BioVaxys Technology Corp.
MANAGEMENT'S DISCUSSION AND ANALYSIS
For the three months ended January 31, 2022
As of April 1, 2022

This Management Discussion and Analysis ("MD&A") of BioVaxys Technology Corp. (the "Company") for the three months ended January 31, 2022 is performed by management using information available as of April 1, 2022. 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 three months ended January 31, 2022, the audited consolidated financial statements for the year ended October 31, 2021, 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 the Company's future revenues, expenses 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 the 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. Prior to the Transaction described below, the Company was a mineral exploration company. The Company's shares are traded on the Canadian Securities Exchange ("CSE") under the symbol "BIOV" and on OTCQB under the symbol "BVAXF". 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 Phase I clinical 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, CoviDTH™, which screens for a protective, long-term, T-cell response in either patients exposed to SARS-CoV-2 or those who have been vaccinated and who are not sure of their immune status. The vaccines and CoviDTH™ are described in greater detail below.

Acquisition of BioVaxys Inc. (the "Transaction")

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. 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 ("WHO") 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 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 (or "US"), Canada 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.

The Company has rapidly adapted to the needs of 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. Refer to further discussion related to COVID-19 implication under the heading **Risks and Uncertainties**.

RECENT HIGHLIGHTS

- On November 6, 2021, the Company announced that results from its *in vivo* animal research study support the safety and tolerability of CoviDTH™ at two intradermal dose levels across a battery of clinical pathology, immunology and histopathology evaluations. The objective of the study was to determine the potential toxicity and toxicokinetic profile of SARS-CoV-2 spike protein when administered two times via intradermal injection in a rabbit model, and to determine the persistence or reversibility of any toxic effects over a one-week recovery period. Conducted together with global contract research organization Inotiv, Inc. ("Inotiv"), the Good Laboratory Practice ("GLP") study successfully met all objectives and demonstrated the safety, tolerability and lack of toxicity of the purified recombinant SARS-CoV-2 s-protein that is a principal constituent of CoviDTH™. The highest dose tested in the study was 5x-10x higher than the probable dose in humans, with no adverse effects, except some mild localized redness.
- On November 18, 2021, the Company announced that its Chief Medical Officer, David Berd, MD, has been invited by the Editorial Board of Therapeutic Advances in Vaccines and Immunotherapy to submit a scientific review article based on his speaking engagement entitled *Haptenized Protein Vaccines for Viral Diseases and Cancer* on December 1 at the World Vaccine & Immunotherapy Congress in San Diego, California.
- On December 7, 2021, the Company announced that it has entered into a major sponsored research collaboration with Ohio State University ("OSU") to further develop BioVaxys' haptenized viral antigen platform to create a broadly reactive pan-sarbecovirus vaccine. This is the second research collaboration in the SARS-CoV-2 field between BioVaxys and OSU, a leading global academic research institute in the fight against SARS-CoV-2. OSU's Wexner Medical Center serves as a site for SARS-CoV-2 multicenter clinical trials.
- On February 16, 2022, the Company announced that studies on BVX-0320 demonstrate that the vaccine does not bind to the Angiotensin Converting Enzyme-2 ("ACE2") receptor. The finding suggests that the Company's haptenized SARS-CoV-2 spike protein vaccine may not lead to the unusual, but serious, myocarditis observed with mRNA vaccines. Previous studies in mice have shown that BVX-0320 stimulates a robust antibody and T-cell response, and was safe and well tolerated.
- On March 17, 2022, the Company announced that it has entered into an agreement with Millipore-Sigma ("Millipore") a global Contract Development and Manufacturing Research Organization ("CDMO"), to manufacture a supply of GLP-grade BVX-1021, the Company's newly developed vaccine ("BVX-1021") for the strain of coronavirus that causes Severe Acute Respiratory Syndrome ("SARS1"), the respiratory illness responsible for the deadly 2002–2004 pandemic. There are no vaccines approved for SARS1. BVX-1021 is the subject of the ongoing research collaboration between The Ohio State University ("Ohio State") and BioVaxys, announced December 7th, 2021, that is evaluating the Company's novel approach for a "universal vaccine" that can treat a broad range of sarbecoviruses ("pan-sarbecovirus vaccine"). Sarbecoviruses are a family of viruses that include SARS-CoV-2 and all current 'Variants of Concern' such as Delta and Omicron (as well as at least ten additional variants that are currently being monitored), SARS1, and a broad range of other potentially dangerous zoonotic viruses.

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 hapentizing antigens to elicit a robust immune response. Current development programs target ovarian cancer, cervical cancer, Human papillomavirus, SARS-CoV-2 and pan-sarbecoviruses.

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

BVX-0320 is the Company's Investigational New Drug ("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. 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, US Food and Drug Administration ("FDA") and Center for Biologics Evaluation and Research ("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 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.

On February 16, 2022, the announced that studies on BVX-0320 conducted by Millipore demonstrate that the vaccine does not bind to the ACE2 receptor. The finding suggests that the Company's haptenized SARS-CoV-2 spike protein vaccine may not lead to the unusual, but serious, myocarditis observed with mRNA vaccines. Previous studies in mice have shown that BVX-0320 stimulates a robust antibody and T-cell response and was safe and well tolerated.

BVX-1021

On March 17, 2022, the Company announced that it has entered into an agreement with Millipore-Sigma ("Millipore") a global Contract Development and Manufacturing Research Organization ("CDMO"), to manufacture a supply of GLP-grade BVX-1021, the Company's newly developed vaccine ("BVX-1021") for the strain of coronavirus that causes Severe Acute Respiratory Syndrome ("SARS1"), the respiratory illness responsible for the deadly 2002–2004 pandemic. There are no vaccines approved for SARS1. BVX-1021 is the subject of the ongoing research collaboration

between The Ohio State University ("Ohio State") and BioVaxys, announced December 7th, 2021, that is evaluating the Company's novel approach for a "universal vaccine" that can treat a broad range of sarbecoviruses ("pan-sarbecovirus vaccine"). Sarbecoviruses are a family of viruses that include SARS-CoV-2 and all current 'Variants of Concern' such as Delta and Omicron (as well as at least ten additional variants that are currently being monitored), SARS1, and a broad range of other potentially dangerous zoonotic viruses.

The collaboration between BioVaxys and Ohio State, which has been underway since early January 2022, is evaluating the combination of BVX-0320 and BVX-1021 in a guinea pig model. The major endpoints of the study are the development of virus-neutralizing antibodies to live virus SARS-CoV-2 and other sarbecoviruses, including bat and pangolin SARS-related coronaviruses. Bats are a major reservoir of many strains of SARS, with several strains have been identified in palm civets, which were likely ancestors of SARS-CoV-1. (*Journal of Virology*. 84 (6): 2808–19, 2010). The presence of neutralizing antibodies in the animal model would strongly suggest that BVX-1021 would confer an additional immune response across all sarbecoviruses in those people fully vaccinated for Covid-19 as well as those with natural immunity.

Ovarian Cancer Vaccine Candidate (BVX-0918)

BVX-0918 is the Company's lead haptenized tumor cell vaccine for ovarian cancer, which is planned to enter a Phase I study in the EU in 2022. 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, while at TJU achieved positive immunological and clinical results in prior Phase I/II trials. The Company has enhanced the first-generation vaccine approach of using a single hapten to now utilize two haptens (bihaptenization) in a second-generation vaccine, which the Company believes will yield superior results.

Since a hapten is either hydrophilic or hydrophobic, a single hapten can only modify either hydrophilic or hydrophobic amino acids on these target proteins. By utilizing the correct pair of haptens, both hydrophilic and hydrophobic amino acids are modified on the target protein, making the protein more foreign to the immune system. Specifically, a much greater number and variety of T-cells are activated by the addition of the second hapten 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-0918, as Phase I and Phase II clinical studies have already been successful with the first generation single hapten approach. The Company is seeking to do a Phase I study in the European Union ("EU") in 2022.

On February 9, 2021, the Company and Procare Health Iberia S.L. ("Procare 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-0918 in Spain for late-stage ovarian cancer. The Company will be responsible for the core technology and vaccine production, with Procare Health overseeing and making a US$900,000 in-kind investment in the clinical program and regulatory planning, Contract Research Organizations ("CRO") management, patient/clinical center recruitment, marketing and opinion leader management. The companies have agreed to equally share costs associated with engaging a European CRO to conduct the study. In exchange for this consideration, Procare Health will have exclusive rights to market and distribute BVX-0918 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-0918 in the US, as well as for all other global markets. Under the agreement, Procare Health will be responsible for marketing and distribution in the EU and will begin launch planning in 2022.

The co-development gives the Company access to Procare Health's clinical development and regulatory expertise in the EU, and to its marketing and sales presence in Europe. Procare Health has an established portfolio of marketed

brands that is focused heavily on the women's health and gynecological oncology markets. The relationship with Procare 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-0918.

On February 18, 2021, the Company signed an agreement with BioElpida S.A.S. ("BioElpida") of Lyon, France, for the build-out for the GMP clinical-grade manufacturing process and aseptic packaging for BXV-0918. 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

Based on an updated timeline (Source: BioElpida 11/2021), BioElpida would complete all necessary process design and validation in mid 2022 to enable the Company to incorporate the bioproduction in the submission of their application in 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. The Company is including blood draws in its ovarian cancer EU Phase I clinical protocol to begin obtaining pre-post vaccination leukocytes.

SARS-CoV-2 Diagnostic Tool (CoviDTH™)

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

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

On March 15, 2021, the Company announced that it has entered into a major bioproduction agreement with WuXi Biologics (Hong Kong) Limited ("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 CoviDTH™ immunodiagnostic program.

In June 2021, BioVaxys science advisor Dr. Barrios, a specialist in Clinical Immunology at Hospital Universitario de Canarias, Tenerife, Spain, and a leading expert in the clinical use of DTH, the mechanism behind CoviDTH™, presented human data offering proof-of-concept and safety on the use of DTH in detection of T-cell activation. The medical research journals *Clinical Immunology and Vaccines* both published the results of two clinical studies led by Dr. Barrios and her colleagues on use of the DTH reaction to measure cellular immune responses to SARS-CoV-2 in patients after infection and in individuals vaccinated with the Pfizer mRNA vaccine. These studies in human volunteers by Dr. Barrios and her colleagues are the first publications of the results obtained using the classical DTH response to the SARS-CoV-2 S-spike protein ("s protein") to assess T-cell immune responses in vaccinated individuals, and proved that this affordable and simple test, which is substantially equivalent to CoviDTH™, is effective and safe, and can answer basic immunogenicity questions in large-scale populations.

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, 4 pending patent applications, and 1 trademark registration in the United States. These 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), PCT/US21/23310 filed March 19, 2021
- US patent application #63106482 – Method and Kit for Detection of Cell Mediated Immune Response (Filed on October 28, 2020), PCT Application filed October 27, 2021
- US Trademark Application April 2021, "CoviDTH", with foreign filing for the trademark completed in October 2021 for Canada, Mexico, China, EU and United Kingdom. Trademark applications in certain countries may be treated as if they had been filed on the filing date of the US application, provided the applications are filed within six months of the US filing date. BioVaxys may still apply for trademark registration of CoviDTH in other countries at a later date, but it will be without the benefit of the earlier US filing date.
- US Provisional Application October 27, 2021 #63/253,149 Methods of Immunization Against Coronavirus

The one-year filing anniversary for the above-listed US Provisional Application No. 62/992,722 Haptenized Coronavirus Spike Proteins was March 20, 2021, and the application was converted to an international PCT 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* was March 24, 2021. The Company has entered National Phase patent prosecution in the jurisdictions of the US, EU, United Kingdom, Japan, China, Republic of Korea, Australia, Russia, Brazil and India.

Licenses

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

- Issued US patent #7,297,330 – Low dose haptenized tumor cell and tumor cell extract immunotherapy (expiration 2024); and
- Issued US patent #8,435,784 – Cryopreservation of haptenized 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$25,000 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$25,000 following FDA allowance for a product utilizing single-hapten cancer vaccine technology; and
- US$100,000 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, 2022 Compared to the Three Months Ended January 31, 2021

During the three months ended January 31, 2022, the Company incurred a comprehensive loss of $1,211,239 compared to $1,518,888 during the three months ended January 31, 2021. The $307,649 decrease in the comprehensive loss is mainly due to the following:

- Advertising and promotion expense was $nil during the three months ended January 31, 2022 (2021 - $528,593). The significant decrease of $528,593 was due to a marketing promotion campaign in the three months ended January 31, 2021 to highlight the acquired technologies and research developments. A similar campaign did not take place during the three months ended January 31, 2022.
- Investor relations was $102,507 for three months ended January 31, 2022 (2021 - $78,136). The $24,371 increase was due to growth in the number of news releases and expanded media relations needed as the Company continues to increase operations.
- Management and consulting fees increased by $59,661 to $618,343 for the three months ended January 31, 2022 (2021 - $558,682). The management fees remained consistent with the comparable period. During the three months ended January 31, 2022, the Company engaged multiple consultants to navigate the regulatory environment associated with the development of vaccines and diagnostic tests.
- Professional fees increased by $21,043 to $59,927 for the three months ended January 31, 2022 (2021 - $38,884) due to legal work related to the private placement, patents and general regulatory filings.

- Research and development expense of $215,136 was recorded during the three months ended January 31, 2022 (2021 - $114,080) due to work related to the intellectual property and the execution of the Company's research programs. In the comparable period, the Company was just starting on multiple research programs which have become more active over time

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:

Quarter Ended	Total Revenue ($)	Comprehensive Loss ($)	Net Loss from Continuing Operations ($)	Net Loss ($)	Basic and Diluted Loss per Share ($)
January 31, 2022	-	1,211,239	1,211,244	1,211,244	0.01
October 31, 2021	-	2,519,066	2,519,768	2,519,768	0.03
July 31, 2021	-	903,291	905,085	905,085	0.01
April 30, 2021	-	1,496,822	1,495,696	1,495,696	0.02
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	188,055	254,855	0.01
April 30, 2020	-	65,425	62,337	65,425	0.00

During the three months ended January 31, 2022, the comprehensive loss decreased by $1,307,827 from the three months ended October 31, 2021. The Company had decreased advertising and promotion expenses by $644,508 due to advertising campaigns in the three months ended October 31, 2021. The Company also decreased expenses related to research and development by $412,398 due to the completion of research milestones during the three months ended October 31, 2021. There was a decrease in share based payments of $152,797 as the number of stock options vesting has decreased. The remaining increase was mainly due to an increase in advertising and promotion caused by a change in the timing of marketing campaigns.

During the three months ended October 31, 2021, the comprehensive loss increased by $1,615,775 from the three months ended July 31, 2021. The Company had increased research and development expenses of $626,398 due to costs associated with progressing the Company's research programs. There was an increase in management and consulting fees of $392,304, as the Company hired additional consultants to navigate the regulatory environment. The Company had increased share-based payments of $173,178 from the prior period due to the granting of stock options. The remaining increase was mainly due to an increase in advertising and promotion caused by a change in the timing of marketing campaigns.

During the three months ended July 31, 2021, the comprehensive loss decreased by $593,531 from the three months ended April 30, 2021. The Company had decreased share-based payments by $367,581 due to a significant amount of stock options granted in the three months ended April 30, 2021. The remaining decrease was mainly due to a decrease in advertising and promotion caused by a change in the timing of marketing campaigns.

During the three months ended April 30, 2021, the comprehensive loss decreased slightly by $22,066 from the three months ended January 31, 2021. The comprehensive loss was relatively flat due to offsetting changes. The Company had increased share-based payments of $344,075 due to the vesting of prior stock options and the granting of new stock options in the quarter. This was offset by a decrease in management and consulting fees of $249,762 and a decrease in advertising and promotion of $206,799.

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 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 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.

OUTSTANDING SHARE DATA

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

- 97,718,415 common shares issued and outstanding (January 31, 2022 - 92,338,681)
- 7,102,424 stock options issued and outstanding (January 31, 2022 – 7,452,424)
- 24,863,574 common share purchase warrants outstanding (January 31, 2022 - 19,540,241)
- 233,874 brokers' warrants outstanding (January 31, 2022 - 233,874)

Subsequent to January 31, 2022, the following share capital transactions occurred:

a) The Company issued 56,401 common shares pursuant to a consulting agreement with a director of the Company.

b) The Company issued 5,323,333 units for proceeds of $798,500 pursuant to a private placement. Each unit is comprised of one common share and one warrant. Each warrant entitles the holder to acquire one common share at a price of $0.30 per share for three years. The Company incurred total finder's fees of $18,840.

c) The Company cancelled 350,000 stock options with an exercise price of $0.465 per share.

LIQUIDITY AND CAPITAL RESOURCES

At January 31, 2022, the Company had cash of $148,992 (October 31, 2021 - $539,115) and a working capital deficiency of $457,815 (October 31, 2021 – working capital surplus of $547,624). 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.

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:

	January 31, 2022	January 31, 2021
General and administrative expenses	$ 2,019	$ 727
Management and consulting fees	175,998	171,998
Professional fees	5,665	3,166
Rent	4,500	4,500
Share-based payments	147,086	115,954
	$ 335,268	$ 296,345

i. During the three months ended January 31, 2022, the Company expensed $31,500 (2021 - $31,500) in management fees and $37,711 (2021 - $26,449) in share-based payments to James Passin, the Chief Executive Officer ("CEO") and a director of the Company. As of January 31, 2022, the Company has included $20,000 (October 31, 2021 - $11,500) 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, 2022, the Company expensed $60,498 (2021 - $60,498) in management fees and $37,711 (2021 - $26,449) in share-based payments to Kenneth Kovan, the Chief Operating Officer and President of the Company. As of January 31, 2022, the Company has included $40,332 (October 31, 2021 - $20,166) due to Mr. Kovan as an amount due to related parties for management fees.

iii. During the three months ended January 31, 2022, the Company expensed $30,000 (2021 - $30,000) in management fees and $37,711 (2021 - $26,449) in share-based payments to Dr. David Berd, the Chief Medical Officer of the Company. As of January 31, 2022, the Company has included $10,000 (October 31, 2021 - $10,000) due to Dr. Berd as an amount due to related parties for management fees.

iv. During the three months ended January 31, 2022, the Company expensed $5,012 (2021 - $10,160) 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 $22,684 (2021 - $18,893) to a company that employs the CFO for accounting services. As of January 31, 2022, the Company included $24,269 (October 31, 2021 - $6,713) in accounts payable to the CFO's employer.

v. During the three months ended January 31, 2022, the Company paid $1,500 (2021 - $nil) in directors' fees and expensed $7,542 (2020 - $5,290) in share-based payments to Daren Hermiston, a director of the Company. As of January 31, 2022, the Company has included $nil (October 31, 2021 - $1,466) due to Mr. Hermiston as an amount due to related parties for consulting fees.

vi. During the three months ended January 31, 2022, the Company paid $1,500 (2021 - $1,500) in directors' fees and expensed $7,542 (2021 - $5,290) in share-based payments to David Wang, a director of the Company. The Company also issued 151,720 shares for $40,000 of services related to a consulting agreement. In addition, there was $1,500 due to related parties for management fees and Goods and Services Tax on consulting fees.

vii. During the three months ended January 31, 2022, the Company expensed $6,000 (2021 - $2,000) in consulting fees, $4,500 (2021 - $4,500) in rent and $11,349 (2021 - $15,869) in share-based payments to Jeremy Poirier, the former CEO and a former director of the Company. As of January 31, 2022, the Company has included $3,600 (October 31, 2021 - $nil) due to Mr. Poirier as accounts payable for reimbursable expenses.

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 forecasted 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, 2022, 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 euro dollar balance in loan receivable, 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 or euro 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 during the three months ended January 31, 2022.

As at January 31, 2022, the Company had a foreign currency cash balance of US$8,941 and accounts payable of US$204,206. A 10% change in the Canadian dollar versus the US dollar would give rise to a gain or loss of approximately $24,800, based on the Company's current net exposure. Additionally, the Company had a loan receivable of €250,000 and accounts payable of €96,000. A 10% change in the Canadian dollar versus the euro would give rise to a gain/loss of approximately $22,000, based on the Company's 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 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, 2022, the Company is not exposed to significant interest rate risk.

Liquidity Risk

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

As of January 31, 2022, the Company had cash of $148,992 (October 31, 2021 - $593,115), accounts payable of $714,268 (October 31, 2021 - $216,465), accrued liabilities of $50,803 (October 31, 2021 - $38,115) and due to related parties of $103,116 (October 31, 2021 - $72,283). 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 at January 31, 2022.

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 2022 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 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 Millipore 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, 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 standalone 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 Quickly Enroll 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 its 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;
- 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 haptenized vaccines. Failure to do so will have a material adverse effect on the Company's business and financial condition.

If Governmental and Insurance Reimbursement is Not Available or is Insufficient, a Market for the Company's Products May Never Develop or be Economically Feasible

The availability of governmental and insurance reimbursements of the costs of the vaccine is critical to ultimate physician and patient acceptance of the autologous vaccine technology. In both the 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 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. The Company is 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. 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.

The acceptance of the haptenized vaccine technology is highly dependent upon the personal reputation and the personal contacts of Dr. Berd. Dr. Berd is also critical in guiding the technology through the regulatory process in both the US and Europe. If the Company lost his services, the development of its technology could be significantly slower and less successful that it otherwise would be with his services, which would in turn materially adversely affect the Company's business and financial condition.

The Trading Volume of the Common Shares is Relatively Low and a More Active Market May Never Develop

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

The Company May Become Party to Litigation

The Company may become party to litigation from time to time in the ordinary course of business, which could adversely affect its business. Should any litigation in which the Company becomes involved be determined against the Company, such a decision could adversely affect the Company's ability to continue operating and the market price of the common shares and could use significant resources. Even if the Company is involved in litigation and wins, litigation can consume significant Company resources.

Disclosure Controls and Internal Control Financial Reporting

Disclosure controls and procedures are designed to provide reasonable assurance that material information is gathered and reported to senior management, including the CEO and CFO, 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, 2022. 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*.