

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

For the three months ended January 31, 2021  
As of April 1, 2021

This Management Discussion and Analysis (“MD&A”) of BioVaxys Technology Corp. (formerly Lions Bay Mining Corp.) (the “Company”) for the three months ended January 31, 2021 is performed by management using information available as of April 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 unaudited condensed consolidated interim financial statements for the three months ended January 31, 2021, the audited consolidated financial statements for the year ended October 31, 2020, and the related notes thereto. These 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;
- the 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;
- 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 the **Risks and Uncertainties** section. 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 the Company, 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 headings **Financial Instruments** and **Risks and Uncertainties**.

## **BUSINESS OVERVIEW**

The Company was incorporated on April 25, 2018 pursuant to the provisions of the *Business Corporations Act* of British Columbia and was a wholly owned subsidiary of Bearing Lithium Corp. ("Bearing"). Prior to the Transaction described below, the Company was a mineral exploration company. The Company's shares are traded on the Canadian Securities Exchange 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 and 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 European Union ("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.

### **Acquisition of BioVaxys Inc.**

On June 2, 2020, the Company and BioVaxys Inc. ("BioVaxys"), an early-stage clinical biotechnology company developing antiviral and anticancer vaccines and immune-diagnostics, entered into a share exchange agreement ("Share Exchange Agreement"). Pursuant to the Share Exchange Agreement, the Company acquired all the issued and outstanding shares 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 certain advisors and 1,160,000 common shares issued to Thomas Jefferson University ("TJU").

### **COVID-19**

In March 2020, the World Health Organization declared coronavirus 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 adapted to the needs of the society and the demand from the market for coronavirus vaccine products. It has initiated the study and development of BVX-0320, its proprietary vaccine candidate for COVID-19.

The extent to which the coronavirus 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 and Uncertainties**.

## RECENT HIGHLIGHTS

- On November 2, 2020, the Company announced that it filed a provisional patent application with the US Patent and Trademark Office entitled *Method and kit for detection of cell mediated immune response #63106482* related to the potential development of the Diagnostic Platform.
- On November 11, 2020, the Company announced that results from its Murine Model Study show that BVX-0320 created a 96.4% positive antibody response of the SARS-CoV-2 s-spike protein.
- 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.
- On November 30, 2020, in connection with the OSU study, the Company announced that the remaining mouse sera that had been collected from mice after receiving BVX-0320 in Murine Model Study was going to be tested for its ability to elicit a neutralizing antibodies response to the live SARS-CoV-2 virus. A neutralizing antibody is an antibody that defends against a pathogen or virus by neutralizing any effect it has biologically. Neutralization renders the virus no longer infectious.
- On December 10, 2020, the Company announced that its submission of Form 211 to the Financial Industry Regulatory Authority had been cleared and the Company's shares qualify for trading in the United States on the OTC Pink Market under the symbol "LMNGF".
- On December 21, 2020, the Company announced that further analysis of the data from its Murine Model Study shows that BXV-0320 elicits a robust T-cell response against SARS-CoV-2. BVX-0320 was found to activate immune system memory 'helper' CD4+ and Killer CD8+ T-cells against SARS-CoV-2, which has potential for longer term viral protection.
- The Company prepared the draft clinical development program for Covid-T™, and in December 2020 engaged global regulatory advisory group Rio Pharmaceutical Services of Bridgewater NJ ("RPS") to provide strategic regulatory guidance, prepare a US Food and Drug Administration ("FDA") pre-submission guidance package, recommend regulatory pathways and support the Company on the registration filing.
- On January 25, 2021, the Company announced that it has commenced the clinical development program for its haptenized tumor antigen vaccine for ovarian cancer ("BVX-0918A"). The Company plans to seek a compassionate use approval in the EU for Stage III and Stage IV ovarian cancer in early 2022, followed by submitting an Investigational New Drug ("IND") in the US. 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. Refer to **Ovarian Cancer Vaccine Candidate** section below for more details.
- On January 28, 2021, the Company announced that it has initiated the clinical development program process for Covid-T™, which is the Company's novel diagnostic platform for detecting T-cell activity. The FDA tentatively agreed to allow the Company to file for a pre-Emergency Use Authorization ("EUA") for Covid-T™, having submitted the EUA application to the FDA in late January 2021.
- In January 2021, RPS recommended that a non-clinical study will be needed to establish the risk profile prior to the start of the clinical studies of Covid-T™. The Company plans to conduct an animal toxicology study in early summer 2021. The Company is currently evaluating proposals from Contract Research Organizations ("CRO") to conduct a toxicology study in a rabbit model. BioVaxys is in the process of obtaining the appropriate cell lines, expression systems and licenses to allow it to produce its own supply of the SARS-CoV-2 s-spike protein, which will be used in the animal toxicology study. As of February 2021, BioVaxys is finalizing a production protocol and contract with a Contract Manufacturer ("CMO") to produce the s-protein for the toxicology study and the Phase I clinical study. BioVaxys anticipates signing the contract for the toxicology study in March 2021, but the start of the animal toxicology study is dependent on the bioproduction CMO completing the bioproduction of the s-protein.

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- On February 2, 2021, the Company announced positive results from the research collaboration with Ohio State University, specifically that its SARS-CoV-2 Vaccine Candidate elicits a neutralizing antibody response against SARS-CoV-2.
- 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.
- On February 9, 2021, Jeremy Poirier resigned from his role as director.
- On February 9, 2021, the Company entered into a heads of agreement (the "Heads of Agreement") with Procure Health Iberia S.L. ("Procure Health") of Barcelona, Spain, for the purpose of a broad collaboration for the co-development, joint commercialization and marketing of the Company's vaccine candidates for ovarian cancer, cervical cancer and human papilloma virus ("HPV"), and the right of first refusal for marketing by the Company in the United States of Procure Health's product, Papilocare™. Refer to **Ovarian Cancer Vaccine Candidate** below for more details.
- On February 12, 2021, the Company announced the appointment of Shmuel Farhi as a Corporate Advisor to the Company. Mr. Farhi, founder and President of Farhi Holding Corporation, a company that owns more than four million square feet of properties across Ontario, Canada, is a prolific investor in the Canadian, American and Israeli biotech industry.
- On February 16, 2021, the Company announced that it has been approved for DTCC full-service eligibility in the United States and its shares are qualified to be held at the Depository Trust Company ("DTC") and traded and serviced through DTC's electronic book-entry system.
- On February 22, 2021, the Company announced the appointment of Dr. Kartik Chandran, Ph.D., to its Scientific Advisory Board. Dr. Chandran is a professor of microbiology and immunology and the Harold and Muriel Block Scholar in Virology at Albert Einstein College of Medicine ("Einstein") in New York City, where he oversees a team of researchers engaged in basic and translational research on emerging RNA viruses and investigating the molecular mechanisms of infection. Dr. Chandran's laboratory focuses on coronaviruses and filoviruses, including SARS-CoV-2, Ebola virus and Marburg virus, and other neglected emerging viruses, such as hantaviruses and Crimean-Congo hemorrhagic fever virus, and leads a multi-institutional collaboration to discover and develop potent, long-lasting antibody treatments against these viruses. Dr. Chandran received his Ph.D. in Biochemistry at the University of Wisconsin-Madison, followed by research fellowships at Harvard Medical School and Brigham and Women's Hospital prior to joining Einstein.
- On March 1, 2021, the Company announced that it is assessing steps to modify BVX-0320 and Covid-T, its SARS-CoV-2 vaccine candidate and T-cell diagnostic, to address the newly emerging variants (the South African, UK and Brazilian variants) of SARS-CoV-2 that are of high concern to worldwide governments, healthcare practitioners and infectious disease researchers.
- On March 15, 2021, the Company announced that it has entered a major bioproduction agreement with WuXi Biologics Limited ("WuXi Bio"), to produce SARS-CoV-2 s-proteins required for BVX-0320 and for its Covid-T™ immunodiagnostic program.
- On March 18, 2021, the Company entered an agreement with Bioanalytical Systems, Inc. d/b/a Inotiv ("Inotiv"), a global CRO, to conduct preclinical toxicology studies for its Covid-T™ immunodiagnostic. Headquartered in West Lafayette, Indiana, Inotiv provides contract research services and monitoring instruments to emerging pharmaceutical companies and some of the world's leading drug development companies and medical research organizations.
- On March 19, 2021, the Company filed International Patent Application No. PCT/US21/23310 HAPTENIZED CORONAVIRUS SPIKE PROTEINS, which included new claims for haptenized SARS-CoV-2 variants United Kingdom (B.1.1.7 lineage), South Africa (B.1.351 lineage) and Brazil (P.1 lineage).

- On March 24, 2021, the Company expanded patent protection of its bihaptenized tumor antigen platform technology by filing National Phase patent applications to include the major pharmaceutical markets of US, EU (including the UK and Turkey), Australia, Canada, China, India, Japan, Russia, Brazil and South Korea.
- On March 25, 2021, on the recommendation of patent and trademark counsel at MorganLewis, the Company instructed the firm to conduct a comprehensive trademark search for the proposed mark(s) Covid-DTH and CovidDTH as additional trademark candidates for Covid-T.
- On March 26, 2021, the Company filed a pre-IND meeting request and submitted a briefing package with the FDA, Center for Biologics Evaluation and Research ("CBER") for Covid-T, its T-cell immune response diagnostic for SARS-CoV-2. The pre-IND meeting is a critical step in the US regulatory approval process, as it affords an opportunity for study sponsor companies to seek clarification from the FDA on clinical trials design, clinical materials manufacturing and quality control.

## **PRODUCTS AND DEVELOPMENT**

### **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. The Company is building a pipeline of vaccine products that are based on this proprietary technology platform of haptenizing antigens to elicit a robust immune response. Current development programs target ovarian cancer, cervical cancer, HPV and SARS-CoV-2.

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

BVX-0320 is the Company's IND-stage vaccine candidate for SARS-CoV-2. The vaccine is the recombinant S1 subunit of the spike protein of SARS-CoV-2 that has been modified with a chemical called a hapten, specifically, dinitrophenyl (DNP). The Company has developed a simple, low-cost procedure for manufacturing its vaccines, and BVX-0320 can be stored in a universally available freezer.

The Company believes that by utilizing a process called haptenization, the S-spike antigens are changed so that they become visible to the patient's immune system. This allows the immune system to mount a response against the S-spike antigen that results in the loss of ability of the virus to attach to human cells.

Studies (May 14, 2020, *Cell*) have demonstrated that patients recovering from SARS-CoV-2 carried helper T-cells that recognized the SARS-CoV-2 S-spike protein; 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 will have an advantage over other developing COVID-19 vaccines.

In December 2020, the Company completed its preclinical program for BVX-0320, which was the Murine Model Study that evaluated *in vivo* immune response, T-cell activation and tolerability of BVX-0320, which were studies suggested by the US Department of Health and Human Services, FDA, and CBER in their published *Guidance on Development and Licensure of Vaccines to Prevent COVID-19* (the "Guidance"). The Guidance is intended to assist in the clinical development and licensure of vaccines for the prevention of COVID-19 and reflects 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 the 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 QS-21, to 28 mice at four dosage levels, 96.4% developed positive antibody

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responses 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 and CD8+ killer T-cells. CD4+ helper 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+ helper 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, 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 in 2021 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 later in 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 that are otherwise not immunogenic. Haptenization is a well-known and well-studied immunotherapeutic approach in cancer studies 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 prior Phase I/II trials. The Company has enhanced the original vaccine approach of using a single hapten to now utilize two haptens ("bihaptenization"), which the Company believes will yield superior results.

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 positive 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 and Stage IV ovarian cancer targeted for 2022.

On February 9, 2021, the Company and Procure Health, a leading privately-held European pharmaceutical company, entered into a broad collaboration. Under the terms of the agreement, 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 Procure Health overseeing and making a US\$900,000 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 CRO to conduct the study. In return, Procure Health will have exclusive rights to market and distribute BVX-0918A in the 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. Under the agreement, Procure Health will be responsible for marketing and distribution in the EU and will begin launch planning in early 2022.

The co-development gives the Company access to Procure Health's clinical development and regulatory expertise in the EU, and to its marketing and sales presence in Europe. Procure Health has an established portfolio of marketed brands that is focused heavily on the women's health and gynecological oncology markets. The relationship with Procure Health will give the Company access to key gynecological oncology opinion leaders for patient access, clinical trial recruitment and a relationship that post-approval will drive vaccine sales. Having a strong EU opinion leader network will also be invaluable for the planned US launch of BVX-0918A.

On February 18, 2021, the Company signed the Term Sheet with BioElpida for the build-out for the clinical-grade manufacturing process and aseptic packaging for BXV-0918A. BioElpida is a biotechnology CDMO that applies single-use bioprocessing for development and manufacturing of biological and cell-based products. BioElpida's expertise extends from research and development 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 and 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 Company expects to finalize the definitive service agreement with BioElpida in early 2021. BioElpida preliminary estimate for GMP process build-out and validation is ~US\$1,000,000.

Based on the following best estimate timeline (Source: BioElpida 2/2021), BioElpida would complete all necessary process design and validation by the end of 2021 to enable the Company to incorporate the bioproduction in the submission of their application in late 2021 or early 2022 for approval of the EU Phase I study.

### **T-Cell Antigen Discovery Program**

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 therapy and Engineered T-Cell Receptor 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")***

Currently, the most common COVID-19 diagnostics only measure antibody-mediated immunity to SARS-CoV-2. Methods of measuring T-cell immunity require the drawing of blood from the test subject and a time-consuming and expensive analysis of the blood sample at laboratories possessing specialized equipment. There is now a large body of data indicating that assaying T-cell-mediated immunity to the virus is of equal or greater importance. A simple, rapid and inexpensive technology that could screen large populations for T-cell responses would constitute an important new weapon in the fight against COVID-19. The principal markets for such a diagnostic will be for high-volume screening of a population to test for the presence of T-cells against SARS-CoV-2 to identify safe populations and at-risk populations (who need to be vaccinated.), and to provide a low-cost, easy-to-administer and accurate tool to evaluate the effectiveness of any SARS-CoV-2 vaccine candidate in stimulating T-cell immunity.

In January 2021, the Company initiated the clinical development program for its novel diagnostic tool, Covid-T™, which is the world's first low cost, disposable, diagnostic to identify a T-cell immune response to the presence of SARS-CoV-2.

Covid-T™ uses Delayed-Type Hypersensitivity ("DTH") technology. DTH is known to be a measure of T-cell immunity and has been used for many years for other infectious diseases, including tuberculosis, fungal diseases and mumps. The test is performed by placing a small amount of synthesized test material, e.g., the SARS-CoV-2 spike protein,

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intradermally and inspecting the site for erythema and induration 24-48 hours later. The test results can be visually interpreted by a physician and measured with a ruler, or optically using a cell phone app that the Company plans to develop.

Covid-T is anticipated to be a single-use disposable syringe with ~3mm (or less) micro needle holding ~1ml of purified, non-infectious, synthesized SARS-CoV-2 s-1 protein in liquid suspension. The proposed syringe is BD Allergist Tray Syringe, 1 ml volume.

With the addition of s-proteins from SARS-CoV-2 variants of interest, Covid-T™ has the potential for detecting differences in T-cell responses between the original SARS-CoV-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 that are spreading worldwide. The Company plans to expand Covid-T's range to include the clinically concerning emerging B.1.1.7 and B.1.351 SARS2 variants. As of the date of this MD&A, the gene sequences for the variants are not yet published. Once the sequences are available, the Company will be able to produce purified s-protein for the variants.

On March 15, 2021, the Company announced that it has entered into a major bioproduction agreement with WuXi Bio, a leading global CDMO and business unit of Shanghai-based Wuxi AppTec, to produce SARS-CoV-2 s-proteins required for BVX-0320 and for its Covid-T™ immunodiagnostic program.

## **INTANGIBLE PROPERTIES**

### ***Intellectual Property***

The Company regards its intellectual property rights as the foundation blocks upon which it continues to build a successful biotechnology company. The Company protects its intellectual property rights through a robust combination of patent, copyright, trademark and trade secrets, as well as with confidentiality and invention assignment agreements.

The Company seeks intellectual property protection in various jurisdictions around the world and owns patents and patent applications relating to products and technologies in the United States, Canada, Europe and other jurisdictions.

At the time of this MD&A, the Company has a total of 2 issued US Patents and 3 pending patent applications in the United States. These patent and patent applications include:

- Issued US patent #7,297,330 – Low dose haptenized tumor cell and tumor cell extract immunotherapy (expiration 2024)
- Issued US patent #8,435,784 – Cryopreservation of Haptenized Tumor Cells (expiration 2026)
- US Patent Application #62/735,381 International Application No. PCT/US2019/052644- BIHAPTENIZED AUTOLOGOUS VACCINES AND USES THEREOF (original filing September 24, 2018)
- US patent application #62/992,722 – Haptenized Coronavirus Spike Protein Vaccine (Filed on March 20, 2020)
- US patent application #63106482 – METHOD AND KIT FOR DETECTION OF CELL MEDIATED IMMUNE RESPONSE (Filed on October 28, 2020)

The one-year filing anniversary for the above-listed US Provisional Application No. 62/992,722 HAPTENIZED CORONAVIRUS SPIKE PROTEINS is March 20, 2021, and the application must be converted to an international PCT application or a US non-provisional application or both before the deadline of March 30, 2021. The Company's patent counsel was instructed to convert #62/992,722 to an international PCT application prior to the deadline.

The National Phase filing deadline for the above-listed International Application No. PCT/US2019/052644 entitled *Bihaptenized Autologous Vaccines and Uses Thereof* is March 24, 2021. The Company will elect those countries it would like to enter, which is typically decided on commercial interest of the invention in such a country, either by manufacture, sale or license. Generally, pharmaceutical PCT applications tend to enter at least the large jurisdictions,



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such as the US, Europe, Japan, China, Australia, Brazil and India. The Company may also consider national phase filing in other markets.

***Licenses***

BioVaxys entered into an exclusive license agreement dated April 25, 2018 with TJU for four older US patents related to a haptized cancer vaccine using a single hapten (the "TJU License"). The licensed patents are:

- Issued US patent #7,297,330 – Low dose haptized tumor cell and tumor cell extract immunotherapy (expiration 2024)
- Issued US patent #8,435,784 – Cryopreservation of haptized tumor cells (expiration 2026)

The TJU License is an exclusive, royalty-bearing license for the rights to the single hapten cancer vaccine technology, and provides for the following payments to TJU upon the occurrence of certain milestones:

- US\$15,000 following enrollment of the first patient in a Phase 3 clinical trial (or foreign equivalent if outside US) for a product utilizing single-hapten cancer vaccine technology;
- US\$15,000 following FDA allowance for a product utilizing single-hapten cancer vaccine technology; and
- US\$50,000 once BioVaxys has reached \$5,000,000 in net sales of a product utilizing single-hapten cancer vaccine technology.

The TJU License includes a royalty payment of 2% on net sales of products based on the TJU License by BioVaxys while covered by an unexpired patent. In addition to the milestone payments and royalty set out above, TJU was issued a warrant to purchase 4% of the outstanding shares of BioVaxys on a fully diluted basis for an exercise price of US\$10 pursuant to a share exchange agreement dated July 7, 2020, between TJU and the Company. TJU exercised its warrant immediately prior to the completion of the Transaction. As a result, TJU received 1,160,000 common shares upon closing of the Transaction. Further, The Company bears the expense of maintaining and defending the patents that are subject to the TJU License.

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

*Three Months Ended January 31, 2021 Compared to the Three Months Ended January 31, 2020*

During the three months ended January 31, 2021, the Company incurred a comprehensive loss of \$1,518,888 compared to \$33,611 during the three months ended January 31, 2020. The change in the comprehensive loss for the three months ended January 31, 2021 compared to the three months ended January 31, 2020 is due to the acquisition of BioVaxys on September 30, 2020. In the prior year, the Company had minimal activity and is now actively developing multiple products. The following are the significant changes:

- Advertising and promotion expense was \$528,593 for the three months ended January 31, 2021 (three months ended January 31, 2020 - \$nil). The significant increase was due to promotion subsequent to the Transaction with BioVaxys to highlight the acquired technologies and research developments.
- Investor relations was \$78,136 for the three months ended January 31, 2021 (three months ended January 31, 2020 - \$nil). The significant increase was due to growth in the number of news releases and expanded media relations needs after the Transaction with BioVaxys.
- Management and consulting fees increased by \$546,982 to \$558,682 for the three months ended January 31, 2021 (three months ended January 31, 2020 - \$11,700) due to the transition to a new executive team subsequent to the Transaction on September 30, 2020. Also, the Company was inactive in the prior period and did not need many consultants. During the three months ended January 31, 2021, the Company has engaged multiple consultants to navigate the regulatory environment associated with the development of vaccines and diagnostic tests.

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- Research and development expense of \$114,080 was recorded during the three months ended January 31, 2021 (three months ended January 31, 2020 - \$nil) 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, resulting \$nil in research and development expense for the three months ended January 31, 2020.
- Share-based payments of \$166,753 during the three months ended January 31, 2021 (three months ended January 31, 2020 - \$nil) was due to the vesting of 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 or vested.
- During the three months ended January 31, 2021, the Company had a foreign currency translation adjustment gain of \$18,502 due to foreign exchange translation of the foreign operation of BioVaxys, as the functional currency of BioVaxys is the US dollar.

**SUMMARY OF QUARTERLY RESULTS**

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

<b>Quarter Ended</b>	<b>Total Revenues (\$)</b>	<b>Comprehensive Loss (\$)</b>	<b>Net Loss from Continuing Operations (\$)</b>	<b>Net Loss (\$)</b>	<b>Basic and Diluted Loss per Share (\$)</b>
January 31, 2021	-	1,518,888	1,537,390	1,537,390	0.02
October 31, 2020	-	821,693	748,732	821,693	0.02
July 31, 2020	-	254,855	254,855	254,855	0.01
April 30, 2020	-	65,425	65,425	65,425	0.00
January 31, 2020	-	33,611	31,811	33,611	0.00
October 31, 2019	-	67,902	67,902	67,902	0.01
July 31, 2019	-	37,822	37,822	37,822	0.00
April 30, 2019	-	58,953	58,953	58,953	0.01

During the three months ended January 31, 2021, the comprehensive loss increased by \$697,195 from the three months ended October 31, 2020. The increase was due to research and development expenses of the new wholly owned subsidiary, BioVaxys. Also, the Company had significant advertising and promotion expenses subsequent to the Transaction with BioVaxys to highlight the acquired technologies and research developments.

During the three months ended October 31, 2020, the comprehensive and net loss increased by \$566,838 from the three months ended July 31, 2020. The increase was due to the acquisition of BioVaxys 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 during 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 Valley 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 \$34,291 from the three months ended October 31, 2019. The decrease was mainly due to lower management and consulting fees by \$35,000.

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## **OUTSTANDING SHARE DATA**

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

- 81,574,469 common shares issued and outstanding (January 31, 2021 - 76,860,366)
- 4,876,716 stock options issued and outstanding (January 31, 2021 - 3,776,716)
- 9,294,363 common share purchase warrants outstanding (January 31, 2021 - 6,869,116)
- 233,874 brokers' warrants outstanding (January 31, 2021 - 233,874)

Subsequent to January 31, 2021, 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 two 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. Among the options granted, 925,000 vested immediately and the remaining vest over six months from the grant date.
- The Company issued 48,320 common shares pursuant to a consulting agreement with David Wang, a director of the Company.
- The Company issued 248,136 common shares pursuant to the exercise of common share purchase warrants for proceeds of \$124,068.

## **LIQUIDITY AND CAPITAL RESOURCES**

At January 31, 2021, the Company had cash of \$857,103 (October 31, 2020 - \$2,423,095) and a working capital of \$961,777 (October 31, 2020 - \$2,161,028). 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 favourable 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:

	Proposed Use of Proceeds	Estimated Use of Proceeds to January 31, 2021
SARS-CoV-2 Vaccine Preclinical Development Program	\$ 122,805	\$ 122,805
SARS -CoV-2 Vaccine Phase I Study	1,057,488	157,625
Ovarian Cancer EU Phase 1/Compassionate Use Vaccine Program	334,700	-
General and administrative expenses	1,150,000	1,150,000
Unallocated working capital	42,007	42,007
<b>Total</b>	<b>\$ 2,707,000</b>	<b>\$ 1,472,437</b>

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**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 by the Company's key management:

<i>For the three months ended</i>	January 31, 2021	January 31, 2020
Management and consulting fees	\$ 171,998	\$ 13,500
Professional fees	3,166	-
General and administrative expenses	727	-
Rent	4,500	-
Share-based payments	115,954	-
	<u>\$ 296,345</u>	<u>\$ 13,500</u>

- i. During the three months ended January 31, 2021, the Company expensed \$31,500 (three months ended January 31, 2020 - \$nil) in management fees and \$26,449 in share-based payments to James Passin, the Chief Executive Officer, and a director of the Company. As of January 31, 2021, the Company has included \$66,102 (October 31, 2020 - \$65,613) due to Mr. Passin as an amount due to related parties for reimbursable expenses and management fees.
- ii. During the three months ended January 31, 2021, the Company expensed \$60,498 (three months ended January 31, 2020 - \$nil) in management fees and \$26,449 in share-based payments to Kenneth Kovan, the Chief Operating Officer and President of the Company. As of January 31, 2021, the Company has included \$20,166 (October 31, 2020 - \$20,166) due to Mr. Kovan as an amount due to related parties for management fees.
- iii. During the three months ended January 31, 2021, the Company expensed \$30,000 (three months ended January 31, 2020 - \$nil) in management fees and \$26,449 in share-based payments to Dr. David Berd, the Chief Medical Officer of the Company. As of January 31, 2021, the Company has included \$10,000 (October 31, 2020 - \$10,000) due to Dr. Berd as an amount due to related parties for management fees.
- iv. During the three months ended January 31, 2021, the Company expensed \$10,160 (three months ended January 31, 2020 - \$nil) in share-based payments to Lachlan McLeod, the Chief Financial Officer ("CFO") of the Company. The Company also incurred management fees and professional fees of \$18,893 (2020 - \$nil) to a company that employs the CFO for accounting services. As at January 31, 2021, the Company included \$6,713 (October 31, 2020 - \$7,288) in accounts payable to the CFO's employer.
- v. During the three months ended January 31, 2021, the Company paid \$1,500 (three months ended January 31, 2020 - \$nil) in directors' fees and expensed \$5,290 (three months ended January 31, 2020 - \$nil) in share-based payments to Daren Hermiston, a director of the Company.
- vi. During the three months ended January 31, 2021, the Company paid \$1,500 (three months ended January 31, 2020 - \$nil) in directors' fees and expensed \$5,290 (three months ended January 31, 2020 - \$nil) in share-based payments to David Wang, a director of the Company. The Company also issued 73,075 shares for \$20,000 of services related to a consulting agreement and accrued \$10,000 for services rendered before January 31, 2021 but was settled in shares subsequent to the period.
- vii. During the three months ended January 31, 2021, the Company expensed \$2,000 (three months ended January 31, 2020 - \$9,000) in consulting fees, \$4,500 (three months ended January 31, 2020 - \$nil) in rent and \$15,869 (three months ended January 31, 2020 - \$nil) in share-based payments to Jeremy Poirier, the former Chief Executive Officer and a former director of the Company. As of January 31, 2021, the Company has included \$nil (October 31, 2020 - \$975) due to Mr. Poirier as accounts payable for reimbursable expenses.
- viii. During the three months ended January 31, 2021, the Company expensed \$nil (three months ended January 31, 2020 - \$4,500) in management fees to Benjamin Asuncion, a former director of the Company.

## **SIGNIFICANT ACCOUNTING ESTIMATES AND JUDGMENTS**

The preparation of the condensed consolidated interim financial statements requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of expenses during the reporting period. Actual outcomes could differ from these estimates. The condensed consolidated interim financial statements include estimates that, by their nature, are uncertain. The impacts of such estimates are pervasive throughout the condensed consolidated interim financial statements and may require accounting adjustments based on future occurrences. Revisions to accounting estimates are recognized in the period in which the estimate is revised and future periods if the revision affects both current and future periods. These estimates are based on historical experience, current and future economic conditions and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

### *Significant Judgments*

The following are critical judgments that management has made in the process of applying accounting policies and that have the most significant effect on the amounts recognized in the condensed consolidated interim financial statements:

- i. Management is required to assess the functional currency of the Company. In concluding that the Canadian dollar is the functional currency of the Company, management considered the currency that mainly influences the operating expenditures in the jurisdiction in which the Company operates.
- ii. The Company's ability to execute its strategy by funding future working capital requirements requires judgment. Estimates and assumptions are continually evaluated and are based on historical experience and other factors, such as expectations of future events that are believed to be reasonable under the circumstances.
- iii. The determination of whether a set of assets acquired, and liabilities assumed, in an acquisition constitute a business may require the Company to make certain judgments, considering all facts and circumstances. A business is presumed to be an integrated set of activities and assets capable of being conducted and managed for the purpose of providing a return in the form of dividends, lower costs, or economic benefits.
- iv. Impairment of intangible assets or cash-generating units are evaluated at each reporting date to determine whether there are any indications of impairment. The Company considers both internal and external sources of information when making the assessment of whether there are indications of impairment for the Company's intangible assets.

### *Estimation Uncertainty*

The following are key assumptions concerning the future and other key sources of estimation uncertainty that have a significant risk of resulting in a material adjustment to the carrying amounts of assets and liabilities within the current and next fiscal financial years:

- i. Estimates of future taxable income are based on forecast cash flows from operations and the application of existing tax laws in each jurisdiction. To the extent that future cash flows and taxable income differ significantly from estimates, the ability of the Company to realize the net deferred tax assets recorded at the date of the condensed consolidated interim statement of financial position could be impacted.
- ii. The measurement of identifiable assets acquired pursuant to the Transaction, assumed at fair value on the date of acquisition and the allocation of the purchase consideration over the fair value of the assets acquired, is subject to management estimation and judgment.

## **FINANCIAL INSTRUMENTS**

### *Fair Value*

As at January 31, 2021, 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 due to 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 in 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 January 31, 2021.

At January 31, 2021, the Company, through its wholly owned subsidiary, had a foreign currency cash balance of US\$3,956 and accounts payable of US\$80,968. A 10% change in the Canadian dollar versus the US dollar would give rise to a gain/loss of approximately \$9,799, 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 moderate 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 this instrument with institutions of high credit worthiness. The Company does not have significant exposure to credit risk.

### *Interest Rate Risk*

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market interest rates. As at January 31, 2021, 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.

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As of January 31, 2021, the Company had cash of \$857,103 (October 31, 2020 - \$2,423,095), accounts payable of \$176,416 (October 31, 2020 - \$753,798), accrued liabilities of \$45,301 (October 31, 2020- \$50,513) and due to related parties of \$97,189 (October 31, 2020 - \$95,780). 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 as of January 31, 2021.

**PROPOSED TRANSACTIONS**

There are no proposed transactions.

**MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL STATEMENTS**

The information provided in this report, including the condensed consolidated interim 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 condensed consolidated interim 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**

Due to 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 and 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. Due to the Company's limited cash and financial resources, its ability to continue as a going concern beyond the next twelve 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

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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 EU.

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 healthcare 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 favourable 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 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;
- 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 to 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 US 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 US 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. The 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 US and European regulatory authorities, adopt the methods for end product standards and methods of analysis, which in the US 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 favourable 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 by 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;

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- 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 ultimately may not 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 haptized 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 US 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 healthcare 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, as 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 US 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 US or Europe designed to limit reimbursement for products, but it believes that there is a credible risk that political and budget considerations could dramatically change 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, and 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

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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 that 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 due to 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 dollars.

### ***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.

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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 than 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 condensed consolidated interim financial statements for the three months ended January 31, 2021. 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](http://www.sedar.com).