

# BIOVAXYS

## **BioVaxys Technology Corp. MANAGEMENT'S DISCUSSION AND ANALYSIS**

For the three and six months ended April 30, 2023 and 2022  
As of June 29, 2023

This Management Discussion and Analysis ("MD&A") of BioVaxys Technology Corp. (the "Company") for the six months ended April 30, 2023 and 2022 is performed by management using information available as of June 29, 2023. Management has prepared this MD&A with reference to National Instrument 51-102 *Continuous Disclosure Obligations* of the Canadian Securities Administrators. This MD&A should be read in conjunction with the Company's unaudited condensed consolidated interim financial statements for the six months ended April 30, 2023 and 2022, the audited consolidated financial statements for the years ended October 31, 2022 and 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 transactions;
- 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.

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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. 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 heading **Financial Instruments**.

## **BUSINESS OVERVIEW**

The Company was incorporated on April 25, 2018, pursuant to the provisions of the Business Corporations Act of British Columbia. 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 the exclusive US licensee and distributor of a portfolio of over-the-counter (OTC) female reproductive health products currently marketed in the EU from the Barcelona-based company, Procure Health Iberia, and is also entering clinical development for BVX-0918, a personalized immunotherapeutic vaccine using our proprietary HapTenix™ neoantigen tumor cell construct platform for treating refractive late-stage ovarian cancer. The Company's OTC female reproductive system products include Papilocare®, a re-epithelializing vaginal gel for the preventative and supportive treatment of lesions caused by HPV, and Papilocare® Immunocaps, a nutritional supplement that helps to normalize the vaginal microbiota and strengthen natural immune defenses. BioVaxys is also exploring the use of its HapTenix™ platform in developing vaccines for SARS-CoV-2, SARS-CoV-1, and a pan-sarbecovirus vaccine through non-dilutive/off balance sheet academic collaborations.

## **RECENT HIGHLIGHTS**

- In June 2023, the Company cancelled the 2,902,236 shares it had previously issued to a vendor. See details under the heading **Subsequent Events** below.
- On May 20, 2023, the Company sold 100% of its common shares in TAETCo to 1402588 BC Ltd. See details under the heading **Subsequent Events** below.
- On March 16, 2023, the Company acquired TAETSoftware Corp ("TAETCo"). TAETCo is a Vancouver-based clinical studies management company engaged in the development and commercialization of the Trial Adverse Events Tracker technology platform, a proprietary software application which will enable clinical study subjects to record and submit clinical trial Adverse Drug Events reports to study sponsors in real time. The Company acquired all outstanding shares of TAETCo in exchange for 24,500,000 common shares, with an additional 2,500,000 common shares payable upon the successful testing of the beta version of the application. This acquisition did not constitute a Business Combination as TAETCo did not qualify as a Business, as defined under IFRS 3 Business Combinations. The acquisition was therefore accounted for as an acquisition of intellectual property. See details under the heading **Acquisition of TAETCo** below.
- On December 19, 2022, the Company, along with Procure Health Iberia, announced it had finalized and executed the United States Distribution Agreement for Papilocare and Oral Immunocaps. Developed by Procure Health, Papilocare is the world's first and only patented vaginal gel product with clinical evidence to prevent and treat HPV-dependent cervical lesions. Immunocaps, which can be used on its own or together with Papilocare, is an oral OTC nutritional supplement that supports immune function and vaginal microbiota to help re-epithelialization of cervical lesions. Procure has begun pursuit of a regulatory determination by the US Food and

Drug Administration ("FDA") and anticipates that this determination would be for a subsequent US regulatory designation as a Class II medical device. As Immunocaps is an OTC supplement, the Company anticipates that regulatory approval will not be required, allowing the rapid build-out of sales channels and revenue generation from the product. The Company plans to begin stocking and distributing Immunocaps in 2023. The Company and Procure Health will next begin discussions on the Company's right-of-refusal in the United States for Ovosicare and Libicare, Procure Health's over-the-counter supplements to support fertility enhancement for late maternity or IVF processes and Menopausal symptoms improvements which includes low libido among women suffering menopausal changes.

- On December 16, 2022, the Company announced that results from the Ohio State University animal study did not demonstrate that immunization of study animals with BVX-1021, followed by administration of BVX-0320 would stimulate development of neutralizing antibodies to a broad range of sarbecoviruses. The Company and Ohio State University believe the technical approach for the sarbecovirus vaccine is sound, but that factors related to the study design and the chosen animal model need to be addressed, such as rethinking the experimental controls, species-specific dose ranging, and use of a different adjuvant. In March 2023, the Company and The Ohio State University mutually agree to extend their research collaboration on sarbecoviruses until September 30, 2023.
- On December 1, 2022, the Company announced the successful sterile and bacteria-free test-run production of BVX-0918. The complete manufacturing of BVX-0918 from an actual cancer patient's surgically excised ovarian tumor now validates the production protocols that had been in development over the past several months for the successful extraction of tumor cells, the cryo-packaging and cryo-preservation of tumor cells, identification of ovarian cancer cells as the components of the vaccine using specially developed monoclonal antibodies and flow cytometry, sterility processes and development of the process for double haptening of the ovarian tumor cells used in the vaccine. The production protocols have reduced the time needed to haptenate the tumor cells by fifty percent having established a semi-automatic technique for mechanically extracting tumor cells from a tumor mass, resulting in a time savings for Good Manufacturing Process ("GMP") manufacturing.
- On November 16, 2022, the Company announced that interim results from its ongoing preclinical of BVX-1021 shows an excellent emerging tolerability profile with no observed side effects or noteworthy clinical observations.

## **PRODUCTS AND DEVELOPMENT**

### ***Haptened Vaccines Platform***

The Company's vaccine platform is based on the established immunological concept that modifying surface proteins, whether they are viral or tumor, with chemicals called haptens, makes them more visible to the immune system. This process of haptening "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. Haptening is based on proven science and backed by extensive clinical data. There is also substantial 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 haptening antigens to elicit a robust immune response. Current development programs target ovarian cancer, with cervical cancer, colorectal cancer, SARS-CoV-2 and pan-sarbecoviruses in the planning stage.

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

BVX-0918 is the Company's lead haptened tumor cell vaccine for ovarian cancer. 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. Haptening 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 Thomas Jefferson University ("TJU") achieved positive immunological and clinical results in prior Phase I/II trials. The Company has enhanced the first-

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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.

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.

On June 15, 2022, the Company announced that, as part of development of the vaccine bioproduction protocol with BioElpida for its Phase 1 study, the Hospices Civils de Lyon, France ("HCL") had surgically excised the first ovarian cancer tumors from cancer patients to be used by the Company for process development and manufacturing "dry runs" of BVX-0918, a major step leading to the completion of the production process for the Company's ovarian cancer vaccine.

On February 9, 2021, the Company and Procure Health Iberia S.L. ("Procure Health"), a leading privately-held European pharmaceutical company, entered into a broad collaboration. Under the terms of the agreement, the companies will jointly conduct a Phase I Clinical Study of BVX-0918 in Spain for late-stage ovarian cancer. The Company will be responsible for the core technology and vaccine production, with Procure Health overseeing and making a US\$900,000 in-kind investment in the clinical program and regulatory planning, 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, Procure 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 Investigational New Drug ("IND") for BVX-0918 in the US, as well as for all other global markets. Under the agreement, Procure Health will be responsible for marketing and distribution in the EU and will begin launch planning in 2023.

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

On June 8, 2022, the Company announced that BioElpida completed the creation of multiple OVCAR-3 cell banks as the next step in the GMP manufacturing process development for BVX-0918. The OVCAR-3 cell line is mandatory for creating the identity assays that will have to be performed on every batch of ovarian cancer vaccine. This assay is required by regulatory bodies in the EU and United States. The cell line is derived from a human ovarian adenocarcinoma, established from a patient refractory to cisplatin, a chemotherapeutic agent used in late-stage

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ovarian cancer. Patients whose tumors are innately cisplatin-resistant at the time of initial treatment generally have poor prognosis, which is the patient population target for BVX-0918.

***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 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 Vaccine Candidate (BVX-0320)***

BVX-0320 is the Company's IND stage vaccine candidate for SARS-CoV-2. The vaccine is the recombinant S1 subunit of the spike protein of SARS-CoV-2 that has been modified with a chemical called a hapten, specifically, dinitrophenyl. 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, Ohio State University

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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 Company 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 hapteneized 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.

**SARS1 Vaccine Candidate (BVX-1021)**

On March 17, 2022, the Company announced that it has entered into an agreement with Millipore-Sigma ("Millipore"), a global 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 Ohio State University and BioVaxys, announced December 7<sup>th</sup>, 2021, that is evaluating the Company's novel approach for a "universal vaccine" that can treat a broad range of sarbecoviruses. 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 University, 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.

On December 16, 2022, the Company announced that results from the Ohio State University animal study did not demonstrate that immunization of study animals with BVX-1021, followed by administration of BVX-0320 would stimulate development of neutralizing antibodies to a broad range of sarbecoviruses.

**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.

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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 CovidDTH™ 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 CovidDTH™, 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 CovidDTH™, 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 through the PCT and selected National Phase patent applications.

### **Acquisition of TAETCo**

On March 16, 2023, the Company acquired TAETSoftware Corp ("TAETCo"). TAETCo is a Vancouver-based clinical studies management company engaged in the development and commercialization of the Trial Adverse Events Tracker technology platform, a proprietary software application which will enable clinical study subjects to record and submit clinical trial Adverse Drug Events reports to study sponsors in real time. The Company acquired all outstanding shares of TAETCo in exchange for 24,500,000 common shares (the "Consideration Shares"), with an additional 2,500,000 common shares payable upon the successful testing of the beta version of the application within three months of the closing date of the agreement.

This acquisition did not constitute a business combination as TAETCo did not qualify as a business under IFRS 3 - *Business Combinations*. As such, this transaction has been accounted for as an acquisition of an asset, being the intellectual property of TAETCo.

This asset acquisition has therefore been measured as the fair value of the Consideration Shares issued for the transaction based on the closing market price of the Company's publicly traded shares on the date of the agreement, plus the fair value of the contingent consideration, less the net assets of TAETCo as at the purchase date. The fair value of the Consideration Shares less the net assets was measured at \$2,082,856.

The Bonus Shares have been classified as equity under IAS 32.16 as this contingent consideration arrangement will result in the issuance of a fixed number of shares if the target is met. As of the acquisition date, the Company estimated the fair value of the contingent consideration as \$180,625, based on the closing market price of the Company's publicly traded shares on the date of the agreement and management's estimation of an 85% probability of the target being met. The technology was fair valued at \$2,263,481.

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The Company sold this intellectual property on May 20, 2023, for consideration estimated at fair value of \$1,316,017. See the **SUBSEQUENT EVENTS** section below for details. Given that the recoverable amount of the asset is less than its carrying value at April 30, 2023, the value of the intellectual property has been written down to its recoverable amount, with a \$947,464 impairment expense recognized in the statement of loss and comprehensive loss.

At the time of this MD&A, the Company had the following patents and registered trademarks:

- Issued US patent #7,297,330 – Low dose haptened tumor cell and tumor cell extract immunotherapy (expiration 2024)
- Issued US patent #8,435,784 – Cryopreservation of Haptened Tumor Cells (licensed from Thomas Jefferson University with expiration of the patent in 2026)
- International Application # PCT/US22/26461 - BIHAPTENIZED AUTOLOGOUS VACCINES AND USES THERFE OF with claims for cervical cancer
- US Patent Application #62/992,722 – Haptened Coronavirus Spike Protein Vaccine
- US Provisional Application #63/253,149 Methods of Immunization Against Coronavirus.
- US Patent Application #63106482- METHOD AND KIT FOR DETECTION OF CELL MEDIATED IMMUNE RESPONSE

### **Licenses**

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

- Issued US patent #7,297,330 – Low dose haptened tumor cell and tumor cell extract immunotherapy (expiration 2024); and
- Issued US patent #8,435,784 – Cryopreservation of haptened 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 this warrant. As a result, TJU received 1,160,000 common shares. 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 April 30, 2023 Compared to the Three Months Ended April 30, 2022***

During the three months ended April 30, 2023, the Company incurred a comprehensive loss of \$1,482,639, compared to \$1,058,777 during the three months ended April 30, 2022. The following are the significant changes:

- Advertising and promotion expenses were \$13,677 for the three months ended April 30, 2023 (2022 - \$51,284). This decrease was due to less promotional activity during the current period.
- Investor relation expenses were \$235,677 for three months ended April 30, 2023 (2022 - \$29,257). The increase was mainly due to the incurrence of public relations services pursuant to an agreement entered into during the current financial year.
- Management and consulting fees were \$300,473 for the three months ended April 30, 2023 (2022 - \$345,023). The decrease was mainly due to the Company's increased reliance on consultants in the same period in the prior year to navigate the regulatory environment associated with the development of vaccines and diagnostic tests, as well as the resignation of a director during the current period.
- Research and development expenses of \$13,333 were recognized during the three months ended April 30, 2023 (2022 - \$372,071). This decrease was due to a reduction in work related to intellectual property and the completion of research programs in comparison to the 2022 comparative period.
- Share based payments decreased to \$46,534 for the three months ended April 30, 2023 (2022 - \$88,491). The decrease was due to a decrease in the number of stock options vesting during the period compared to the same period in the prior year.
- Other income for the three months ended April 30, 2023, was \$171,195 (2022 - \$nil). The other income relates to an accounts payable balance written off during the period.

### ***Six Months Ended April 30, 2023 Compared to the Six Months Ended April 30, 2022***

During the six months ended April 30, 2023, the Company incurred a comprehensive loss of \$2,446,027 compared to \$2,270,016 during the six months ended April 30, 2022. The following are the significant changes:

- General and administrative expenses were \$99,619 for the six months ended April 30, 2023 (2022 - \$67,307). This increase was due to the Company being charged for current and overdue office rent expenses during the period ended April 30, 2023.
- Investor relations was \$444,377 for six months ended April 30, 2023 (2022 - \$131,764). The increase was mainly due to the receipt of public relations services received pursuant to an agreement entered into during the period.
- Management and consulting fees decreased to \$673,067 for the six months ended April 30, 2023 (2022 - \$963,366). The decrease was mainly due to the Company's increased reliance on consultants in the same period of the prior year to navigate the regulatory environment associated with the development of vaccines and diagnostic tests, as well as the resignation of a director during the current period.
- Research and development expenses of \$133,108 were recognized during the six months ended April 30, 2023 (2022 - \$587,207). This decrease was due to a reduction in work related to intellectual property and the completion of research programs in comparison to the 2022 comparative period.
- Share based payments decreased to \$111,442 for the six months ended April 30, 2023 (2022 - \$252,119) The decrease was due to a decrease in the number of stock options vesting during the period compared to the same period in the prior year.

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- Other income for the six months ended April 30, 2023, was \$171,195 (2022 - \$nil). This other income relates to an accounts payable balance written off during the period.

**SUMMARY OF QUARTERLY RESULTS**

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

<b>Quarter Ended</b>	<b>Total Revenue (\$)</b>	<b>Comprehensive Loss (\$)</b>	<b>Net Loss (\$)</b>	<b>Basic and Diluted Loss per Share (\$)</b>
April 30, 2023	-	1,482,639	1,489,178	0.01
January 31, 2023	-	963,388	956,045	0.01
October 31, 2022	-	8,562,409	8,546,680	0.08
July 31, 2022	-	912,004	912,168	0.01
April 30, 2022	-	1,058,777	1,057,352	0.01
January 31, 2022	-	1,211,239	1,211,244	0.01
October 31, 2021	-	2,519,066	2,519,768	0.03
July 31, 2021	-	903,291	905,085	0.01

During the three months ended April 30, 2023, the comprehensive loss increased by \$519,251 as compared to the three months ended January 31, 2023. The increase was mainly due to the impairment of intellectual property of \$947,464 during the current period, as compared to \$nil in the previous quarter. This increased expense was slightly offset by an increase in other income of \$171,195, which relates to the forgiveness of a debt owing to a vendor during the current period. There was no such other income in the previous quarter.

During the three months ended January 31, 2023, the comprehensive loss decreased by \$7,599,021 from the three months ended October 31, 2022. The decrease was mainly due to an impairment charge of \$7,396,821 on the Company's intangible assets and a \$248,110 loss on debt settlement recorded in the prior quarter. Share-based compensation expenses also decreased compared to the prior quarter due to a decrease in the number of stock options vesting during the period.

During the three months ended October 31, 2022, the comprehensive loss increased by \$7,650,405 from the three months ended July 31, 2022. The increase was due to the receipt of promotional services received from a financial media company. Share-based compensation expenses also increased due to the grant of new options during the three months ended October 31, 2022. The Company also recognized an impairment charge of \$7,396,821 on its intangible assets during the three months ended October 31, 2022.

During the three months ended July 31, 2022, the comprehensive loss decreased by \$146,773 from the three months ended April 30, 2022. Advertising and promotion decreased by \$51,284 from the previous quarter due the company reducing the amount of promotion work being completed. The Company decreased expenses related to research and development by \$89,274 due to changes in the timing of the completion of research programs.

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.

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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.

### **OUTSTANDING SHARE DATA**

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

- 145,111,821 common shares issued and outstanding (October 31, 2022 – 108,812,635)
- 9,955,000 stock options issued and outstanding (October 31, 2022 – 9,955,000)
- 20,597,947 common share purchase warrants outstanding (October 31, 2022 – 28,213,574)
- 56,000 brokers' warrants outstanding (October 31, 2022 - nil)

During the six months ended April 30, 2023, the following share capital transactions occurred:

- The Company issued 1,550,000 units for proceeds of \$155,000 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 \$0.20 per share for two years from the closing date. The Company incurred total finder's fees of \$18,400.
- The Company issued 1,500,000 units valued at \$150,000 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 \$0.20 per share for two years from the closing date. The Company also issued 1,427,000 common shares in connection with the exercise of warrants. The warrants had a total exercise value of \$513,500. The total consideration of \$663,500 from these share issuances was netted against amounts payable of \$629,071, resulting in a \$34,429 loss on settlement of debt.
- The Company issued 940,000 units for proceeds of \$117,500 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 \$0.20 per share for two years from the closing date. The Company incurred total finder's fees of \$7,000 and issued 56,000 finders warrants with a fair value of \$7,371. Each finder's warrant is exercisable at \$0.20 per share for three years from the closing date. The fair value of the finders' warrants was determined using the Black-Scholes option pricing model with the following weighted average assumptions: a 3 year expected life; share price at grant date of \$0.165; 149.73% volatility; risk-free interest rate of 3.91%; and a dividend yield of 0%.
- The Company issued 5,360,000 common shares for proceeds of \$670,000 pursuant to a non-brokered private placement.
- The Company issued 272,186 common shares pursuant to a consulting agreement with a director of the Company. The shares were issued in exchange for management services from October 2022 to January 2023 valued at \$40,000.

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- The Company issued 2,902,236 common shares to a vendor in consideration for past services rendered by the Company. These common shares were deemed to have a value of \$nil as both parties agreed to terminate the engagement of the vendor and shares were cancelled subsequent to the period end.
- The Company issued 750,000 common shares with a fair value of \$120,000 to settle amounts payable of \$150,000 to a vendor pursuant to a debt settlement agreement. The Company recognized a \$30,000 gain on settlement of debt.
- The Company issued 24,500,000 shares with a fair value of \$2,082,856 to the shareholders of TAETCo, pursuant to the Share Purchase Agreement (See "*Intellectual Property*" section above). The Company recognized the commitment to issue shares for the Bonus Shares at a fair value of \$180,625.

### **LIQUIDITY AND CAPITAL RESOURCES**

At April 30, 2023, the Company had cash of \$28,478 (October 31, 2022 - \$141,898) and a working capital deficiency of \$587,285 (October 31, 2022 - \$924,567). The improvement in working capital is mainly due to an increase in the intellectual property and prepaid expenses.

Net cash used in operating activities for the six months ended April 30, 2023, was \$1,029,085 (2022 - \$1,289,801) primarily due to the large net loss incurred by the Company during the six months ended April 30, 2023. These losses were caused by significant management and consulting fees and investor relation fees incurred during the period. The Company continues to have negative cash flows from operating activities as the Company does not generate revenues to cover its operating expenses.

Net cash provided by financing activities was \$917,100 for the three months ended April 30, 2023 (2022 - \$779,645). This cash inflow was from proceeds received through the issuance of shares.

The Company does not have any commitments to make capital expenditures in future fiscal periods.

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.

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**ADDITIONAL DISCLOSURE FOR ISSUERS WITHOUT SIGNIFICANT REVENUE**

During the three and six months ended April 30, 2023 and 2022, the Company incurred the following research and development expenses pursuant to the development of its technology platform:

	For the three months ended		For the six months ended	
	April 30, 2023	April 30, 2022	April 30, 2023	April 30, 2022
	\$	\$	\$	\$
Research and Development				
GMP manufacturing process development	-	320,450	45,777	459,785
Sarbecovirus vaccine evaluation	-	33,384	21,357	33,384
Development of CoviDTH™	-	18,238	-	94,038
Ovarian cancer vaccine research	-	-	52,642	-
Conference costs	13,332	-	13,332	-
	13,333	372,072	133,108	587,207

The Company plans to finance its research and development activities through raising equity or debt capital financing. Through continued development of its product offering, the Company expects to earn revenues. These revenues will be used to eventually fund operating expenses.

**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:

	Three months ended		Six months the ended	
	April 30, 2023	April 30, 2022	April 30, 2023	April 30, 2022
	\$	\$	\$	\$
General and administrative expenses	-	5,513	-	7,532
Management and consulting fees	156,498	169,998	329,496	345,996
Professional fees	-	10,318	-	15,983
Rent	-	-	-	4,500
Share-based payments	20,691	67,794	54,207	214,880
	177,189	253,623	383,703	588,891

- i. During the three and six months ended April 30, 2023, the Company recognized \$31,500 and \$63,000 (2022 - \$31,500 and \$63,000) in management and directors' fees and \$2,710 and \$9,227 (2022 - \$12,827 and \$50,538) in share-based payments for services provided by James Passin, the Chief Executive Officer ("CEO") of the Company. As of April 30, 2023, due to related parties balance included \$60,999 (October 31, 2022 - \$32,422) owing to the CEO.
- ii. During the three and six months ended April 30, 2023, the Company recognized \$60,498 and \$120,996 (2022 - \$60,498 and \$120,996) in management fees and \$2,710 and \$9,227 (2022 - \$12,827 and \$50,538) in share-based payments for services provided by Kenneth Kovan, the Chief Operating Officer ("COO") and President of the Company. As of April 30, 2023, due to related parties balance included \$177,399 (October 31, 2022 - \$100,830) owing to the COO.

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- iii. During the three and six months ended April 30, 2023, the Company expensed \$30,000 and \$60,000 (2022 - \$30,000 and \$60,000) in management fees and \$2,710 and \$9,227 (2022 - \$12,827 and \$50,538) in share-based payments for services provided by Dr. David Berd, the Chief Medical Officer ("CMO") of the Company. As of April 30, 2023, due to related parties balance included \$70,000 (October 31, 2022 - \$30,000) owing to the CMO.
- iv. During the three and six months ended April 30, 2023, the Company expensed \$12,000 and \$30,000 (2022 - \$nil) in management fees and \$5,809 and \$11,618 (2022 - \$nil) in share-based payments for services provided by Craig Loverock, the former Chief Financial Officer ("CFO") of the Company. As of April 30, 2023, due to related parties balance included \$25,200 (October 31, 2022 - \$6,600) owing to the former CFO of the Company. The former CFO is now the current director of the Company.
- v. During the three and six months ended April 30, 2023, the Company expensed \$21,000 and \$52,500 (2022 - \$21,500 and \$63,000) in management and directors' fees and \$542 and \$1,845 (2022 - \$2,565 and \$10,107) in share-based payments for services provided by David Wang, a former director of the Company. As of April 30, 2023, due to related parties balance included \$22,500 (October 31, 2022 - \$13,466) owing to the former director.
- vi. During the three and six months ended April 30, 2023, the Company expensed \$1,500 and \$3,000 (2022 - \$nil) in directors' fees and \$6,399 and \$13,063 (2022 - \$17,707) in share-based payments for services provided by Anthony Dutton, a director of the Company. As of April 30, 2022, due to related parties balance included \$6,100 (October 31, 2022 - \$3,100) owing to this director.

## **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 significant accounting estimates and judgments are set out in Note 2 to the consolidated financial statements for the year ended October 31, 2022, and the condensed consolidated interim financial statements for the three and six months ended April 30, 2023.

## **FINANCIAL INSTRUMENTS**

In the normal course of business, the Company is inherently exposed to certain financial risks, including market risk, credit risk and liquidity risk, through the use of financial instruments. The timeframe and manner in which the Company manages these risks varies based upon management's assessment of the risk and available alternatives for mitigating risk. All transactions undertaken are to support the Company's operations. These financial risks and the Company's exposure to these risks are provided in various tables in note 9 of the condensed consolidated interim financial statements.

## **CAPITAL MANAGEMENT**

The capital of the Company consists of items included in shareholder's equity. The Company's objectives for capital management are to safeguard its ability to support the Company's normal operating requirements on an ongoing basis.

The Company manages its capital structure and adjusts considering changes in its economic environment and the risk characteristics of the Company's assets. To effectively manage the entity's capital requirements, the Company has in place a planning, budgeting and forecasting process to help determine the funds required to ensure the Company has the appropriate liquidity to meet its operating and growth objectives. As at April 30, 2023, the Company expects its capital resources, along with planned additional financing, will support its normal operating requirements for the next twelve months. There are no externally imposed capital requirements with which the Company has not complied. There have been no changes to the Company's objectives in terms of capital management during the six months ended April 30, 2023.

## **OFF-BALANCE SHEET ARRANGEMENTS**

The Company does not have any off-balance sheet arrangements at April 30, 2023.

## **PROPOSED TRANSACTIONS**

There are no proposed transactions.

## **SUBSEQUENT EVENTS**

### *Disposal of Intellectual Property*

On May 20, 2023, the Company sold 100% of the common shares of TAETCo to 1402588 BC Ltd (the "Buyer", together the "Parties") in exchange for consideration of 500,000 shares of the Buyer. These shares will then be exchanged into shares in XGC Software Inc (XGC), the sole shareholder of the Buyer, on a 1:1 basis, such that BioVaxys will become a shareholder of XGC. The Parties also agreed that BioVaxys would make the following payments to the Buyer upon achievement of the milestones described below ("Milestone Payments"):

- 500,000 shares of XGC, issuable within 30 days of the first commercial licence sale of the software
- 500,000 shares of XGC, issuable within 30 days of the first achievement of cumulative revenue of USD\$1,000,000 in any one fiscal year
- USD\$500,000 cash payment, payable within 30 days of the filing of any financial statement that shows the first achievement of cumulative revenue of USD\$5,000,000 in any one fiscal year
- USD\$500,000 cash payment, payable within 30 days of the filing of any financial statement that shows the first achievement of cumulative revenue of USD\$10,000,000 in any one fiscal year
- USD\$1,000,000 cash payment, payable within 30 days of the filing of any financial statement that shows the first achievement of cumulative revenue of USD\$5,000,000 in any one fiscal quarter
- USD\$2,000,000 cash payment, payable within 30 days of the filing of any financial statement that shows the first achievement of cumulative revenue of USD\$10,000,000 in any one fiscal quarter

### *Cancellation of Shares*

In June 2023, BioVaxys cancelled the 2,902,236 shares it had previously issued to a vendor for past services rendered. These shares were cancelled as parties mutually agreed to terminate their engagement.

## **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.

Management of the Company, under the supervision of the Chief Executive Officer and the Chief Financial Officer, is responsible for the design and operations of internal controls over financial reporting. There have been no changes in the Company's disclosure controls and procedures during the six months ended April 30, 2023.

The Company's management is responsible for establishing and maintaining adequate internal controls over financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. 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.

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There have been no changes in the Company's internal control over financial reporting during the six months ended April 30, 2023, that have materially affected, or are reasonably likely to materially affect, its internal controls over financial reporting.

***Limitations of Controls and Procedures***

The Company's management, including the Chief Executive Officer and Chief Financial Officer, believe that any disclosure controls and procedures or internal controls over financial reporting, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, they cannot provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been prevented or detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by unauthorized override of the control. The design of any systems of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Accordingly, because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**APPROVAL**

The Company's Board of Directors has approved the condensed consolidated interim financial statements for the three and six months ended April 30, 2023 and 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](http://www.sedar.com).