

**BIOVAXYS TECHNOLOGY CORP.**

**ANNUAL INFORMATION FORM**

For the Financial Year Ended October 31, 2021

Dated May 18, 2022

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## INTRODUCTORY NOTES

### Date of Information

Unless otherwise noted, all information contained in this Annual Information Form ("AIF") of Bio Vaxys Technology Corp. (the "Company") is presented as of October 31, 2021.

### Currency and Exchange Rates

All dollar amounts herein are expressed in Canadian dollars unless otherwise indicated.

### Forward-Looking Information

Certain statements in this AIF constitute forward-looking information or forward-looking statements under applicable securities laws (collectively, "**forward-looking statements**"). These statements relate to future events or future performance, business prospects or opportunities of the Company. All statements other than statements of historical fact may be forward-looking statements. Any statements that express or involve discussions with respect to predictions, expectations, beliefs, plans, projections, objectives, assumptions or future events or performance (often, but not always, using words or phrases such as "seek", "anticipate", "plan", "continue", "estimate", "expect", "may", "will", "project", "predict", "forecast", "potential", "targeting", "intend", "could", "might", "should", "believe" and similar expressions) are not statements of historical fact and may be "forward-looking statements".

Forward-looking information in this AIF includes, without limitation, statements concerning:

- expectations regarding the Company's ability to raise capital;
- estimates of the Company's future revenues and profits;
- treatment under government regulatory and taxation regimes;
- the Company's ability to conduct all required clinical and non-clinical trials for its products, including the timing and result of such trials;
- ability to obtain and protect the Company's intellectual property and proprietary rights;
- timing and costs associated with completing research and development work relating to the development of the Company's products;
- projections of market prices and costs and the future market for the Company's products and conditions affecting same;
- the Company's strategies, objectives and plans to pursue the commercialization of its products;
- 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;
- projections of market prices and costs and the future market for the Company's products and conditions affecting same;
- statements relating to the business and future activities of, and developments related to the Company;
- market position, and future financial or operating performance of the Company; and

- liquidity of the **common shares** of the Company.

The actual results could differ materially from those anticipated in the forward-looking information contained in this AIF as a result of numerous known and unknown risks and uncertainties, including, but not limited to:

- the Company's lack of operating income and need for additional capital which may not be available in a timely manner or at all;
- the possibility that future research and development results will not be consistent with the Company's expectations;
- rapid technological change and competition from pharmaceutical companies, biotechnology companies and universities, which may make the Company's technology or products obsolete or uncompetitive;
- liabilities inherent in research and development and biopharmaceutical operations;
- whether the clinical and non-clinical trials of the Company will be successful;
- whether the Company's products can be successfully commercialized;
- fluctuations in currency and interest rates;
- critical illness or death of the principals of the Company;
- competition for, among other things, customers, supply, capital, capital acquisitions of products and skilled personnel;
- risks relating to global financial and economic conditions;
- alteration of tax regimes and treatments;
- limited operating history;
- changes in legislation affecting operations; and
- risk factors set out under the "Risk Factors" section below or identified in the Company's other public filings under the Company's profile on SEDAR at [www.sedar.com](http://www.sedar.com).

The list of risk factors set out in this AIF are not exhaustive of the factors that may affect any forward-looking information. Forward-looking information in this AIF is based on certain material factors, estimates or assumptions, which may prove to be incorrect, including, but not limited to assumptions about: general business and current global economic conditions; future success of current research and development activities; achievement of development milestones; inability to achieve product cost targets; competition; changes to tax rates and benefits; the availability of financing on a timely basis; the Company's and competitors' costs of production and operations; the Company's ability to attract and retain skilled employees; receipt of all applicable regulatory approvals/clearances; protection of the Company's intellectual property rights; market acceptance of the Company's product candidates; the Company's ability to meet the continued listing requirements of Canadian Securities Exchange ("CSE"); and that the BioVaxys Risk Factors will not cause the Company's actual results or events to differ materially from the forward-looking information. The Company cautions that the foregoing list of important factors and assumptions is not exhaustive.

For all of the reasons set forth above, which do not represent an exhaustive list of factors that may affect the forward-looking information, investors should not place undue reliance on forward looking information. The forward-looking information is based on the beliefs, assumptions, opinions and expectations of the Company's management at the time

they are made, and the Company does not assume any obligation to update any forward-looking information should those beliefs, assumptions, opinions or expectations, or other circumstances change, except as required by law.

Data relevant to estimated market sizes in connection with Company's lead products under development are presented in this AIF. These data have been obtained from a variety of published resources, including published scientific literature, websites and information generally available through publicized means. The Company attempts to source reference data from multiple sources whenever possible for confirmatory purposes. Although the Company believes the data is reliable, the Company has not independently verified the accuracy and completeness of this data.

## CORPORATE STRUCTURE

### Name, Address and Incorporation

The Company was incorporated pursuant to the *Business Corporations Act* (British Columbia) (the "**BCBCA**") on April 25, 2018, under the name Lions Bay Mining Corp. On April 29, 2020, the Company completed a subdivision of its Common Shares on a two for one basis. On September 30, 2020, by way of a share exchange agreement (the "**Share Exchange Agreement**"), the Company acquired all of the issued and outstanding common shares of BioVaxys Inc. (the "**Share Exchange Transaction**"). Following the closing of the Share Exchange Transaction, the Company changed its name to "BioVaxys Technology Corp." and BioVaxys Inc. became a wholly-owned subsidiary of the Company ("**BioVaxys Inc.**" or the "**Operating Subsidiary**"). The Share Exchange Transaction was determined to be a "fundamental change" pursuant to the policies of the CSE the Company re-classified itself from being a resource issuer to an industrial issuer operating in the life science industry

The Company is headquartered in Vancouver, British Columbia, with its head and registered office located at 503 - 905 West Pender Street, Vancouver, British Columbia, Canada, V6C 1L6.

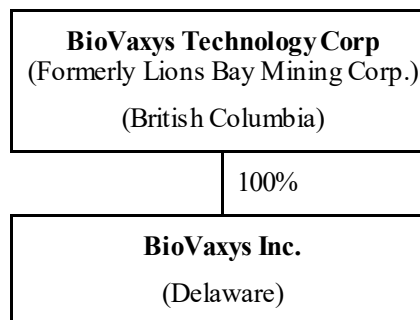
The Company is a reporting issuer in Canada in the Provinces of British Columbia, Alberta, and Ontario, and not in any other jurisdiction. The Company's common shares (the "**Common Shares**") are listed on the CSE under the trading symbol "BIOV".

### Intercorporate Relationships

The Company owns 100% of the shares of BioVaxys Inc., a private Delaware corporation under the Delaware General Corporation Law. The head and registered office of BioVaxys Inc. is located at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801.

See "*General Development of the Business*" and "*Description of the Business*" for a description of the business of the Company and the Operating Subsidiary.

The following chart illustrates the Company's corporate structure:



## GENERAL DEVELOPMENT OF THE BUSINESS

### THREE YEAR HISTORY

#### Prior to the Completion of the Share Exchange Transaction

On April 25, 2018, the Company was incorporated for the purposes of completing a plan of arrangement (the "**Arrangement**") with Bearing Lithium Corp. ("**Bearing**") pursuant to Section 288 of the BCBCA on the terms set out in an arrangement agreement dated May 23, 2018.

The Arrangement with Bearing was completed on July 19, 2018. Immediately prior to closing of the Arrangement, the Company and Bearing entered into an asset purchase agreement pursuant to which the Company acquired Bearing's interest in the Fish Lake Project located in Nevada and Bearing's interest in the HY, VM and VBA properties in the Yukon, Canada.

On November 22, 2018, the Common Shares were listed on the CSE under the symbol "LBM". In connection with the listing, the Company completed a private placement of 5,000,000 units at a price of \$0.10 per unit for gross proceeds of \$500,000, with each unit consisting of one Common Share and one common share purchase warrant (the entitling the holder to purchase one additional common share at a price of \$0.10 for 24 months following closing).

On April 17, 2020, the Company entered into a letter of intent with BioVaxys Inc., setting out the terms for the acquisition by the Company of all of the issued and outstanding securities of BioVaxys Inc., by way of a share exchange.

On April 29, 2020, the Company completed a subdivision of its Common Shares on a two for one basis.

On June 2, 2020, the Company and BioVaxys Inc. entered into the Share Exchange Agreement, in respect of the Share Exchange Transaction. Pursuant to the Share Exchange Agreement, each BioVaxys Inc. shareholder transferred their BioVaxys Inc. shares to the Company in exchange for fully paid and non-assessable Common Shares. Upon execution of the Share Exchange Agreement, an aggregate loan amount of up to US\$180,000 was made available to BioVaxys Inc. for draw down to cover reasonable costs and expenses of BioVaxys Inc.

On August 26, 2020, and September 3, 2020, in connection with the Share Exchange Transaction, the Company completed a non-brokered private placement of 13,738,235 units (the "**Units**") at a price of \$0.22 per Unit, for gross proceeds of \$3,022,412. Each Unit is comprised of one Common Share and one-half of one common share purchase warrant. Each whole common share purchase warrant entitles the holder thereof to acquire one Common Share at a price of \$0.50 per Common Share for a period of twenty-four (24) months. In connection with this offering, the Company paid certain eligible finders a finder's fee of 7% of the gross proceeds raised, payable in finders warrants and 7% in cash commissions. Each finders warrant had the same terms as the common share purchase warrants.

On September 30, 2020, the Share Exchange Transaction was completed pursuant to the terms of the Share Exchange Agreement. Pursuant to the Share Exchange Transaction, the Company issued 29,000,000 Common Shares (issued at a deemed price of \$0.28 per Common Share) in exchange for all of the issued and outstanding securities of BioVaxys Inc. (including 3,688,800 Common Shares issued to certain advisors of BioVaxys Inc. and 1,160,000 Common Shares issued to Thomas Jefferson University ("**TJU**")). In connection with the Share Exchange Transaction, the Company also issued an aggregate of 2,100,000 Common Shares to certain advisors of the Company. Upon closing of the Share Exchange Transaction, BioVaxys Inc. became a wholly-owned subsidiary of the Company.

In connection with the closing of the Share Exchange Transaction, the Company changed its name from "Lions Bay Mining Corp." to "BioVaxys Technology Corp." The Company's stock symbol was changed from "LBM" to "BIOV".

On October 6, 2020, the Company's Common Shares commenced trading on the CSE under its new stock symbol "BIOV".

On September 24, 2020, the Board appointed the following senior executive officers of the Company, effective on the closing of the Share Exchange Transaction, as James Passin (Chief Executive Officer), Kenneth Kovan (President and Chief Operating Officer), David Berd (Chief Medical Officer) and Lachlan McLeod (Chief Financial Officer and Corporate Secretary).

On October 15, 2020, Dave Hermiston was appointed as director of the Company, replacing Timothy Heenan, who resigned to pursue other endeavors. David Wang was appointed as director of the Company shortly thereafter on October 20, 2020.

### **BioVaxys Inc. Prior to the Completion of the Transaction**

BioVaxys Inc. is an early-stage clinical biotechnology company developing antiviral and anticancer vaccines and immune-diagnostics.

On April 25, 2018, BioVaxys Inc. executed a license agreement with TJU related to four US Patents (two of which have since expired) related to a "first generation" haptenized cancer vaccine platform using a single hapten. The platform includes melanoma, ovarian cancer as well as other resectable tumor types. These patents were previously licensed from TJU by Avax Technologies Inc. ("**Avax**").

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

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

On March 3, 2020, BioVaxys Inc. filed Provisional Application # 62/992722 for "*Haptenized Coronavirus Spike Protein Vaccine*". This application forms the technology platform for BXV-0320, the Company's SARS-CoV-2 vaccine candidate ("**BXV-0320**" or the "**SARS-CoV-2 Vaccine Candidate**") described later in this AIF.

In June 2020, BioVaxys Inc. contracted, for consideration of US\$172,800, Charles River Laborites Inc. ("**CRL**"), a leading independent contract research organization, to conduct a preclinical animal study (the "**Murine Model Study**") of BXV-0320.

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

In June 2020, the BioVaxys Inc. engaged MilliporeSigma Inc. ("**MilliporeSigma**"), in consideration of US \$10,000, for the production of a single batch of non-Good Manufacturing Practices ("**non-GMP**") haptenized s-spike protein ("**Non-GMP Protein**") for the Murine Model Study. The initial non-GMP batch was completed by MilliporeSigma on August 27, 2020. Non-GMP means any substance intended for non-clinical use, including that intended to meet the requirement for pre-clinical use pursuant to GLP requirements, such as, for example, a substance intended for use in GLP toxicology studies. Good Laboratory Practice ("**GLP**") is a quality system concerned with the process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. Preclinical studies are typically done with the test substance produced under non-GMP or GLP conditions. Clinical studies must be done under GMP conditions.



In July 2020, BioVaxys Inc. selected QS-21 to be administered with BVX-0320, its SARS-CoV-2 Vaccine Candidate. On August 31, 2020, BioVaxys Inc. purchased 6mg of QS-21 from Desert King for use in the Murine Model Study. Cost of the QS-21 was paid to Desert King out of the Loan Facility proceeds.

In July 2020, BioVaxys Inc. contacted the FDA, and was asked to submit a request for an investigational new drug ("IND"), Written Responses Only ("WRO") for BVX-0320. An Investigational New Drug Application is a request for review and authorization from the Food and Drug Administration to administer an investigational drug or biological product to humans. A WRO is a type of formal contact with the FDA that is requested by a new drug applicant to receive written answers to specific written questions related to a new drug application. Following the late 2020 approval of the Pfizer/BioNTech mRNA vaccine by the FDA, and in consultation with its regulatory consultants, the Company determined that it was in its best interest to complete the preclinical program and bioproduction plan prior to submitting a WRO request.

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

Alongside antibodies, the immune system produces T cells that target viruses. Some of these, known as "killer T cells" (or CD8<sup>+</sup> T cells), have the capacity to kill cells infected by the virus, thereby stopping viral replication in those cells. Others, called "helper T cells" or "CD4<sup>+</sup> T cells" are important for various immune functions, including stimulating the production of antibodies and killer T cells. CD4<sup>+</sup> 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 'helper' CD4<sup>+</sup> T cells retain information about the virus, which enables them to respond rapidly after viral exposure. T cells do not prevent infection, because they kick into action only after a virus has infiltrated the body but are important for clearing an infection that has already started. In the case of Covid-19, killer T cells could mean the difference between a mild infection and a severe one. In addition to providing long-term "memory" protection against the virus, T-cell response could reduce transmission of Covid-19 by restricting the amount of virus circulating in an infected person, meaning that the person sheds fewer virus particles into the community.

In August 2020, BioVaxys Inc. began preparing a provisional patent application with the United States Patent and Trademark Office ("USPTO") for a novel diagnostic platform invented by BioVaxys Inc. (the "**Diagnostic Platform**" or "**CoviDTH™**") The Diagnostic Platform is designed to screen for an immune system T-cell response in patients SARS-CoV-2 to evaluate viral infection status, presence of immune response to new SARS-CoV-2 variants, and vaccine efficacy.

On September 1, 2020, CRL completed the design and validation of the assay to be used to evaluate the immune response of BVX-0320 in the Murine Model Study, with final validation analysis of the assay provided to BioVaxys Inc.

### **The Company Following Completion of the Transaction**

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

On October 26, 2020, the Company announced that it entered into a research collaboration with The Ohio State University, Wexner School of Medicine ("OSU"), for BVX-0320. The objective of the research collaboration, which was the first between the Company and OSU, was to study neutralizing antibodies generated against live SARS-CoV-2 virus by BVX-0320.

## **Year Ended October 31, 2021 to Present**

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

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

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

On December 21, 2020, the Company announced that further analysis of the data from its Murine Model Study showed that BVX-0320 elicited a robust T-cell response against SARS-CoV-2. BVX-0320 was found to activate immune system memory helper' CD4+ cells and killer CD8+ T cells against SARS-CoV-2, which has potential for longer-term viral protection. Specifically, using a technique called flow cytometry, the Murine Model Study found that its haptenized SARS-CoV-2 s-spike vaccine candidate, BVX-0320, activated CD4+ helper T cells and CD8+ killer T cells that express the activation markers, CD69 and CD25. This result indicates that immunization with BVX-0320 at two different dose levels of 3µg or 10µg stimulated CD4+ helper T cells CD8+ killer T cells. CD4+ 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.

On February 2, 2021, the Company announced positive results from the research collaboration with OSU, specifically that its SARS-CoV-2 Vaccine Candidate elicits a neutralizing antibody response against SARS-CoV-2. These findings were obtained from a Plaque Reduction Neutralizing Test, where the endpoint is reduction of plaques by 50%, after using the available remaining mouse sera from the murine immune response study. Plaques are produced by infection of cultured human cells by a live SARS-CoV-2 virus. A neutralizing antibody is an antibody that defends against a pathogen or virus by neutralizing any effect it has biologically. Neutralization renders the virus no longer infectious.

On February 16, 2022, the Company announced that studies on BVX-0320 demonstrated that the vaccine does not bind to the Angiotensin Converting Enzyme 2 ("ACE2") receptor. The finding suggests that BVX-0320 may not lead to the unusual but serious myocarditis which has been observed with mRNA vaccines. The study on ACE2 binding inhibition by CDMO MilliporeSigma was included as part of a new additional bioproduction run of BVX-0320 that was contracted by BioVaxys last September; the new batch is being used for the Company's vaccine collaboration with OSU.

### ***BVX-1021 (Pan-Sarbecovirus Vaccine Program)***

On October 20, 2021, the Company announced that it had filed a provisional patent application with the USPTO for its haptenized viral antigen vaccine platform to elicit a broad cross-reactive immune response against most or all sarbecoviruses, the family of coronaviruses that includes SARS-CoV-2.

On December 7, 2021, the Company announced that it had entered into a second sponsored research collaboration with OSU to further develop the Company's haptenized viral antigen platform to create a broadly reactive pan-sarbecovirus vaccine. The clinical goal of the program is to stimulate virus cross-reactivity and induce immunity against all or most sarbecoviruses by immunizing people who have recovered from a documented Covid-19 infection

or received a full course of any currently approved Covid-19 vaccine, leading to a pan-sarbecovirus vaccine that encompasses current and emerging SARS-CoV-2 variants. OSU will conduct animal studies with BVX-0320, together with a newly developed haptenized protein vaccine from the Company for SARS-CoV-1 ("**BVX-1021**"), the sarbecovirus strain 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 a hapten-modified recombinant S-protein from SARS-CoV-1, whereas BVX-0320, BioVaxys' Covid-19 vaccine, is a hapten-modified recombinant S-spike protein from SARS-CoV-2, the virus which causes Covid-19. Results from the study are anticipated in early September 2022.

In March 2022, BioVaxys announced that it has entered into an agreement with MilliporeSigma to manufacture a supply of GLP-grade BVX-1021, the Company's newly developed vaccine. BVX-1021 will be utilized in the pan sarbecovirus research collaboration with OSU, with the non-GMP BVX-1021 anticipated to be ready in August 2022.

### ***CoviDTH™ (Diagnostic Platform)***

In January 2021, the Company initiated a development program for its novel diagnostic tool, CoviDTH™, which is a low cost, disposable, diagnostic tool to identify a T-cell immune response to the presence of SARS-CoV-2. CoviDTH™ is based on the process of Delayed-Type Hypersensitivity ("**DTH**"), which is an inflammatory response that develops 24-72 hours after exposure to an antigen that the immune system recognizes as "foreign." The Company also engaged a consultant to provide strategic regulatory guidance, prepare an FDA pre-submission guidance package, recommend regulatory pathways and support the Company on the registration filing.

In January 2021, the Company's advisors recommended that a non-clinical study be conducted to establish the risk profile prior to the start of the clinical studies of CoviDTH™ and the Company began to prepare for an animal toxicology study. In March 2021, the Company announced that it had entered into a bio-production agreement with WuXi Biologics Limited to produce the SARS-CoV-2s proteins required for the Company's research on BVX-0320 and CoviDTH™.

On March 26, 2021, the Company filed a pre-IND meeting request and submitted a briefing package to the FDA for CoviDTH™. A pre-IND meeting affords an opportunity for companies to seek clarification on clinical trials design, clinical materials manufacturing and quality control before submission of an IND application. The FDA responded to the Company in June 2021 stating that it had determined that a written response from the FDA would be sufficient to address the Company's questions. The FDA provided its written response to the Company in July 2021 and stated that the Company's chemistry, manufacturing and controls, and other elements of the proposed clinical development program were acceptable. The FDA also noted that animal toxicity studies were not required and that the Company could start its clinical development program with a combined Phase I/II study. Based on this feedback, the Company determined that it would begin preparation of an IND application to support a Phase I/II safety, dosing, and efficacy study. Notwithstanding that the FDA indicated that an animal toxicology study was not required, the Company decided to continue with its planned animal study.

On August 31, 2021, Immunologist Yvelise Barrios, MD, PhD a specialist in Clinical Immunology at Hospital Universitario de Canarias, Tenerife, Spain, joined the Company as a Scientific Adviser to support development of CoviDTH™. Dr. Barrios is a leading expert in the clinical use of DTH as an immuno-diagnostic tool.

On October 28, 2021, the Company announced that it had filed an international patent application for CoviDTH™ through the Patent Cooperation Treaty ("**PCT**") for broad geographic market coverage outside the United States,

On November 9, 2021, the Company announced the results of the animal toxicology study. The objective of this 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. The study was conducted together with global contract research organization Inotiv, Inc. ("**Inotiv**") and 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™.

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

On January 25, 2021, the Company announced that it had commenced the clinical development program for BVX-0918, its haptenized tumor antigen vaccine for ovarian cancer ("**BVX-0918**" or the "**Ovarian Cancer Vaccine Candidate**").

On February 9, 2021, the Company entered into a heads of agreement (the "**Heads of Agreement**") with Procure Health Iberia S.A. ("**Procure Health**") for the purpose of a broad collaboration for the co-development, joint commercialization, and marketing of the Company's vaccine candidates for ovarian cancer, development of new vaccines for cervical cancer, and human papilloma virus ("**HPV**"), and the right of first refusal for marketing by the Company in the United States of Procure Health's product, **Papilocare**<sup>™</sup> ("**Papilocare**"), for the treatment of (pre-cancerous) cervical lesions. Under the terms of the Heads of Agreement, Procure Health and the Company will have the exclusive rights with each other and will use their best endeavors to negotiate in good faith separate future definitive agreements addressing specific details on the collaborations set out within the Heads of Agreement (collectively the "**Definitive Agreements**"). The Definitive Agreements will include: (1) a Clinical Study (Phase 1 Clinical Study for BVX-0918 in the EU), and the distribution of BCX-0918 in the European Union (the "**EU**") or individual EU markets and the UK; (2) feasibility, proof-of-concept, and potentially further development of a cervical cancer vaccine and an HPV viral vaccine; and (3) BioVaxys' marketing of Papilocare<sup>™</sup> in the United States. The Definitive Agreements shall be contractually independent from each other. A Phase I Clinical Study Protocol for BVX-0918 was completed December 2021, and recruitment of Principal Investigators and EU Study Centers for the Phase I study has begun. In February 2022, ProCare Health and BioVaxys agreed to extend the Heads of Agreement for an additional year (to February 2023), with all other terms of the Heads of Agreement remaining unchanged. As of the date of this AIF, no Definitive Agreements have been entered into.

In May 2021, the Company signed a definitive agreement with BioElpida S.A.S. ("**BioElpida**") of Lyon, France for the build-out for the GMP manufacturing process and aseptic packaging for BVX-0918. BioElpida is a biotechnology contract development and manufacturing service that applies single-use bioprocessing for development and manufacturing of biological and cell-based products. In June 2021, BioElpida initiated design of a GMP clean room facility needed for producing a clinical supply of BVX-0918. In September 2021, the Company announced that the technology process transfer with BioElpida had been completed, and BioElpida had begun the process for construction of a dedicated GMP manufacturing suite for BVX-0918, which is scheduled for completion in Summer 2022.

In April 2022, BioVaxys entered into an agreement with The Deaconess Research Institute ("**DRI**") to supply BioVaxys with surgically debulked tumors from Stage III/Stage IV ovarian cancer patients undergoing treatment at Deaconess Healthcare System ("**Deaconess**"). DRI, based in Evansville, Indiana, is the clinical studies arm of Deaconess, a premier regional provider of health care services in the United States. Access to ovarian cancer tumor cells is a critical step enabling BioVaxys to validate the manufacturing process for BVX-0918.

Standard of care for late-stage ovarian cancer typically involves surgically debulking of the tumor mass. The debulked tumor cells will be used to test and validate the tumor collection protocol, cryopackaging, cryopreservation, and supply chain logistics for BVX-0918 bioproduction. Following shipment to BioElpida, the tumor cells will then be used for process testing and manufacturing "dry runs" of BVX-0918, a major step leading to the completion of GMP production, a requirement for the planned Clinical Trial Application with the European Medicines Agency. Access to debulked tumor means that BioElpida can begin the final stages of the vaccine production protocol and GMP validation. BioVaxys and BioElpida have also designed and fabricated a specialized shipping package which would cryopreserve the tumor sample while in transit from any hospital site to the BioElpida site.

### **BVX-0922 (Colorectal Cancer Vaccine)**

In March 2022, BioVaxys announced the expansion of its cancer vaccine platform with its autologous haptenized tumor vaccine ("**BVX-0922**") for colorectal cancer ("**CRC**"). BioVaxys plans to advance an Investigator Sponsored Clinical Trial Application in the EU with the European Medicines Agency this year for BVX-0922. An Investigator Sponsored Clinical Study is submitted to regulatory authorities by a clinical investigator who both initiates and conducts an initial clinical study of a new drug or procedure, and under whose immediate direction the investigational drug is administered. No new technology is required, as haptenization of CRC tumor cells is the same process as that for ovarian tumor cells and is covered under the Company's broad bihaptenization patents.

### ***Corporate Developments***

On December 10, 2020, the Company announced that the Company's Common Shares had been listed for trading in the United States on the OTC Pink Market under the symbol "LMNGF". The OTC symbol was changed to "BVAXF" on April 21, 2021.

On February 5, 2021, the Company announced that it closed a non-brokered private of 4,417,647 units at a price of \$0.255 per unit for total gross proceeds of approximately \$1,126,500. Each Unit consists of one Common Share and one warrant. Each warrant is exercisable for one additional Common Share at an exercise price of \$0.50 for a period of 24 months.

On February 9, 2021, Jeremy Poirier resigned from his role as director of the Company.

On February 16, 2021, the Company announced that its Common Shares are now eligible to be held at the Depository Trust Company ("DTC") and serviced through DTC's electronic book system.

On May 19, 2021, the Company announced that it had been uplisted from the OTC Pink Sheets to the OTCQB Venture Market, the mid-tier OTC equity market, in the United States.

During July 2021, the Company completed a non-brokered private placement of 9,161,614 units at a price of \$0.22 per unit for gross proceeds of \$2,015,555. Each unit consists of one Common Share and one warrant. Each warrant is exercisable for one additional Common Share at an exercise price of \$0.50 for a period of 30 months.

On February 10, 2022, the Company announced it had completed a non-brokered private placement of 2,680,000 units at a price of \$0.15 per unit for gross proceeds of \$402,000. Each unit consists of one Common Share and one warrant. Each warrant is exercisable for one additional Common Share at an exercise price of \$0.30 for a period of 36 months. On February 28, 2022, the Company announced that it had issued an additional 2,643,033 units on the same terms for additional gross proceeds of \$396,500.

## **DESCRIPTION OF BUSINESS**

### **General**

The Company is an early clinical-stage biotechnology company that is developing antiviral and anticancer vaccines based on its haptized antigen technology platform as well as CoviDTH™, the Company's diagnostic tool.

**Current Product Portfolio**

Product Portfolio					BIOVAXYS
PRODUCT	INDICATION	PRECLINICAL	IND/PHASE I	PHASE II/III	Partner
BVX-0918	Stage III/IV Platinum Resistant Ovarian Cancer				 (European Union)
CovidTH®	SARS -CoV-2 T-Cell Diagnostic				
BVX-0320	Monovalent SARS -CoV-2 Vaccine				
BVX-1021	Pan -Sarbecovirus				
BVX-0204	Colorectal Cancer				
Papilocar® (U.S. Rights)	Cervical Lesions				 (Approved in EU)

**Haptenized Antigen Vaccines Technology Platform**

The Company's vaccine platform is based on the concept of haptentization. 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 haptentization "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 is supported by extensive clinical data. There is also growing evidence that the haptentized antigen platform can be used for many different viruses and a range of resectable (i.e., surgically removable) solid tumor. The Company is building a pipeline of vaccine products that are based on this proprietary technology platform of haptentizing antigens (tumor or viral) to elicit a robust immune response. Current vaccine development programs target ovarian cancer, SARS-CoV-2, and pan-sarbecoviruses with vaccines for cervical cancer, HPV and other tumor types being evaluated.

**Oncology Programs**

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

BVX-0918 is the Company's haptentized tumor cell vaccine for ovarian cancer, for which a Phase I clinical study in the EU is being planned for 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 tumor cell antigens that are otherwise not immunogenic. Haptenization is a well-known and well-studied immunotherapeutic approach, and in cancer studies has been clinically 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 the Company, achieved positive immunological and clinical results in prior FDA approved Phase I/II trials of over 600 subjects (combined total for studies conducted at Thomas Jefferson University and by Avax Technologies, Inc.) for melanoma, ovarian cancer, and renal cell carcinoma.

The Company has enhanced the original vaccine approach of using a single hapten to now utilize two haptens ("bihaptenization"), which the Company believes will yield superior results. 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. 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 inhibitors", 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 these studies have already been successful with the prior single-hapten approach.

While at Thomas Jefferson University, Dr. Berd tested the first generation single hapten vaccine in 447 patients. The tumor types were: melanoma - 407, ovarian carcinoma - 30, renal cell carcinoma - 10. The toxicity was mild and usually limited to the reaction at the vaccine injection site<sup>(1-7)</sup>.

Following administration of the autologous, haptenized vaccine to 83 evaluable patients with widely metastatic stage IV melanoma there were 11 anti-tumor responses, two of which were complete. Responses lasted from 5 to 47 months. In a group of 214 patients administered the vaccine after surgical excision of large lymph node metastases, the 5-year overall survival rate was 46%, about double the percentage would have been expected with surgery alone.<sup>(1-7)</sup>

The autologous, haptenized vaccine also was tested in women with advanced ovarian cancer who had ceased to respond to conventional chemotherapy. The results were encouraging: In 24 patients, the median overall survival was 25.4 months with a range of 4.5-57.4 months; 8 patients survived for more than 2 years<sup>(1-7)</sup>.

BioVaxys believes that these results can be made even better with the addition of a second hapten as well as the use of a checkpoint inhibitor.

## **References**

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## ***Ovarian Cancer Market***

Worldwide, over 300,000 women are diagnosed with ovarian cancer each year (World Cancer Research Fund, 2019), with ovarian cancer the leading cause of death from gynecologic malignancy in the United States (American Cancer Society Facts & Figures 2020). An estimated 21,750 new cases of ovarian cancer are expected in the US in 2020 with 13,940 deaths (National Cancer Institute, Surveillance and Epidemiology Program, 2020). The case-to-fatality ratio

is nearly 3x that of breast cancer. The majority of women with stage III or IV cancer will ultimately have recurrent disease resistant to chemotherapy. Patients who have relapsed after platinum-based chemotherapy have limited life expectancy even with multiple salvage regimens. This large group of non-responders to, or those who relapse after, first line therapy is the initial target market for the Company.

The global cancer immunotherapy market size is likely to reach USD\$126.9 billion by 2026, according to *Covid-19 Treatment Market Size and Trends Analysis*, a 2019 report by Grand View Research, Inc., exhibiting a CAGR of 9.6% during the forecast period. The increasing patient pool and higher mortality rate are augmenting the need for cancer immunotherapy globally. Furthermore, the increasing number of approvals for new immunotherapeutic drugs is driving the global market. Adverse effects, such as recurrence of cancer and organ failure, associated with conventional chemotherapies and rising demand for technologically advanced healthcare solutions are boosting the demand for immunotherapies.

### ***Limited Treatment Options and Current Competitive Environment***

There is a significant unmet therapeutic need for new ovarian cancer treatments.

The current standard of practice following cytoreductive surgery is to use a taxane (taxol or taxotere) with carboplatinum. Three FDA approved therapies for treatment failure of first-line therapy include topotecan, liposomal doxorubicin, and gemcitabine. Other available drugs with low levels of anti-tumor activity are oral etoposide and vinorelbine. More recently, the inhibitors of the enzyme poly ADP ribose polymerase ("PARP"), olaparib, has been shown to be of value as initial treatment of stage III, but mainly in patients with the breast cancer gene ("BRCA") mutations. In addition to these approved therapies, new approaches and treatment for second-line therapies are being explored to improve patient outcome. Because there is no single agent or combination therapy that is standard in this relapse patient population, an important alternative is participation in a clinical trial. More recently, anti-immune checkpoint T-lymphocyte-associated protein ("CTLA4") and anti-programmed cell death protein-1 ("PDA") checkpoint antibodies have generated significant clinical interest based on their efficacy, especially in melanoma. An important part of the immune system is its ability to tell between normal cells in the body and those it sees as "foreign". This lets the immune system attack the foreign cells while leaving the normal cells alone. To do this, it uses "checkpoints" – molecules on certain immune cells that need to be activated (or inactivated) to start an immune response. Cancer cells sometimes find ways to use these checkpoints to avoid being attacked by the immune system. But drugs that target these checkpoints hold a lot of promise as cancer treatments. PD-1 is a checkpoint protein on T-cells. It normally acts as a type of "off switch" that helps keep the T-cells from attacking other cells in the body. It does this when it attaches to PD-L1, a protein on some normal (and cancer) cells. When PD-1 binds to PD-L1, it basically tells the T-cell to leave the other cell alone. Some cancer cells have large amounts of PD-L1, which helps them evade immune attack. Monoclonal antibodies that target either PD-1 or PD-L1 can block this binding and boost the immune response against cancer cells. However, the use of checkpoint inhibitors in ovarian cancer has been disappointing to date. Significant anti-tumor responses occur in less than 5% of patients. New regulatory clarity and deeper scientific understandings have led to a broad array of marketed and development stage programs chimeric antigen receptor T cells ("CAR-T"), oncolytic viruses, monoclonal antibody-drug conjugates, and cancer vaccines. There is also an appreciation among clinicians and researchers that no single approach will work for all patients with a single tumor type, and as a result, combination immunotherapeutics are recognized as holding significant promise, with many of these combinations based on vaccines.

### ***Cancer Vaccine History***

Cancer immunotherapy, including vaccines, has been in clinical testing for more than 50 years. Early generation cancer vaccines couldn't stimulate enough immune 'firepower' to kill tumors, had uncompetitive pricing, suffered manufacturing difficulties, and were hampered by poor clinical study design, among other reasons. However, recent successes with checkpoint inhibitors have established immunotherapy as scientifically sound and effective. Older data indicating that certain cancer vaccines have therapeutic value are getting a second look. The principle behind cancer vaccines is to work with a cancer patient's immune system to generate an immunologic response, particularly a T cell response, against the tumor. Although conventional vaccines are commonly used for prevention, there are certain challenges to using cancer vaccines therapeutically. Tumor antigens are generally weakly immunogenic, and, therefore, the body tolerates them as self, letting the cancer cells grow and metastasize without any impedence.



Previous competitive efforts with "off-the-shelf" product approaches have been to use peptides or allogeneic cell lines as a source of tumor associated antigens ("TAA"), but randomized trials with this approach mainly have been negative or unconvincing. Given inter-patient tumor heterogeneity, any "one-size-fits-all" vaccine using well-characterized common antigens or allogeneic tumor cells as TAA sources, have not advanced, and BioVaxys believes that the ideal source of TAA should be a patient's own tumor if one wants to exploit the full range of potential TAA in that patient. The approach to breaking this "self-tolerance" can be one of increasing the immune system's ability to recognize tumor cells as foreign. More specifically, the autologous approach may have advantages over other approaches. Because autologous tumor cells by definition have the patient's unique set of antigens already on them, the challenge is to increase the immune system's ability to recognize the ovarian tumor cells as foreign, breaking the "self-tolerance". A way to achieve this is by the use of a hapten. This is the foundation for BioVaxys' autologous haptenized cancer vaccines.

Although there are several autologous cell-based products in development for various cancers, the Company believes it has the only haptenized autologous vaccine platform in the world.

### ***Cervical Cancer and HPV Vaccine Program***

Leveraging the recent proven ability of its haptenized viral antigen vaccine platform in stimulating both a 96.4% positive immune response and powerful 'memory' T-cell activation against SARS-CoV-2, BioVaxys will use the platform's flexibility to swap in viral antigens for HPV, with the intent to develop a treatment for adults who are already infected with HPV. There are vaccines to protect against getting HPV, but none to treat someone who already has HPV. BioVaxys and Procure Health will split costs for feasibility, proof-of-concept, and preclinical development for a HPV viral vaccine, as well as a cervical cancer vaccine based on the BioVaxys cancer vaccine platform. In return, Procure Health will have an exclusive right in the EU and UK for an HPV and/or cervical cancer vaccine, with BioVaxys retaining rights to North America and Rest of World. Development milestones, go/no-go decisions, and other details will be finalized in 2022.

### ***BVX-0922 (Colorectal Cancer)***

BVX-0922 is the Company's autologous haptenized tumor vaccine for colorectal cancer. BioVaxys plans to advance an Investigator-Sponsored Clinical Study in the EU this year for BVX-0922. An Investigator Sponsored Clinical Study is done by a clinical investigator, typically at an academic hospital, who both initiates and conducts an initial clinical study of a new drug or procedure, and under whose immediate direction the investigational drug is administered.

CRC is the third most common malignancy and the second most deadly cancer world-wide, with an estimated 1.9 million new CRC cases diagnosed and 0.9 million deaths globally in 2020. The incidence of CRC is higher in highly developed countries, with global new CRC cases predicted to reach 3.2 million in 2040. When diagnosed early, the five-year relative survival rate for stage I and stage II colon cancer is 90%; however, CRC patients often experience no signs or symptoms associated with the disease. The 5-year survival rate for patients diagnosed at Stage IV is only 14% (*Journal of Translational Oncology, Global Colorectal Cancer Burden in 2020 And Projections to 2040, Vol 14, Issue 10, October 2021*). A major benefit of the Company's autologous haptenized tumor vaccine technology platform is the rapid scalability into a range of tumor types, especially those where the standard of care for these cancer patients typically involves surgical excision of tumor tissue. Access to these tumor cells is necessary for BioVaxys to manufacture autologous haptenized tumor cell vaccines, such as BVX-0918 for late-stage ovarian cancer or BVX-0922 for CRC. No new technology is required, as haptenization of CRC tumor cells is the same process as that for ovarian tumor cells and is covered under the Company's broad bihaptenization patents.

Worldwide rights are available for BVX-0922, and the Company has not yet determined whether it will retain this product in its portfolio or outlicense to a partner.

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

In addition to the Company's haptenized vaccines for ovarian cancer and other tumor types, the Company is exploring additional ways to leverage its technology. 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-vaccine 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 academic collaborations to identify novel cancer antigens eliciting a T-cell response, which may lead to further new intellectual property. The Company is including blood draws in its EU Phase I clinical protocol to begin obtaining pre-post vaccination leukocytes.

## **Viral Vaccine Programs**

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

The viral envelope of coronaviruses is typically made up of three proteins that include the membrane protein (M), the envelope protein (E), and the spike protein (S). Without the S protein, SARS-CoV-2 would not be able to enter cells of potential hosts like animals and humans to cause infection. As a result, the S protein represents an ideal target for vaccine and antiviral research endeavors.

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 the hapten dinitrophenyl ("**DNP**"). As the S-protein is highly immunogenic, it is an ideal drug and vaccine target. The Company has developed a simple, low-cost procedure for manufacturing its vaccines, and BVX-0320 can be stored in conditions of -40 degrees Fahrenheit, which is universally available.

The Company believes that by using the process of 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.

The highly promising neutralizing antibody and T cell response, excellent emerging safety and toxicity profile, ACE2 binding, and cold chain logistics profile lead BioVaxys to believe it has a very promising SARS-CoV-2 vaccine candidate that should be progressed into a Phase I study. The Company has elected to further development of BVX-0320 as part of its pan-sarbecovirus program via a collaborative partnership or through non-dilutive funding.

### ***BVX-1021 (SARS1/ Pan-Sarbecovirus Vaccine Candidate)***

The mRNA and adenoviral vector vaccine approaches have been a significant medical advance against Covid-19. Although there remains much room for improvement in safety, tolerability, cost of goods, and level of T-cell response for long term protection, the Company believes that it can use its technology platform to focus on the major unmet need of creating a "pan-coronavirus" (or more properly, a pan sarbecovirus) vaccine that will target the range of emerging SARS-CoV-2 variants as well as other sarbecoviruses such as the SARS1 virus and other emerging CoVs.

The Company has entered into a second sponsored research collaboration with OSU to further develop the Company's haptenized viral antigen platform to create a broadly reactive pan-sarbecovirus vaccine. The clinical goal of the program is to stimulate virus cross-reactivity and induce immunity against all or most sarbecoviruses by immunizing people who have recovered from a documented Covid-19 infection or received a full course of any currently approved Covid-19 vaccine, leading to a pan-sarbecovirus vaccine that encompasses current and emerging SARS-CoV-2 variants. OSU plans to conduct animal studies with BVX-0320, together with a newly developed haptenized protein vaccine from the Company, BVX-1021, for SARS-CoV-1, the sarbecovirus strain that causes SARS1, the respiratory illness responsible for the deadly 2002–2004 pandemic. As at the date of this AIF, there are no vaccines approved for SARS1. BVX-1021 is a hapten-modified recombinant S-protein from SARS-CoV-1, whereas BVX-0320, BioVaxys' Covid-19 vaccine, is a hapten-modified recombinant S-spike protein from SARS-CoV-2, the virus which causes Covid-19. Results from the study are anticipated in August 2022.

### ***World Health Organization and Pan Sarbecovirus Vaccines***

In January, 2022, Phillip Krause, MD, Chair of the World Health Organization ("**WHO**") Covid Vaccines Research Expert Group, presented on the critical need for a pan-sarbecovirus vaccine ("*Why do we need a pan-sarbecovirus?*")

January 28, 2022, World Health Organization). Although an increase in worldwide immunity against SARS-CoV-2 is anticipated, the WHO believes that the next clinically important variant will still evolve, with future variants likely to be more transmissible, more evasive of previous immunity, and with uncertain virulence. The WHO summarizes that the current vaccines are becoming less effective against evolving variants, and the waning of boosters indicates that there is not a practical vaccine for the future. Furthermore, it is even possible that another bat sarbecovirus will jump to the human population, and that there is very high urgency for a pan-sarbecovirus vaccine with a better chance of blocking transmission and facilitating herd immunity.

### ***Diagnostic Program***

#### ***SARS-CoV-2 T-Cell Activity Diagnostic (CoviDTH™)***

In January 2021 the Company initiated development of CoviDTH™, the world's first low cost, disposable, diagnostic to identify a T-cell immune response to the presence of the SARS-CoV-2.

The most common current Covid-19 diagnostics only measure antibody-mediated activity against SARS-CoV-2, or molecular screening for Covid-19 based on reverse transcriptase polymerase chain reaction ("RT-PCR") detection of viral RNA of SARS-CoV-2. There is now significant evidence that a T cell-mediated immune response is required for protection against SARS-CoV-2 [Sariol, A.; Perlman, S. Lessons for Covid-19 Immunity from Other Coronavirus Infections. *J. Immun.* 53, 248–263 and Tay, M.Z.; Poh, C.M.; Rénia, L.; Macary, P.A.; Ng, L.F.P. The trinity of Covid-19: Immunity, inflammation and intervention. *Nat. Rev. Immunol.* 2020,20, 363–374], and also that T cell-mediated immunity is a more reliable correlate of vaccine protection than antibody titers in seniors [Haq, K.; E McElhaney, J. Immunosenescence: Influenza vaccination and the elderly. *Curr. Opin. Immunol.* 29, 38–42], strongly supporting the need for a determination of T cell response in Covid-19 vaccine design and population screening.

Current methods of measuring T cell activity 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. 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 that cannot be accomplished with current diagnostics.

CoviDTH™ is based on DTH which is known to be a measure of T cell reactivity and has been used for many years to identify T cell response to other infectious diseases including tuberculosis, fungal diseases, and mumps. The CoviDTH™ test is performed by placing a small amount of purified recombinant test material (the SARS-CoV-2 spike protein or subunits) intradermally and inspecting the skin site for erythema and induration 24-48 hours later. CoviDTH™ will provide clinicians with a fundamental tool to answer immunogenicity questions basic to understanding how long T-cell immune responses are detectable in exposed and vaccinated individuals. This simple test is also ideal for those groups of patients that do not have easy access to troublesome *in vitro* studies, such as the young and pediatric population, and extremely useful because it can be visually interpreted by any non-specialist medical doctor or trained pharmacy technician. The study of cellular immune responses in Covid-vaccinated individuals will also provide insight to optimized dosing and type of vaccines in different scenarios of selected groups of patients such as immunodeficient and transplant patients.

### ***Competitive COVID-19 Testing Environment***

Several serological assays have been developed since the beginning of Covid-19 pandemic, including enzyme-linked immunosorbent assays ("ELISA"), rapid antibody immunochromatographic tests, fluorescence assays, and chemiluminescence immunoassays. Covid-19 IgG antibody testing checks for a type of antibody called immunoglobulin G (IgG). If someone has been exposed to the virus that causes Covid-19, they generally produce IgG antibodies. In the United States, the cost of getting a standard Covid-19 test at hospitals varying by state, according to a nationwide study conducted in 2020 by Hospital Pricing Specialists. The state with the highest average cost is New Jersey at a price of \$302, whereas the lowest cost is in Maryland at \$62.

Commercial ELISA kits for IgG screening are also available, such as The Human SARS-CoV-2 Spike (Trimer) Ig Total ELISA kit from ThermoFisher which is a US\$490 serology assay that measures and quantitates immunoglobulin (Ig) antibodies against SARS-CoV-2 Spike (Trimer) in human serum or plasma.

Detection of viral nucleic acid in nasal swabs takes place by quantitative PCR method by specialized laboratories under biological safety class 2 protections. However, RT-PCR kits can give some false-negative results, depending on swab sampling and extraction method, and on the possibility that virus, even if present in the individuals, is not detectable in the nasal mucous membrane. Incidence of false negatives in molecular tests sometimes force repetition of the test, up to three times in clinically suspected Covid-19 patients. One of the more popular kits is a US\$109 RT-PCR nasal swab kit marketed by Everlywell, Inc. ("**Everlywell**"), which requires inserting a swab into the sinus cavity to collect a sample, shipping it to an Everlywell laboratory for analysis, then waiting ~3-5 days for results.

A major drawback of nucleic acid and antibody screening is that some people who previously had SARS-CoV-2 but tested negative for antibodies went on to test positive for T-cells activated against SARS-CoV-2---meaning some people may have more immunity than previously thought, and for longer. Further, a majority of in vitro diagnostic companies do not report nature of the antigen(s) utilized in the assays and therefore difficult to understand whether antibodies detected with different kits and methodologies have a neutralizing effect on the virus, possibly through binding with the viral spike protein S subunits receptor-binding domain (Nuccetelli, M., Pieri, M., Grelli, S. *et al.* SARS-CoV-2 infection serology: a useful tool to overcome lockdown? *Cell Death Discovery*. **6**, 38 (2020)).

### ***T-Cell Screening***

T-cells are becoming increasingly recognized for their role in SARS-CoV-2 infection and immunity; measuring the presence and size of any T-cell response can give more information than that available by serology. The only T-cell tests available are laboratory-based, and require submission of a blood sample to a central processing lab. Oxford Immunotec Ltd. (now owned by PerkinElmer Inc.) ("**Oxford**"), and Qiagen N.V. ("**Oiagen**") currently offer T-cell diagnostics; however, both are approved for "research use only." Oxford's *T-Spot Discovery SARS-CoV-2* kit and Qiagen's *QuantiFERON* platform are both based on diagnostics for latent tuberculosis, and assessing the immune response to cytomegalovirus infections in transplant patients. Oxford will be the sole supplier of T-cell testing for SARS-CoV-2 specific responses in the UK's Covid-19 vaccine trials, highlighting the importance now being placed on the role of T-cell activation in combatting SARS2. Pricing of Oxford's *T-Spot Discovery SARS-CoV-2* kit is expected to be similar to their T-SPOT® *TB* test at ~US\$220.

Adaptive Biotechnologies Corporation ("**Adaptive**") recently introduced a T-cell diagnostic, however, it requires a blood draw, with sera sent to central laboratories for processing. Adaptive uses a PCR test performed on peripheral blood lymphocytes. The Company believes that it's low-cost, easy-to-administer, and accurate tool to evaluate the effectiveness of any SARS-CoV-2 vaccine candidate in stimulating T cell immunity is superior to current diagnostics.

### ***CoviDTH™ Regulatory Status***

In late 2021, the Company engaged a global regulatory advisory group RPS, LLC, to provide strategic regulatory guidance, prepare an FDA pre-submission guidance package, recommend regulatory pathway, and support the Company on the registration filing. RPS has provided pharmaceutical and medical-device advisory services across the entire drug, biologic and device development and approval spectrum of the pharmaceutical industry since 2000. Collectively, the RPS team of pharmaceutical industry executives offers nearly 150 years of experience in providing advice and support services for medical, scientific, clinical-trial and regulatory issues to clients including a majority of Fortune 500 pharmaceutical companies.

In 2021, the Company approached the FDA for regulatory guidance and was asked to submit an EUA for CoviDTH™, which the Company filed in February 2021. Under section 564 of the Federal Food, Drug, and Cosmetic Act (the "**FD&C Act**"), the FDA can allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives.

FDA currently and proactively triages all SARS-CoV-2 related industry interactions. Following its initial approach to FDA, the Company was informed that CoviDTH™ will be reviewed by the FDA as an *in vivo* device, with review having been assigned to the FDA's Center for Biologics Evaluation and Research ("CBER").

In March 2021, BioVaxys submitted a Pre-IND meeting request and briefing package with CBER for CoviDTH™. The Pre-IND review is a critical step in the US regulatory approval process, as it affords an opportunity for study sponsor companies to seek clarification from the FDA on clinical trials design, clinical materials manufacturing, quality controls, etc.

In an official Written Response from the FDA received in July 2021 to the Company's request for a Pre-IND Type B review of CoviDTH™ as a diagnostic for evaluating T-cell immune response to SARS-CoV-2, the FDA found the Chemistry, Manufacturing and Controls, and other elements of the clinical development program proposed by BioVaxys to be acceptable and provided guidance and feedback supportive of BioVaxys' clinical development plans for CoviDTH™. In addition, the FDA indicated that animal toxicity studies for CoviDTH™ were not required and that the Company could start its clinical development program with a combined Phase I/II study. Based on this feedback, BioVaxys began preparation of an IND application to support a Phase I/II safety, dosing, and efficacy study.

Although the animal tox study was deemed discretionary by the FDA, the Company believes the data will be very supportive of its IND.

### ***Toxicology***

Results from an *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, the 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.

### ***Clinical Development Plan***

Based on the FDA Written Response, the Toxicology Study, regulatory input, sample size statistical analysis, and other key learnings, in 2021 the Company completed a preliminary clinical development plan for the Phase I/II IND submission for CoviDTH™. Objectives of this pivotal study will be to measure the DTH response to the S1 subunit of SARS-CoV-2 in human subjects who have prior immunity to the virus as defined by prior administration of an FDA-approved vaccine or by prior infection, to compare the DTH results with the levels of circulating antibody to SARS-CoV-2 S-protein, and determine the safety of CoviDTH™. The remaining component of the Phase I/II IND is the GMP manufacturing plan for bioproduction of recombinant SARS-CoV-2 s-spike protein, and will be available when the GMP s-protein completes quality control validation which is targeted for later in 2022.

### ***S-Protein Sourcing***

For the Toxicology Study, the Company purchased commercially available recombinant s-protein. However, the SARS-CoV-2 proteins currently available from commercial suppliers are not sufficiently well-characterized for human use, QC/QA not integrated in production, and it is not available in GMP-clinical grade, so the Company will need to develop its own supply of GMP-grade protein. The Company's biomanufacturing step in 2022 is to produce a supply of recombinant, clinical-grade, SARS-CoV-2 RBD protein for the Phase I/II study, the principal reagent used in CoviDTH™.

RBD protein will be produced by inserting the gene sequence for the RBD protein into a well-characterized cell line that can then be grown to produce the protein. The specific cell line is proprietary as they are highly specialized and must have analytical documentation to be acceptable to regulatory authorities for human use. The Company will require a license to use the cell line and expression system technology. To make the protein, company scientists first take a common mammalian cell, called a CHO cell, and insert DNA instructions to create the protein. They use the newly infused CHO cell to create a Master Cell Bank, which is then grown in large bioreactors (where the RBD protein is produced).

Production of RBD protein will require obtaining a license to use a third-party proprietary cell line and expression system, with a one-time license fee and access to the cell line costing approximately US\$250,000.

The Company has identified a supplier in Switzerland to provide the cell expression system under license, and a CDMO organization in Germany to produce the GMP-grade RBD protein. Proposals have been obtained from both groups, with the total cost for the license and GMP clinical supply for the Phase I/II study to be approximately US\$2.0M,

### ***Human Clinical Studies***

In June, the medical research journals *Clinical Immunology and Vaccines* both published the results of two clinical studies [The Beauty of Simplicity: Delayed-Type Hypersensitivity Reaction to Measure Cellular Immune Responses in RNA-SARS-Cov-2 Vaccinated Individuals. Barrios Y, Franco A, Sánchez-Machín I, Poza-Guedes P, González-Pérez R, Matheu V. *Vaccines* (Basel). 2021 Jun 1;9(6):575. doi: 10.3390/vaccines9060575 and A Novel Application of Delayed-Type Hypersensitivity Reaction to Measure Cellular Immune Response in SARS-CoV-2 Exposed Individuals. Barrios Y, Franco A, Sanchez-Machin I, Poza-Guedes P, Gonzalez-Perez R, Matheu V. *Clin Immunol*. 2021 May;226:108730. doi: 10.1016/j.clim.2021.108730. Epub 2021 Apr 16.] led by Dr. Yvelise Barrios and her colleagues at Hospital Universitario de Canarias in Spain 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, is effective and safe, and can answer basic immunogenicity questions in large-scale populations. As this test was not done under GMP condition, the FDA will not permit its use in an IND; however, it is proof of safety, tolerability and effectiveness in human volunteers and eliminates many unknowns prior to the submission of the Company's IND.

Dr. Barrios is a member of the Company's Scientific Advisory Board.

### ***Phase I/II Study***

In 2021 the Company solicited a proposal from a global clinical research organization ("**CRO**") to conduct a *Double-Blinded, Prospective, Multi-Center, Phase I/II Study to Evaluate the Predictive Efficacy & Safety of a Covid-19 DTH Test in Subjects who have Tested Positive and Negative for Historical Infection with Covid-19 and/or Vaccination*. Cost for the ~95 subject study is US\$1.3M (inclusive of all project management, protocol preparation, informed consents, regulatory submissions, study conduct, bioanalysis, data management, biostatistics, PK/PD, clinical site monitoring, clinical study report, etc.) with an estimated completion time of 12 months. This study has not commenced as of the date of this AIF.

## ANTICIPATED MILESTONES

BIOVAXYS

### Anticipated Milestones

Milestone	Period
BVX-0918 GMP bioproduction process completed/Submission of CTA	Q3 '22
Completion of clinical scale bioproduction for CoviDTH Phase I/II study	Q4 '22
Vaccination of first Phase I ovarian cancer study subjects	Q4 '22
CoviDTH IND filed	Q1 '23
CoviDTH Phase I/II study	Q1 '23
Final Phase I ovarian cancer subjects vaccinated	Q1 '23
Anticipated US launch of Papilocare	Q2 '23
BVX-0918 US IND submission (utilize EU data)	Q4 '23

Not for Distribution

5

## COMMERCIALIZATION

The Company intends to commercialize its products in the United States, and seek commercial partners for the European Union, Asia/Pacific, and Latin American markets (the "**Intended Markets**") via a combination of licensing agreements for ex-US markets and retaining commercial rights for the US.

The Company is currently in confidential discussions with a prospective partner to distribute and market CoviDTH™ in Israel, and with a prospective Chinese pharmaceuticals company to collaborate on clinical research for its oncology and virus vaccine programs.

### Research and Development

The Company's research and development activities are centered around developing its products and programs, described above.

The research, pre-clinical development, clinical trials, product manufacturing and marketing conducted by the Company or on its behalf are subject to regulation by the FDA in the U.S. as well as the European Medical Evaluation Agency ("**EMA**") which has broad oversight over most European Union Member States. The Company's Products and technologies also may be subject to certain other international, U.S. federal, state and local government regulations, including, the FD&C Act, Public Health Service Act, and their state, local and foreign counterparts. The development process and risks are generally similar for the U.S. and EU.

For clinical investigation and marketing outside the U.S., the Company will be subject to certain foreign regulatory requirements governing human clinical trials and marketing approval for drugs. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement can vary for European countries both within and outside the EU. Normally, foreign marketing authorizations are applied for at a national level, although within the EU certain registration procedures are available to companies wishing to market their products in more than one EU member state. If any applicable regulatory authority is satisfied that adequate evidence of safety, quality and efficacy

has been presented, a marketing authorization will be granted. The system for obtaining marketing authorizations within the EU registration system is a dual one in which certain products, such as biotechnology and high technology products and those containing new active substances, will have access to a central regulatory system that provides registration throughout the entire EU. Other products will be registered by national authorities in individual EU member states, operating on a principle of mutual recognition.

The FDA and EMEA generally follow the same clinical development path, with the EMEA and FDA concurring >90% of the time in their decisions to approve new drugs, according to a study from EMA and FDA officials that looked at 107 new drug applications from 2014 to 2016 (European Medicines Agency, *EMA/FDA analysis shows high degree of alignment in marketing application decisions between EU and US*, August 16, 2019).

### ***Contracting***

The Company does not anticipate any near-term need for establishing chemistry or other internal laboratory facilities. Preclinical, non-GMP and GMP manufacturing, and other development work is and will continue to be contracted to CDMOs, outsourced or partnered, which management of the Company believes makes the Company a leaner and more efficient operation.

### ***Specialized Skills and Knowledge***

The nature of the Company's business requires specialized skills and knowledge, including expertise in haptenized protein vaccines, clinical oncology research, finance, and operations. Management of the Company have specialized skills that will enable the Company to achieve its development goals.

- The Chief Medical Officer and founder of BioVaxys Inc., Dr. David Berd, is a clinical oncologist and one of the world's foremost experts on haptenized protein vaccines, and as such, contributes haptenized protein vaccine, immunology, clinical oncology research, production and regulatory know how which is unique to the Company.
- As a founder of Avax, BioVaxys Inc. President and Chief Operating Officer, Kenneth Kovan, has developed a deep understanding of the science behind haptenized protein vaccines, their manufacture, and commercialization, and possesses unique know-how related to the business. Mr. Kovan has over 30 years of experience in biopharmaceuticals commercial and corporate development, has held senior global product marketing roles, and launched pharma brands worldwide.
- As a major investor in Avax, BioVaxys Inc. founder and Chief Executive Officer, James Passin, has a specialized and unique understanding of the science and commercialization of haptenized protein vaccines.

### ***Competition***

Management believes that the Company is strategically poised to a competitive player in the development of its Products.

### ***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 AIF, the Company has a total of two issued US patents, eight pending US and PCT patent applications, National Phase applications for the US, EU, UK and seven other markets, and international trademark registrations:

- 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 – Bihaptenized Autologous Vaccines and Uses Thereof (original US filing September 24, 2018) International Application No. PCT/US2019/052644- BIHAPTENIZED AUTOLOGOUS VACCINES AND USES THEREOF (original filing September 24, 2018). The National Phase filing deadline for 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.
- International Application # PCT/US22/26461 - BIHAPTENIZED AUTOLOGOUS VACCINES AND USES THEREOF with claims for cervical cancer (April 27, 2022)
- US Patent Application #62/992,722 – Haptenized Coronavirus Spike Protein Vaccine (Filed on March 20, 2020), PCT/US21/23310 filed March 19, 2021
- 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.
- US Patent Application #63106482- METHOD AND KIT FOR DETECTION OF CELL MEDIATED IMMUNERESPONSE (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.

National Phase filing costs (US\$) are estimated as follows (source: *Morgan Lewis & Bockius LLP*):

	Official / Associate	Translation	In-House / Miscell.	Total
Australia	\$3,884	\$0	\$0	\$3,884
Brazil	\$3,076	\$1,845	\$0	\$4,921
Canada	\$2,861	\$0	\$0	\$2,861
China	\$2,230	\$2,822	\$0	\$5,052
European Patent Office	\$13,243	\$804	\$0	\$14,047
India	\$1,462	\$0	\$0	\$1,462
Japan	\$3,163	\$4,688	\$0	\$7,851
Mexico	\$2,875	\$1,665	\$0	\$4,540
Russian Federation	\$2,305	\$2,952	\$0	\$5,257
Singapore	\$3,784	\$0	\$0	\$3,784
United States of America	\$1,965	\$0	\$0	\$1,965
Report Totals	\$40,848	\$14,776	\$0	\$55,624

The Company also relies, in part, upon unpatented trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. The Company protect our proprietary rights through a variety of methods, including confidentiality and assignment agreements with suppliers, employees, consultants, and others who may have access to our proprietary information.

While there is no active litigation involving any of the Company's patents or other intellectual property rights and the Company has not received any notices of patent infringement, the Company may be required to enforce or defend its intellectual property rights against third parties in the future.

Patents and other proprietary rights are very valuable to the Company and involve complex legal and factual issues. The Company has no assurance that all of its patent applications will result in the issuance of patents. Even issued patents may not provide the Company with a competitive advantage against competitors with similar technologies, or who have designed around the Company's patents. Furthermore, the Company's patents may be invalidated or found unenforceable if challenged. Intellectual property laws vary from country to country which may result in varying levels of intellectual property protection.

Because of the substantial length of time and expense associated with developing new products, the pharmaceutical, medical device, and biotechnology industries place considerable importance on obtaining patent protection for new technologies, products, and processes. The Company's policy is to file patent applications to protect inventions, technology, and improvements that are important to the development of our business and with respect to the application of our products and technologies to the treatment of a number of diseases. The Company's policy also includes regular reviews related to the development of each technology and product in light of its intellectual property protection, with the goal of protecting all key research and developments by patent.

#### *Licenses*

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

- Issued U.S. patent # 7,297,330 – Low dose haptenized tumor cell and tumor cell extract immunotherapy (expiration 2024)
- Issued U.S. 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 Inc. 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 Inc. 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 Inc. 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. As a result, TJU received 1,160,000 Common Shares upon closing of the Share Exchange Transaction. Further, the Company bears the expense of maintaining and defending the patents that are subject to the TJU License.

### ***Therapeutics Clinical Development, Approval, and Manufacturing Process***

The research, pre-clinical development, clinical trials, product manufacturing and marketing conducted by the Company or on its behalf are subject to regulation by the FDA in the U.S. as well as the EMEA which has broad oversight over most European Union Member States. The Issuer's proposed products and technologies also may be subject to certain other international, U.S. federal, state and local government regulations, including, the FD&C Act, Public Health Service Act, and their state, local and foreign counterparts. The development process and risks are generally similar for the U.S. and EU.

For clinical investigation and marketing outside the U.S., the Company will be subject to certain foreign regulatory requirements governing human clinical trials and marketing approval for drugs. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement can vary for European countries both within and outside the EU. Normally, foreign marketing authorizations are applied for at a national level, although within the EU certain registration procedures are available to companies wishing to market their products in more than one EU member state. If any applicable regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization will be granted. The system for obtaining marketing authorizations within the EU registration system is a dual one in which certain products, such as biotechnology and high technology products and those containing new active substances, will have access to a central regulatory system that provides registration throughout the entire EU. Other products will be registered by national authorities in individual EU member states, operating on a principle of mutual recognition.

The FDA and EMEA generally follow the same clinical development path, with the EMEA and FDA concurring >90% of the time in their decisions to approve new drugs, according to a study from EMA and FDA officials that looked at 107 new drug applications from 2014 to 2016 (*European Medicines Agency, EMA/FDA analysis shows high degree of alignment in marketing application decisions between EU and US, August 16, 2019*).

The following discussion focuses on the regulatory framework in the United States. The European regulatory framework largely parallels that of the United States.

***Clinical Development:*** Every new drug approval in the US and EU follows the same general path: (i) preclinical development (ii) the submission to the FDA of an IND application for human clinical testing, that must become effective before human clinical trials commence (in the EU this is called the "Clinical Trial Application" or "CTA"); (iii) adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug; (iv) the submission of a marketing application to the FDA; (v) approval of the manufacturing processes and controls; and (vi) FDA (or EMEA) approval of the marketing application prior to any commercial sale or shipment of the drug.

The first step required before a pharmaceutical or therapeutic biological agent may be marketed in the U.S. (and other countries) is the pre-clinical development stage, which consists of laboratory tests, pre-clinical studies in animals, toxicity studies and formulation studies. Pre-clinical studies include laboratory evaluation of the product, and animal studies to assess the pharmacological activity and the potential safety and effectiveness of the drug. The results of the pre-clinical studies are submitted to the FDA in an IND application. Unless the FDA objects to an IND, it becomes effective 30 days following submission and the clinical trial described in the IND may then begin. Clinical trials begin when a drug is approved for testing on humans. There are generally three main phases of clinical trials that a drug must go through in the U.S. before the drug is approved to be manufactured and marketed to the public. These phases may involve testing of drugs in healthy human volunteers (Phase I) for assessment of safety, followed by tests of effectiveness and safety in patients with illnesses the drug is designed to treat (Phases II and III). In most instances, Phase III studies are the final group of studies that are conducted before a product can be approved by the FDA for commercial use. In general, Phase I trials involve small numbers of patients, with Phase II requiring higher patient enrollment and Phase III having the largest patient enrollment to enable statistical analysis of different treatment groups. In the case of life-threatening illness, the study process and phases of clinical trials may be compressed and accelerated. In some cases, Phase II trials are deemed sufficient for market approval by the FDA or foreign regulatory authorities. Pivotal registration trials are large-scale Phase II or III trials, the data obtained from which are intended to be used to provide for the registration of a drug or product for market use.

Every clinical trial must be conducted under the review and oversight of an institutional review board ("**IRB**") at each medical institution participating in the trial. The IRB evaluates, among other things, ethical factors, the safety of

human subjects, and the possible liability of the institution. In addition, when a sponsor has more than one clinical site participating in a study, they typically establish a Data Safety Monitoring Board that has oversight responsibilities for the safe conduct of the clinical studies.

**Early Access Program ("EAP"):** EAP allows physicians and patients access to pre-approval, investigational drugs outside of the clinical trial setting. An EAP can also be called a Managed Access Program (MAP), Early Access Program, Expanded Access, or a Compassionate Use Program (CUP). EAP programs are for patients suffering from a serious or life-threatening illness who have no viable treatment options available to them. This means that:

- There are no approved treatments available in the patient's home country
- If there are approved treatments available, the patient has tried them, and they have been ineffective
- It is not possible to enroll in an active clinical trial

Late-Stage ovarian cancer patients who have relapsed after platinum-based chemotherapy have limited life expectancy even with multiple salvage regimens, and would be candidates for an EAP. Under an EAP, early studies will generally have been completed, but a full safety profile and/or dosage guidelines may not be fully established.

Fundamentally, there must be an unmet clinical need. The provision of a drug through expanded access can only be granted by the drug manufacturer (sponsor) – no regulatory body or third-party provider can facilitate access without sponsor approval.

**Accelerated Approval:** FDA regulations and policies permit applicants to request accelerated or priority review pathways for products intended to treat certain serious or life-threatening illnesses in certain circumstances. If granted by the FDA, these review pathways can provide a shortened timeline to commercialize the product, although the shortened review timeline is often accompanied with additional post-market requirements.

**Manufacturing:** In addition to obtaining FDA approval for each product, each domestic drug manufacturing facility must be registered with, and approved by the FDA. Domestic manufacturing facilities are subject to inspections by the FDA and must comply with current GMP. To supply products for use in the U.S., foreign manufacturing facilities also must comply with current GMP, and are subject to periodic inspection by the FDA or by comparable foreign regulatory agencies under reciprocal agreements with the FDA.

### ***Employees***

As at the end of the Company's most recently completed financial year, October 31, 2021, the Company had no employee and six consultants. As of the date of this AIF, the Company had no employee and six consultants.

### ***Revenue***

The Company has revenue generating activities.

### ***Bankruptcy and Receivership***

The Company has not been the subject of any bankruptcy or any receivership or similar proceedings or any voluntary bankruptcy, receivership or similar proceedings, within any of the three most recently completed financial years (as applicable) or the current financial year.

## **RISK FACTORS**

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 AIF. These risks and uncertainties are not the only ones facing the Company. Additional risks and uncertainties not presently known to the Company, or that the

Company currently deems immaterial, may also impair the operations of the Company. If any such risks actually occur, the business, financial condition and/or liquidity and results of operations of the Company could be materially adversely affected.

### **Going Concern**

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

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

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

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

The Company is an early-stage biopharmaceutical company with a limited operating history. The likelihood of success of the Company's business plan must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which the Company operates. Biopharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. Therefore, the Company expects to incur expenses without any meaningful corresponding revenues unless and until it is able to obtain regulatory approval and subsequently sell its products in significant quantities. To date, the Company has not generated any revenue from its products. The Company has incurred losses and anticipates that its losses will increase as it continues its development and clinical trials and seeks regulatory approval for the sale of its therapeutic product. There can be no assurance that it will have earnings or positive cash flow in the future. Further, even if the Company is able to commercialize any of its product candidates, there can be no assurance that the Company will generate significant revenues or ever achieve profitability.

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

### **Coronavirus Pandemic**

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

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

## **Research and Development Risks**

The following discussion of risks under this heading primarily reflect the US regulatory framework, but similar risks broadly apply to the 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 health care systems. If the Company is unable to successfully market and commercialize any of its products, its financial condition and results of operation may be materially and adversely affected. The Company can make no assurance that any future studies, if undertaken, will yield favorable results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials after achieving positive results in early-stage development, and the Company cannot be certain that it will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval. If the Company fails to produce positive results in its future clinical trials and other programs, the development timeline and regulatory approval and commercialization prospects for the Company's product candidates, and correspondingly, its business and financial prospects, would be materially adversely affected.

## **Preclinical and Clinical Development Risks**

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

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

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

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

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

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

- Size and nature of the patient population;
- Eligibility and exclusion criteria for the trial;
- Design of the study protocol;
- Competition with other companies for clinical sites or patients;
- The perceived risks and benefits of the product candidate under study; and
- The patient referral practices of physicians; and the number, availability, location and accessibility of clinical trial sites.

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

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

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

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

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

- Regulatory authorities' failure to grant permission to proceed or placing the clinical trial on hold;

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

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

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

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

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



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

### ***Safety and Efficacy***

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

### **Manufacturing Risks**

#### ***Reliance on Third Party Contract Manufacturers***

The Company has limited manufacturing experience and relies on CMOs over which it has limited control to manufacture its product candidates for preclinical studies and clinical trials. The Company relies on CMOs for manufacturing, filling, packaging, storing and shipping of drug products in compliance with GMP regulations applicable to the Company's products. FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with GMP regulations. The GMP regulations for drugs contain minimum requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product. There can be no assurances that CMOs will be able to meet the Company's timetable and requirements. If the Company is unable to arrange for alternative third-party manufacturing sources on commercially reasonable terms or in a timely manner, the Company may be delayed in the development of the product candidates. Further, CMOs must operate in compliance with GMP and failure to do so could result in, among other things, the disruption of product supplies. The Company's dependence upon third parties for the manufacture of its products may adversely affect the profit margins and the ability to develop and deliver products on a timely and competitive basis.

#### ***Success of Quality Control Systems***

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

### **Regulatory Risks**

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

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

will delay the Company's ability to produce product for clinical testing and would delay the Company's ability to enter into clinical trials.

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

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

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

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

- Disagreement with the design or implementation of its clinical trials;
- Failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- Failure of clinical trials to meet the level of statistical significance required for approval;
- Failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- Disagreement with the Company's interpretation of data from preclinical studies or clinical trials;
- The insufficiency of data collected from clinical trials of the Company's product candidates to support the submission and filing of a submission to obtain regulatory approval;
- Deficiencies in the manufacturing processes or the failure of facilities of collaborators with whom the Company contracts for clinical and commercial supplies to pass a pre-approval inspection;
- Changes in the approval policies or regulations that render the Company's preclinical and clinical data insufficient for approval;
- A regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and the Company's commercialization plans, or the Company may decide to abandon the development program;
- If the Company is successful in obtaining approval, regulatory authorities may approve any of its product candidates for fewer or more limited indications than the request, may grant approval contingent on the

performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate; or

- Depending on any safety issues associated with the Company's product candidates that garner approval, the FDA or other authorities may impose a risk evaluation and mitigation strategy, thereby imposing certain restrictions on the sale and marketability of such products.

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

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

### **Commercial/Marketing Risks**

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

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

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

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

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

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

Even if the Company's vaccine technology is safe and effective, there is no guarantee of commercial acceptance. Because its vaccine technology is a new approach to the treatment of cancer and viral infections, it must be accepted by both patients and physicians before it can be successfully commercialized. Due to the nature of the vaccine

technology, it requires that current practitioners revise the way they think about infectious disease and cancer treatment. The marketplace of ideas, technologies and information is crowded, and the Company must develop the means to reach leading specialist physicians in each market with the haptenized vaccines. Failure to do so will have a material adverse effect on the Company's business and financial condition.

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

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

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

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

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

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

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

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

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

## **Intellectual Property Risks**

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

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

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

The Company's success will depend in part upon its ability to protect its intellectual property and proprietary technologies and upon the nature and scope of the intellectual property protection it receives. The ability to compete effectively and to achieve partnerships will depend on the Company's ability to develop and maintain proprietary aspects of its technology and to operate without infringing on the proprietary rights of others. The presence of such proprietary rights of others could severely limit the Company's ability to develop and commercialize its products, to conduct existing research and could require financial resources to defend litigation, which may be in excess of its ability to raise such funds. There is no assurance that its pending patent applications will be approved in a form that will be sufficient to protect the Company's proprietary technology and gain or keep any competitive advantage that it may have or, once approved, will be upheld in any post-grant proceedings brought by any third parties. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Patents issued to the Company may be challenged, invalidated or circumvented. To the extent the Company's intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, the Company is exposed to a greater risk of direct competition. If the Company's intellectual property does not provide adequate protection against its competitors' products, the Company's competitive position could be adversely affected, as could its business, financial condition and results of operations. Both the patent application process and the process of managing patent disputes can be time consuming and expensive, and the laws of some foreign countries may not protect the Company's intellectual property rights to the same extent as do US patent laws. The Company will be able to protect its intellectual property from unauthorized use by third parties only to the extent the Company's proprietary technologies, key products, and any future products are covered by valid and enforceable intellectual property rights including patents or are effectively maintained as trade secrets, and provided the Company has the funds to enforce its rights, if necessary.

### ***Third Party License Risk.***

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

are unavailable to license on acceptable terms. The Company's inability to obtain such licenses may hinder or eliminate an ability to manufacture and market products.

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

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

### **General Operational Risks**

#### ***Conflict of Interest***

Certain directors and senior officers of the Company may, from time to time, be employed by or affiliated with organizations that have entered into agreements with the Company. As disputes may arise between these organizations and the Company, or certain organizations may undertake or have undertaken research with competitors of the Company, there exists the possibility for such persons to be in a position of conflict. Any decision or recommendation made by these persons involving the Company will be made in accordance with his or her duties and obligations to deal fairly and in good faith with the Company and such other organizations. In addition, as applicable, such directors and officers will refrain from voting on any matter in which they have a conflict of interest.

#### ***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.

### ***Uninsured Risks***

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

### ***Market for Securities and Volatility of Share Price***

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

### ***Competition***

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

### ***Fluctuating Prices***

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

### ***Key Person Insurance***

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

### ***Currency Exchange Risks***

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

### ***Other Risks***

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

The Company is dependent upon its founders and management team to obtain funding for the research and development of its products, to decide which of its products to promote, to shepherd the products through the clinical trial and regulatory approval process, and to stimulate business development and seek out new products and

technologies for development. In addition, the Company's current financial condition makes it more difficult for it to retain its current executives and recruit key employees.

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

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

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

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

***The Company may become party to litigation.***

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

## **DIVIDENDS AND DISTRIBUTIONS**

The Company has not declared nor paid any cash dividends on any of its issued equity securities since its inception. Other than requirements imposed under applicable corporate law, there are no other restrictions on the Company's ability to pay dividends under the Company's constituting documents. The Company has not paid any dividends on the Common Shares since its incorporation. It is expected that the directors of the Company will review its dividend policy from time to time in context of the Company's earnings, financial condition, capital requirements and other relevant factors; however, the Company has no present intention of paying dividends on the Common Shares, as it anticipates that all available funds will be invested to finance the growth of its business and, when appropriate, retire debt.

## **DESCRIPTION OF CAPITAL STRUCTURE**

The Company's authorized share capital consists of an unlimited number of Common Shares without par value.

As of the date of this AIF, there are 97,863,324 Common Shares issued and outstanding as fully paid and non-assessable. In addition, 7,819,976 Common Shares are reserved for issuance under Options and 24,863,574 Common Shares are reserved for issuance under Warrants.

### **Common Shares**

The Company's authorized share capital consists of an unlimited number of Common Shares without par value, each such Common Share carrying one vote per share at all meetings of shareholders and the right to participate ratably in any dividends declared by the management of the Company on the Common Shares, and each shareholder is entitled, on the liquidation, dissolution, winding-up or other distribution of assets of the Company for the purposes of winding-up its affairs, to a pro rata share of the assets of the Company after payment of all its liabilities and obligations.



The Common Shares are not subject to any pre-emptive rights, conversion or exchange rights, or provisions providing for redemption, retraction, purchase for cancellation or surrender. There are no sinking or purchase fund provisions, no provisions permitting or restricting the issuance of additional securities or any other material restrictions, and there are no provisions which are capable of requiring a security holder to contribute additional capital.

### **Warrants**

As of October 31, 2021, there were 19,774,115 Warrants outstanding with a weighted average exercise price of \$0.50 and with expiry dates ranging from August 26, 2022 to January 28, 2024.

### **Options**

As of October 31, 2021, there were 5,234,864 Options to purchase Common Shares outstanding with a weighted average exercise price of \$0.412 and expiry dates ranging from December 31, 2021 to September 3, 2026.

## **MARKET FOR SECURITIES**

### **Market**

The Company's Common Shares are listed on the CSE under the symbol "BIOV" and trade on the Frankfurt Bourse (FRA: 5LB) and US OTC: LMNGF. The table below lists the high and low trading prices and the trading volume for the periods indicated.

<b>Month</b>	<b>High (\$)</b>	<b>Low (\$)</b>	<b>Total Volume</b>
October 2021	0.465	0.315	4,221,960
September 2021	0.65	\$0.215	19,468,485
August 2021	0.2450	0.20	917,318
July 2021	0.335	0.20	4,200,405
June 2021	0.29	0.20	3,769,076
May 2021	0.375	0.20	2,594,565
April, 2021	0.46	0.275	4,248,568
March 2021	0.62	0.355	8,420,549
February 2021	0.78	0.31	21,065,224
January 2021	0.45	0.14	18,801,575
December 2020	0.32	0.19	6,124,713
November 2020	0.60	0.18	14,664,362

## **PRIOR SALES**

### **The Company**

During the year ended October 31, 2021, the Company issued the following securities that are not listed or quoted on a marketplace:

### Options

The following table summarizes grants of Options by the Company during the most recently completed financial year:

<b>Date of Grant</b>	<b>Number of Options Granted</b>	<b>Exercise Price</b>	<b>Expiry Date</b>
February 12, 2021	350,000	\$0.465	February 12, 2026
February 12, 2021	750,000	\$0.57	February 12, 2026
September 3, 2021	1,000,000	\$0.25	September 3, 2026

### Warrants

The following table summarizes grants of Warrants by the Company during the most recently completed financial year:

<b>Date of Grant</b>	<b>Number of Warrants Granted</b>	<b>Exercise Price</b>	<b>Expiry Date</b>
February 5, 2021	4,417,647	\$0.50	February 5, 2023
July 14, 2021	3,812,159	\$0.50	January 14, 2024
July 28, 2021	5,349,455	\$0.50	January 28, 2024

### ESCROWED SECURITIES

The following table sets forth the number of securities of each class of the Company held, to the Company's knowledge, in escrow and the percentage that number represents of the outstanding securities of that class as of the date of this AIF:

<b>Designation of Security</b>	<b>Number of Securities Held in Escrow or that are subject to a contractual restriction on transfer</b>	<b>Percentage of Class</b>
Common Shares	10,567,578	10.8%

### DIRECTORS AND OFFICERS

#### Name, Occupation and Security Holding

The following table sets forth information regarding the directors and executive officers of the Company.

<b>Name and Residence</b>	<b>Positions with the Company</b>	<b>Date of Appointment</b>	<b>Principal Occupation Within the Past Five Years<sup>(1)</sup></b>
James Passin <sup>(2)</sup> <i>Illinois, United States</i>	Chief Executive Officer and Director	September 30, 2020	Chief Executive Officer of the Company; co-founder, BioVaxys Inc. (now a subsidiary of the Company), 2016 to present; Hedge Fund Manager/Private

Name and Residence	Positions with the Company	Date of Appointment	Principal Occupation Within the Past Five Years <sup>(1)</sup>
			Equity Fund Manager, FGS Advisors, LLC 2005 to June 2019. Chairman, TraceSafe Inc. (formerly Blockchain Holdings, Ltd. and Khot Infrastructure Holdings, Ltd.) ("TraceSafe")
Kenneth Kovan <i>Wayne, PA, United States</i>	President and Chief Operating Officer	September 30, 2020	Senior Management Team, Corporate Licensing Partner, Horizon Discovery Group plc, Cambridge, United Kingdom, 2019 to 2020; Managing Principal & Owner, Bingham Hill Ventures 2012 to present
David Berd <i>Jenkintown, PA, United States</i>	Chief Medical Officer	September 30, 2020	Co-founder, BioVaxys Inc., 2016 to present;
Lachlan McLeod <i>British Columbia, Canada</i>	Chief Financial Officer and Corporate Secretary	July 3, 2020	Senior Consultant, Fehr & Associates, 2018 to present Senior Accountant, KPMG, 2015 to 2018
Daren Hermiston <sup>(2)(4)</sup> <i>British Columbia, Canada</i>	Director	October 14, 2020	CEO of Kona Consulting Inc. (management consulting company) January 2009 to present; agent and advisor with Pointswest Sports and Entertainment from January 2009 to present; director of Baden Resources Inc., July 2020 to present.
David Wang <sup>(2)</sup> <i>British Columbia, Canada</i>	Director	October 20, 2020	CEO of Encounter Technology Limited. Healthcare Consultant for South America, Omron.
Anthony Dutton <sup>(2)</sup> <i>British Columbia, Canada</i>	Director	April 25, 2022	Business Executive; President and CEO of Delu Corp. since January 2000.

(1) The information as to the principal occupation, business or employment is not within the knowledge of the Company and has been furnished by the respective director/officer.

(2) Member or proposed member of the Audit Committee.

(4) Daren Hermiston is not standing for re-election at the Company's upcoming annual general meeting scheduled for May 27, 2022. Anthony Dutton will take Mr. Hermiston's place on the Audit Committee.

### Term of Office

The term of office of each director of the Company expires at the end of the annual meeting of Shareholders each year.

As of the date of the AIF, the Company's directors and executive officers, as a group, beneficially owned, directly or indirectly, or exercised control or direction over 24,509,912 Common Shares, representing approximately 25% of the issued and outstanding Common Shares.

## **Biographies**

The following are brief profiles of the executive officers and directors of the Company.

### ***James Passin (Chief Executive Officer and Director)***

Mr. Passin was the Co-founder of BioVaxys Inc. At the closing of the Transaction, Mr. Passin was appointed Chief Executive Officer and director of the Company. Mr. Passin is a former hedge fund and private equity fund manager at FGS Advisors, LLC, an affiliate of New York-based Firebird Management LLC. He has 20 years of experience as a professional investor, a deep experience of financing and developing venture-stage companies, and directed and managed over \$150 million of equity and debt investment into biotech companies including the former Avax, one of the world's first cellular immunotherapeutic vaccine companies. Mr. Passin is a director of several public companies, including BDBSec JSC and Mindset Pharma Inc., and is the Chairman of TraceSafe. He is a Chartered Market Technician and member of the CMT Association. Mr. Passin attended St. John's College (Annapolis, Maryland) and has a B.A. in Philosophy and Classical Literature. He is a Graduate of the Listed Company Director Program from the Singapore Institute of Directors.

### ***Kenneth Kovan (President and Chief Operating Officer)***

Mr. Kovan was the Co-founder of BioVaxys Inc. and at the closing of the Transaction Mr. Kovan was appointed President and Chief Operating Officer of the Company. Mr. Kovan has over 30 years of experience in biopharmaceuticals commercial development. He served from 2019 to 2020 as Corporate Development Partner with Horizon Discovery plc in the United Kingdom, and is Managing Principal & Owner of Bingham Hill Ventures, a life sciences advisory practice he founded in 2012 that specializes in corporate development, technology licensing, and business planning. He is an experienced biotech CEO and board member, and founder of biotechnology companies including the former Avax. Mr. Kovan's professional background includes several years in technology transfer with TJU), Strategic Marketing with GlaxoSmithKline, and Global New Product Development with Wyeth-Ayerst Pharmaceuticals. His therapeutic experience includes infectious disease, antivirals, oncology, vaccines, cell/gene therapy, and gene editing. Mr. Kovan has a broad international business background, having launched pharma brands in Latin American and Asia/Pacific markets, and has worked in Europe for several years. Mr. Kovan holds a U.S. patent for a synergistic drug combination. It is anticipated that Mr. Kovan will devote 100% of his working time to the Company in order to fulfill his duties as President and Chief Operating Officer. Mr. Kovan is a consultant of the Company and has entered into a non-competition and non-disclosure agreement with the Company. Mr. Kovan attended the University of Pennsylvania (Philadelphia, PA) and has a Bachelors of Science.

### ***David Berd (Chief Medical Officer)***

Dr. David Berd was the Co-founder and Chief Medical Officer of BioVaxys Inc. At the closing of the Transaction, Dr. David Berd was appointed as the Chief Medical Officer of the Company. Dr. David Berd is a medical oncologist with a lifelong record of clinical research in medical oncology and cancer immunotherapy. He co-founded cancer immunotherapy company Avax and is the inventor of the cancer vaccines MVax™ and OVax™ and served as Chief Medical Officer from 2005-2008. As National Director for Immunotherapy at Cancer Treatment Centers of America, Dr. Berd investigated the application of haptenized autologous vaccines for ovarian cancer. Previously, Dr. Berd was Professor of Medicine at TJU, where for 20 years he conducted clinical research on melanoma immunotherapy. He also spent nine years as a research physician at Fox Chase Cancer Center. Over the course of his career, Dr. Berd has published more than 85 original papers in numerous medical journals alongside dozens of editorials, reviews and abstracts. He has ten issued patents dealing with cancer vaccines. Dr. Berd received his BS from Pennsylvania State University and his MD from Jefferson Medical College of TJU. It is anticipated that Dr. Berd will devote 100% of his working time to the Company in order to fulfill his duties as Chief Medical Officer. Dr. Berd is a consultant to the Company and has entered into a non-competition and non-disclosure agreement with the Company.

### ***Lachlan McLeod (Chief Financial Officer and Corporate Secretary)***

Mr. McLeod, a Chartered Professional Accountant, holds a Bachelor's Degree in Science with an Economics major and a Business minor from the University of Victoria. Mr. McLeod has 7 years of experience focusing on financial

reporting under IFRS, governance for public companies, and technical accounting issues, including work as an auditor at KPMG. Mr. McLeod currently works as a Senior Consultant at Fehr & Associates CPA, which provides external consulting and accounting services.

***Daren Hermiston (Director)***

Mr. Hermiston is the founder and CEO of Kona Consulting Inc. and acts as an Agent with PointsWest Sports and Entertainment representing hockey players for over 11 years. Mr. Hermiston has an extensive background in marketing public and private companies throughout various sectors and is a guest lecturer at Simon Fraser University for Sports and Entertainment Marketing. Mr. Hermiston also currently holds positions with a number of private companies, including acting as a director of Baden Resources Inc., which has filed a preliminary prospectus and is seeking a listing on the CSE.

***David Wang (Director)***

Mr. Wang, a seasoned medical technology executive, is Healthcare Consultant for South America for Omron, a USD\$1.5 billion market capitalization company listed on the Tokyo Stock Exchange. Mr. Wang is the former CEO of CAUS Capital and the former CEO of Beijing Century Medical. Mr. Wang is fluent in Chinese and Japanese.

***Anthony Dutton, Director***

Mr. Dutton has been President and CEO of Delu Corp. since January 2000. He was also CEO of IBC Advanced Alloys Corp. for over 8 years, between November 2007 and October 2016. He graduated from the University of British Columbia with a BA in Economics, and from Dalhousie University with a Master of Architecture. He also holds an MBA from the Cranfield School of Management, UK. Mr. Dutton has also served as Director and sometimes CEO of several listed companies, including Trakopolis IoT Corp., IBC Advanced Alloys Corp., Green Park Capital Corp., Josephine Mining Corporation, Centric Energy Corp., War Eagle Mining Company Inc. and Arco Resources Corp.

**Cease Trade Orders, Bankruptcies, Penalties or Sanctions**

Other than as described below, no director or executive officer of the Company is, as at the date of this AIF, or has been within 10 years before the date of this AIF, a director, chief executive officer or chief financial officer of any company (including the Company), that:

- (a) was subject to a cease trade order ("CTO"), an order similar to a cease trade order, or an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days, that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer, or
- (b) was subject to a cease trade order, an order similar to a cease trade order, or an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days, that was issued after the director or executive officer ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

Other than as described below, no director or executive officer of the Company, nor a shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company:

- (a) is, as at the date of this AIF, or has been within 10 years before the date of this AIF, a director or executive officer of any company (including the Company) that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or

- (b) has, within 10 years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the proposed director.

No director or executive officer of the Company has been subject to:

- (a) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or
- (b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable security holder in deciding whether to vote for a proposed director.

### ***James Passin***

Mr. Passin is Chairman and Director of TraceSafe, which was subject to a CTO issued by the Ontario Securities Commission (the "OSC") on May 5, 2017, for failure to file its audited annual financial statements for the year ended December 31, 2016. On August 2, 2017, TraceSafe filed its audited annual financial statements for the year ended December 31, 2016, and paid the applicable filing fees, as required by applicable securities legislation. On February 2, 2018, TraceSafe obtained an order from the OSC revoking the CTO.

Mr. Passin was Chairman and Director of Vanoil Energy Ltd. from December 10, 2009, to September 20, 2017, which is subject to a CTO issued by the BCSC on February 3, 2017, for failure to file its audited annual financial statements for the year ended September 30, 2016. The cease trade order remains in effect.

### ***Anthony Dutton***

Mr. Dutton was appointed as a director of Mjardin Group Inc. ("**MJar**") on May 23, 2021 to assist with the restructuring of MJar, which owed a significant amount of secured debt to Bridging Finance Inc. and related entities (collectively, "**Bridging**"). On September 2, 2021, Mr. Dutton was appointed as Interim Chief Financial Officer of MJar. MJar was ultimately not successful in the restructuring and, on March 23, 2022 PricewaterhouseCoopers Inc., as the court appointed receiver of Bridging, successfully applied to have KSV Restructuring Inc. ("**KSV**") appointed as receiver and manager of MJAR under the *Bankruptcy and Insolvency Act* (Canada). Immediately prior to the appointment of KSV, Mr. Dutton resigned as both an officer and a director of KSV.

Mr. Dutton was previously a director of Trakopolis IoT Corp. ("**Trakopolis**") and resigned from this position on January 3, 2020. In December 2019, Trakopolis filed a proposal under the *Bankruptcy and Insolvency Act* (Canada). Subsequent to this filing, Trakopolis completed a sale of substantially all of its assets pursuant to these insolvency proceedings.

### **Conflicts of Interest**

No director or executive officer of the Company, or shareholder beneficially owns, or controls or direct, directly or indirectly, more than 10% of the outstanding Common Shares, or any known associates or affiliates of such persons, has or has had any material interest, direct or indirect, in any transaction or in any proposed transaction that has materially affected or is reasonably expected to materially affect the Company.

## **PROMOTERS**

James Passin is a promoter of the Company. James Passin has ownership and control of 12,982,333 common shares, representing approximately 13% of the issued and outstanding shares of the Company as of the date of this AIF. James Passin does not beneficially own, directly or indirectly, or exercise control over, any voting or equity securities in the Operating Subsidiary.

## **LEGAL PROCEEDINGS AND REGULATORY ACTIONS**

There are no legal proceedings or regulatory actions to which the Company is or was a party to or of which any of its property is or was the subject of during the year ended October 31, 2021, or in the subsequent months to the date of this AIF and the Company is not aware of any such proceedings that are pending, threatened or contemplated.

## **INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

Other than as disclosed elsewhere in this AIF and in the audited consolidated financial statements of the Company for the year ended October 31, 2021, none of the directors or executive officers of the Company, or any Shareholders who beneficially own, control or direct, directly or indirectly, more than 10% of the Company's outstanding Common Shares, or any known associates or affiliates of such persons, had any material interests, direct or indirect, in any transaction within the three most recently completed financial years or during the current financial year that has materially affected or is reasonably expected to materially affect the Company.

## **TRANSFER AGENT AND REGISTRARS**

The transfer agent and registrar of the Company is the Odyssey Trust Company, located at United Kingdom Building, 323 – 409 Granville Street, Vancouver, British Columbia V6C 1T2.

## **MATERIAL CONTRACTS**

There are no material contracts, other than those contracts entered into in the ordinary course of business, which have been entered into within the last financial year, or which have been entered into before the beginning of the last financial year that are still in effect, and which are required to be filed with Canadian securities regulatory authorities in accordance with section 12.2 of National Instrument 51-102 – Continuous Disclosure Obligations.

## **INTERESTS OF EXPERTS**

### **Names of Experts**

The Company's auditors are Dale Matheson Carr-Hilton Labonte LLP (the "**Auditor**"), who have prepared an independent auditor's report dated March 1, 2021, in respect of the Company's audited consolidated annual financial statements for the two most recent fiscal years ended October 31, 2021, and October 31, 2020. The Auditor has advised that they are independent with respect to the Company within the meaning of the CPABC Code of Professional Conduct.

### **Interests of Experts**

To the knowledge of management of the Company, none of the persons above held, at the time of or after such person prepared the statement, report or valuation, any registered or beneficial interests, direct or indirect, in any securities or other property of the Company or of one of its associates or affiliates or is or is expected to be elected, appointed or employed as a director, officer or employee of the Company or of any associate or affiliate of the Company.

## **AUDIT COMMITTEE**

Information on the Company's Audit Committee is contained in its management information circular dated April 25, 2022, which is available for review under the Company's profile at [www.sedar.com](http://www.sedar.com).

### **ADDITIONAL INFORMATION**

Additional information relating to the Company may be found on SEDAR at [www.sedar.com](http://www.sedar.com). Financial information about the Company is provided in the Company's comparative annual financial statements to October 31, 2021, a copy of which, together with Management's Discussion and Analysis thereon, can be found on the Company's SEDAR profile at [www.sedar.com](http://www.sedar.com). Additional financial information concerning the Company may be obtained by any security holder of the Company free of charge by contacting the Company at 646-452-7000.



## SCHEDULE "A"

### AUDIT COMMITTEE CHARTER

#### 1. Mandate

The audit committee will assist the board of directors (the "**Board**") in fulfilling its financial oversight responsibilities. The audit committee will review and consider in consultation with the auditors the financial reporting process, the system of internal control and the audit process. In performing its duties, the committee will maintain effective working relationships with the Board, management, and the external auditors. To effectively perform his or her role, each committee member must obtain an understanding of the principal responsibilities of committee membership as well as the company's business, operations and risks.

#### 2. Composition

The Board will appoint from among their membership an audit committee after each annual general meeting of the shareholders of the Company. The audit committee will consist of a minimum of three directors.

##### *2.1 Independence*

A majority of the members of the audit committee must not be officers, employees or control persons of the Company.

##### *2.2 Expertise of Committee Members*

Each member of the audit committee must be financially literate or must become financially literate within a reasonable period of time after his or her appointment to the committee. At least one member of the committee must have accounting or related financial management expertise. The Board shall interpret the qualifications of financial literacy and financial management expertise in its business judgment and shall conclude whether a director meets these qualifications.

#### 3. Meetings

The audit committee shall meet in accordance with a schedule established each year by the Board, and at other times that the audit committee may determine. The audit committee shall meet at least annually with the Company's Chief Financial Officer and external auditors in separate executive sessions.

#### 4. Roles and Responsibilities

The audit committee shall fulfil the following roles and discharge the following responsibilities:

##### *4.1 External Audit*

The audit committee shall be directly responsible for overseeing the work of the external auditors in preparing or issuing the auditor's report, including the resolution of disagreements between management and the external auditors regarding financial reporting and audit scope or procedures. In carrying out this duty, the audit committee shall:

- (a) recommend to the Board the external auditor to be nominated by the shareholders for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company;
- (b) review (by discussion and enquiry) the external auditors' proposed audit scope and approach;
- (c) review the performance of the external auditors and recommend to the Board the appointment or discharge of the external auditors;

- (d) review and recommend to the Board the compensation to be paid to the external auditors; and
- (e) review and confirm the independence of the external auditors by reviewing the non-audit services provided and the external auditors' assertion of their independence in accordance with professional standards.

#### *4.2 Internal Control*

The audit committee shall consider whether adequate controls are in place over annual and interim financial reporting as well as controls over assets, transactions and the creation of obligations, commitments and liabilities of the Company. In carrying out this duty, the audit committee shall:

- (a) evaluate the adequacy and effectiveness of management's system of internal controls over the accounting and financial reporting system within the Company; and
- (b) ensure that the external auditors discuss with the audit committee any event or matter which suggests the possibility of fraud, illegal acts or deficiencies in internal controls.

#### *4.3 Financial Reporting*

The audit committee shall review the financial statements and financial information prior to its release to the public. In carrying out this duty, the audit committee shall:

##### *General*

- (a) review significant accounting and financial reporting issues, especially complex, unusual and related party transactions; and
- (b) review and ensure that the accounting principles selected by management in preparing financial statements are appropriate.

##### *Annual Financial Statements*

- (a) review the draft annual financial statements and provide a recommendation to the Board with respect to the approval of the financial statements;
- (b) meet with management and the external auditors to review the financial statements and the results of the audit, including any difficulties encountered; and
- (c) review management's discussion & analysis respecting the annual reporting period prior to its release to the public.

##### *Interim Financial Statements*

- (a) review and approve the interim financial statements prior to their release to the public; and
- (b) review management's discussion & analysis respecting the interim reporting period prior to its release to the public.

##### *Release of Financial Information*

- (a) where reasonably possible, review and approve all public disclosure, including news releases, containing financial information, prior to its release to the public.

#### 4.4 *Non-Audit Services*

All non-audit services (being services other than services rendered for the audit and review of the financial statements or services that are normally provided by the external auditor in connection with statutory and regulatory filings or engagements) which are proposed to be provided by the external auditors to the Company or any subsidiary of the Company shall be subject to the prior approval of the audit committee.

##### *Delegation of Authority*

- (a) The audit committee may delegate to one or more independent members of the audit committee the authority to approve non-audit services, provided any non-audit services approved in this manner must be presented to the audit committee at its next scheduled meeting.

##### *De-Minimis Non-Audit Services*

- (b) The audit committee may satisfy the requirement for the pre-approval of non-audit services if:
  - (i) the aggregate amount of all non-audit services that were not pre-approved is reasonably expected to constitute no more than five per cent of the total amount of fees paid by the Company and its subsidiaries to the external auditor during the fiscal year in which the services are provided; or
  - (ii) the services are brought to the attention of the audit committee and approved, prior to the completion of the audit, by the audit committee or by one or more of its members to whom authority to grant such approvals has been delegated.

##### *Pre-Approval Policies and Procedures*

- (c) The audit committee may also satisfy the requirement for the pre-approval of non-audit services by adopting specific policies and procedures for the engagement of non-audit services, if:
  - (i) the pre-approval policies and procedures are detailed as to the particular service;
  - (ii) the audit committee is informed of each non-audit service; and
  - (iii) the procedures do not include delegation of the audit committee's responsibilities to management.

#### 4.5 *Other Responsibilities*

The audit committee shall:

- (a) establish procedures for the receipt, retention and treatment of complaints received by the company regarding accounting, internal accounting controls, or auditing matters;
- (b) establish procedures for the confidential, anonymous submission by employees of the company of concerns regarding questionable accounting or auditing matters;
- (c) ensure that significant findings and recommendations made by management and external auditor are received and discussed on a timely basis;

- (d) review the policies and procedures in effect for considering officers' expenses and perquisites;
- (e) perform other oversight functions as requested by the Board; and
- (f) review and update this Charter and receive approval of changes to this Charter from the Board.

#### *4.6 Reporting Responsibilities*

The audit committee shall regularly update the Board about committee activities and make appropriate recommendations.

### **5. Resources and Authority of the Audit Committee**

The audit committee shall have the resources and the authority appropriate to discharge its responsibilities, including the authority to:

- (a) engage independent counsel and other advisors as it determines necessary to carry out its duties;
- (b) set and pay the compensation for any advisors employed by the audit committee; and
- (c) communicate directly with the internal and external auditors.

### **6. Guidance – Roles & Responsibilities**

The following guidance is intended to provide the Audit Committee members with additional guidance on fulfillment of their roles and responsibilities on the committee:

#### *6.1 Internal Control*

- (a) evaluate whether management is setting the goal of high standards by communicating the importance of internal control and ensuring that all individuals possess an understanding of their roles and responsibilities;
- (b) focus on the extent to which external auditors review computer systems and applications, the security of such systems and applications, and the contingency plan for processing financial information in the event of an IT systems breakdown; and
- (c) gain an understanding of whether internal control recommendations made by external auditors have been implemented by management.

#### *6.2 Financial Reporting General*

- (a) review significant accounting and reporting issues, including recent professional and regulatory pronouncements, and understand their impact on the financial statements; and
- (b) ask management and the external auditors about significant risks and exposures and the plans to minimize such risks; and
- (c) understand industry best practices and the Company's adoption of them.

### 6.3 *Annual Financial Statements*

- (a) review the annual financial statements and determine whether they are complete and consistent with the information known to committee members, and assess whether the financial statements reflect appropriate accounting principles in light of the jurisdictions in which the Company reports or trades its shares;
- (b) pay attention to complex and/or unusual transactions such as restructuring charges and derivative disclosures;
- (c) focus on judgmental areas such as those involving valuation of assets and liabilities, including, for example, the accounting for and disclosure of loan losses; warranty, professional liability; litigation reserves; and other commitments and contingencies;
- (d) consider management's handling of proposed audit adjustments identified by the external auditors; and
- (e) ensure that the external auditors communicate all required matters to the committee.

### 6.4 *Interim Financial Statements*

- (a) be briefed on how management develops and summarizes interim financial information, the extent to which the external auditors review interim financial information;
- (b) meet with management and the auditors, either telephonically or in person, to review the interim financial statements; and
- (c) to gain insight into the fairness of the interim statements and disclosures, obtain explanations from management on whether:
  - (i) actual financial results for the quarter or interim period varied significantly from budgeted or projected results;
  - (ii) changes in financial ratios and relationships of various balance sheet and operating statement figures in the interim financial statements are consistent with changes in the company's operations and financing practices;
  - (iii) generally accepted accounting principles have been consistently applied;
  - (iv) there are any actual or proposed changes in accounting or financial reporting practices;
  - (v) there are any significant or unusual events or transactions;
  - (vi) the Company's financial and operating controls are functioning effectively;
  - (vii) the Company has complied with the terms of loan agreements, security indentures or other financial position or results dependent agreement; and
  - (viii) the interim financial statements contain adequate and appropriate disclosures.

### 6.5 *Compliance with Laws and Regulations*

- (a) periodically obtain updates from management regarding compliance with this policy and industry "best practices";

- (b) be satisfied that all regulatory compliance matters have been considered in the preparation of the financial statements; and
- (c) review the findings of any examinations by securities regulatory authorities and stock exchanges.

6.6 *Other Responsibilities*

Review, with the company's counsel, any legal matters that could have a significant impact on the company's financial statements.