing of its expenditures, or sell assets. The Company is not subject to externally imposed capital requirements.

While the Company believes that it has the ability to generate sufficient amounts of cash, in the short term and long term, to maintain current operational capacity, additional sources of capital and/or financing will be required to meet planned growth requirements and to fund development activities at the operating facility. Liquidity will fluctuate based on demand for working capital resources required for these initiatives.

The Company is subject to risks and uncertainties that could significantly impair its ability to raise funds through debt or equity or to generate profits sufficient to meet future obligations, operational, or development needs. See "Risks and Uncertainties" for information on the risks and uncertainties that could have a negative effect on the Company's liquidity.

Statements of cash flows

	Six months ended June 30,	
	2019	2018
	$	$
Cash and cash equivalents	9,843,824	31,704,577
Net cash provided by (used in):		
Operating activities	(11,367,285)	(4,323,260)
Investing activities	(553,285)	(4,442,265)
Financing activities	629,464	35,730,114
Net (decrease) increase in cash and cash equivalents	(11,291,106)	26,964,589

Cash Flows Used in Operating Activities
Cash flows used in operating activities for the six months ended June 30, 2019 were $11,367,285 compared to cash flows used in operating activities of $4,323,260 for the six months ended June 30, 2018. The increase in cash flows used in operating activities was primarily the result of an increase in net loss of $10,873,075 as well as decrease of $3,019,746 in cash flows from changes in working capital offset by non-cash expenses by $6,848,796 for the six months ended June 30, 2019.

Cash Flows Used in Investing Activities
Cash flows used in investing activities for the six months ended June 30, 2019 were $553,285 compared to $4,442,265 for the six months ended June 30, 2018. The decrease in cash outflows for investing activities of $3,888,980 was due to a decrease in additions to property, plant and equipment of $2,686,660 and decrease in other investments of $1,199,991.

Cash Flows from Financing Activities
Cash flows from financing activities for the six months ended June 30, 2019 was $629,464 compared to $35,730,114 for the six months ended June 30, 2018. The decrease in cash inflows from financing activities of $38,255,695 was mainly due to the $35.7 million financing during the six months ended June 30, 2018 as compared to the issuance of $0.6 million of shares issued as a result of stock options exercised in the six months ended June 30, 2019.

DISCLOSURE OF OUTSTANDING SHARE DATA

The Company's outstanding capital was as follows as at the dates indicated:

	June 30 2019		August 23 2019	
	Basic	Diluted	Basic	Diluted
Class A voting	15,000	15,000	15,000	15,000
Class B subordinate voting	1,516,019,834	1,801,396,982	1,527,686,831	1,801,396,982
Stock options	162,040,267		150,373,270	
Warrants	123,336,881		123,336,881	

TRANSACTIONS WITH RELATED PARTIES

Key management personnel are defined as those individuals having authority and responsibility for planning, directing, and controlling the activities of the Company. Compensation to those individuals during the 6 month period ended June 30, 2019 included:

(a) The Company's President and a director received salary compensation of $137,500 (2018 - $437,500) and a car allowance of $9,000 (2018 - $9,000).

(b) The former President and Chief Executive Officer of FV Pharma Inc. received salary compensation of $96,250 (2018 - $496,250) and a car allowance of $4,500 (2018 - $9,000). He also received termination pay of $770,000 in 2019 as a retirement benefit.

(c) The Company's Chief Financial Officer received the amount of $96,000 in management fees (2018 - $12,000), which fees were paid to a private company controlled by him.

(d) The current President of FV Pharma Inc. received salary compensation of $70,500 (2018 - $nil) and a car allowance of $2,400 (2018 - $nil).

(e) Certain independent directors of the Company are being remunerated at the rate of $40,000 per year with a Chairman of any committee of the Board receiving an additional $10,000 per year. For the period ended June 30, 2019, the Company's independent directors were paid the amount of $61,667 (2018 - $6,666), of which $43,333 is included in accounts payable. The amount is unsecured, non-interest bearing and due on demand.

(f) All directors and officers of the Company are eligible to participate in the Company's stock option plan. During 2019 and 2018, certain directors and officers were granted options to purchase Class B shares of the Company, some of which were exercised and the remainder being held as at June 30, 2019. Aggregate stock option values as calculated by the Black Scholes option pricing model are disclosed in the table below.

(g) The Company's former Chief Operating Officer received consulting fees of $16,667 (2018 - $50,000) and a car allowance of $nil (2018 - $2,250) during the period ended June 30, 2019, which were paid to a company controlled by him.

(h) The Company's former Chief Financial Officer received consulting fees of $26,500 during the period ended June 30, 2018 and a car allowance of $1,500.

(i) Key management personnel compensation during the period is comprised of:

	June 30 2019 ($)	June 30 2018 ($)
Salaries and benefits	1,319,443	251,750
Bonuses	-	700,000
Share based payments	4,021,830	-

CRITICAL ACCOUNTING ESTIMATES, JUDGMENTS, ACCOUNTING POLICIES AND PRONOUNCEMENTS

Critical Accounting Estimates

Financial reporting requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the reporting date and reported amounts of revenues and expenses during the reporting period. Actual outcomes could differ from these estimates. Financial statements include estimates that, by their nature, are uncertain. The impacts of such estimates are pervasive throughout the financial

statements, and may require accounting adjustments based on future occurrences. Revisions to accounting estimates are recognized in the period in which the estimate is revised and future periods if the revision affects both current and future periods. These estimates are based on historical experience, current and future economic conditions and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

The following are the critical judgments and estimate areas that have the most significant effect on the amounts recognized in consolidated financial statements:

Business combinations

Judgment is used in determining whether an acquisition is a business combination or an asset acquisition.

Biological assets and inventory

In calculating the value of the biological assets and inventory, management is required to make a number of estimates, including estimating the stage of growth of the cannabis up to the point of harvest, harvesting costs, selling costs, average or expected selling prices and list prices, expected yields for the cannabis plants, and oil conversion factors. In calculating final inventory values, management compares the inventory cost to estimated net realizable value.

Estimated useful lives and depreciation and amortization of property, plant and equipment

Depreciation and amortization of property, plant and equipment is dependent upon estimates of useful lives and the determination as to when an items of property, plant and equipment is ready for use, which are determined through the exercise of judgment. The assessment of any impairment of these assets is dependent upon estimates of recoverable amounts that take into account factors such as economic and market conditions and the useful lives of assets.

Share-based payments

In calculating the share-based payments expense, key estimates such as the rate of forfeiture of options granted, the expected life of the option, the volatility of the Company's stock price and the risk free interest rate are used. To calculate the share-based payments expense related to key employee performance milestones associated with the terms of an acquisition, the Company must estimate the number of shares that will be earned and when they will be issued based on estimated discounted probabilities.

Fair value of other investments not quoted in an active market or private company investments

Where the fair values of financial assets and financial liabilities recorded on the consolidated statement of financial position cannot be derived from active markets, they are determined using a variety of valuation techniques. The inputs to these models are derived from observable market data where possible, but where observable market data are not available, judgment is required to establish fair values.

Critical accounting judgments

Income, value added, withholding and other taxes

The Company is subject to income, value added, withholding and other taxes. Significant judgment is required in determining the Company's provisions for taxes. There are many transactions and calculations for which the ultimate tax determination is uncertain during the ordinary course of business. The Company recognizes liabilities for anticipated tax audit issues based on estimates of whether additional taxes will be due. The determination of the Company's income, value added, withholding and other tax liabilities requires interpretation of complex laws and regulations. The Company's interpretation of taxation law as applied to transactions and activities may not coincide with the interpretation of the tax authorities. All tax related filings are subject to government audit and potential reassessment subsequent to the financial statement reporting period. Where the final tax outcome of these matters

is different from the amounts that were initially recorded, such differences will impact the tax related accruals and deferred income tax provisions in the period in which such determination is made.

Recognition of deferred taxes

Deferred tax assets are recognized in respect of tax losses and other temporary differences to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Judgment is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and level of future taxable profits, together with future tax planning strategies.

Restoration, rehabilitation and environmental obligations

Management's assumption of no material restoration, rehabilitation and environmental exposure, is based on the facts and circumstances that existed in the current and prior periods.

Contingencies

See note 19 of the consolidated unaudited interim financial statements for the period ended March 31 2019.

Accounting policies

Reference is made to the Company's audited financial statements for a full discussion of its significant accounting policies.

Recent accounting pronouncements

Effective January 1 2019, the Company has adopted the following new and revised standard, along with any consequential amendments. These changes were made in accordance with the applicable transitional provisions.

IFRS 16 – Leases ("IFRS 16") was issued in January 2016 and replaces IAS 17 – Leases, as well as some lease related interpretations. With certain exceptions for leases under twelve months in length or for assets of low value, IFRS 16 states that upon lease commencement a lessee recognises a right-of-use asset and a lease liability. The right-of-use asset is initially measured at the amount of the liability plus any initial direct costs. After lease commencement, the right-of-use asset is measured at cost less accumulated depreciation and accumulated impairment. Effective January 1, 2019, the Company adopted this standard using the modified retrospective approach.

For contracts entered into before January 1, 2019, the Company determined whether the arrangement contained a lease under IAS 17 Leases ("IAS 17") and its interpretive guidance. Prior to the adoption of IFRS 16, these leases were classified as operating or finance leases based on an assessment of whether the lease transferred significantly all the risks and rewards of ownership of the underlying asset.

Upon transition to the new standard, lease liabilities were measured at the present value of the remaining lease payments discounted by the Company's incremental borrowing rate as at January 1, 2019. Right-of-use assets and lease liabilities were recognized on the consolidated statement of financial position.

At transition, lease liabilities of $243,818 and right-of-use assets of $243,818 were recognized in the consolidated statement of financial position.

IFRS 3 – Business Combinations ("IFRS 3") was amended in October 2018 to clarify the definition of a business. This amended definition states that a business must include inputs and a process and clarified that the process must be substantive and the inputs and process must together significantly contribute to operating outputs. In addition it narrows the definitions of a business by focusing the definition of outputs on goods and services provided to customers and other income from ordinary activities, rather than on providing dividends or other economic benefits directly to investors or lowering costs and added a test that makes it easier to conclude that a company has acquired a group of assets, rather than a business, if the value of the assets acquired is substantially all concentrated

in a single asset or group of similar assets. The Company early adopted the amendments to IFRS as of January 1, 2019.

Accounting Standards Issued But Not Yet Applied

Certain new standards, interpretations, amendments and improvements to existing standards were issued by the IASB or IFRIC that are mandatory for accounting periods beginning on January 1 2020 or later. Updates that are not applicable or are not consequential to the Company have been excluded. The following have not yet been adopted and are being evaluated to determine their impact on the Company.

IAS 1 – Presentation of Financial Statements ("IAS 1") and IAS 8 – Accounting Policies, Changes in Accounting Estimates and Errors ("IAS 8") were amended in October 2018 to refine the definition of materiality and clarify its characteristics. The revised definition focuses on the idea that information is material if omitting, misstating or obscuring it could reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. The amendments are effective for annual reporting periods beginning on or after January 1 2020. Earlier adoption is permitted.

RISKS AND UNCERTAINTIES

The risks and uncertainties described below are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any event arising from these risks occurs, the Company's business, results of operations, financial condition or prospects, could be materially adversely affected. The risks discussed below include forward-looking statements, and our actual results may differ materially from those discussed in these forward-looking statements. See "*Forward Looking Statements*".

Risks Related to the Cannabis Production Business

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

The continuation and development of the Company's business is dependent on the good standing of the License and any other permits or approvals required to engage in such activities and upon adhering to all regulatory requirements related to such activities.

Failure to comply with the requirements of the License or any failure to maintain the License would have a material adverse impact on the business, financial condition and operating results of the Company. Although the Company believes it will meet the requirements of the Cannabis Act and Cannabis Regulations for future extensions or renewals of its License, there can be no guarantee that Health Canada will extend or renew the License or that, if extended or renewed, the License will be extended or renewed on the same or similar terms. Should Health Canada not extend or renew the License or should it renew the License on different terms, the business, financial condition and results of the operation of the Company would be materially and adversely affected.

The Company's limited operating history makes it difficult to evaluate its current business and future prospects and may increase the risk that it will not be successful.

While FV Pharma was incorporated and began carrying on business in 2011 it has yet to generate significant revenue. Other than the Facility, the Company has no significant assets or other financial resources. See *"–The Company is reliant on the Facility as its only property for cannabis cultivation and related ancillary businesses and adverse changes or developments affecting the Facility will have an adverse impact on the Company*". The Company is therefore subject to many of the risks common to early-stage enterprises, including undercapitalization, cash shortages, limitations with respect to personnel, financial, and other resources and lack of revenues. The Company's limited operating history makes it difficult to evaluate its current business and future prospects. There is no assurance that the Company will be successful in achieving a return on shareholders' investment and the likelihood of success must be considered in light of the early stage of operations.

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

The Company's auditor has indicated in the Company's audited annual financial statements that there is substantial doubt about the Company's ability to continue as a going concern. The Company 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 Company and the recoverability of amounts shown for property, plant and equipment in the Company's audited annual financial statements are dependent upon the ability of the Company to obtain sufficient financing to complete the development of its facilities and extraction processes, and if they are proven successful, the existence of future profitable production, or alternatively, upon the Company's ability to dispose of its interest on an advantageous basis, all of which are uncertain. Importantly, the inclusion in the Company's financial statements of a going concern opinion may negatively impact the Company's ability to raise future financing and achieve future revenue. If the Company is unable to obtain additional financing from outside sources and/or eventually generate enough revenues, the Company may be forced to sell a portion or all of the Company'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 Company's financial statements do not include any adjustments to the Company's recorded assets or liabilities that might be necessary if the Company becomes unable to continue as a going concern. See *"– The Company may be unable to raise the capital necessary for it to execute its strategy on favorable terms or at all*".

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

Pharmaceutical and biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Prismic is a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate its business and prospects. In addition, PP-101 is in the pre-clinical development phase. Our product candidates will require substantial additional development time, including extensive clinical research, and resources before it would be able to apply for or receive regulatory approvals and begin generating revenue from product sales.

We have no pharmaceutical products approved for commercial sale and have not generated any revenue from pharmaceutical product sales. We will 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 one or more pharmaceutical product candidates.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of its expenses, or when it will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. 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 or the development of our pharmaceutical product candidates that it may identify. Even if our future pharmaceutical product candidates that we may identify are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved pharmaceutical product candidate and ongoing compliance efforts.

We may never be able to develop or commercialize a marketable drug or achieve profitability. Revenue from the sale of any product candidate for which 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 such products, even if approved. Even if we are able to generate revenue from the sale of any approved products, 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 our product candidates, if approved, that we may identify and pursue or continue our operations.

The Company 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 Company has incurred losses since its inception in 2011. The Company may not be able to generate revenue, achieve or maintain profitability and may continue to incur significant losses in the future. In addition, the Company expects to continue to increase operating expenses as it implements initiatives to continue to grow its business. If the Company'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 Company 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 Company 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 Company's cannabis operations will require significant additional financing over several years. To achieve our ultimate objective of 3,800,000 square feet dedicated to cannabis cultivation and related ancillary business all under one roof, multiple rounds of additional funding will be required. The failure to raise such capital could result in the delay or indefinite postponement of current business strategy or the Company ceasing to carry on business. There can be no assurance that additional capital or other types of financing will be available if needed or that, if available, the terms of such financing will be favorable to the Company, at times for reasons beyond the Company's control. For example, economic downturns or uncertain market conditions, whether affecting the economy in general or the cannabis industry in particular, could adversely impact the Company's ability to raise capital through equity or debt financing. In addition, any further issuances of equity securities could have a significant dilutive effect on the holders of Class B Shares.

In addition, from time to time, the Company 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 Company'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 Company to obtain additional capital and to pursue business opportunities, including potential acquisitions.

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

The Company'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 Company's founders, Thomas Fairfull, Zeeshan Saeed and Anthony Durkacz. See "*Principal Shareholders*". Class A Shares have 276,660 votes per share and Class B Shares have one vote per share. Shareholders who hold Class A Shares together hold approximately 79% of the voting power of the Company's outstanding voting shares and

therefore have significant influence over management and affairs of the Company 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 Company'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 Company's directors and officers owes a fiduciary duty to the Company and must act honestly and in good faith with a view to the best interests of Company. 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 Company's shareholders generally. The inability of the Class B Shares to control the matters affecting the Company, combined with the ability of holders of Class A Shares to control matters affecting the Company 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 Company is subject to risks inherent in an agricultural business.

The Company's business involves the growing of cannabis, an agricultural product. Such business is subject to the risks inherent in the agricultural business, such as insects, plant diseases and similar agricultural risks. Although all such growing is expected to be completed indoors under climate controlled conditions, there can be no assurance that natural elements will not have a material adverse effect on any such future production. In addition, if the Company cannot successfully develop its products, or if the Company experiences difficulties in the development process, such as quality control problems or other disruptions, the Company may not be able to develop market-ready commercial products at acceptable costs, which would affect its ability to successfully enter the market.

The Company is vulnerable to rising energy costs

The Company's cannabis growing operations consume considerable energy, which make the Company vulnerable to rising energy costs. Accordingly, rising or volatile energy costs may adversely impact the business of the Company and its ability to operate profitably.

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

Any adverse changes affecting the development or construction of the Facility and expansion of production could have a material and adverse effect on the Company's business, financial condition and prospects. See "*—The expansion of the Facility is subject to various potential problems and uncertainties and may be delayed or adversely affected by a number of factors beyond the Company's control*". There is a risk that these changes or developments could adversely affect the Facility due to a variety of factors, including some that are discussed elsewhere in these risk factors and the following:

- delays in obtaining, or conditions imposed by, regulatory approvals;
- plant design errors;
- environmental pollution;
- non-performance by third party contractors;
- increases in materials or labour costs;
- construction performance falling below expected levels of output or efficiency;
- breakdown, aging or failure of equipment or processes;
- contractor or operator errors;
- labour disputes, disruptions or declines in productivity;
- inability to attract sufficient numbers of qualified workers;
- disruption in the supply of energy and utilities; or
- major incidents and/or catastrophic events such as fires, explosions, earthquakes or storms.

It is also possible that the costs of maintaining and expanding production may be significantly greater than anticipated by the Company's management, and may be greater than funds available to the Company, including through additional financing, in which case the Company may curtail or extend the timeframes for completing its business plans. This could have an adverse effect on the financial results of the Company.

In addition, any potential expansion of the Facility is subject to Health Canada regulatory approvals. While management currently holds the requisite approvals for the expansion of 30,000 square feet of the Facility, the delay or denial of approvals of additional expansion may have a material adverse impact on the business and may result in the Company not meeting anticipated or future demand when it arises.

The success of the Company 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 Company'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 Company 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 Company 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 Company. On March 13, 2019, the Company announced the departure of Thomas Fairfull as President of FV Pharma and the subsequent appointment of Sara May as President of FV Pharma. On June 3, 2019, the Company 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 Company'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 Company 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 Company's business, operating results or financial condition.

In addition, the Company'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 Company may incur significant costs to attract and retain them, if it is able to hire them at all.

The Company 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 Company 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 Company in respect of any such liabilities. The Company is also subject to zoning and other local regulations that may interfere with the Company's activities. For example, several buildings on the Company's property have been designated by the Town of Cobourg as buildings of cultural heritage value under the Ontario Heritage Act and the Company 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 Company is subject to insurance risks.

The Company'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 Company 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 Company 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 Company is not generally available on acceptable terms. The Company might also become subject to liability for pollution or other hazards which may not be insured against or which the Company may elect not to insure against because of premium costs or other reasons. Losses from these events may cause the Company to incur significant costs that could have a material adverse effect upon its business, results of operations, financial condition and prospects.

The Company may not be able to realize its cannabis production targets.

Our ability to produce cannabis is affected by a number of factors, including plant design errors, non-performance by third party contractors, increases in materials or labour costs, construction performance falling below expected levels of output or efficiency, environmental pollution, contractor or operator errors, breakdowns, aging or failure of equipment or processes, labour disputes, receipt of regulatory approvals as well as factors specifically related to indoor agricultural practices, such as reliance on provision of energy and utilities to the facility, and potential impacts of major incidents or catastrophic events on the facility, such as fires, explosions, earthquakes or storms. See *"– The expansion of the Facility is subject to various potential problems and uncertainties and may*

be delayed or adversely affected by a number of factors beyond the Company's control". Should any such factors materialize it could have a material adverse effect on our cannabis production and results of operations.

Any significant interruption in the supply chain for key inputs could materially impact the Company'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 Company will be successful in maintaining its required supply of skilled labour, specialized knowledge, equipment, parts and components.

The ability of the Company to compete and grow cannabis will be dependent on it having access to, at a reasonable cost and in a timely manner, skilled labour, individuals with specialized knowledge, equipment, parts and components. No assurances can be given that the Company will be successful in maintaining its required supply of skilled labour, individuals with specialized knowledge, equipment, parts and components. It is also possible that the final costs of the major equipment contemplated by the Company may be significantly greater than anticipated by management, and may be greater than funds available, in which circumstance the Company 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 Company.

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. See *"–Companies existing in the markets for the medical and recreational cannabis products face substantial competition and in particular the legalization of recreational cannabis may result in increased levels of competition in the overall cannabis market*". In particular, specialized knowledge with respect to cultivating and growing medical cannabis and processing such materials into THC and CBD concentrates and derivative products is important to the industry. If we are unable to identify, attract, hire and retain qualified personnel in the future, such inability could have a material adverse effect on our business, operating results and financial condition.

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

The proposed activities and resources of the Company's production division are primarily focused within the Facility. The Company's operations and the conditions of the Facility is, and will be, subject to hazards inherent in the cannabis industry, including, but not limited to, equipment defects, equipment malfunctions, natural disasters, fire, explosions, disease or infestation of our crops, power failures or other accidents that may cause damage to the Facility, or a material failure of the Company's security infrastructure, could reduce or require us to entirely suspend our production of cannabis. A significant failure of the Facility's security measures and other requirements, including any failure to comply with regulatory requirements, could have an impact on our ability to continue operating under our existing Health Canada licenses. In addition, development impediments such as construction delays or cost over-runs in respect to the development of the Facility, will delay or prevent our ability to produce cannabis at the Facility. Any adverse changes or developments affecting the Facility could have a material and adverse effect on the Company's business, financial condition and prospects.

The expansion of the Facility is subject to various potential problems and uncertainties and may be delayed or adversely affected by a number of factors beyond the Company's control.

Any expansion of the Facility is subject to various potential problems and uncertainties, and may be delayed or adversely affected by a number of factors beyond the Company's control. These uncertainties include the failure to obtain regulatory approvals, permits, delays in the delivery or installation of equipment by suppliers, difficulties in integrating new equipment with existing facilities, shortages in materials or labor, defects in design or construction, diversion of management resources, and insufficient funding or other resource constraints. The actual cost of

construction may exceed the amount budgeted for expansion. As the result of construction delays, cost overruns, changes in market circumstances or other factors, the Company may not be able to achieve the intended economic benefits from any expansion of operations at the existing facility, which in turn may affect the Company's business, results of operations, financial condition and prospects.

Three buildings that are part of the Facility have been designated by the Town of Cobourg as heritage buildings. The buildings must be retained, and the Company must follow the Town's by-laws and official plan regulations with respect to expansion and upkeep. The Company continues to work with various contractors and the Town to ensure the buildings are retained and restored. The cost to restore one of the buildings in particular is expected to be significant and future costs with respect to restoration and upkeep are unknown.

The Company was previously party to a joint venture with Auxly, whereby the parties agreed to combine their respective capabilities to develop and expand certain portions of the Facility in mutually agreed upon phases on identified areas within the Facility. Under the Auxly Agreement, Auxly assumed primary carriage through the implementation of each project phase at the Facility, including, but not limited to: the design of each phase of development at the Facility and the management and supervision of all professional services performed in connection therewith, including architectural services, engineering services, construction services and security services; assisting in the hiring, training and oversight of professional and operational staff; and assisting with the regulatory licensing process including facilitating interaction between the Company and Health Canada. The Auxly Agreement also provided that Auxly had primary responsibility for financing and/or sourcing the funds required for the capital expenditures for each project phase at the Facility, to be comprised of both equity and debt financing provided directly by Auxly or by a third party lender arranged for and designated by Auxly.

It had been anticipated by the Company and Auxly that the first phase of construction would be completed and ready for Health Canada approval by the end of December 2018, but this did not materialize. On February 6, 2019, the Company terminated the Auxly Agreement. Auxly claims that it identified contractual breaches relating to the Company's management and staffing obligations of the Facility, as well as significant concerns regarding certain aspects of the Facility's infrastructure. The Company maintains that it terminated the Auxly Agreement in response to Auxly's failure to perform its obligations under the Auxly Agreement to develop all aspects of the Facility in mutually agreed upon staged phases.

The Company has retained Matheson Constructors Limited to continue the expansion of the Facility, however, as a result of the termination of the Auxly Agreement, the first phase of the expansion of the Facility to create an approximately 30,000 square foot self-contained cultivation facility, including GMP processing spaces, is not expected to be completed until the end of the first quarter of 2020. One of the Company's goals is still to further expand the Facility; however, the expansion of the Facility is subject to various challenges and uncertainties. Additional phases of development may suffer from delays, cancellations, interruptions or increased costs due to many factors, some of which may be beyond the Company's control, including, without limitation: construction performance falling below expected levels of output or efficiency; denial or delays in receipt of regulatory approvals; additional requirements imposed by changes in laws or non-compliance with conditions imposed by regulatory approvals; labour disputes or disruptions or the unavailability of skilled labour; increases in costs of materials; additional requirements imposed by changes in laws, including environmental laws; availability of capital; sufficiency of demand for products to warrant continued expansion; and changes in project scope of errors in design.

The continued development of the Facility will require significant additional financing over the next several years. The failure to raise such capital could result in the delay or indefinite postponement of completing the Facility and there is no guarantee that the Company will be able to raise such capital and achieve the full or partial expansion of the Facility. See *"—The Company be unable to raise the capital necessary for it to execute its strategy on favorable terms or at all*".

The Company 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 Company's business, results of operations, financial conditions and prospects.

The Company may be subject to growth-related risks including capacity constraints and pressure on its internal systems and controls. The ability of the Company 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 Company to deal with this growth may have a material adverse effect on the Company'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 Company to provide reliable financial reports and to help prevent fraud. Although the Company 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 Company under Canadian securities law, the Company cannot be certain that such measures will ensure that the Company will maintain adequate control over financial processes and reporting. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm the Company's results of operations or cause it to fail to meet its reporting obligations. The Company 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 Company or its auditors discover a material weakness, the disclosure of that fact, even if quickly remedied, could reduce the market's confidence in the Company'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.

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

In contrast to the certificates that will be required of the Company pursuant to Rule 15d-14(a) under the Exchange Act as a public company in the United States and the certificates required under National Instrument 52-109 Certification of Disclosure in Issuers' Annual and Interim Filings ("**NI 52-109**"), the Company utilizes the Venture Issuer Basic Certificate which does not include representations relating to the establishment and maintenance of DCP and ICFR. In particular, the certifying officers who have filed the Company's certificates have not made any representations relating to the establishment and maintenance of: (a) controls and other procedures designed to provide reasonable assurance that information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and (b) a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS.

We will incur increased costs as a result of operating as a public company in the United States and our management will be required to devote substantial time 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 Company 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 Company's business, results of operations, financial condition and prospects, including its future prospects for acquisitions or partnerships. There is no assurance that the Company 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 Company 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. Current examples include the Company's letter of intent with Solarvest and its memoranda of understanding with SciCann. The Company 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 Company 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 Company is reliant on the operations of its partners and has little or no control over such operations.

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

objectives; (iii) be unable or unwilling to fulfill their obligations under their agreements with the Company; 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 Company'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 Company is entitled may have a material adverse effect on the Company. In addition, the Company 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 Company by its partners contains material inaccuracies or omissions, the Company's ability to accurately forecast or achieve its stated objectives, or satisfy its reporting obligations, may be materially impaired.

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

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

The Company terminated the Auxly Agreement on February 6, 2019 by sending a Notice of Default to Auxly. Later that same day, Auxly sent a Notice of Default to the Company 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 Company. To date, neither party has taken any steps to commence litigation with respect to the termination of the Auxly Agreement.

The Company is currently a defendant to a proposed class action lawsuit launched on February 22, 2019. The plaintiff shareholder alleges that the Company misrepresented information with respect to the progress of the build-out of the first phase the Facility by the Company and Auxly. When the Company 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 Company'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 MD&A, 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 Company in various purported damages. The Company intends to defend the breach of contract action and has taken steps to obtain particulars and inspect documents of the plaintiff.

The Company 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 Company and its directors and officers as a result of other business activities undertaken by such individuals.

Certain directors and officers of the Company are, and may in the future become, directors and officers of other entities, or are otherwise engaged, and will continue to be engaged, in activities that may put them in conflict with the business strategy of the Company. In particular: the Company'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 Company's interim chief financial officer, Donal Carroll, currently is also a director of World Class and Bird River Resources Inc.; and the Company's executive co-chairman of the board, Anthony Durkacz, is currently a director and executive vice president at First Republic Capital

Company, which has acted as the exclusive agent of the Company and has raised approximately $53 million of equity capital for the Company to date in such capacity with First Republic Capital Company. Mr. Durkacz is also a director of World Class and of iWallet Company. Sara May, President of FV Pharma, is a director of Cannara. Gerry Goldberg, a director of the Company, is also a director of Capicorn Business Acquisition Inc., Baymount Incorporated, Leo Acquisitions Corp. and Osoyoos Cannabis Inc. David Urban, a director of the Company, is also a director of Virtu Financial, Inc. 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 Company'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 Company'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 Company. Circumstances (including with respect to future corporate opportunities) may arise that may be resolved in a manner that is unfavorable to the Company. 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 Company has not paid dividends in the past and does not anticipate paying dividends in the near future.

The Company has not paid dividends in the past and does not anticipate paying dividends in the near future. The Company expects to retain earnings to finance the development and enhancement of its products and to otherwise reinvest in the Company'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 Company'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.

Risks Related to the Medical Cannabis Industry

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

The Company operates in a new industry which is highly regulated and is in a market that is very competitive and evolving rapidly. The Company's operations are subject to various laws, regulations and guidelines by governmental authorities, particularly Health Canada, relating to the manufacture, marketing, management, transportation, storage, sale and disposal of medical marijuana, and also including laws and regulations relating to health and safety, the conduct of operations and the protection of the environment. Laws and regulations, applied generally, grant government agencies and self-regulatory bodies broad administrative discretion over the activities of the Company, including the power to limit or restrict business activities as well as impose additional disclosure requirements on the Company's products and services. The Company's business objectives are, in part, contingent upon compliance with regulatory requirements enacted by these governmental authorities and obtaining all regulatory approvals, where necessary, for the sale of its products. The Company cannot predict the time required to secure all appropriate regulatory approvals for its products, or the extent of testing and documentation that may be required by governmental authorities. Any delays in obtaining, or failure to obtain regulatory approvals would significantly delay the development of markets and products and could have a material adverse effect on the business, results of operations and financial condition of the Company.

Although the operations of the Company are currently carried out in accordance with all applicable rules and regulations, no assurance can be given that new rules and regulations will not be enacted or that existing rules and regulations will not be applied in a manner which could limit or curtail the Company's ability to produce or sell medical or recreational cannabis, should it decide to apply for a license to sell recreational cannabis in the future. Amendments to current laws and regulations governing the importation, distribution, transportation and/or production of medical or recreational cannabis, more stringent implementation thereof or other unanticipated events could have a material adverse impact on the business, financial condition and operating results of Company. In addition, the Company incurs ongoing costs and obligations related to regulatory compliance. Failure to comply with regulations may result in additional costs for corrective measures, penalties or restrictions on our operations. In addition, changes in regulations, more vigorous enforcement thereof or other unanticipated events could require extensive changes to our operations, increased compliance costs or give rise to material liabilities, which could have a material adverse effect on the business, results of operations and financial condition of our business.

To the knowledge of management, the Company is currently in compliance under the Cannabis Act. Failure to comply with the laws and regulations applicable to its operations may lead to possible sanctions including the revocation or imposition of additional conditions on its licenses to operate the Company's business; the suspension or expulsion from a particular market or jurisdiction or of its key personnel; and the imposition of fines and censures. To the extent that there are changes to the existing or the enactment of future laws and regulations that affect the sale or offering of the Company's product or services in any way it may have a material adverse effect on our business, financial condition and results of operations.

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

The Company's operations are subject not only to a variety of laws, regulations and guidelines relating to the manufacture, management, transportation, storage and disposal of medical cannabis, but also to regulations relating to health and safety, privacy, the conduct of operations and the protection of the environment in the jurisdictions in which they operate. Changes to such laws, regulations and guidelines, including changes related to government taxes and levies, may materially and adversely affect the Company's businesses, financial conditions and results of operations.

The Cannabis Act came into effect on October 17, 2018 to create a regulated adult-use recreational market for cannabis in Canada. The Cannabis Act and Cannabis Regulations prohibit testimonials, lifestyle branding and packaging as well as certain other promotional activity that is appealing to youth and set out broad prohibitions on

the promotion of cannabis at the federal level. Such regulations are applicable to both medical and recreational cannabis products. Provincial or territorial governments may add an additional layer of regulations on promotion of cannabis. The federal, provincial and territorial restrictions on advertising, marketing and the use of logos and brand names may reduce the value of certain of our products and brands or negatively impact our ability to compete with other companies in the cannabis market, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, the governments of every Canadian province and territory have enacted and implemented their respective regulatory regimes for the distribution and sale of cannabis for adult-use purposes within those jurisdictions. The provincial or territorial legislation and regulatory regimes may change in ways that impact our ability to continue our business as currently conducted or proposed to be conducted. There is no guarantee that provincial or territorial regulatory regimes governing the distribution and sale of cannabis for adult-use recreational purposes in each jurisdiction will remain as currently enacted or that any such legislation and regulation will create the growth opportunities that we currently anticipate. The federal and provincial or territorial legislation and regulatory regimes for cannabis products also include excise duties payable by licensed cannabis producers on adult-use recreational cannabis products, in addition to goods and services tax/harmonized sales tax in certain provinces and territories. The rate of the excise duties for cannabis products varies by province and territory. Any significant increase in the rate of excise duties on cannabis products in the future could reduce consumer demands for cannabis products and adversely impact the adult-use recreational cannabis industry and the medical cannabis market in general. In addition, any increase in the rate of excise duties on cannabis products in the future could reduce our margins and profitability in the event that we could not or chose not to pass along such increases to consumers. Any of the foregoing could result in a material adverse effect of our business, results of operations, financial condition and prospects.

The adult-use recreational cannabis industry and market in Canada shares many of the risks that are currently applicable to the medical cannabis market, which are described elsewhere in this "*Risk Factors*" section. If any of these shared risks occur, our business, results of operations, financial condition and prospects could be adversely affected in a number of ways, including by not being able to successfully compete in the cannabis industry generally and by being subject to fines, damage awards and other penalties as a result of regulatory infractions or other claims brought against us.

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

The market for cannabis (including medical and recreational cannabis) in Canada is regulated by the Cannabis Act, the Narcotic Control Regulations, and other applicable law. Health Canada is the primary regulator. The Cannabis Act aims to treat cannabis like any other narcotic used for medical purposes by creating conditions for a new commercial industry that is responsible for its production and distribution.

The Cannabis Act will subject the Company to stringent ongoing compliance and reporting requirements. Failure to comply with the requirements of its License or any failure to maintain the License could have a material adverse impact on the business, financial condition and operating results of the Company. Furthermore, the License has an expiry date of October 13, 2020. Upon expiration of the License, the Company will be required to submit an application for renewal to Health Canada containing information prescribed under the Cannabis Act and any such renewal cannot be assured.

Applicants and licensed producers are required to demonstrate compliance with regulatory requirements, such as quality control standards, record-keeping of all activities as well as inventories of cannabis, and physical security measures to protect against potential diversion. Licensed producers are also required to employ qualified quality assurance personnel who ultimately approve the quality of the product prior to making it available for sale. This approval process includes testing (and validation of testing) for microbial and chemical contaminants to ensure that they are within established tolerance limits for herbal medicines for human consumption as required under the Food and Drugs Act, and determining the percentage by weight of the two active ingredients of cannabis, delta-9-Tetrahydrocannabinol and cannabidoil.

The Company may not be able to successfully develop new products or find a market for their sale.

The medical cannabis industry and the recreational cannabis industry are in their early stages of development and it is likely that we, and our competitors, will seek to introduce new products in the future. In attempting to keep pace with any new market developments, we may need to expend significant amounts of capital in order to successfully develop and generate revenues from new products introduced by us. As well, we may be required to obtain additional regulatory approvals from Health Canada and any other applicable regulatory authority, which may take significant amounts of time. We may not be successful in developing effective and safe new products, bringing such products to market in time to be effectively commercialized, or obtaining any required regulatory approvals, which, together with any capital expenditures made in the course of such product development and regulatory approval processes, may have a material adverse effect on our business, financial condition and results of operations.

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

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

In the future, cannabis producers in Canada may produce more cannabis than is needed to satisfy the collective demand of the Canadian adult-use recreational and medical markets, and they may be unable to export that oversupply into other markets where cannabis use is fully legal under all applicable jurisdictional laws. As a result, the available supply of cannabis could exceed demand, resulting in a significant decline in the market price for cannabis. If such supply or price fluctuations were to occur, our revenue and profitability may fluctuate materially and our business, results of operations, financial condition and prospects may be adversely affected.

The barriers to entry into the Canadian cannabis market are low, as the most significant hurdle to becoming a licensed producer is obtaining a license from Health Canada. As seen in the market, there are currently hundreds of applications for licensed producer status being processed by Health Canada. As capacity comes online for new as well as existing licensed producers in the market, there is a potential for oversupply. The number of licensed producers ultimately authorized by Health Canada, a change in the difficulty of obtaining a license and the aggregate production capacity of these licensed producers could have an adverse impact on our ability to compete for market share in Canada's medical cannabis industry.

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

As a licensed producer under the Cannabis Act, certain key employees are subject to a security clearance by Health Canada. Under the Cannabis Act a security clearance cannot be valid for more than five years and must be renewed before the expiry of a current security clearance. There is no assurance that any of our existing personnel who presently or may in the future require a security clearance will be able to obtain or renew such clearances or that new personnel who require a security clearance will be able to obtain one. A failure by a key employee to maintain or renew his or her security clearance, would result in a material adverse effect on our business, financial condition and results of operations. In addition, if a key employee leaves us, and we are unable to find a suitable replacement that has a security clearance required by the Cannabis Act in a timely manner, or at all, there could occur a material adverse effect on our business, financial condition and results of operations. See "*Description of the Business—General Overview—Security Clearances*."

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

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

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

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

Future research reports, findings, regulatory proceedings, litigation, media attention or other publicity that are perceived as less favorable than, or that question, earlier research reports, findings or publicity could have a material adverse effect on the demand for the Company's proposed products and the business, results of operations, financial condition and cash flows of the Company. The Company's dependence upon consumer perceptions means that adverse scientific research reports, findings, regulatory proceedings, litigation, media attention or other publicity, whether or not accurate or with merit, could have a material adverse effect on the Company, the demand for the Company's proposed products, and the results of operations, financial condition and cash flows of the Company.

Further, adverse publicity reports or other media attention regarding the safety, efficacy and quality of medical cannabis in general, or the Company's proposed products specifically, or associating the consumption of medical cannabis with illness or other negative effects or events, could have such a material adverse effect. Such adverse publicity reports or other media attention could arise even if the adverse effects associated with such products resulted from consumers' failure to consume such products appropriately or as directed.

The Company 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.

Marketing constraints under the regulatory framework, including plain packaging regulations, limit the Company's ability to compete for market share in a manner similar to other industries.

The development of our business and operating results may be hindered by applicable restrictions on sales and marketing activities imposed by Health Canada. The regulatory environment in Canada limits our ability to

compete for market share in a manner similar to other industries. If we are unable to effectively market our products and compete for market share, or if the costs of compliance with government legislation and regulation cannot be absorbed through increased selling prices for our products, our sales and operating results could be adversely affected.

Moreover, the Cannabis Act imposes further packaging, labelling and advertising restrictions on producers. If we fail to comply with the packaging, labelling and advertising restrictions, we will be subject to monetary penalties, required to suspend sale of noncompliant products and/or be disqualified as a vendor by government-run provincial distributors.

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

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

Previously unknown adverse reactions resulting from human consumption of the Company's products alone or in combination with other medications or substances could occur. The Company may be subject to various product liability claims, including, among others, that the Company'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 Company could result in increased costs, could adversely affect the Company'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 Company. There can be no assurances that the Company will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities. Such insurance is expensive and may not be available in the future on acceptable terms, or at all. The inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of the Company's potential products.

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

Management regularly reviews the amount of inventory on hand, reviews the remaining shelf life and estimates the time required to manufacture and sell such inventory; however, write-down of inventory may still be required due to extraneous factors such as lower prices in the market. Any such write-down of inventory could have a material adverse effect on our business, financial condition, and results of operations.

Fair value adjustments to the biological assets could affect the results of operations of our business

The fair value changes in biological assets included in inventory sold as well as unrealized gain on changes in fair value of biological assets are significant accounting estimates that go into the calculation of our earnings figures. These line items have the ability to change the profitability of the business from an accounting standpoint. These adjustments necessitate estimates relating to the ultimate selling price of cannabis as well as direct costs (such as cost of supplies, nutrients, materials, salaries for personnel directly involved in growing cannabis plants and depreciation of equipment directly related to production). Because there is no actively traded commodity market for cannabis products, the valuation of the biological assets is obtained using valuations techniques where the inputs are based on unobservable market data. The scope of estimates required combined with the magnitude of the biological asset adjustments creates a risk that the financials do not accurately reflect the underlying economics of our business. Further, any volatility in the input estimates could cause significant variability of results of operations across time periods.

The Company's products may be subject to recalls for a variety of reasons, which could require the Company 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 Company's products are recalled due to an alleged product defect or for any other reason, the Company could be required to incur the unexpected expense of the recall and any legal proceedings that might arise in connection with the recall. The Company 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 Company 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 Company's significant brands were subject to recall, the image of that brand and the Company could be harmed. A recall for any of the foregoing reasons could lead to decreased demand for the Company's products and could have a material adverse effect on the results of the operations and financial condition of the Company. Additionally, product recalls may lead to increased scrutiny of the Company's operations by Health Canada or other regulatory agencies, requiring further management attention and potential legal fees and other expenses.

Companies existing in the markets for the medical and recreational cannabis products face substantial competition and in particular the legalization of recreational cannabis may result in increased levels of competition in the overall cannabis market.

The markets for the medical and recreational cannabis products appear to be sizable and Health Canada has only issued a limited number of licenses under the former ACMPR and the new Cannabis Act regime to produce and sell medical and recreational cannabis. There are several hundred existing applicants for licenses in queue. The number of licenses issued could have an impact on the operations of the Company. Because of the early stage of the industry in which the Company operates, the Company expects to face additional competition from new entrants. According to Health Canada, as of the date of this MD&A there were 218 licensees under the Cannabis Act. If the number of users of medical and recreational cannabis in Canada increases, the demand for products will increase and the Company expects that competition will become more intense, as current and future competitors begin to offer an increasing number of diversified products. The Company expects significant competition from other companies applying for production licenses that may have significantly greater financial, technical, marketing and other resources, which may be able to devote greater resources to the development, promotion, sale and support of their products and services, and may have more extensive customer bases and broader customer relationships.

To remain competitive, the Company will require a continued level of investment in research and development, marketing, sales and client support. The Company may not have sufficient resources to maintain research and development, marketing, sales and client support efforts on a competitive basis, which could materially and adversely affect the business, financial condition and results of operations of the Company. If the Company is not successful in investing sufficient resources in these areas, their ability to compete in the market may be adversely affected, which in turn could materially and adversely affect the Company's business, financial conditions and results of operation.

The Company currently faces intense competition from other companies, many of which have longer operating histories and more financial resources and manufacturing and marketing experience than us. Many such companies are already producing large quantities of cannabis for both medical and recreational use, are generating significant revenues and are currently listed on national securities exchanges in the United States and Canada with superior access to the capital markets. Increased competition by larger and better financed competitors could materially and adversely affect the business, financial condition and results of operations of the Company's business. Additionally, the Company is not currently licensed to sell cannabis for recreational use, and has no immediate plans for apply for a license that would allow it to do so.

The Company also faces competition from illegal cannabis dispensaries that are selling cannabis to individuals despite not having a valid license to do so. As well, the legal landscape for medical and recreational

cannabis is changing internationally. More countries have passed laws that allow for the production and distribution of medical cannabis in some form or another which increases import and export competition from international cannabis producers as well. Finally, there is potential that the industry will undergo consolidation, creating larger companies that may have increased geographic scope and other economies of scale. Increased competition by larger, better-financed competitors with geographic or other structural advantages could materially and adversely affect the business, financial condition and results of operations of the Company.

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

Research regarding the medical benefits, viability, safety, efficacy, dosing and social acceptance of cannabis or isolated cannabinoids (such as CBD and THC) remains in early stages. There have been relatively few clinical trials on the benefits of CBD and THC. Although the Company believes that the articles, reports and studies support its beliefs regarding the therapeutic benefits, viability, safety, efficacy, dosing and social acceptance of cannabis, future research and clinical trials may prove such statements to be incorrect, or could raise concerns regarding, and perceptions relating to, cannabis. Given these risks, investors should not place undue reliance on such articles, reports and studies. Future research studies and clinical trials may draw opposing or negative conclusions regarding the facts and perceptions related to cannabis, which could have a material adverse effect on the demand for the Company's products with the potential to lead to a material adverse effect on the Company's business, results of operations, financial condition or prospects.

Third parties with whom we do business may perceive that they are exposed to reputational risk as a result of our 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 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 Company's ability to produce and sell its medical products in, and export its medical products to, other jurisdictions outside of Canada is dependent on compliance with additional regulatory and other requirements.

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 Company 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 Company 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 Company. Although it is the general intent of the Company 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 Company 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 Company does maintain a control position with respect to its investments, the Company'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 Company, or may be in a position to take (or block) action in a manner contrary to the Company's objectives. The Company 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 Company to regulatory or agency proceedings which could divert management's attention and resources and have a material adverse impact on the Company's business, financial condition and results of operation.

The Company's business requires compliance with many laws and regulations. Failure to comply with these laws and regulations could subject the Company to regulatory or agency proceedings or investigations and could also lead to damage awards, fines and penalties. The Company 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 Company's reputation, require the Company to take, or refrain from taking, actions that could harm its operations or require the Company 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 Company's business, financial condition and results of operation.

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

The Company must rely largely on its own market research to forecast sales as detailed forecasts are not generally obtainable from other sources and prices for the Company's products may vary considerably from our forecasts at this early stage of the cannabis industry in Canada. A failure in the demand for its products to materialize as a result of competition, technological change or other factors could have a material adverse effect on the business, results of operations and financial condition of the Company. We must rely largely on our market research due to the early stages of the cannabis industry in Canada. As a result of these forecasts, if we underestimate the demand for our products, we may not be able to produce products to meet our stringent requirements, and this could result in delays in the shipment of our products and our failure to satisfy demand, as well as damage to our reputation and partner relationships. If we overestimate the demand for our products, we could face inventory levels in excess of demand, which could result in inventory write-downs or write-offs and the sale of excess inventory at discounted prices, which would harm our gross margins and our brand management efforts. In addition, failure to accurately predict consumption behavior of our products at the individual level (including average revenue per user, frequency of use and number of grams per year purchased) could cause a decline in revenue and harm our profitability and financial condition.

Further, the price of production, sale and distribution of cannabis, including the price per gram of dried flowers and extracts may fluctuate significantly due to how young the cannabis industry is and the lack of external market research and studies. In addition, prices are affected by numerous factors beyond our control including international, economic and political trends, expectations of inflation, currency exchange fluctuations, interest rates, global or regional consumptive patterns, speculative activities and increased production due to new production and distribution developments and improved production and distribution methods. The effect of these factors on the price of our products and, therefore, their economic viability may be difficult to predict accurately or at all.

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 Company 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.

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

Due to the perishable nature of its proposed products, the Company will depend on fast and efficient third party transportation services to distribute its product. Any prolonged disruption of third party transportation services could have an adverse effect on the financial condition and results of operations of the Company.

Due to the nature of our products, security of the product during transportation to and from our facilities is of the utmost concern. A breach of security during transport or delivery could have a material and adverse effect on our business, financial condition and prospects. Any breach of the security measures during transport or delivery, including any failure to comply with recommendations or requirements of Health Canada, could also have an impact on our ability to continue operating under the License or the prospect of renewing the License.

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.

The nascent status of the medical and recreational cannabis industry involves unique circumstances and there can be no assurance that the industry will continue to exist or grow as currently anticipated.

The Company is operating its business in a relatively new medical and adult-use recreational cannabis industry and market. In addition to being subject to general business risks, a business involving an agricultural product and a regulated consumer product, we need to continue to build brand awareness in this industry and market through significant investments in our strategy, our production capacity, quality assurance, and compliance with regulations. These activities may not promote our brand and products as effectively as intended, or at all.

Competitive conditions, consumer tastes, patient requirements and spending patterns in this new industry and market are relatively unknown and may have unique circumstances that differ from existing industries and markets.

In addition, the Cannabis Act also permits patients to produce a limited amount of cannabis for their own purposes or to designate a person to produce a limited amount of cannabis on their behalf. This could potentially significantly reduce the market for our products, which could have a material adverse effect on our business, financial condition and results of operations.

Accordingly, there are no assurances that this industry and market will continue to exist or grow as currently estimated or anticipated, or function and evolve in a manner consistent with management's expectations and assumptions. Any event or circumstance that affects the medical cannabis industry and market could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to the Pharmaceutical Business

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

The Company was founded as a medical cannabis company and the growth and sale of cannabis remains a central part of the Company's business. While all pharmaceutical companies face risks in developing and bringing pharmaceutical products to market successfully, the Company's involvement in the cannabis industry may increase the risks that any pharmaceutical company would face. For example, while some U.S. states have legalized cannabis growth and possession, U.S. federal law continues to ban the possession, sale or import of cannabis into the United States and prohibits the financing of activities outside the United States that are unlawful under Canadian or other foreign laws. As a U.S. federal agency, the FDA may review the Company's activities, clinical trials, if any, and applications for approval with heightened scrutiny because of the Company's involvement in the Canadian cannabis industry, its stated goals of utilizing cannabis-based products such as THC and CBD in its pharmaceutical products and the limited history of medical research on cannabis products, and the Company's applications may be

more likely to be subject to enhanced scrutiny. Finally, third-parties, especially those in the United States, may avoid doing business with the Company due to its involvement in the cannabis industry or may only provide their services and products to the Company at a premium to account for increased counter-party risks. See "Risks Related to the Medical Cannabis Industry—the Company's ability to produce and sell its medical products in, and export its medical products to, other jurisdictions outside of Canada is dependent on compliance with additional regulatory and other requirements," "—third parties with whom we do business may perceive that they are exposed to reputational risk as a result of our cannabis-related business activities and may ultimately elect not to do business with us" and "—results from future clinical research may draw opposing or negative conclusions regarding the facts and perceptions related to cannabis, which could have a material adverse effect on the Company's business, results of operations, financial condition and prospects." If any of the foregoing delay or prevent the Company from attaining the approvals it requires to commercialize its products, in addition to the risks inherent in the pharmaceutical business outlined below, it may have a material adverse effect on the Company's business, results of operations, financial condition and prospects.

Our product candidates are in preclinical development, which is a lengthy and expensive process with uncertain outcomes and the potential for substantial delays. Our product candidates may not receive regulatory approval, which is necessary before they can be commercialized.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. To date, we have focused substantially all of our efforts and financial resources on identifying, acquiring, and developing our product candidates, including conducting lead optimization, nonclinical studies, preclinical studies and clinical trials, and providing general and administrative support for these operations. We cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. Our inability to successfully complete preclinical and 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 product candidates. We currently have no pharmaceutical products approved for sale and have not generated any revenue from sales of pharmaceutical products, and we may never be able to develop or successfully commercialize a marketable pharmaceutical product.

All of our product candidates require significant additional development; management of preclinical, 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. Many of our product candidates are in early-stage research or translational phases of development, and the risk of failure for these programs is high. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, 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.

If we are unable to obtain regulatory approval in one or more jurisdictions for any product candidates that we may identify and develop, our business will be substantially harmed.

We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. 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 a product candidate's development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We have not obtained regulatory approval for any product candidates, and it is possible that our current product candidates and any other product candidates which we may seek to develop in the future will not ever obtain regulatory approval. We cannot

be certain that any of our product candidates 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 our product candidates for many reasons, including but not limited to:

- the inability to demonstrate to the satisfaction of the FDA or comparable other regulatory authorities that the applicable product candidate 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 product candidates that we may identify and pursue may not be sufficient to support the submission of an NDA, biologics license application ("**BLA**"), 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 a product candidate'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 product candidates that we may pursue in the United States or elsewhere, which would significantly harm our business, results of operations, financial condition and prospects.

We may encounter substantial delays in clinical 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 any of our ongoing and planned clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, even if these trials are initiated or conducted on a timely basis, issues may arise that could result in the suspension or termination of such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our ongoing and future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

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

- delays in reaching agreement on acceptable terms with prospective 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 ("**CTA**") 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 our clinical trial 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; or 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 our clinical trials;

- delays in identifying, recruiting and enrolling suitable patients to participate in clinical trials, and delays caused by patients withdrawing from clinical 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 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 our product candidates, we may be required to or we may elect to conduct additional nonclinical studies or clinical trials to bridge data obtained from our modified product candidates to data obtained from nonclinical and clinical research conducted using earlier versions. Clinical trial delays could also shorten any periods during which our products have 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 one or more of our product candidates.

Delays in the initiation, conduct or completion of any clinical trial of our product candidates 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 our product candidates. In the event we identify any additional product candidates to pursue, we cannot be sure that submission of an IND or a CTA will result in the FDA or comparable other regulatory authority allowing clinical trials to begin in a timely manner, if at all. Any of these events could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical studies, preclinical studies and clinical trials that

the applicable product candidate is both safe and effective for use in each target indication, and in the case of our product candidates regulated as biological products, that the product candidate is safe, pure, and potent for use in its targeted indication. Each product candidate 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 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 have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

We cannot be certain that our current clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, 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 our product candidates 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 our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

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 our product candidates to justify proceeding to advanced clinical trials or an application for regulatory approval.

The results of nonclinical and preclinical studies and clinical trials 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. In addition, for certain of our product candidates that we acquired, we did not undertake the preclinical studies and clinical trials. 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 our product candidates 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 these product candidates. Our failure to obtain marketing approval for our product candidates would substantially harm our business, results of operations, financial condition and prospects.

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

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

to identify and enroll a sufficient number of patients, or those with required or desired characteristics and criteria, in a timely manner.

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

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

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

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

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

Moreover, if our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate if approved. We may also be required to modify or terminate our study plans based on findings in our preclinical studies or clinical trials. Many product candidates that initially show promise in

early-stage testing may later be found to cause side effects that prevent further development. As we work to advance existing product candidates and to identify new product candidates, we cannot be certain that later testing or trials of product candidates that initially showed promise in early testing will not be found to cause similar or different unacceptable side effects that prevent their further development.

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

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

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

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

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

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

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

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

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

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

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

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 become 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. 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.

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

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

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

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

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

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

In connection with the clinical development of our drug candidates for certain indications, we may work with collaborators to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our drug candidates. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable other regulatory authorities regulate *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic drug candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators

may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic drug candidates, or experience delays in doing so, the development of these therapeutic drug candidates may be adversely affected, these therapeutic drug candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic candidates.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "**ACA**"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("**BPCIA**") which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

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

The ability of the FDA to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average

review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved, or for other actions to be taken, by relevant government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown could prevent the timely review of our patent applications by the United States Patent and Trademark Office ("**USPTO**"), which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

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

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

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

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

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, directors, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and comparable other regulatory authorities; provide true, complete and accurate information to the FDA and comparable other regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar other fraudulent misconduct laws; or report financial information or data

accurately or to disclose unauthorized activities. If we obtain FDA approval of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We intend to adopt a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees, directors and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

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

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

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

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

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

unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

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

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

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

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

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

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

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

Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.

The commercial success of our product candidates will depend upon their degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Even if any product candidates we may develop receive marketing approval, they 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 any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the potential and perceived advantages compared to alternative treatments, including any similar generic treatments;
- the ability to offer these products for sale at competitive prices;
- the ability 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 the product candidate is approved by FDA 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 the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning these products 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 AEs.

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 our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidates we develop do not

achieve an adequate level of acceptance, we may not generate significant product revenue, and we may not become profitable.

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

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

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

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

- the inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop internally. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us or them. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively or may expose us to legal and

regulatory risk by not adhering to regulatory requirements and restrictions governing the sale and promotion of prescription drug products, including those restricting off-label promotion. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates, if approved.

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

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

Our ability to successfully commercialize our product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

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

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable other regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("**CMS**"), an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No

uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

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

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

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

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

The United States and many other jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell

any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

There have been, and likely will continue to be, legislative and regulatory proposals in other jurisdictions as well as at the U.S. federal and state levels directed at containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

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

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute and the U.S. federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of ownership, pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including compensation of physicians with stock or stock options, could, despite efforts to comply, be subject to challenge under one or more of such laws. Additionally, FDA or other regulators may not agree that we have mitigated any risk of bias in our clinical trials due to payments or equity interests provided to investigators or institutions which could limit a regulator's acceptance of

those clinical trial data in support of a marketing application. Moreover, efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to international equivalents of the healthcare laws mentioned above, among other local laws.

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

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

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

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

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

If any of these competitors or competitors for our other product candidates receive FDA approval before we do, our product candidates would not be the first treatment on the market, and our market share may be limited. In addition to competition from other companies targeting our target indications, any products we may develop may also face competition from other types of therapies.

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

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

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

We expect to rely on third parties to conduct our clinical trials and some 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 product 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 each of our respective clinical 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 our clinical 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 our clinical 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 any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines. 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 our clinical 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.

The drug substance and drug product for certain of our product candidates 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 certain of our product candidates, 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 these product candidates 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 our product candidates.

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 our product candidates or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers could have a material adverse impact upon on our business.

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

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including our existing CMOs for all of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in

accordance with GMP, or similar regulatory requirements outside the United States. These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production, seizures or recalls of product candidates or marketed drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect clinical or commercial supplies of our product candidates.

We or our CMOs must supply all necessary documentation in support of an NDA, BLA or MAA on a timely basis and must adhere to regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our CMOs have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the CMOs, we cannot control the manufacturing process of, and are completely dependent on, our CMO partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

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

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

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

Risks Related to our Intellectual Property

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

As is the case with other pharmaceutical and biopharmaceutical companies, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others, particularly patents, in the United States and other countries with respect to our product candidates and

technology. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to micro-PEA or other product candidates that we may identify.

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

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

Our ability to enforce patent rights also depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable.

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

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates to ours, or limit the duration of the patent protection of our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

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

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

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

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

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

Parties making claims against us, may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there

is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

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

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

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

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain other countries upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any other country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

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

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

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

We seek to protect our confidential proprietary information, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and

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

Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. We may not be able to obtain adequate remedies in the event of such unauthorized use. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Trade secrets will also over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position, business, results of operations, financial conditions, and prospects would be harmed.

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

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

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

Our agreements with employees and our personnel policies provide that any inventions conceived by an individual in the course of rendering services to us shall be our exclusive property. Although our policy is to have all

such individuals complete these agreements, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property may not be automatic upon the creation of an invention and despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Issued patents covering our product candidates 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 one or more of our product candidates, the defendant could counterclaim that the patent covering the relevant product candidate 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 novelty, nonobviousness, 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 USPTO, 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 our product candidates. 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 our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

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

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

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

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

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

CAPITAL MANAGEMENT

The Company manages its capital with the following objectives:

- to ensure sufficient financial flexibility to achieve the ongoing business objectives including funding of future growth opportunities, and pursuit of accretive acquisitions; and
- to maximize shareholder return through enhancing the share value.

The Company monitors its capital structure and makes adjustments according to market conditions in an effort to meet its objectives given the current outlook of the business and industry in general. The Company may manage its capital structure by issuing new shares, repurchasing outstanding shares, adjusting capital spending, or disposing of assets. The capital structure is reviewed by management and the board of directors on an ongoing basis.

The Company considers its capital to be equity, comprising share capital, reserves and deficit.

The Company manages capital through its financial and operational forecasting processes. The Company reviews its working capital and forecasts its future cash flows based on operating expenditures, and other investing and financing activities. The forecast is updated based on activities related to its business activities.

The Company's capital management objectives, policies and processes have remained substantially unchanged during 2019 and 2018.

The Company is not subject to any externally imposed capital requirements.

DISCLOSURE AND INTERNAL FINANCIAL CONTROLS

Management has established processes, which are in place to provide them sufficient knowledge to support management representations that they have exercised reasonable diligence that (i) the unaudited interim financial statements do not contain any untrue statement of material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it is made, as of the date of and for the periods presented by the financial statements, and that (ii) the financial statements fairly present in all material respects the financial condition, results of operations and cash flows of the Company, as of the date of and for the periods presented by the financial statements.

In contrast to the certificate required under National Instrument 52-109 Certification of Disclosure in Issuers' Annual and Interim Filings (NI 52-109), the Company utilizes the Venture Issuer Basic Certificate which does not include representations relating to the establishment and maintenance of disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as defined in NI 52-109. In particular, the certifying officers filing the Certificate are not making any representations relating to the establishment and maintenance of: (a) controls and other procedures designed to provide reasonable assurance that information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and (b) a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP.

The Company’s certifying officers are responsible for ensuring that processes are in place to provide them with sufficient knowledge to support the representations they are making in this certificate.

Investors should be aware that inherent limitations on the ability of certifying officers of a venture issuer to design and implement on a cost effective basis DC&P and ICFR as defined in NI 52-109 may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.