# BioVaxys Technology Corp. (formerly Lions Bay Mining Corp.) MANAGEMENT'S DISCUSSION AND ANALYSIS

For the Year Ended October 31, 2020 As of March 1, 2021

This management discussion and analysis ("MD&A") of BioVaxys Technology Corp. (formerly Lions Bay Mining Corp, the "Company") for the years ended October 31, 2020 and 2019 is performed by management using information available as of March 1, 2021. Management has prepared this MD&A with reference to National Instrument 51-102 – *Continuous Disclosure Obligations* of the Canadian Securities Administrators. This MD&A should be read in conjunction with the Company's audited consolidated financial statements for the year ended October 31, 2020, and the related notes thereto ("Annual Financial Statements"). The Company's Annual Financial Statements are prepared in accordance with International Financial Reporting Standards ("IFRS"). All amounts are expressed in Canadian dollars unless otherwise indicated.

This MD&A contains certain "forward-looking statements" and certain "forward-looking information" as defined under applicable Canadian securities laws that may not be based on historical facts, including, without limitation, statements containing the words "believe", "may", "plan", "will", "estimate", "continue", "anticipate", "intend", "expect", "predict", "project", "potential", "continue", "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words and similar expressions. Forward-looking statements are necessarily based on estimates and assumptions made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as the factors we believe are appropriate. Forward-looking statements in this MD&A include but are not limited to statements relating to:

- estimates of our future revenues and profits;
- treatment under government regulatory and taxation regimes;
- projections of market prices and costs and the future market for the Company's products and conditions affecting same;
- ability to obtain and protect the Company's intellectual property and proprietary rights;
- expectations regarding the Company's ability to raise capital;
- timing and costs associated with completing research and development work relating to the Company's products;
- the Company's strategies, objectives and plans to pursue the commercialization of its products;
- the Company's ability to conduct all required clinical and non-clinical trials for its products, including the timing and result of such trials;
- the Company's estimates of the size of the potential markets for its products and the rate and degree of market acceptance of such products;
- statements and information concerning the Transaction (see heading "Transaction");
- statements relating to the business and future activities of, and developments related to the Company after the date of this MD&A and thereafter;
- market position, and future financial or operating performance of the Company; and
- liquidity of the common shares of the Company.

Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements. All forward-looking statements, including those not specifically identified herein, are made subject to cautionary language above and on pages 16-27. Readers are advised to refer to the cautionary language when reading any forward-looking statements.

Such statements reflect our current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by BioVaxys, as of the date of such statements, are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies.

In evaluating forward-looking statements, current and prospective shareholders should specifically consider various factors, including the risks outlined below under the heading "Financial Instruments" and below under the heading "Risks".

#### SIGNIFICANT TRANSACTION

On April 17, 2020, the Company entered into a non-binding letter of intent ("LOI") to acquire BioVaxys Inc. ("BioVaxys") a private Delaware corporation. Upon execution of the LOI, the Company agreed to provide the BioVaxys with a secured bridge loan facility of up to US\$200,000 bearing interest at a rate of 9% per annum.

On June 2, 2020, the Company and BioVaxys entered into a share exchange agreement ("Share Exchange Agreement"). Pursuant to the Share Exchange Agreement, the Company acquired all the shares issued and outstanding of BioVaxys by way of a share exchange with shareholders of BioVaxys on September 30, 2020 ("Transaction"), specifically, each shareholder of BioVaxys transferred their shares of BioVaxys to the Company in exchange for fully paid and non-assessable common shares of the Company. As a result, the Company issued 31,100,000 common shares at an agreed price of \$0.28 per share in exchange for all of the issued and outstanding securities of BioVaxys, which included 6,788,800 common shares issued to Thomas Jefferson University ("TJU").

At the date of the Transaction, \$160,068 (US\$120,000) had been advanced to BioVaxys which was eliminated on consolidation upon the completion of the Transaction as an intercompany balance.

#### COVID-19

In March 2020, the World Health Organization declared corona virus Covid-19 a global pandemic. This contagious disease outbreak, which has continued to spread, and any related adverse public health developments, has adversely affected workforces, economies, and financial markets globally, potentially leading to an economic downturn.

The Company has rapidly adopted to the needs of the society and the demand from the market for corona virus vaccine products. It has initiated the study and development of BVX-0320, its proprietary vaccine candidate for Covid-19.

The extent to which the corona virus may further impact the Company's business activities will depend on future developments, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. These events are highly uncertain and as such, the Company cannot determine their financial impact at this time.

Refer to the further discussion related to COVID-19 implication under the heading "Risks".

### **BUSINESS OVERVIEW**

The Company was incorporated on April 25, 2018 pursuant to the provisions of the Business Corporations Act of BC and was a wholly owned subsidiary of Bearing Lithium Corp. ("Bearing"). Prior to the Transaction described above, the Company was a mineral exploration company. The Company's shares are traded on the Canadian Securities Exchange (the "CSE") under the symbol "BIOV". The registered and records office is located at Suite 503, 905 West Pender Street, Vancouver, British Columbia, V6C 1L6.

The Company is a leader in haptenized protein vaccines and immuno-diagnostics and is currently developing antiviral & anticancer vaccine platforms. The Company is evaluating, BVX-0320, a potential SARS-CoV-2 vaccine based on its haptenized viral protein technology, and advancing a compassionate use trial in the EU to evaluate its haptenized cell vaccine for late-stage ovarian cancer. The Company is also developing a novel diagnostic platform, Covid-T™, which screens for an immune system response in patients exposed to SARS-CoV-2. The vaccines and Covid-T™ are described in greater detail below.

#### HIGHLIGHTS DURING THE YEAR ENDED OCTOBER 31, 2020

- Effective April 29, 2020, the Company completed a forward split of its issued and outstanding common shares on the basis of a two-for-one (2:1) stock split of the Company's common shares. Shareholders received two new shares for every one common share held (the "Split"). All references to share and per shares amounts in this MD&A have been retroactively restated to reflect the Split.
- On August 26, 2020 and September 3, 2020, the Company issued 13,738,235 units for gross proceeds for proceeds of \$3,022,412, net with share issuance costs of \$71,282. Each unit is comprised of one common share and one-half of one warrant. Each warrant entitles the holder to acquire one common share at a price of \$0.50 per common share for 2 years. The Company paid cash commissions of \$37,379 and issued 233,874 brokers' warrants with a fair value of \$21,902. The brokers' warrants are exercisable for a period of 2 years at an exercise price of \$0.50 per share. The brokers' warrants were valued using the following Black-Scholes Option Pricing Model assumptions: risk free rate of 0.29%, estimated annualized volatility of 91.82%, expected life of 2 years, exercise price of \$0.50, expected dividend yield of 0% and share price of \$0.22.
- On September 3, 2020, the Company granted 600,000 incentive stock options an officer and a consultant of the Company. The options are each exercisable for one common share at an exercise price of \$0.28 for five years and vest over a four-month period.
- On September 30, 2020, the Company completed the transaction with BioVaxys Inc. Please refer to "Significant Transaction" section above for details.
- On October 20, 2020, the Company granted an aggregate of 3,000,000 incentive stock options to certain officers and directors of the Company. The Options are each exercisable for one common share at an exercise price of \$0.45 for five years and vest over a two-year period.
- The Company issued 7,581,520 common shares pursuant to the exercise of warrants for proceeds of \$379,076. Upon the exercise of the warrants, the fair value of \$3,342 was reclassified from reserves to share capital.
- The Company issued 200,000 common shares pursuant to the exercise of stock options for proceeds of \$2,500. Upon the exercise of the stock options, the fair value of \$2,290 was reclassified from reserves to share capital.
- On December 10, 2020, the Company announced that its submission of Form 211 to the Financial Industry Regulatory Authority ("FINRA") has been cleared and the Company's shares qualify for trading in the United States on the OTC Pink Market under the symbol "LMNGF".
- On February 5, 2021, the Company closed its non-brokered private placement and issued 4,417,647 units at a price of \$0.255 per unit to certain strategic investors for proceeds of \$1,126,500. Each unit consists of one common share and one warrant. Each warrant is exercisable for one additional common share at an exercise price of \$0.50 for a period of two years. In connection with the private placement, the Company paid cash finder's fee of \$60,000.

### **Management and Directors**

On July 6, 2020, Julia Stone resigned as Chief Financial Officer and Corporate Secretary to pursue other endeavors. Lachlan McLeod was appointed as the new Chief Financial Officer and Corporate Secretary. Mr. McLeod, a Chartered Professional Accountant, holds a Bachelor's Degree in Science with an Economics major and a Business minor from the University of Victoria. Mr. McLeod has 6 years of experience focusing on financial reporting under IFRS, governance for public companies, and technical accounting issues, including work as an auditor at KPMG.

- On September 30, 2020, at the closing of the Transaction:
  - Jeremy Poirier resigned as Chief Executive Office of the Company and Ben Asuncion resigned as a Director of the Company
  - James Passin was appointed the new Chief Executive Officer and a Director of the Company. Mr. Passin was the Co-founder of BioVaxys Inc. He is a former hedge fund and private equity fund manager at FGS Advisors, LLC, an affiliate of New York-based Firebird Management LLC. He has 20 years of experience as a professional investor, a deep experience of financing and developing venture-stage companies, and directed and managed over \$150 million of equity and debt investment into biotech companies including the former Avax, one of the world's first cellular immunotherapeutic vaccine companies. Mr. Passin is a director of several public companies, including BDSec JSC and Mindset Pharma Inc., and is the Chairman of TraceSafe.
  - Kenneth Kovan was appointed as President and Chief Operating Officer. Mr. Kovan was the Cofounder of BioVaxys Inc. Mr. Kovan has over 30 years of experience in biopharmaceuticals commercial development. He served from 2019 to 2020 as Corporate Development Partner with Horizon Discovery plc in the United Kingdom, and is Managing Principal & Owner of Bingham Hill Ventures, a life sciences advisory practice he founded in 2012 that specializes in corporate development, technology licensing, and business planning. He is an experienced biotech CEO and board member, and founder of biotechnology companies including the former Avax.
  - o Dr. David Berd was appointed as the Chief Medical Officer of the Company. Dr. David Berd was the Co-founder and Chief Medical Officer of BioVaxys Inc. Dr. David Berd is a medical oncologist with a lifelong record of clinical research in medical oncology and cancer immunotherapy. He co-founded cancer immunotherapy company Avax and is the inventor of the cancer vaccines MVax™ and OVax™ and served as Chief Medical Officer from 2005-2008. As National Director for Immunotherapy at Cancer Treatment Centers of America, Dr. Berd investigated the application of haptenized autologous vaccines for ovarian cancer.
- On October 14, 2020, Timothy Heenan resigned from his role as Director.
- On October 15, 2020, Daren Hermiston was appointed as a Director of the Company. Mr. Hermiston is the founder and CEO of Kona Consulting Inc. and acts as an Agent with PointsWest Sports and Entertainment. Mr. Hermiston has an extensive background in marketing public and private companies throughout various sectors and is a guest lecturer at Simon Fraser University for Sports and Entertainment Marketing. Mr. Hermiston also currently holds positions with a number of private companies, including acting as a director of Baden Resources Inc.
- On October 20, 2020, David Wang was appointed as a Director of the Company. Mr. Wang, a seasoned medical technology executive, is Healthcare Consultant for South America for Omron, an USD\$1.5 billion market capitalization company listed on the Tokyo Stock Exchange. Mr. Wang is the former CEO of CAUS Capital and the former CEO of Beijing Century Medical and is fluent in Chinese and Japanese.
- On February 9, 2021, Jeremy Poirier resigned from his role as Director.

#### **INTANGIBLE ASSET**

#### **Haptenized Vaccines Platform**

The Company's vaccine platform is based on the concept of haptenization. Haptenization is based on the established immunological concept that modifying surface proteins, whether they are viral or tumor, with simple chemicals called haptens makes them more visible to the immune system. This process of haptenization "teaches" a patient's immune system to recognize and make target proteins more 'visible', thereby stimulating a T-cell mediated immune response. This is critical for fighting viral pathogens or cancer cells, as T-cells directly battle viruses or tumors by targeting and destroying infected or cancerous cells. Haptenization is based on proven science and extensive clinical data. There

is also growing evidence that it can be used for many viruses and any resectable (i.e. surgically-removable) solid tumors.

### SARS-CoV-2 Vaccine Candidate (BVX-0320)

The Company's lead vaccine candidate in preclinical development for SARS-CoV-2 is BVX-0320, a haptenized s-Spike protein of SARS-CoV-2 which is a critical protein on the surface of the virus that is required for the virus' ability to bind to and enter human cells.

Studies have demonstrated that patients recovering from Covid-19 infection carried helper T-cells that recognized the SARS-CoV-2 S-spike protein, and virus-specific killer T-cells were detected in 70% of the test subjects. As haptenized proteins are known to induce potent T-cell responses, the Company believes BVX-0320 could have an advantage over other developing Covid-19 vaccines. Furthermore, the Company's clinical experience with haptenization and safety data from prior clinical development of "first generation" haptenized vaccines may prove advantageous from a regulatory perspective and lead to an accelerated development process.

In December 2020, the Company completed its preclinical program for BVX-0320 suggested by the U.S. Department of Health and Human Services, Food and Drug Administration ("FDA") Center for Biologics Evaluation and Research ("CBER") in their published guidance on *Development and Licensure of Vaccines to Prevent COVID-19*. The FDA's guidance is intended to assist in the clinical development and licensure of vaccines for the prevention of COVID-19, and reflect the FDA's current thinking on the issue.

Conducted by Charles River Laboratories, Inc. ("CRL") under contract with the Company, the preclinical program which began in September 2020 evaluated the anti-virus immune response elicited by BVX-0320 in a controlled murine model ("Murine Model Study") by measuring the development of antibodies to the protein that binds the virus to human cells. Following two injections of BVX-0320 together with the immunological adjuvant, QS21, to 28 mice at four dosage levels, 96.4% developed positive antibody responses detected at week 6. The Company also found that BVX-0320 activated CD4+ helper T-cells and CD8+ killer T-cells that express the activation markers, CD69 and CD25. This result indicates that immunization with BVX-0320 at two different dose levels of 3µg or 10µg stimulated CD4+ helper T-cells CD8+ killer T-cells. CD4+ T-cells are crucial in achieving a regulated effective immune response to viral pathogens, and are central to adaptive immune responses. Generated following an immune response, memory CD4+ T-cells retain information about the virus, which enables them to respond rapidly after viral exposure. CD8+ killer T-cells have the capacity to kill cells infected by the virus, thereby stopping viral replication in those cells.

BVX-0320 also elicits a neutralizing antibody response against SARS-CoV-2, as evidenced by further analysis of sera samples from the Murine Model Study. Under a Company research collaboration, Ohio State University ("OSU") researchers observed in a pooled sample that BVX-0320 elicited the production of neutralizing antibodies to SARS-CoV-2. The findings were obtained from a Plaque Reduction Neutralization Test, where the endpoint is reduction of plaques by 50%, after using available remaining mouse sera from the immune response assay. Plaques are produced by infection of cultured human cells by a live SARS-CoV-2 virus.

The Company's next step is to produce a supply of clinical-grade SARS-CoV-2 s-protein, followed by haptenizing it for development into the GMP-grade vaccine suitable for a Phase I clinical trial being planned for 2021.

#### Ovarian Cancer Vaccine Candidate (BVX-0918A)

BVX-0918A is the Company's lead haptenized tumor cell vaccine for ovarian cancer, which it has sought EU regulatory approval for compassionate use in Stage III and Stage IV of the disease. The Company's cancer vaccines are created by extracting a patient's own (e.g. 'autologous') cancer cells, chemically linking them with a hapten, and re-injecting them into the patient to induce an immune response to proteins which are otherwise not immunogenic. Haptenization is a well-known and well-studied immunotherapeutic approach in cancer treatment, and has been evaluated in both regional and disseminated metastatic tumors. A first generation single-hapten vaccine developed by Dr. David Berd, Chief Medical Officer and a founder of BioVaxys, achieved positive immunological and clinical results in Phase I/II trials. The Company has enhanced the original vaccine approach of using a single hapten to now utilizing two haptens ("bihaptenization"), which the Company believes will yield superior results.

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Single haptenization only modifies hydrophilic amino acids on antigenic proteins, but utilizing two haptens modifies both hapten hydrophilic and hydrophobic amino acids on these target proteins, making the protein more foreign to the immune system with modification of these additional amino acids. A greater number of T-cells is activated by the addition of the second hapten (i.e. more modified amino acids) so the number of T-cells potentially reactive to the unmodified protein increases.

Further, the Company plans to combine the use of its vaccine with "checkpoint antibodies", which are a relatively new class of cancer therapy. The rationale for the combination is that checkpoint inhibitors on their own are powerful augmenters of cellular immune response. The Company believes its vaccine changes the tumor environment to make them more susceptible to checkpoint inhibitors, and expects a synergistic response from the combination. The Company is optimistic for Phase I and Phase II clinical outcomes for BVX-0918A, as these studies have already been successful with the prior single hapten approach. The Company is seeking EU regulatory approval for compassionate use in Stage III & Stage IV ovarian cancer targeted for 2022.

On February 10, 2021, the Company and Procare Health Iberia, S.L., of Barcelona, Spain ("Procare Health"), a leading privately-held European pharmaceutical company, announced that they entered into a broad collaboration. Under the terms of the agreement, which was executed on February 9th, 2021, the companies will jointly conduct a Phase I Clinical Study of BVX-0918A in Spain for late-stage ovarian cancer. The Company will be responsible for the core technology and vaccine production, with Procare Health overseeing and making a \$US900,000 in-kind investment in the clinical program and regulatory planning, CRO management, patient/clinical center recruitment, marketing, and opinion leader management. Both companies have agreed to equally share costs associated with engaging a European clinical research organization ("CRO") to conduct the study. In return, Procare Health will have exclusive rights to market and distribute BVX-0918A in the European Union ("EU"), and the United Kingdom. Clinical data from the Spanish Phase I study will be used by BioVaxys to support its planned IND for BVX-0918A in the US next year, as well as for all other global markets. The two companies will be working out any remaining details by summer 2021.

On February 18, 2021 the Company signed a term sheet (the "Term Sheet") with BioElpida S.A.S. ("BioElpida") of Lyon, France for the build-out for the clinical-grade manufacturing process and aseptic packaging for BXV-0918A. BioElpida is a biotechnology CDMO which applies single-use bioprocessing for development and manufacturing of biological and cell-based products. BioElpida's expertise extends from R&D to pharmaceutical manufacturing and release of clinical batches, and intermediate steps such as process development, feasibility studies, analytical method validation, as well as aseptic fill & finish and other bioproduction services. BioElpida's facility is certified for clinical bioproduction by France's National Security Agency of Medicines and Health Products (the "ANSM"). The Company expects to finalize the definitive service agreement with BioElpida in early 2021. BioElpida preliminary estimate for GMP process build-out and validation is ~\$US1.0M.

#### T-Cell Antigen Discovery Program ("TADP")

In addition to the Company's haptenized cell vaccines for ovarian cancer and other tumor types, the Company is exploring ways to leverage its technology platform in the field of Adoptive Immunotherapy, which is also of significant interest in the immune-oncology market. Adoptive Immunotherapy is where T-cells are collected from a patient and grown in the laboratory. This increases the number of T-cells that are able to kill cancer cells.

The Company's ovarian cancer clinical studies and manufacturing protocol will provide the Company with the unique ability to collect T-cells from patients, both pre- and post- vaccine administration. The Company's objective is to use T-cells made responsive to its vaccines to identify new antigens that can be synthesized and explored, as they may prove useful as diagnostic agents or as new, chemically-defined, patient-specific vaccines. These novel antigens may be distinct for each patient, or present across all tumor cells. The Company intends to explore partnerships with Chimeric Antigen Receptor T-Cell ("CAR-T") therapy and Engineered T-Cell Receptor ("TCR") therapy companies to identify novel cancer antigens eliciting a T-cell response, which will develop extensive new intellectual property for the Company.

#### SARS-CoV-2 Diagnostic Tool ("Covid-T")

In January 2021, The Company initiated the clinical development of Covid-T™. The product was designed to screen for an immune system T-cell response in patients who may have been exposed to SARS-CoV-2, and a T-cell response in those patients who have received a vaccine for SARS-CoV-2 (not limited to the SARS-CoV-2 Vaccine Candidate), to evaluate viral infection status, vaccine efficacy, etc. Covid-T™ is based on the well-established concept of Delayed Type Hypersensitivity ("DTH"), the oldest and most reliable test of human T lymphocyte function. The process involves an intradermal "skin prick" of an immunogenic composition of the SARS-CoV-2 S-protein, where an inflammatory response develops 24-72 hours after skin exposure to the s-spike antigen. The Company anticipates that once clinical testing is complete, Covid-T™ would have the potential for detecting differences in T-cell responses between the original SARS-CoVC-2 virus and the two new strains of SARS-CoV-2 that had originally been identified in the UK and South Africa---B.1.1.7 and 501Y.V2, respectively--- but which are spreading worldwide.

BioVaxys Inc. is obtaining quotes from several proposed contract development and manufacturing organizations ("CDMO") to produce a reliable and well-characterized source of s-protein. Production of s-protein will require obtaining a license to use a third-party proprietary cell line and expression system, with a one-time license fee anticipated of approximately US\$150,000. Bioproduction estimates will be in addition to the license fee, and are anticipated to be available from the selected CDMO in February 2021.

#### BioVaxys Developments Prior to the Transaction

On April 25, 2018, BioVaxys entered into a license agreement with TJU related to four US Patents (two of which have since expired) related to a "first generation" haptenized cancer vaccine using a single hapten. Prior to this, these patents were licensed to Avax Technologies Inc. ("Avax").

In 2018, BioVaxys received a preliminary non-binding proposal from Bio Elpida s.a, a CDMO located in Lyon, France, to subcontract BioVaxys' Good Manufacturing Practices ("GMP") production of its ovarian cancer vaccine.

On September 24, 2018, Dr. David Berd filed Provisional Application # 62/735,381 with the US Patent Office for "Bihaptenized Autologous Vaccines and Uses Thereof". This Provisional Application was amended on October 16, 2018, under Provision Application #62/746,066. These form the technology platform for "bihaptenized cancer vaccines". On October 4, 2019, Dr. Berd assigned these patent applications to BioVaxys.

On March 3, 2020, BioVaxys filed Provisional Application # 62/992,722 for "Haptenized Coronavirus Spike Protein Vaccine". This application forms the technology platform for BXV-0320, the Company's SARS-CoV-2 vaccine candidate.

In June 2020, BioVaxys contracted CRL, a leading independent contract research organization, to conduct a preclinical animal study of BXV-0320.

In June 2020, BioVaxys obtained a supply of a saponin QS-21 adjuvant ("QS-21") from Desert King International ("Desert King"). Adjuvants are like immune system "amplifiers", and are frequently used in combination with many vaccines for this purpose. One of the most widely used and potent immunological adjuvants is QS-21, which is obtained from quillaja saponarioa, a Chilean soap bark tree. QS-21 exhibits exceptional adjuvant properties for a range of antigens, possessing an ability to amplify clinically significant antibody and T-cell responses to vaccine antigens. QS-21 has been approved by the FDA for use in several other vaccines.

In July 2020, BioVaxys selected QS-21 to be administered with its SARS-CoV-2 vaccine candidate. BioVaxys had discussions with Desert King and on August 31, 2020, purchased 6mg of QS-21 for use in the CRL study.

In July 2020, BioVaxys contacted the FDA, and was asked to submit a request for an investigational new drug ("IND"), Written Responses Only ("WRO"). The Company sent preliminary information its SARS-CoV-2 program in February, 2021. At the time of this MD&A, the FDA had not yet provided a response. Following the approval of two mRNA vaccines by the FDA, and in consultation with its regulatory consultants, the Company determined that it was in its best interest to complete the preclinical program and bioproduction plan prior to submitting WRO request. In July

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2020, BioVaxys supplemented the Murine Model Study to also include quantitative analysis of the level of post-vaccination T-cell activation. The additional analysis was designed to use cryopreserved spleen cells (as the spleen is an organ that produces T-cells) from the same mice used in the Murine Model Study, with the additional T-cell activation data. Possessing both immune response data and T-cell activation from the Murine Model Study done to offer a more complete assessment of potential efficacy.

On August 27, 2020, production of the initial batch of non-Good Manufacturing Practices ("non-GMP") haptenized s-spike protein ("Non-GMP Protein") for the Murine Model Study was completed by custom manufacturer MilliporeSigma Inc. ("MilliporeSigma"), which in June 2020 was engaged under contract by BioVaxys in consideration of US\$10,000 to produce this single batch. CRL received the batch of completed Non-GMP Protein from MilliporeSigma, for use in the Murine Model Study, on August 28, 2020.

In August 2020, BioVaxys began preparing a provisional patent application with the United States Patent and Trademark Office ("USPTO") for a novel diagnostic platform invented by BioVaxys. The diagnostic platform is designed to screen for an immune system T-cell response in patients who may have been exposed to SARS-CoV-2, and a T-cell response in those patients who have received a vaccine for SARS-CoV-2 (not limited to the SARS-CoV-2 Vaccine Candidate), to evaluate viral infection status, vaccine efficacy, etc.

On September 1, 2020, CRL completed the design and validation of the assay to be used to evaluate the immune response of the SARS-CoV-2 Vaccine Candidate in the Murine Model Study, with final validation analysis of the assay provided to BioVaxys.

### **Developments Following Completion of the Transaction**

On October 14, 2020, the Company announced that interim results from the Murine Model Study shows a good emerging tolerability profile with no observed side effects or noteworthy clinical observations.

On October 26, 2020, the Company announced that it entered into a research collaboration with OSU for the SARS-CoV-2 Vaccine Candidate. The objective of the research collaboration, which will be the first between the Company and OSU, is to study neutralizing antibodies generated against live SARS-CoV-2 virus by the SARS-CoV-2 Vaccine Candidate.

On November 2, 2020, the Company announced that it filed a provisional patent application with the U.S. Patent and Trademark Office entitled "Method and kit for detection of cell mediated immune response" related to the potential development of a diagnostic for evaluating the presence or absence of a T-cell immune response to SARS-CoV-2.

On November 11, 2020, the Company announced that results from its Murine Model Study show that the vaccine created a 96.4% positive antibody response of the SARS-CoV-2 s-spike protein. Specifically, following two injections of BVX-0320 together with QS-21, to 28 mice at four dosage levels, 96.4% developed positive antibody responses detected at week 6. Prior to administering BVX-0320, all animals were antibody-negative, except for one mouse that had a borderline response. Importantly, mice that received QS-21 without BVX-0320 developed no antibody responses.

On November 30, 2020, the Company announced that the Murine Model Study demonstrated that immunizing mice with two doses of BVX-0320, induced high levels of antibodies against the S1 fragment of the SARS-CoV-2 spike protein associated with inhibition of the binding of the virus to cells of the respiratory tract. The Company's scientists also observed a clear dose-response, with lower levels of antibodies induced by the two lowest doses tested of 0.3ug and 1ug (median titers 1:59 and 1:124, respectively), and with significantly higher antibody levels with the two highest doses tested of 3ug and 10ug (median titers 1:4800 and 1:9430, respectively). No toxicity was noted in mice at any dose level.

On November 30, 2020, in connection with the OSU study, the Company announced that mouse sera had been collected from the Murine Model Study and was going to be tested for ability to inactivate live SARS-CoV-2 virus.

On December 21, 2020, the Company announced that further analysis of the data from its Murine Model Study elicits a robust T-cell response against SARS-CoV-2. BVX-0320 was found to activate immune system memory CD4+ and killer CD8+ T-cells against SARS-CoV-2, which has potential for longer-term viral protection.

On January 25, 2021, the Company announced that it has commenced the clinical development program for BVX-0918A, its haptenized tumor antigen vaccine for ovarian cancer ("BVX-0918A"). The Company plans to seek a compassionate use approval in the European Union for Stage III & Stage IV ovarian cancer, followed by submitting an IND in the US. The Company is in discussions with its designated contract manufacturing organization ("CMO") and anticipates the execution of a manufacturing contract in early 2021. The Company plans to submit its clinical trial application for BVX-0918A with the European Medicines Agency later in 2021.

On January 28, 2021, the Company made the following announcement initiation of the clinical development program for Covid-T™. The FDA has tentatively agreed to allow the Company to file for a pre-Emergency Use Authorization ("EUA") for Covid-T™. Under an EUA, FDA permits the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives. The Company prepared the clinical development plan for Covid-T™, and engaged global regulatory advisory group Rio Pharmaceutical Services ("RPS") to provide strategic regulatory guidance, prepare an FDA pre-submission guidance package, recommend regulatory pathway, and support the Company on the registration filing. A non-clinical study will be needed to establish the risk profile prior to the start of the clinical studies of Covid-T™.

#### **Selected Annual Information**

The following table sets forth selected financial information for the Company for the financial years ended October 31, 2020, 2019 and 2018. This information has been derived from the Company's audited consolidated financial statements for the year, and should be read in conjunction with the consolidated financial statements and the notes thereto.

	October 31, 2020		October 31, 2018	
Total revenue	\$ -	\$ -	\$ -	
Net loss, continuing operation	(1,102,623)	(216,882)	(161,226)	
Net loss, discontinued operation	(71,688)	(13,239)	-	
Net loss	(1,174,311)	(230,121)	(161,226)	
Loss per share, basic and fully diluted	(0.04)	(0.02)	(0.05)	
Total assets	10,458,940	306,264	108,743	
Total non-current financial liabilities	-	-	-	
Cash dividends declared per common share	-	-	-	

#### RESULTS OF OPERATIONS AND SELECTED QUARTERLY FINANCIAL DATA

Year Ended October 31, 2020 Compared to the Year Ended October 31, 2019

During the year ended October 31, 2020, the Company incurred a net and comprehensive loss of \$1,175,584 compared to \$230,121 during the year ended October 31, 2019. The change in the net and comprehensive loss for the year ended October 31, 2020 compared to the year ended October 31, 2019 is mainly related to the following:

- Advertising and promotion increased by \$84,510 (2019 \$nil) from expenses related to the promotion of the acquisition of BioVaxys and the related intellectual property.
- Investor relations increased by \$41,290 to \$42,075 for the year ended October 31, 2020 (2019 \$785). The increase was due to the Transaction with BioVaxys Inc and the related communications.
- Professional fees increased by \$142,174 to \$214,874 for the year ended October 31, 2020 (2019 \$72,700).
   The increase in professional fees is related to the legal and accounting expenses for the due diligence of the acquisition of BioVaxys Inc which completed on September 30, 2020.
- Research and development of \$238,744 during the year ended October 31, 2020 (2019 \$nil) was due to work related to the intellectual property and the execution of the research programs. Prior to the transaction on September 30, 2020, the Company did not have any intellectual property or research programs.
- Share-based payments of \$347,713 during the year ended October 31, 2020 (2019 \$nil) was due to the vesting on 600,000 stock options granted on September 3, 2020 and 3,000,000 stock options granted on October 20, 2020. In the comparable period, there was no stock options granted.
- Transfer agent, regulatory and listing fees increased by \$14,690 to \$47,238 for the year ended October 31, 2020 (2019 \$32,548) due to costs associated with the exercise of 7,435,000 common share purchase warrants. In the comparable period, there was only 50,000 common share purchase warrants exercised.
- In the year ended October 31, 2020, the Company had a net loss from discontinued operation of \$71,688 (2019 \$13,239) which included the impairment of mineral property of \$55,000. The impairment was due to the recoverable amount of the Fish Lake Project was determined to be less than the book value.

Three Months Ended October 31, 2020 Compared to the Three Months Ended October 31, 2019

During the three months ended October 31, 2020, the Company incurred a net and comprehensive loss of \$821,693 compared to \$67,902 during the three months ended October 31, 2019. The change in the net and comprehensive loss for the three months ended October 31, 2020 compared to the three months ended October 31, 2019 is mainly related to the following:

- Investor relations expense was \$29,625 for the three months ended October 31, 2020 (2019 \$nil). The increase was due to the Transaction with BioVaxys Inc and the related communications.
- Management and consulting fees increased by \$64,758 to \$80,158 for the three months ended October 31, 2020 (2019 - \$48,500) due to the transition to a new executive team subsequent to the Transaction on September 30, 2020.
- Professional fees increased by \$85,421 to \$85,671 for the three months ended October 31, 2020 (2019 \$14,675). The increase in professional fees is related to the legal and accounting expenses for the due diligence of the acquisition of BioVaxys Inc which completed on September 30, 2020.
- Research and development of \$238,744 during the three months ended October 31, 2020 (2019 \$nil) was due to work related to the intellectual property and the execution of the research programs. Prior to the transaction on September 30, 2020, the Company did not have any intellectual property or research programs.
- Share-based payments of \$347,713 during the three months ended October 31, 2020 (2019 \$nil) was due to the vesting on 600,000 stock options granted on September 3, 2020 and 3,000,000 stock options granted on October 20, 2020. In the comparable period, there was no stock options granted.
- Transfer agent, regulatory and listing fees increased by \$22,274 to \$25,987 for the three months ended October 31, 2020 (2019 \$3,713) due to costs associated with the exercise of 7,435,000 common share purchase warrants. In the comparable period, there was only 50,000 common share purchase warrants exercised.

• In the three months ended October 31, 2020, the Company had a net loss from discontinued operations of \$71,688 which included the impairment of mineral property. The impairment was due to the recoverable amount of the Fish Lake Project was determined to be less than the book value.

### **SUMMARY OF QUARTERLY RESULTS**

The following table summarizes selected financial information from the Company's unaudited consolidated financial statements for the most recent eight quarters:

Quarter Ended	Total Revenues (\$)	Comprehensive & Net Loss from Continuing Operations (\$)	Total Comprehensive & Net Loss (\$)	Basic and Diluted Loss per Share (\$)
October 31, 2020	-	748,732	821,693	0.02
July 31, 2020	-	254,855	254,855	0.01
April 30, 2020	-	65,425	65,425	0.00
January 31, 2020	-	33,611	33,611	0.00
October 31, 2019	-	67,910	67,910	0.01
July 31, 2019	-	37,822	37,822	0.00
April 30, 2019	-	58,953	58,953	0.01
January 31, 2019	-	65,444	65,444	0.01

During the three months ended October 31, 2020, the comprehensive and net loss increased by \$493,877 from the three months ended July 31, 2020. The increase was due to the acquisition of BioVaxys Inc and the related research and development expenses of the new wholly owned subsidiary. Also, the Company had \$347,713 of share-based payments compared to \$nil in the three months ended July 31, 2020.

During the three months ended July 31, 2020, the comprehensive and net loss increased by \$189,430 from the three months ended April 30, 2020 due to an increase in professional fees and promotion expenses. Also, there was an impairment of the mineral property of \$55,000 as the recoverable amount of the Fish Lake Project was determined to be less than the book value.

During the three months ended April 30, 2020, the comprehensive and net loss increased by \$31,814 from the three months ended January 31, 2020. The increase was mainly due to higher professional fees by \$25,000.

During the three months ended January 31, 2020, the comprehensive and net loss decreased by \$34,299 from the three months ended October 31, 2019. The decrease was mainly due to lower management and consulting fees by \$35,000.

#### **OUTSTANDING SHARE DATA**

As at the date of this MD&A the Company had:

- 81,529,016 common shares issued and outstanding (October 31, 2020 74,074,611)
- 4,876,716 stock options issued and outstanding (October 31, 2020 3,876,716)
- 11,066,127 common share purchase warrants outstanding (October 31, 2020 9,384,116)
- 233,874 brokers' warrants outstanding (October 31, 2020 331,554)

Subsequent to October 31, 2020, the following share capital transactions occurred:

 On February 5, 2021, the Company issued 4,417,647 units at a price of \$0.255 per unit to certain strategic investors for total proceeds of \$1,126,500. Each unit consists of one common share and one whole common share purchase warrant. Each warrant is exercisable for one common share at an exercise price of \$0.50 for

- a period of 2 years. In connection with the private placement, the Company paid a cash finder's fee equal to 8% of the gross proceeds.
- On February 12, 2021, the Company granted 1,100,000 stock options with a weighted average exercise price of \$0.54 and a maturity date of February 12, 2026. Half of the options vest immediately with the remaining vesting over 6 months
- The Company issued 100,000 common shares pursuant to the exercise of stock options for proceeds of \$1,250.
- The Company issued 97,680 common shares pursuant to the exercise of brokers' warrants for proceeds of \$4,884.
- The Company issued 103,442 common shares pursuant to a consulting agreement with David Wang, a Director of the Company.
- The Company issued 2,735,636 common shares pursuant to the exercise of common share purchase warrants for proceeds of \$236,068.

#### LIQUIDITY AND CAPITAL RESOURCES

At October 31, 2020, the Company had cash of \$2,423,095 (October 31, 2019 - \$228,980) and a working capital of \$2,161,028 (October 31, 2019 - \$190,112). Whether and when the Company can obtain profitability and positive cash flows from operations is uncertain. The Company intends to finance its future requirements through a combination of debt and/or equity issuance. There is no assurance that the Company will be able to obtain such financings or obtain them on favorable terms. These uncertainties cast doubt on the Company's ability to continue as a going concern.

The Company's ability to continue its operations is dependent on its success in raising equity through share issuances, suitable debt financing and/or other financing arrangements. While the Company's management has been successful in raising equity in the past, there can be no guarantee that it will be able to raise sufficient funds to fund its activities and general and administrative costs if required in the future.

#### **USE OF PROCEEDS FROM FINANCING**

A comparison of the unaudited use of proceeds disclosed in the Filing Statement on October 5, 2020 to management's current estimate of the use of proceed is as follows:

	Prop	osed Use of Proceeds	P	ated Use of Proceeds to er 31, 2020
SARS-CoV-2 Vaccine Preclinical Development Program	\$	122,805	\$	122,805
SARS -CoV-2 Vaccine Phase I Study Ovarian Cancer EU Phase 1/Compassionate Use Vaccine		1,057,488		73,611
Program		334,700		-
General and Administrative Expenses		1,150,000		700,071
Unallocated working capital		42,007		42,007
Total	\$	2,707,000	\$	938,494

#### RELATED PARTY TRANSACTIONS

Key management consists of the Officers and Directors who are responsible for planning, directing and controlling the activities of the Company. The following expenses were incurred to the Company's key management:

For the year ended	October 31, 2020	October 31, 2019
Management and consulting fees	\$ 91,166	\$ 54,000
Professional fees	52,796	-
Rent	6,000	-
Share-based payments	299,241	-
	\$ 449,203	\$ 54,000

- During the year ended October 31, 2020, the Company expensed \$10,000 (October 31, 2019 \$nil) in management fees and \$69,968 in share-based payments to James Passin, the Chief Executive Officer and a Director of the Company. As of October 31, 2020, the Company has included \$65,613 (October 31, 2019 \$nil) due to James Passin as an amount due to related parties for reimbursable expenses and management fees.
- ii. During the year ended October 31, 2020, the Company expensed \$20,166 (October 31, 2019 \$nil) in management fees and \$69,968 in share-based payments to Kenneth Kovan, the Chief Operating Officer and President of the Company. As of October 31, 2020, the Company has included \$20,166 (October 31, 2019 \$nil) due to Kenneth Kovan as an amount due to related parties for management fees.
- iii. During the year ended October 31, 2020, the Company expensed \$10,000 (October 31, 2019 \$nil) in management fees and \$69,968 in share-based payments to David Berd, the Chief Medical Officer of the Company. As of October 31, 2020, the Company has included \$10,000 (October 31, 2019 \$nil) due to David Berd as an amount due to related parties for management fees.
- iv. During the year ended October 31, 2020, the Company expensed \$19,371 (October 31, 2019 \$nil) in share-based payments to Lachlan McLeod, the Chief Financial Officer of the Company. The Company also incurred management fees and professional fees of \$57,796 to a company that employs the CFO for accounting services. At October 31, 2020, the Company included \$7,288 in accounts payable to the CFO's employer.
- v. During the year ended October 31, 2020, the Company expensed \$13,994 (October 31, 2019 \$nil) in share-based payments to Daren Hermiston, a Director of the Company.
- vi. During the year ended October 31, 2020, the Company expensed \$13,994 (October 31, 2019 \$nil) in share-based payments to David Wang, a Director of the Company.
- vii. During the year ended October 31, 2020, the Company expensed \$27,000 (October 31, 2019 \$36,000) in consulting fees, \$6,000 (2019 \$nil) in rent, and \$41,978 in share-based payments to Jeremy Poirier, the former Chief Executive Officer and a former Director of the Company. As of October 31, 2020, the Company has included \$975 (October 31, 2019 \$39,000) due to Jeremy Poirier as accounts payable for reimbursable expenses.
- viii. During the year ended October 31, 2020, the Company expensed \$9,000 (October 31, 2019 \$18,000) in management fees to Benjamin Asuncion, a former Director of the Company. As of October 31, 2020, the Company has included \$nil (October 31, 2019 \$21,000) due to Benjamin Asuncion as an amount due to related parties.
- ix. During the year ended October 31, 2020, the Company expensed \$10,000 in consulting fees to Bearing, the former parent of the Company.

#### RECENT ACCOUNTING PRONOUNCEMENTS

# Changes in significant accounting policies and adoption of a new accounting standard

The Company adopted the requirements of IFRS 16 Leases effective November 1, 2019. This new standard replaces IAS 17 Leases and the related interpretative guidance. IFRS 16 applies a control model to the identification of leases, distinguishing between a lease and a service contract based on whether the customer controls the asset. Control is considered to exist if the customer has the right to obtain substantially all the economic benefits from the use of an identified asset and the right to direct the use of that asset. For those assets determined to meet the definition of a lease, IFRS 16 introduces significant changes to the accounting by lessees, introducing a single, on-balance sheet accounting model that is similar to the current finance lease accounting, with limited exceptions for short-term leases or leases of low value assets.

Upon adoption, the Company has elected to apply the available exemptions as permitted by IFRS 16 to recognize a lease expense on a straight-line basis for short-term leases (lease term of 12 months or less) and low value assets. The Company has also elected to apply the practical expedient whereby leases whose term ends within 12 months of the date of initial application would be accounted for in the same way as short-term leases.

Upon the adoption of IFRS 16, the Company has applied the short-term lease exemption on its lease of the office premise and therefore was not required to recognize any right-of-use assets and lease liabilities.

For any new contracts entered on or after November 1, 2019, the Company considers whether a contract is or contains a lease. A lease is defined as "a contract, or part of a contract, that conveys the right to use an asset (the underlying asset) for a period of time in exchange for consideration". To apply this definition, the Company assesses whether the contract meets three key evaluations, which are whether:

- i. The contract contains an identified asset, which is either explicitly identified in the contract or implicitly specified by being identified at the time the asset is made available to the Company.
- ii. The Company has the right to obtain substantially all the economic benefits from use of the identified asset throughout the period of use, considering its rights within the defined scope of the contract.
- iii. The Company has the right to direct the use of the identified asset throughout the period of use. The Company assess whether it has the right to direct "how and for what purpose" the asset is used throughout the period of use.

#### Measurement and recognition of leases as a lessee

At lease commencement date, the Company recognizes a right-of-use asset and a lease liability on the statement of financial position. The Company depreciates the right-of-use assets on a straight-line basis from the lease commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term. The Company also assesses the right-of-use asset for impairment when such indicators exist.

At the commencement date, the Company measures the lease liability at the present value of the lease payments unpaid at that date, discounted using the interest rate implicit in the lease, if that rate is readily available. If the interest rate implicit in the lease is not readily available, the Company discounts using the Company's incremental borrowing rate. Lease payments included in the measurement of the lease liability are made up of fixed payments (including insubstance fixed), variable payments based on an index or rate, amounts expected to be payable under a residual value guarantee and payments arising from options reasonably certain to be exercised.

Subsequent to initial measurement, the liability will be reduced for payments made and increased for interest. It is remeasured to reflect any reassessment or modification, or if there are changes in in-substance fixed payments. When the lease liability is remeasured, the corresponding adjustment is reflected in the right-of-use asset, or profit and loss if the right-of-use asset is already reduced to zero.

#### FINANCIAL INSTRUMENTS

#### Fair value

As at October 31, 2020, the Company's financial instruments consist of cash, accounts payable and due to related parties. The fair values of these financial instruments approximate their carrying values because of their current nature.

IFRS 13, *Fair Value Measurement*, establishes a fair value hierarchy based on the level of independent, objective evidence surrounding the inputs used to measure fair value. A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. IFRS 13 prioritizes the inputs into three levels that may be used to measure fair value:

- Level 1 Unadjusted quoted prices in active markets that are accessible at the measurement date for identical unrestricted assets or liabilities.
- Level 2 Inputs that are observable, either directly or indirectly, but do not qualify as Level 1 inputs (i.e. quoted prices for similar assets or liabilities).
- Level 3 Prices or valuation techniques that are not based on observable market data and require inputs that are both significant to the fair value measurement and unobservable market data.

The Company is exposed to varying degrees to a variety of financial instrument related risks:

### Foreign Exchange Risk

The Company is exposed to currency fluctuations. From time to time, the Company has US dollar balances in cash and accounts payable, and is therefore exposed to gains or losses on foreign exchange. A significant change in the currency exchange rate between the Canadian dollar relative to the US dollar could have an effect on the Company's profit or loss, financial position and/or cash flows. The Company has not hedged its exposure to currency fluctuations at October 31, 2020.

At October 31, 2020, the Company, through its wholly owned subsidiary, had a foreign currency cash balance of US\$3,956 and accounts payable of US\$434,285. A 10% change in the Canadian dollar versus the US dollar would give rise to a gain/loss of approximately \$57,300, based on the Company's current net exposure. In practice, the actual results may differ from this sensitivity analysis, and the difference may be material. Management considers foreign exchange to be a significant risk.

# Credit Risk

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation. The Company's cash is exposed to credit risk. The Company reduces its credit risk on cash by placing these instruments with institutions of high credit worthiness. The does not have significant exposure to credit risk.

# Interest Rate Risk

Interest rate risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market interest rates. As at October 31, 2020, the Company is not exposed to significant interest rate risk.

# Liquidity Risk

Liquidity risk is the risk that the Company will encounter difficulty in meeting obligations associated with financial liabilities. The Company manages liquidity risk by maintaining sufficient cash balances to enable settlement of transactions on the due date.

As of October 31, 2020, the Company had cash of \$2,423,095 (2019 - \$228,980), accounts payable of \$753,798 (2019 - \$37,820), accrued liabilities of \$50,513 (2019 - \$18,332) and due to related parties of \$95,780 (2019 - \$60,000). The Company's accounts payable and accrued liabilities are due within 90 days. Amounts due to related parties are due on demand. The Company addresses its liquidity through debt and equity financing obtained through the sale of common shares and the exercise of warrants and options. There is no assurance that it will be able to do so in the future. Liquidity risk is assessed as high.

#### **OFF-BALANCE SHEET ARRANGEMENTS**

The Company does not have any off-balance sheet arrangements for the year ended October 31, 2020.

#### PROPOSED TRANSACTIONS

There are no proposed transactions.

#### MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL STATEMENTS

The information provided in this report, including the consolidated financial statements, is the responsibility of management. In the preparation of these statements, estimates are sometimes necessary to make a determination of future values for certain assets or liabilities. Management believes such estimates have been based on careful judgments and have been properly reflected in the accompanying consolidated financial statements.

#### **RISKS AND UNCERTAINTIES**

The following are certain risk factors relating to the business and securities of the Company. The following information is a summary only of certain risk factors and is qualified in its entirety by reference to, and must be read in conjunction with, the detailed information appearing elsewhere in this MD&A. These risks and uncertainties are not the only ones facing the Company. Additional risks and uncertainties not presently known to the Company, or that the Company currently deems immaterial, may also impair the operations of the Company. If any such risks actually occur, the business, financial condition and/or liquidity and results of operations of the Company could be materially adversely affected.

#### **Going Concern**

Because of the Company's continuing need for capital, there remain questions as to its ability to continue as a going concern.

The Company presently anticipates that its current cash resources will be sufficient to fund operations through 2021 to the foreseeable future, depending upon how aggressively the Company implements its development plans. The Company has only a limited ability to generate revenues from operations, and any revenues it generates are almost certain to be substantially less than its operating expenses. Accordingly, it will be necessary to raise additional equity capital. Because of the Company's limited cash and financial resources, its ability to continue as a going concern beyond the next 12 months and the foreseeable future is in question.

The Company has no way of knowing if it will be able to complete any additional financings.

#### **Limited Operating History and Lack of Profits**

The Company is an early-stage biopharmaceutical company with a limited operating history. The likelihood of success of the Company's business plan must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which the Company operates. Biopharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. Therefore, the Company expects to incur expenses without any meaningful corresponding revenues unless and until it is able

to obtain regulatory approval and subsequently sell its products in significant quantities. To date, the Company has not generated any revenue from its products. The Company has incurred losses and anticipates that its losses will increase as it continues its development and clinical trials and seeks regulatory approval for the sale of its therapeutic product. There can be no assurance that it will have earnings or positive cash flow in the future. Further, even if the Company is able to commercialize any of its product candidates, there can be no assurance that the Company will generate significant revenues or ever achieve profitability.

The Company expects to continue to incur substantial losses for the foreseeable future, and these losses may be increasing. The Company is uncertain about when or if it will be able to achieve or sustain profitability. If the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods.

#### **Coronavirus Pandemic**

The current outbreak of COVID-19 and any future emergence and spread of similar pathogens could have an adverse impact on global economic conditions, which may adversely impact the Company's operations, and the operations of its suppliers, contractors and service providers, the ability to obtain financing and maintain necessary liquidity, and the ability to market the Company's product menu. The outbreak of COVID-19 and political upheavals in various countries have caused changes to traditional methods of conducting business. While these effects are expected to be temporary, the duration of the business disruptions internationally and related financial impact cannot be reasonably estimated at this time.

Similarly, the Company cannot estimate whether or to what extent this outbreak and the potential financial impact may extend to countries outside of those currently impacted. Travel bans and other government restrictions may also adversely impact the Company's operations and the ability of the Company to grow its business. In particular, if any employees or consultants of the Company become infected with Coronavirus or similar pathogens and/or the Company is unable to source necessary consumables or supplies, due to government restrictions or otherwise, it could have a material negative impact on the Company's operations and prospects, including the complete shutdown of its marketing activities. The situation is dynamic and changing day-to-day. The Company is exploring several options to deal with any repercussions that may occur as a result of the COVID-19 outbreak.

# **Research and Development Risks**

The following discussion of risks under this heading primarily reflect the US regulatory framework, but similar risks broadly apply to the European Union.

The Company can make no assurance that its research and development programs will result in regulatory approval or commercially viable products. To achieve profitable operations, the Company, alone or with others, must successfully develop, gain regulatory approval for, and market the Company's future products. The Company currently has no products that have been approved by the FDA, or any similar regulatory authority. To obtain regulatory approvals for the Company's product candidates being developed and to achieve commercial success, clinical trials must demonstrate that the product candidates are safe for human use and that they demonstrate efficacy. The Company has not yet commenced clinical trials for its product candidates. Many product candidates never reach the stage of clinical testing and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Product candidates may fail for a number of reasons, including but not limited to being unsafe for human use or due to the failure to provide therapeutic benefits equal to or better than the standards of treatment at the time of testing. Unsatisfactory results obtained from a particular study relating to a research and development program may cause the Company to abandon commitments to that program. Positive results from early preclinical research may not be indicative of favourable outcomes in later-stage clinical trials, and the Company can make no assurance that any future studies, if undertaken, will yield favourable results. The stage of the Company's research makes it particularly uncertain as to whether any of its product development efforts will prove to be successful and meet applicable regulatory requirements, and whether any of its product candidates will receive the necessary regulatory approvals, be capable of being manufactured at a reasonable cost or be successfully marketed.

If the Company is successful in developing its current and future product candidates into approved products, the Company will still experience many potential obstacles, which would affect the Company's ability to successfully market and commercialize such approved products, such as the need to develop or obtain manufacturing, marketing and distribution capabilities, price pressures from third-party payors, or proposed changes in health care systems. If the Company is unable to successfully market and commercialize any of its products, its financial condition and results of operation may be materially and adversely affected. The Company can make no assurance that any future studies, if undertaken, will yield favorable results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials after achieving positive results in early-stage development, and the Company cannot be certain that it will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval. If the Company fails to produce positive results in its future clinical trials and other programs, the development timeline and regulatory approval and commercialization prospects for the Company's product candidates, and correspondingly, its business and financial prospects, would be materially adversely affected.

# **Preclinical and Clinical Development Risks**

#### Third Party Risk with respect to Preclinical Studies and Clinical Trials

The Company relies on and will continue to rely on MilliporeSigma as the source of its non-GMP vaccine product for preclinical studies, and on CLR for its preclinical development work, and on other third parties to conduct other preclinical and clinical development activities. Preclinical activities include in vivo studies that provide immunogenicity, T-cell activation, and other critical data sets, pharmacology and toxicology studies and assay development. Clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in the Company's relations with CRL or with any other chosen third parties for preclinical studies or for any clinical trials, or if they are unable to provide quality services in a timely manner and at a feasible cost, the Company's active development programs will face delays. Further, if any of these third parties fails to perform as the Company expects or if the Company's work fails to meet regulatory requirements, the Company's testing could be delayed, cancelled or rendered ineffective.

### Sourcing the Vaccine Adjuvant Bacillus Calmette-Guerin ("BCG")

The Company administers the vaccine adjuvant BCG with autologous haptenized vaccines for ovarian cancer. BCG is an approved product for Bladder Cancer and can be administered by physicians as a stand-alone vaccine. There are several sources of BCG, each formulation of which differs based upon the original source of the product. If the Company is unable to continue to obtain the current strain of BCG (the "Tice" strain) used in is clinical trials, the Company may not be permitted by regulatory authorities to use another strain of BCG without conducting additional clinical studies with the new strain of BCG.

### **Enrolling Patients in Clinical Trial**

As the Company's product candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, the Company will need to enroll an increasing number of patients that meet its eligibility criteria. There is significant competition for recruiting patients in clinical trials, and the Company may be unable to enroll the patients it needs to complete clinical trials on a timely basis or at all. The factors that affect the Company's ability to enroll patients are largely uncontrollable and include, but are not limited to, the following:

- Size and nature of the patient population;
- Eligibility and exclusion criteria for the trial;
- Design of the study protocol;

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- Competition with other companies for clinical sites or patients;
- · The perceived risks and benefits of the product candidate under study; and
- The patient referral practices of physicians; and the number, availability, location and accessibility of clinical trial sites.

The Company will compete with other clinical programs and other treatments for patients for its clinical trials, which will affect its ability to enroll quickly the Company's clinical trials.

Companies with clinical trials, including the Company, provide information and other incentives to infectious disease specialists, oncologists, and other specialists as an inducement to participate in clinical trials. A physician is required to place patients in clinical trials based upon the physician's assessment of the likely benefits of that clinical trial to the patient. The information provided by the Company regarding any future clinical trials may not be sufficient to persuade physicians to place their patients in its clinical trials. The Company's business and financial condition will be materially and adversely affected by the failure to enroll its clinical trials.

#### **Delays in Clinical Testing**

The Company cannot predict whether any clinical trials will commence as planned, will need to be restructured, or will be completed on schedule, or at all. The Company's product development costs will increase if it experiences delays in clinical testing or approval or if it needs to perform more or larger clinical trials than planned.

Significant clinical trial delays could shorten any periods during which the Company may have the exclusive right to commercialize its product candidates or allow its competitors to bring products to market before the Company, which would impair its ability to successfully commercialize its product candidates and may harm its financial condition, results of operations and prospects. The commencement and completion of clinical trials for the Company's products may be delayed for a number of reasons, including delays related but not limited to:

- Regulatory authorities' failure to grant permission to proceed or placing the clinical trial on hold;
- Patients failing to enroll or remain in our trials at the rate the Company expects;
- Suspension or termination of clinical trials by regulators for a variety of reasons, including failure of the Company's CROs to satisfy their contractual duties or meet expected deadlines;
- Inspections of clinical trial sites by regulatory authorities, regulatory authorities or ethics committees finding regulatory violations that require the Company to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- One or more regulatory authorities or ethics committees rejecting, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial;
- Failure to reach agreement on acceptable terms with prospective clinical trial sites;
- Changes in regulatory requirements or policies may occur and the Company may need to amend study
  protocols to reflect these changes, and amendments may require the Company to resubmit its study protocols
  to regulatory authorities or ethics committees for re-examination, which may impact the cost, timing or
  successful completion of that trial, including concerns about patient safety or failure of the Company's
  collaborators to comply with GMP requirements;
- Product candidates demonstrating a lack of safety or efficacy during clinical trials;
- Patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects or other reasons;
- Reports of clinical testing on similar technologies and products raising safety or efficacy concerns;
- Competing clinical trials and scheduling conflicts with participating clinicians; and
- Clinical investigators not performing the Company's clinical trials on its anticipated schedule, dropping out of a trial, or employing methods not consistent with the clinical trial protocol, regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner.

#### Negative Results from Clinical Trials or Studies of Others and Adverse Safety Events

From time to time, studies or clinical trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to the Company's product candidates, or the therapeutic areas in which its product candidates compete, could adversely affect its future commercialization efforts, its share price and its ability to finance future development of its product candidates, and its business and financial results could be materially and adversely affected.

# The clinical trial and regulatory approval process for the Company's products will be expensive and time consuming and the outcome uncertain.

To obtain regulatory approval for the commercial sale of the Company's products, it must demonstrate through clinical trials that its products are safe and effective. The Company will incur substantial expense for, and devote a significant amount of time to pre-clinical testing and clinical trials of the Company's products in the U.S. and/or other markets. The results from pre-clinical testing and early clinical trials are not totally predictive of results that may be obtained in later clinical trials. Data obtained from pre-clinical testing and clinical trials are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. The Company's business and financial condition will be materially and adversely affected by any delays in, or termination of, its clinical trials.

The Company may not be able to obtain the funding to complete the regulatory approval process or it may fail to obtain FDA approval for its products, or regulatory approval in other markets. The Company may never be able to commercialize its vaccine products in the U.S. or other markets.

# Safety and Efficacy

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, the Company must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, despite promising results in earlier trials. The Company does not know whether the clinical trials it conducts will demonstrate adequate efficacy and safety to result in regulatory approval to market any of its product candidates in any jurisdiction. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk faced by the Company is the possibility that none of the product candidates will successfully gain market approval from regulatory authorities, resulting in the inability to derive any commercial revenue from them after investing significant amounts of capital in their development.

# **Manufacturing Risks**

#### Reliance on Third Party Contract Manufacturers

The Company has limited manufacturing experience and relies on CMOs over which it has limited control to manufacture its product candidates for preclinical studies and clinical trials. The Company relies on CMOs for manufacturing, filling, packaging, storing and shipping of drug products in compliance with GMP regulations applicable to the Company's products. FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with GMP regulations. The GMP regulations for drugs contain minimum requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product. There can be no assurances that CMOs will be able to meet the Company's timetable and requirements. If the Company is unable

to arrange for alternative third-party manufacturing sources on commercially reasonable terms or in a timely manner, the Company may be delayed in the development of the product candidates. Further, CMOs must operate in compliance with GMP and failure to do so could result in, among other things, the disruption of product supplies. The Company's dependence upon third parties for the manufacture of its products may adversely affect the profit margins and the ability to develop and deliver products on a timely and competitive basis.

# Success of Quality Control Systems

The quality and safety of the Company's vaccine products are critical to the success of its business and operations. As such, it is imperative that the Company's service providers' quality control systems operate effectively and successfully. Quality control systems can be negatively impacted by the design of the quality control systems, the quality training program, and adherence by personnel to quality control guidelines.

#### **Regulatory Risks**

The Company is operating in a regulated industry where the guidance for acceptable manufacturing and testing of the Company's products and processes is evolving, which creates uncertainties, delays and expense.

Regulatory standards require that the Company produce its products in compliance with current GMP. These requirements, as dictated by the applicable U.S. and European regulatory authorities, adopt the methods for end product standards and methods of analysis, which in the U.S. guidance is published in the United States Pharmacopoeia (similar guidance for Europe is published in the European Pharmacopoeia). The Company will be required to adapt its existing physical facilities, processes and procedures to these standards for the production of its products during clinical testing and for future commercialization. The inability to adapt to these evolving standards will delay the Company's ability to produce product for clinical testing and would delay the Company's ability to enter into clinical trials.

# The FDA and other regulatory agencies have substantial discretion in both the product approval process and manufacturing facility approval process.

As a result of this discretion and uncertainties about outcomes of testing, the Company cannot predict at what point, or whether, the FDA or other regulatory agencies will be satisfied with its (or any collaborator's) submissions or whether the FDA or other regulatory agencies will raise questions that may be material and delay or preclude product approval or manufacturing facility approval. In light of this discretion and the complexities of the scientific, medical and regulatory environment, the Company's interpretation or understanding of the FDA's or other regulatory agencies' requirements, guidelines or expectations may prove incorrect, which also could delay further or increase the cost of the approval process.

# The Company's development and commercialization activities and product candidates are significantly regulated by the FDA and other foreign governmental entities should it attempt product registration in those countries.

Regulatory approvals are required prior to each clinical trial and the Company may fail to obtain the necessary approvals to commence or continue clinical testing. The time required to obtain approval by regulatory authorities is unpredictable but outside special circumstances can typically take many years following the commencement of preclinical studies and clinical trials. Any analysis of data from clinical activities the Company performs is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Even if the Company's management believes results from the clinical trials are favorable to support the marketing of the product candidates, the FDA or other regulatory authorities may disagree. Approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary jurisdictions. The Company has not obtained regulatory approval for any product candidate and it is possible that none of the Company's existing product candidates or any future product candidates

will ever obtain regulatory approval. The Company could fail to receive regulatory approval for its product candidates for many reasons, including but not limited to:

- Disagreement with the design or implementation of its clinical trials;
- Failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- Failure of clinical trials to meet the level of statistical significance required for approval;
- Failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- Disagreement with the Company's interpretation of data from preclinical studies or clinical trials;
- The insufficiency of data collected from clinical trials of the Company's product candidates to support the submission and filing of a submission to obtain regulatory approval;
- Deficiencies in the manufacturing processes or the failure of facilities of collaborators with whom the Company contracts for clinical and commercial supplies to pass a pre-approval inspection;
- Changes in the approval policies or regulations that render the Company's preclinical and clinical data insufficient for approval;
- A regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and the Company's commercialization plans, or the Company may decide to abandon the development program:
- If the Company is successful in obtaining approval, regulatory authorities may approve any of its product candidates for fewer or more limited indications than the request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate; or
- Depending on any safety issues associated with the Company's product candidates that garner approval, the FDA or other authorities may impose a risk evaluation and mitigation strategy, thereby imposing certain restrictions on the sale and marketability of such products.

Although the Company may pursue the FDA's accelerated or priority review programs, the Company cannot guarantee the FDA will permit the use of these pathways or that the FDA's review of the Company's application will not be delayed.

Even if the FDA agrees to an accelerated or priority review of any of the Company's applications, the Company may not ultimately be able to obtain approval of the application in a timely fashion or at all. The FDA and foreign health authorities have substantial discretion in the drug and biologics approval processes. Despite the time and expense incurred, failure can occur at any stage, and the Company could encounter problems that cause the Company to abandon clinical trials or to repeat or perform additional preclinical, clinical or manufacturing-related studies. As the Company accumulates additional clinical data, it will submit it to the FDA and other regulatory agencies, as appropriate, and such data may have a material impact on the approval process.

#### Commercial/Marketing Risks

The Company is an early clinical stage biotechnology company that is developing antiviral and anticancer vaccine platforms, and it may never develop or successfully market any products.

Investors must evaluate the Company in light of the expenses, delays, uncertainties and complications typically encountered by development stage biotechnology businesses, many of which the Company already experienced and many of which are beyond its control. These risks can include an inability to generate any meaningful revenues from any other products or services while it works to develop its lead products and technologies, and cutbacks to development programs due to limited cash resources or emerging scientific data related to its lead products, which will require the Company to raise additional capital.

As a result of these and likely continuing challenges of being a development stage biotechnology company that is developing antiviral and anticancer vaccine platforms, the Company's products may never be successfully developed or marketed.

# The Company may not be able to compete with other companies, research institutes, hospitals or universities that are developing and producing cancer treatment products and technologies.

Many other companies, research institutes, hospitals and universities are working to develop products and technologies in the Company's specific field of vaccine research. Many of these entities have more experience than the Company does in developing and producing vaccines. Most of these entities also have much greater financial, technical, manufacturing, marketing, distribution and other resources than the Company possesses. The Company believes that numerous pharmaceutical companies are engaged in research and development efforts for products that could directly compete with its products under development. In addition, some of the Company's competitors have already begun testing products and technologies similar to its own. These other entities may succeed in developing products before the Company or that are better than those that the Company is developing. The Company expects competition in its specific area of research to intensify.

# Even if the Company's vaccines receive regulatory approval and are determined to be safe and effective, its products may not gain commercial acceptance.

Even if the Company's vaccine technology is safe and effective, there is no guarantee of commercial acceptance. Because its vaccine technology is a new approach to the treatment of cancer and viral infections, it must be accepted by both patients and physicians before it can be successfully commercialized. Due to the nature of the vaccine technology, it requires that current practitioners revise the way they think about infectious disease and cancer treatment. The marketplace of ideas, technologies and information is crowded, and the Company must develop the means to reach leading specialist physicians in each market with the haptenized vaccines. Failure to do so will have a material adverse effect on the Company's business and financial condition.

# If governmental and insurance reimbursement is not available or is insufficient, a market for the Company's products may never develop or be economically feasible.

The availability of governmental and insurance reimbursements of the costs of the vaccine is critical to ultimate physician and patient acceptance of the autologous vaccine technology. In both the U.S. and other countries, sales of the Company's products will depend in part upon the availability of reimbursement from third-party payors, which include government health administration authorities, managed care providers, and private health insurers. For new products or technologies, reimbursement must be established under existing governmental or insurance regulations or practices. The Company will be required to obtain reimbursement approvals (both governmental and insurance) in each country in which it obtains appropriate regulatory authority to market the autologous vaccines products.

In addition, third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. Significant uncertainty surrounds the reimbursement status of newly approved health care products, and the Company's products may not be considered cost effective by a particular governmental authority or insurer. Adequate third-party reimbursement may not be available to enable the Company to maintain price levels sufficient to realize an appropriate return on its investment in the research and development of its products.

# The Company may lose control over the marketing and distribution of its vaccines if it cannot afford to support its products.

The Company may have to depend on third parties to develop, market and distribute its products. It is particularly difficult and expensive to develop and distribute the autologous vaccines products, because they are custom made for each individual patient. The Company may have less control over marketing and distribution activities performed by third parties than if it was performing those functions with its own facilities and employees. This lack of direct control could adversely affect the results of these activities and consequently, the business and financial condition of the Company.

#### The Company may not be able to control the pricing of its products overseas.

Foreign government regulations and programs will likewise affect foreign pricing opportunities for the Company's products. Virtually all foreign countries regulate or set the prices of pharmaceutical products, which is a separate determination from whether a particular product will be subject to reimbursement under that government's health plans. There are systems for reimbursement and pricing approval in each country and moving a product through those systems is time consuming and expensive.

#### Current and future legislation may make the Company's products unprofitable.

Current and future legislation can and likely will continue to affect directly the ultimate profitability of pharmaceutical products and technologies. The U.S. and other countries continue to propose and pass legislation designed to reduce the cost of healthcare. Accordingly, legislation and regulations affecting the pricing of the Company's products may change before the products are approved for marketing to the public. Adoption of new legislation and regulations could further limit reimbursement for the Company's products. If third-party payors fail to provide adequate coverage and reimbursement rates for the Company's products, the market acceptance of the products may be adversely affected. In that case, the Company's business and financial condition will suffer. The Company is not aware of any specific legislation or regulation in the U.S. or Europe designed to limit reimbursement for products, but it believes that there is a credible risk that political and budget considerations could change dramatically the funding available for vaccine reimbursement.

#### **Intellectual Property Risks**

#### Risks Related to Potential Inability to Protect Intellectual Property.

The Company's success is heavily dependent upon its intellectual property. The Company licenses certain of its intellectual property from third parties and there can be no assurance that the Company will be able to continue licensing these rights on a continuous basis. The Company relies upon copyrights, trade secrets, unpatented proprietary know-how and continuing technology innovation to protect the intellectual property that it considers important to the development of its business. The Company relies on various methods to protect its proprietary rights, including patent applications, confidentiality agreements with its consultants, service providers and management that contain terms and conditions prohibiting unauthorized use and disclosure of its confidential information. However, despite the Company's efforts to protect its intellectual property rights, unauthorized parties may attempt to copy or replicate its intellectual property. There can be no assurances that the steps taken by the Company to protect its intellectual property will be adequate to prevent misappropriation or independent third-party development of its intellectual property. It is possible that other companies may try to duplicate the Company's products or production processes. To the extent that any of the above could occur, the Company's revenue could be negatively affected, and in the future, it may have to litigate to enforce its intellectual property rights, which could result in substantial costs and divert the Company's management's attention and its resources.

### Protection and Enforcement of the Company's Intellectual Property.

The Company's success will depend in part upon its ability to protect its intellectual property and proprietary technologies and upon the nature and scope of the intellectual property protection it receives. The ability to compete effectively and to achieve partnerships will depend on the Company's ability to develop and maintain proprietary aspects of its technology and to operate without infringing on the proprietary rights of others. The presence of such proprietary rights of others could severely limit the Company's ability to develop and commercialize its products, to conduct existing research and could require financial resources to defend litigation, which may be in excess of its ability to raise such funds. There is no assurance that its pending patent applications will be approved in a form that will be sufficient to protect the Company's proprietary technology and gain or keep any competitive advantage that it may have or, once approved, will be upheld in any post-grant proceedings brought by any third parties. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Patents issued to the Company may be challenged, invalidated or circumvented. To the extent the Company's intellectual property, including licensed intellectual

property, offers inadequate protection, or is found to be invalid or unenforceable, the Company is exposed to a greater risk of direct competition. If the Company's intellectual property does not provide adequate protection against its competitors' products, the Company's competitive position could be adversely affected, as could its business, financial condition and results of operations. Both the patent application process and the process of managing patent disputes can be time consuming and expensive, and the laws of some foreign countries may not protect the Company's intellectual property rights to the same extent as do US patent laws. The Company will be able to protect its intellectual property from unauthorized use by third parties only to the extent the Company's proprietary technologies, key products, and any future products are covered by valid and enforceable intellectual property rights including patents or are effectively maintained as trade secrets, and provided the Company has the funds to enforce its rights, if necessary.

#### Third Party License Risk.

The Company may require third-party licenses to effectively develop and manufacture its key products or future technologies and the Company is currently unable to predict the availability or cost of such licenses. A substantial number of patents have already been issued to other biotechnology and pharmaceutical companies. To the extent that valid third-party patent rights cover the Company's products or services, the Company or its strategic collaborators would be required to seek licenses from the holders of these patents in order to manufacture, use or sell these products and services, and payments under them would reduce the Company's profits from these products and services. We are currently unable to predict the extent to which the Company may wish or be required to acquire rights under such patents, the availability and cost of acquiring such rights, and whether a license to such patents will be available on acceptable terms or at all. There may be patents in the US or in foreign countries or patents issued in the future that are unavailable to license on acceptable terms. The Company's inability to obtain such licenses may hinder or eliminate an ability to manufacture and market products.

# Disclosure of Proprietary Information and Trade Secrets to Third Parties.

Due to the Company's reliance on third parties to develop the Company's products, the Company must share trade secrets with them. The Company seeks to protect its proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with its collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of the Company's collaborators, advisors, employees and consultants to publish data potentially relating to its trade secrets. Academic and clinical collaborators typically have rights to publish data, provided that the Company is notified in advance and may delay publication for a specified time in order to secure intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by the Company, although in some cases the Company may share these rights with other parties. The Company may also conduct joint research and development programs which may require it to share trade secrets under the terms of research and development collaborations or similar agreements. Despite the Company's efforts to protect its trade secrets, the Company's competitors may discover the Company's trade secrets, either through breach of these agreements, independent development or publication of information including the Company's trade secrets in cases where the Company does not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of the Company's trade secrets may impair its competitive position and could have a material adverse effect on the Company's business and financial condition.

#### **General Operational Risks**

#### Conflict of Interest

Certain directors and senior officers of the Company may, from time to time, be employed by or affiliated with organizations that have entered into agreements with the Company. As disputes may arise between these organizations and the Company, or certain organizations may undertake or have undertaken research with competitors of the Company, there exists the possibility for such persons to be in a position of conflict. Any decision or recommendation made by these persons involving the Company will be made in accordance with his or her duties

and obligations to deal fairly and in good faith with the Company and such other organizations. In addition, as applicable, such directors and officers will refrain from voting on any matter in which they have a conflict of interest.

#### **Uninsured Risks**

The Company may become subject to liability for hazards that cannot be insured against or against which it may elect not to be so insured because of high premium costs. Furthermore, the Company may incur liabilities to third parties (in excess of any insurance coverage) arising from any damage or injury caused by the Company's operations.

### Market for Securities and Volatility of Share Price

There can be no assurance that an active trading market in the Company's securities will be established or sustained. The market price for the Company's securities could be subject to wide fluctuations. Factors such as announcements of quarterly variations in operating results, as well as market conditions in the industry, may have a significant adverse impact on the market price of the securities of the Company. The stock market has from time-to-time experienced extreme price and volume fluctuations, which have often been unrelated to the operating performance of particular companies.

#### Competition

The Company faces competition from other biotechnology and pharmaceutical companies and its operating results will suffer if the Company fails to compete effectively. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. The Company's potential competitors globally include large, well-established pharmaceutical companies, specialty pharmaceutical sales, and marketing companies. Many of these competitors have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than the Company. If the Company is not able to compete effectively against its current and future competitors, its business will not grow and its financial condition and operations will suffer.

### Fluctuating Prices

The Company's revenues, if any, are expected to be in large part derived from products and services. Factors beyond the control of the Company including, but not limited to, international economic and political trends, currency exchange fluctuations, economic inflation and expectations for the level of economic inflation in the consuming economies, interest rates and global and local economic health and trends, may impact the price of such products and services. There is no assurance that the Company will always be able to reduce the risk or minimize the effect of any such fluctuations.

#### Key Person Insurance

The Company does not maintain key person insurance on any of its officers, and as a result, the Company would bear the full loss and expense of hiring and replacing any officer in the event the loss of any such persons by their resignation, retirement, incapacity, or death, as well as any loss of business opportunity or other costs suffered by the Company from such loss of any officer.

#### Currency Exchange Risks

In the event that a market for the Company's products develop in a foreign market and income is received in a foreign currency or if the Company has payables in a foreign currency, the Company would be exposed to fluctuations of such currency as compared to the Canadian and United States dollar.

#### Other Risks

#### The Company will be heavily dependent on its founders and current management team.

The Company is dependent upon its founders and management team to obtain funding for the research and development of its products, to decide which of its products to promote, to shepherd the products through the clinical trial and regulatory approval process, and to stimulate business development and seek out new products and technologies for development. In addition, the Company's current financial condition makes it more difficult for it to retain its current executives and recruit key employees.

# The Company is heavily dependent upon the personal reputation and personal contacts of its Chief Medical Officer, and the loss of his services could materially adversely affect its plan of operation.

The Company is leveraging its know-how of haptenized cell vaccines developed by one of its founders, Dr. David Berd, while at TJU in Philadelphia, Pennsylvania, and from his experience with the former Avax Technologies, Inc. The acceptance of the haptenized vaccine technology is highly dependent upon the personal reputation and the personal contacts of Dr. Berd. Dr. Berd is also critical in guiding the technology through the regulatory process in both the US and Europe. If the Company lost his services, the development of its technology could be significantly slower and less successful that it otherwise would be with his services, which would in turn materially adversely affect the Company's business and financial condition.

### The trading volume of the Common Shares is relatively low and a more active market may never develop.

The average daily trading volume in the Common Shares varies significantly, but is usually low. This low average volume and low average number of transactions per day may affect the ability of the Company's shareholders to sell their Common Shares in the public market at prevailing prices. A more active trading market for the Company's Common Shares may never develop.

# The Company may become party to litigation.

The Company may become party to litigation from time to time in the ordinary course of business, which could adversely affect its business. 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 of the Common Shares and could use significant resources. Even if the Company is involved in litigation and wins, litigation can consume significant Company resources.

#### Disclosure Controls and Internal Control Financial Reporting

Disclosure controls and procedures are designed to provide reasonable assurance that material information is gathered and reported to senior management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to permit timely decisions regarding public disclosure.

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. Any system of internal control over financial reporting, no matter how well designed, has inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

The Canadian Securities Administrators do not require any certification on the effectiveness of these controls at this time.

#### **APPROVAL**

The Company's Board of Directors has approved the Company's consolidated financial statements for the year ended October 31, 2020. The Company's Board of Directors has also approved the disclosures contained in this MD&A. A copy of this MD&A will be provided to anyone who requests it and is available on *www.sedar.com*.