

**BIOVAXYS TECHNOLOGY CORP.
(FORMERLY LIONS BAY MINING CORP.)**

ANNUAL INFORMATION FORM

For the Financial Year Ended October 31, 2020

Dated March 10, 2021

TABLE OF CONTENTS

INTRODUCTORY NOTES	1
Date of Information	1
Currency and Exchange Rates	1
Forward-Looking Information	1
GLOSSARY OF TERMS	3
CORPORATE STRUCTURE	6
Name, Address and Incorporation	6
Intercorporate Relationships	6
GENERAL DEVELOPMENT OF THE BUSINESS	7
Prior to the Completion of the Transaction	7
The Company Following Completion of the Transaction	10
DESCRIPTION OF BUSINESS	12
General	12
Products and Services	12
Market	23
RISK FACTORS	28
Going Concern	29
Limited Operating History and Lack of Profits	29
Coronavirus Pandemic	29
Research and Development Risks	30
Preclinical and Clinical Development Risks	30
Manufacturing Risks	33
Regulatory Risks	33
Commercial/Marketing Risks	35
Intellectual Property Risks	37
General Operational Risks	38
Other Risks	39
DIVIDENDS AND DISTRIBUTIONS	40
DESCRIPTION OF CAPITAL STRUCTURE	40
Common Shares	40
Warrants	41
Options	41
MARKET FOR SECURITIES	41
Market	41
PRIOR SALES	42
The Company	42
ESCROWED SECURITIES	42
DIRECTORS AND OFFICERS	42
Name, Occupation and Security Holding	42
Term of Office	43
Biographies	43
Cease Trade Orders, Bankruptcies, Penalties or Sanctions	45
James Passin	46

Conflicts of Interest	46
PROMOTERS	46
LEGAL PROCEEDINGS AND REGULATORY ACTIONS	46
INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS	46
TRANSFER AGENT AND REGISTRARS	47
MATERIAL CONTRACTS	47
INTERESTS OF EXPERTS.....	47
Names of Experts	47
Interests of Experts	47
AUDIT COMMITTEE	47
Audit Committee Charter	47
Composition of the Audit Committee.....	47
Relevant Education and Experience	48
Reliance on Certain Exemptions	48
Audit Committee Oversight	48
Pre-Approval Policies and Procedures	48
External Auditor Service Fees (By Category)	49
ADDITIONAL INFORMATION	49
SCHEDULE "A" AUDIT COMMITTEE CHARTER.....	A-1

INTRODUCTORY NOTES

Date of Information

Unless otherwise noted, all information contained in this Annual Information Form ("**AIF**") of BioVaxys Technology Corp. (the "**Company**") is presented as of October 31, 2020.

Currency and Exchange Rates

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

Forward-Looking Information

The information provided in this Annual Information Form (the "**AIF**"), contains "forward-looking statements" and "forward-looking information" within the meaning of applicable Canadian securities laws (collectively, "**forward looking information**"). Forward-looking information means disclosure regarding possible events, conditions or financial performance that is based on assumptions about future economic conditions and courses of action and includes financial projections and estimates; statements regarding plans, goals, objectives, intentions and expectations with respect to the Company's future business, operations, research and development, including the focus of the Company's primary vaccine candidates and Covid-19 diagnostic tool and other information relating to future periods. Forward-looking information is subject to a variety of risks, uncertainties and other factors which could cause actual events or results to differ from those expressed or implied by the forward-looking information, including, without limitation those risks outlined here and other factors discussed under the "Risk Factors" section below.

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 (together the "**BioVaxys Risk Factors**").

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.

GLOSSARY OF TERMS

The following is a glossary of certain terms used in this AIF:

"Arrangement Agreement" means arrangement agreement dated May 23, 2018, between Bearing and the Company;

"AIF" means this annual information form of the Company dated March 10, 2021 for the year ended October 31, 2020;

"Audit Committee" means a committee established by and among the Board for the purpose of assisting the Board in fulfilling its financial oversight responsibilities;

"Audit Committee Charter" has the meaning set forth under the heading "*Audit Committee – Audit Committee Charter*";

"Auditor" has the meaning set forth under the heading "*Interests of Experts – Names of Experts*";

"Avax" means Avax Technologies Inc.;

"BCBCA" means the *Business Corporations Act* (British Columbia);

"BCSC" means the British Columbia Securities Commission;

"Bearing" means Bearing Lithium Corp.;

"BioVaxys Risk Factors" means risk factors set out under the heading "*Risk Factors*" or identified in the Company's other public filings under the Company's profile on SEDAR at www.sedar.com;

"Board" or **"Board of Directors"** means the board of directors of the Company;

"BVX-0918A" means the Company's haptenized tumor antigen vaccine for ovarian cancer;

"BXV-320" means the technology platform for BXV-0320, the Company's SARS-CoV-2 vaccine candidate;

"CAR-T" means Chimeric Antigen Receptor T Cell Therapy;

"CDMO" means a contract development and manufacturing organization;

"CMO" means contract manufacturing organization;

"Common Shares" means the issued and outstanding common shares in the capital of the Company;

"Company" means BioVaxys Technology Corp.;

"**Covid-T™**" means the novel diagnostic platform made by BioVaxys Inc.;

"**CRL**" means Charles River Laborites Inc.;

"**CROs**" means contract research organizations;

"**CSE**" means the Canadian Securities Exchange;

"**CTO**" means cease trade order;

"**Desert King**" means Desert King International, the US supplier of QS-21;

"**DTH**" means Delayed Type Hypersensitivity;

"**Diagnostic Platform**" means the novel diagnostic platform made by BioVaxys Inc.;

"**EMEA**" means European Medical Evaluation Agency;

"**EU**" means European Union;

"**EUA**" means an Emergency Use Authorization allowed by the FDA;

"**FDA**" means the U.S. Food and Drug Administration;

"**Finders Warrants**" means the Common Share purchase warrants paid to the certain eligible finders;

"**FINRA**" means the Financial Industry Regulatory Authority;

"**Forward looking information**" has the meaning set forth under the heading "*Forward-Looking Information*";

"**GMP**" means Good Manufacturing Practices;

"**Golden Predator**" means Golden Predator Mining Corp.;

"**IND**" means investigational new drug;

"**Intended Markets**" means the United States, European Union, Asia/Pacific, and Latin American markets;

"**Letter of Intent**" means the letter of intent dated April 17, 2020, between the Company and BioVaxys Inc.;

"**Loan Facility**" means the secured bridge loan facility made available by the Company on April 17, 2020, to BioVaxys Inc. in connection with the Letter of Intent.;

"**MilliporeSigma**" means MilliporeSigma Inc.;

"**Murine Model Study**" means a preclinical animal study of BXV-0320 conducted by CRL;

"**NI 52-110**" means National Instrument 52-110 – *Audit Committees*;

"**Non-GMP**" means non-Good Manufacturing Practices;

"**Non-GMP Protein**" means non-GMP haptenized s-spike protein;

"Offering" means the completed non-brokered private placement of 13,738,235 units at a price of \$0.22 per unit, for gross proceeds of \$3,022,412 by the Company on August 26, 2020 and September 3, 2020, in connection with the Transaction;

"Operating Subsidiary" means the wholly-owned subsidiary of the Company;

"Options" means incentive stock options to purchase Common Shares issued pursuant to the Option Plan;

"OSC" means the Ontario Securities Commission;

"OSU" means The Ohio State University;

"Ovarian Vaccine Candidate" means the Company's haptenized tumor antigen vaccine for ovarian cancer;

"Private Placement" means the non-brokered private placement closed on February 5, 2021, whereby the Company issued 4,417,647 Units at a price of \$0.255 per unit to certain strategic investors for total gross proceeds of approximately \$1,126,500;

"Procure Health" means Procure Health Iberia, S.L., of Barcelona, Spain;

"Products" means the vaccines, BVX-0320 and BVX-0918A, and Covid-T™;

"RPS" means Rio Pharmaceutical Services;

"SARS COV-2 Vaccine Candidate" means the technology platform for BXV-0320, the Company's SARS-CoV-2 vaccine candidate;

"SEDAR" means the System for Electronic Document Analysis and Retrieval of the Canadian Securities Administrators, accessible at www.sedar.com

"Shareholders" means the shareholders of the Company;

"Share Exchange Agreement" means the share exchange agreement dated June 2, 2020, between the Company, BioVaxys Inc. and the stockholders of BioVaxys Inc.;

"Share Split" means the subdivision of the Common Shares on a two for one basis;

"SinoBiological" means SinoBiological Inc.;

"SQ-21" means a saponin QS-21 adjuvant;

"TCR" means Engineered T Cell Receptor Therapy;

"TJU" means Thomas Jefferson University;

"TJU License" means the exclusive license agreement, dated April 25, 2018, between BioVaxys Inc. and TJU;

"TraceSafe" means TraceSafe Inc.;

"Transaction" means the acquisition of all of the outstanding securities of BioVaxys Inc. by the Company whereby BioVaxys Inc. became a wholly-owned subsidiary of the Company;

"Warrants" means one common share purchase warrant of the Company exercisable into one Common Share of the Company at an exercise price of \$0.50 for a period of 24 months from the closing of the Offering;

"WRO" means Written Responses Only;

"Units" means units in the capital of the Company.

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 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 "**Transaction**"). Following the closing of the 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 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.

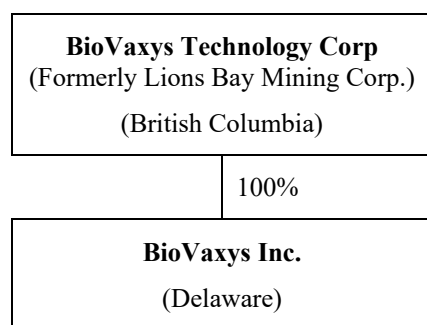
The Company is a reporting issuer in Canada in the Provinces of British Columbia, Alberta, and Ontario, and not in any other jurisdiction. The Company's common shares (the "Common Shares") are listed on the CSE under the trading symbol "BIOV".

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 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. The Hy and VM properties were subject to a mineral property purchase agreement with Golden Predator Mining Corp. ("**Golden Predator**") pursuant to which Golden Predator agreed to purchase all of the Company's undivided interest in certain mineral claims in the Yukon Territory for total cash payments in the amount of \$275,000, payable over a 48- month period from the execution date of the agreement.

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 "**Warrants**") 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 (the "**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 share exchange agreement.

On April 17, 2020, in connection with the Letter of Intent, the Company made a secured bridge loan facility of up to US\$200,000, bearing interest at a rate of 9% per annum, available to BioVaxys Inc. (the "**Loan Facility**"). Upon execution of the Letter of Intent, the Company advanced an initial US\$20,000 to BioVaxys Inc.

On April 29, 2020, the Company completed a subdivision of its Common Shares (the "**Share Split**") on a two for one basis, resulting in 10,727,428 pre-Share Split Common Shares being subdivided into 21,484,856 post-Share Split Common Shares.

On June 2, 2020, the Company and BioVaxys Inc. entered into the Share Exchange Agreement, in respect of the 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 under the Loan Facility in advances to cover reasonable costs and expenses of BioVaxys Inc., in accordance with the terms of the Loan Facility.

On August 26, 2020, and September 3, 2020, in connection with the Transaction, the Company completed a non-brokered private placement (the "**Offering**") 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 Warrant. Each 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 the Offering, the Company paid certain eligible finders a finder's fee of 7% of the gross proceeds raised, payable in finders warrants (the "**Finders Warrants**") and 7% in cash commissions. Each Finders Warrant has the same terms as the Warrants.

On September 30, 2020, the Transaction was completed pursuant to the terms of the Share Exchange Agreement. Pursuant to the 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 Transaction, the Company also issued an aggregate of 2,100,000 Common Shares to certain advisors of the Company. Upon closing of the Transaction, BioVaxys Inc. became a wholly-owned subsidiary of the Company.

In connection with the closing of the 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".

Prior to the closing of the Transaction, the directors of the Company were Jeremy Poirier, William Timothy Heenan, and Ben Asuncion. Following the closing of the Transaction, the directors of the Company were confirmed as Jeremy Poirier, William Timothy Heenan, and James Passin.

On September 24, 2020, the Board appointed the following senior executive officers of the Company, effective on the closing of the 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" haptized cancer vaccine platform using a single haptent. 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 "Bihaptized 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 "Bihaptized 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 "*Haptized 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/ ("**Desert King**"). 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 Millipore Sigma 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⁺ 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⁺ T cells) are important for various immune functions, including stimulating the production of antibodies and killer T cells. CD4⁺ T cells are crucial in achieving a regulated effective immune response to viral pathogens, and are central to adaptive immune responses. Generated following an immune response, memory 'helper' CD4⁺ 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 they 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 that requires hospital treatment. 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 "**Covid-T™**"). The Diagnostic Platform is designed to screen for an immune system T-cell response in patients who may have been exposed to SARS-CoV-2, and a T-cell response in those patients who have received a vaccine for SARS-CoV-2 (not limited to BVX-0320, the BioVaxys SARS-CoV-2 Vaccine Candidate), 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.

On September 30, 2020, pursuant to the closing of the Transaction, BioVaxys Inc. became a wholly owned subsidiary of the Company.

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 21, 2020, the Company announced that it granted an aggregate of 3,000,000 incentive stock options (the "**Options**") to certain officers and directors of the Company. The Options are each exercisable for one Common Share at an exercise price of \$0.45 for five years and vest over a two-year period.

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 is the first between the Company and OSU, is to study neutralizing antibodies generated against live SARS-CoV-2 virus by BVX-0320.

Events Subsequent to October 31, 2020

On November 2, 2020, the Company announced that it filed a provisional patent application on 10/28/2020 with the U.S. Patent and Trademark Office entitled "Method and kit for detection of cell mediated immune response" #63106482 related to the potential development of the Diagnostic Platform.

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

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

On November 30, 2020, in connection with the OSU study, the Company announced that the remaining mouse sera that had been collected from mice after receiving BVX-0320 in Murine Model Study was going to be tested for its ability to elicit a neutralizing antibodies response to the live SARS-CoV-2 virus. A neutralizing antibody is an antibody that defends against a pathogen or virus by neutralizing any effect it has biologically. Neutralization renders the virus no longer infectious.

On December 10, 2020, the Company announced that its submission of Form 211 to the Financial Industry Regulatory Authority ("**FINRA**") has been cleared and the Company's shares qualify for trading in the United States on the OTC Pink Market under the symbol "LMNGF".

On December 21, 2020, the Company announced that further analysis of the data from its Murine Model Study shows that BVX-0320 elicits a robust T-cell response against SARS-CoV-2. BVX-0320 was found to activate immune system memory 'helper' CD4+ and Killer CD8+ T cells against SARS-CoV-2, which has potential for longer-term viral protection. 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.

The Company prepared the draft clinical development program for Covid-T™, and in December 2020 engaged global regulatory advisory group Rio Pharmaceutical Services of Bridgewater NJ ("**RPS**") to provide strategic regulatory guidance, prepare an FDA pre-submission guidance package, recommend regulatory pathways, and support the Company on the registration filing.

On January 25, 2021, the Company announced that it has commenced the clinical development program for BVX-0918A, its haptenized tumor antigen vaccine for ovarian cancer ("**BVX-0918A**" or the "**Ovarian Cancer Vaccine Candidate**"). The Company plans in early 2022 to seek a compassionate use approval in the European Union for Stage III & Stage IV ovarian cancer, followed by submitting an IND in the US. On February 18, 2021 the Company signed a term sheet ("**Term Sheet**") with BioElpida S.A.S. ("**BioElpida**") of Lyon, France for the build-out for the clinical-grade manufacturing process and aseptic packaging for BVX-0918A. BioElpida is a biotechnology Contract Development & Manufacturing Organization ("CDMO"). A CDMO is an organization with the facilities and expertise to conduct drug development and manufacturing on a contractual basis. BioVaxys and BioElpida anticipate completion of the Master Services Agreement outlining the complete bioproduction arrangement in late March 2021. The Company plans to submit its clinical trial application for BVX-0918A with the European Medicines Agency late 2021.

On January 28, 2021, the Company made the following announcements regarding their Covid-T™ (Note that the Company has not yet filed this trademark, but intends to do so once the Phase I study starts, approximately August 2021). The Company initiated the clinical development program process for Covid-T™, which is the Company's novel diagnostic platform for detecting T-cell activity. The FDA tentatively agreed to allow the Company to file for a pre-Emergency Use Authorization ("**EUA**") for Covid-T™, having submitted the EUA application to the FDA in late January 2021. As of this AIF, BioVaxys is waiting to hear a formal response from the FDA on the assignment for a review of the EUA to an internal group at the FDA. Under an EUA, the FDA permits the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives.

Also in January 2021, RPS recommended that a non-clinical study will be needed to establish the risk profile prior to the start of the clinical studies of Covid-T™. The Company plans to conduct an animal toxicology study in early summer 2021. The Company is currently evaluating proposals from a Contract Research Organizations ("**CRO**") to conduct a toxicology study in a rabbit model. BioVaxys is in the process of obtaining the appropriate cell lines, expression systems, and licenses to allow it to produce its own supply of the SARS-CoV-2 s-spike protein, which will be used in the animal toxicology study. As of February 2021, BioVaxys is finalizing a production protocol and contract with a Contract Manufacturer (CMO) to produce the s-protein for the tox study and the Phase I clinical study. BioVaxys anticipates signing the contract for the tox study in March 2021, but the start of the animal toxicology study is dependent on the bioproduction CMO completing the bioproduction of the s-protein.

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 inflection 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 5, 2021, the Company announced that it closed its non-brokered private placement (the "**Private Placement**"), which was previously announced on February 2, 2021. Under the Private Placement, the Company issued 4,417,647 Units at a price of \$0.255 per Unit to certain strategic investors 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 two years. In connection with the Private

Placement, the Company paid cash finder's fee of \$60,000. All securities issued pursuant to the Private Placement are subject to a statutory hold period for four months and one day from the date of issuance.

On February 9, 2021, Jeremy Poirier resigned from his role as Director.

On February 9, 2021, the Company entered into a heads of agreement (the "**Heads of Agreement**") with Procure Health Iberia S.L. ("**Procure Health**") for the purpose of a broad collaboration for the co-development joint commercialization, and marketing of the Company's vaccine candidates for ovarian cancer, cervical cancer, and human papilloma virus ("**HPV**"), and the right of first refusal for marketing by the Company in the United States of Procure Health's product, Papilocare™.

Under the terms of the **Heads of Agreement**, Procure Health and the Company will have the exclusive right 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 include: (1) The Clinical Study (Phase 1 Clinical Study for BVX-0918A, BIOV's candidate vaccine for late-stage ovarian cancer, in the EU), and the distribution of BCX-0918A in 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) BIOV's marketing of Papilocare™ in the United States. The Definitive Agreements shall be contractually independent from each other and if one Definitive Agreement is not entered into within the Term (defined below) the other Definitive Agreements will remain in full force and effect. Further, should the parties not agree on any of the Definitive Agreements within the Term, no obligation among the Parties will survive, and the Parties will not have right to any indemnification or compensation.

DESCRIPTION OF BUSINESS

General

Following the Closing of Transaction, the Company re-classified itself from being a resource issuer to an industrial issuer operating in the life science industry. The Company, a British Columbia-registered biotechnology company, is a leader in haptenized protein vaccines and immuno-diagnostics. The Company is currently developing antiviral & anticancer vaccine platforms. The Company is evaluating BVX-0320, a potential SARS-CoV-2 vaccine based on its haptenized viral protein technology, and advancing a compassionate use trial application in the EU to evaluate BVX-0918A, its haptenized cell vaccine for late-stage ovarian cancer. The Company is also developing a novel diagnostic platform, Covid-T™, which screens for an immune system response in patients exposed to SARS-CoV-2. The vaccines and Covid-T™ (together, the "**Products**") are described in greater detail below.

Products and Services

Haptenized Vaccines Platform

The Company's vaccine platform is based on the established immunological concept that modifying surface antigens, whether these proteins are viral or tumor, with simple chemicals called haptens makes them more visible to the immune system. This process of haptenization "teaches" a patient's immune system to recognize and make target proteins more 'visible'; thereby stimulating a T-cell mediated immune response. This is critical for fighting viral pathogens or cancer cells, as T-cells directly battle viruses or tumors by targeting and destroying infected or cancerous cells. Haptenization is based on proven science and extensive clinical data. There is also growing evidence that it can be used for a range of viruses and any resectable (i.e. surgically-removable) solid tumors. BioVaxys is building a pipeline of vaccine products that are based on this proprietary technology platform of haptenizing antigens to elicit a robust immune response. Current development programs target ovarian cancer, cervical cancer, HPV, and SARS-CoV-2.

SARS-CoV-2 Program

There is a range of technology platforms being evaluated for SARS-CoV-2, including mRNA vaccines, virus-like particle, peptide, viral vector (replicating and non-replicating), recombinant protein, live attenuated virus and

inactivated virus approaches (Nature Reviews, April 2020), with many reliant on unproven technologies and many of which may have significant manufacturing hurdles or other issues. For example, risks with inactivated live-virus vaccines include potentially infecting a healthy recipient with SARS-CoV-2.

At the time of this AIF, there are four authorized vaccines—ones from Moderna, Pfizer/BioNTech, AstraZeneca/Oxford University, and most recently, Janssen Pharma. There are also more than 50 COVID-19 vaccine candidates in trials and at least 80 others in early stages of development, worldwide. Both the Moderna and Pfizer/BioNTech are mRNA vaccines and have an equivalent 94%-95% immune response. A replication-deficient chimpanzee viral vector based on a weakened adenovirus vaccine from AstraZeneca/Oxford University has also been approved, but providing only a ~63% immune response. Janssen's adenovirus vector vaccine, which has just been approved as of this AIF, has been shown to provide ~66% immune response.

As the most data is available for the Pfizer/BioNTech and Moderna vaccines, it appears that although the antibody response is very good, the emerging safety and tolerability profile of these two vaccines is proving to be an issue, and neither vaccine can guarantee long-term protection (*Pfizer/BioNTech FDA Briefing Document*, November 2020). Further, there are emerging logistical considerations with mRNA vaccines, such as extraordinary refrigerated storage requirements. Little is known about the T-cell response to either the Moderna or Pfizer vaccines.

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

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

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

Studies (May 14, 2020, *Cell*) have demonstrated that patients recovering from SARS-CoV-2 carried helper T-cells that recognized the SARS-CoV-2 S-spike protein, and virus-specific killer T-cells were detected in 70% of the test subjects. As haptimized proteins are known to induce potent T-cell responses, the Company believes BVX-0320 will have an advantage over other developing Covid-19 vaccines.

In December 2020, the Company completed its preclinical program for BVX-0320, which was the murine model study ("Murine Model") that evaluated *in vivo* immune response, T-cell activation, and tolerability of BVX-0320, which were studies suggested by the U.S. Department of Health and Human Services, FDA, Center for Biologics Evaluation and Research ("CBER") in their published *Guidance on Development and Licensure of Vaccines to Prevent COVID-19* (the "*Guidance*"). The *Guidance* is intended to assist in the clinical development and licensure of vaccines for the prevention of COVID-19, and reflects the FDA's current thinking on the issue.

Conducted by CRL, under contract with the Company, the preclinical program which began in September 2020 evaluated the anti-virus immune response elicited by BVX-0320 in the Murine Model Study by measuring the development of antibodies to the protein that binds the virus to human cells. Following two injections of BVX-0320 together with QS-21, to 28 mice at four dosage levels, 96.4% developed positive antibody responses at week 6. The Company also found that BVX-0320 activated CD4+ helper T cells and CD8+ killer T cells that express the activation markers, CD69 and CD25. This result indicates that immunization with BVX-0320 at two different dose levels of 3µg or 10µg stimulated CD4+ helper T cells and CD8+ killer T cells. CD4+ helper T cells are crucial in achieving a regulated effective immune response to viral pathogens, and are central to adaptive immune responses. Generated following an immune response, memory CD4+ helper T cells retain information about the virus, which enables them to respond rapidly after viral exposure. CD8+ killer T cells have the capacity to kill cells infected by the virus, thereby stopping viral replication in those cells.

BVX-0320 also elicits a neutralizing antibody response against SARS-CoV-2, as evidenced by further analysis of sera samples from the Murine Model Study. Under a Company research collaboration, OSU researchers observed in a pooled sample that BVX-0320 elicited the production of neutralizing antibodies to SARS-CoV-2. The findings were

obtained from a Plaque Reduction Neutralization Test, where the endpoint is reduction of plaques by 50%, after using available remaining mouse sera from the immune response assay. Plaques are produced by infection of cultured human cells by a live SARS-CoV-2 virus.

Principal Markets for BVX-0320

The first stage of the U.S. COVID-19 vaccine rollout fell short of federal projections as vaccinations proceeded unevenly across the states. After focusing first on hospitals and other institutional health-care settings, the next phase of vaccinations will draw more on pharmacies and health clinics—places where vaccines are more traditionally administered—and will broaden the pool of people eligible to get the shots. Some states are turning sport stadiums and theme parks into mass vaccination centers. In the U.S., the latest vaccination rate is 1,817,502 doses per day, on average. At this rate, it will take an estimated 7 months to cover 75% of the population with a two-dose vaccine. Globally, the latest vaccination rate is 6,791,190 doses per day, on average. At this rate, it will take an estimated 4.5 years to cover 75% of the population with a two-dose vaccine (*Bloomberg*, March 1, 2021). With only a fraction of the population receiving one of the current approved vaccines over the next several months, there is significant opportunity for new, improved, vaccines such as BVX-0320 in unvaccinated population. Further, given some of the resistance to the mRNA vaccines due to safety/tolerability concerns, it is likely that BVX-0320 can penetrate the market of those initial vaccine “refusers” based on an emerging superior tolerability profile for BVX-0320. As the importance of eliciting a post-vaccination T-cell response and the relationship of a T cell response to longer-term protection becomes a treatment priority, BioVaxys believes it can replace the “first generation” mRNA vaccines launched by Pfizer/BioNTech and Moderna as the SARS-CoV-2 vaccine of choice.

Vaccine Clinical Supply BioProduction

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

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. The principal material used in BVX-0320 is the SARS-CoV-2 s-1 subprotein, which is then chemically bound with a hapten to create the vaccine. As the s-protein is highly immunogenic, it is an ideal drug and vaccine target.

For the Murine Model Study, the Company purchased commercially available s-protein from Sino Biological. However, the s-protein currently available from Sino Biological and other suppliers of non-GMP product is not well-characterized, QC/QA not integrated in production, and most critical, it is not available in GMP-clinical grade. The Company will therefore need to develop its own supply of GLP and GMP-grade s-protein. A strategy to produce the s-1 protein component of BVX-0320 has been devised and will be presented to the FDA during the WRO and subsequent pre-IND meeting (when scheduled by the FDA). As this s-protein is the same as will be used in Covid-T, bioproduction of the s-protein can be efficiently shared between programs. The s-1 protein will be produced by inserting the gene sequence for the s-1 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, and is obtaining the license. To make the s-protein, company scientists first take a common mammalian cell, called a CHO cell, and insert DNA instructions to create the spike protein. They use the newly infused CHO cell to create a Master Cell Bank, which is then grown in large bioreactors where the spike protein is produced. The s-protein is isolated, purified and ready to be conjugated to the hapten to create the vaccine product. As of this AIF, the Company is finalizing the bioproduction proposal and associated costs with a Chinese CDMO, who will provide the license for the cell line and expression system, synthesize the s-1 protein, and perform the hapten conjugation. BioVaxys expects to have s-1 protein late summer 2021.

Haptenization of the s-protein to create the final vaccine product will follow production of s-protein supply. The haptenization process is straight forward, with BioVaxys having “tested” the basic production protocol with Millipore-

Sigma when they were preparing the non-GMP vaccine supply for the Murine Model study last summer. BioVaxys' plan is to utilize the same CDMO that is producing the s-protein to also handle the haptization.

Potential Multivalent Line Extension

The Company has an interest in producing a "multi-valent" vaccine that can address the emerging variants of SARS-CoV-2. In recent months, several new variants of the original virus have been spotted that appear to cause major changes in the way the virus acts, including alterations to its contagiousness and clinical severity. Most disconcerting are findings that the approved Covid-19 vaccines may not work as well against these variants. These variations have quickly emerged in different geographical regions, i.e. the UK, South Africa and Brazil, and in some cases have outcompeted the existing variants. Although improved surveillance and sequencing efforts might partly explain why these variants are appearing now, some repetition in their patterns suggest the mutations are not random (*Scientific American: January 2021*). Given the flexibility in the Company's approach of haptizing viral antigens, the Company is contemplating the creation of a multivalent vaccine for the clinically concerning emerging B.1.1.7 and B.1.351 SARS2 variants. As of the date of this AIF, the gene sequences for the variants are not yet published. Once the sequences are available, the Company should be able to produce multivalent vaccine. Should the sequences of the SARS2 variants become available by late spring, BioVaxys might be able to include the s-proteins from the variants in its anticipated Phase I study this fall.

2021 Best Estimate Development Timing

- Phase I Development Partners (2Q21): Selection of a development partner to share development costs and an academic institution to sponsor the Phase I
- Joint GMP s-protein sourcing with COVID-T™ program (8/2021): Bioproduction process would yield sufficient s-spike protein (and s-spike protein for SARS2 variants should the sequences become available)
- BVX-0320 IND Submission (3Q/2021) for Monovalent vaccine (original SARS-CoV-2 strain): Or for a multi-valent (includes emerging B.1.1.7 and B.1.351 variants) vaccine based on availability of s-proteins
- Phase I Study (late 3Q21)

Development Partnering

Given the significant opportunities in its product pipeline with Covid-T, cancer vaccines, and other viral vaccines, BioVaxys believes that the best way to develop and commercialize BVX-0320 will be jointly with a partner. In February 2021, the Company entered into a contract with Jenni Byrne & Associates ("JBA") of Toronto, Ontario, to provide strategic government relations support to the Company, with the mandate to seek ~CDN\$5.0M funding from the Canadian Federal government, or any Canadian provincial government, to support the BVX-0320 Phase I program. JBA will also make introductions to Canadian universities, research facilities, and other potential collaborative partners. The engagement is initially for three (3) months, at a rate of CDN\$15,000 per month. Upon obtaining Phase I data, BioVaxys will be well-positioned to identify an appropriate partner to share in joint development of BVX-0320 later in 2021.

Ovarian Cancer

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 are 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 antiprogrammed 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 PDL1, which helps them evade immune attack. Monoclonal antibodies that target either PD-1 or PDL1 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 Vaccines

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 sometimes strikingly 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 impedance.

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.

Ovarian Cancer Vaccine Candidate (BVX-0918A)

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

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

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

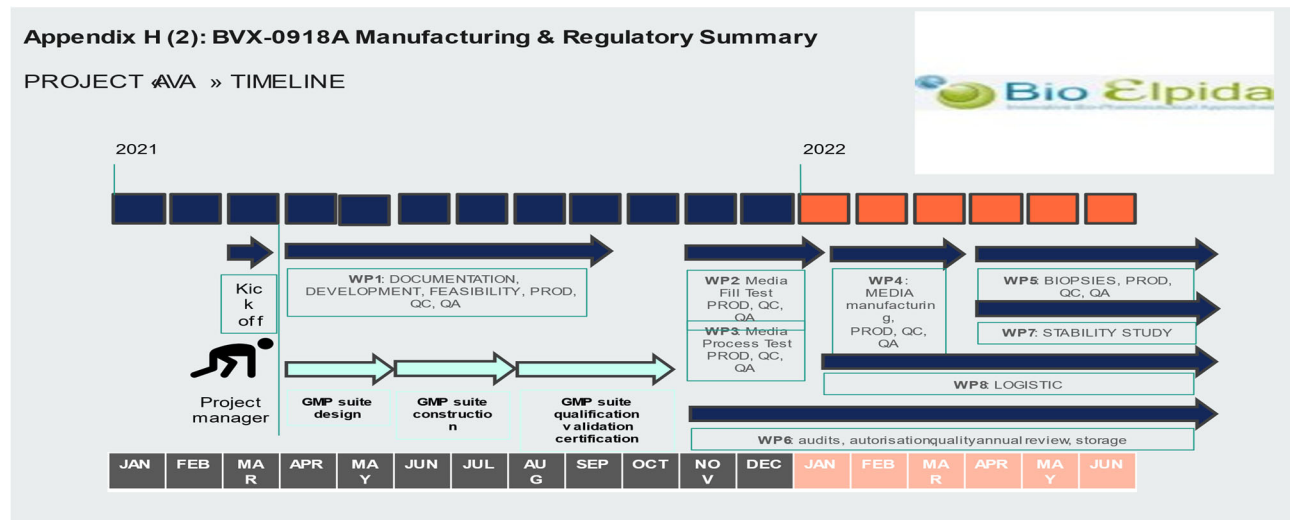
BVX-0918A BioProduction

On February 18, 2021 the Company signed a term sheet (the "**Term Sheet**") with BioElpida S.A.S. ("**BioElpida**") of Lyon, France for the build-out for the clinical-grade manufacturing process and aseptic packaging for BVX-0918A. BioElpida is a biotechnology CDMO which applies single-use bioprocessing for development and manufacturing of biological and cell-based products. BioElpida's expertise extends from R&D to pharmaceutical manufacturing and release of clinical batches, and intermediate steps such as process development, feasibility studies, analytical method validation, as well as aseptic fill & finish and other bioproduction services. BioElpida's facility is certified for clinical bioproduction by France's National Security Agency of Medicines and Health Products (the "**ANSM**"). The Company expects to finalize the definitive service agreement with BioElpida in 1Q21. BioElpida preliminary estimate for GMP process build-out and validation is ~\$US1.0M.

Based on the following best estimate timeline (Source: *BioElpida 2/2021*), BioElpida would complete all necessary process design and validation by the end of 4Q2021 to enable BioVaxys to incorporate the bioproduction in the submission of their application in late 4Q2021/early 1Q2022 for approval of the EU Phase I study.

Development Plan Summary: Compassionate use in EU of BVX-0918A Study design & CRO selection (2Q/2021)

- Bihaptenized vaccine (only): Safety primary endpoint, immunological data is secondary endpoint
- Protocol will recommend post-study optional use of a checkpoint inhibitor (investigator post-study evaluation of patient survival)
- Phase I, n=30, open-label, single-dose, multi-center, duration 3-4 months
- Manufacturing ramp-up/GMP process validation w/ BioElpida (4Q2021)
- EU Compassionate Use (1Q2022)
- Submit US IND for bihaptenized vaccine + checkpoint antibody in ovarian cancer (utilize EU data in US IND) 4Q2022



The Company & Procure Health Iberia Collaboration

On February 10, 2021, the Company and Procure Health Iberia, S.L., of Barcelona, Spain ("**Procure Health**"), a leading privately-held European pharmaceutical company, announced that they entered into a broad collaboration for the co-development, joint commercialization, and marketing of the Company's vaccines for ovarian cancer, cervical cancer, and human papilloma virus ("**HPV**"), and the right of first refusal for marketing by BioVaxys in the United States of Procure Health's vaginal gel product, Papiicare™, the world's first and only product to prevent and treat HPV-dependent cervical lesions. Left untreated, HPV infection generally leads to cervical cancer (World Health Organization, *HPV and Cervical Cancer*, 11 November 2020). Formed in 2012 as a spin-out from Procter & Gamble Pharmaceuticals, Procure Health is a market leader in the women's health field in the European Union ("**EU**"), with marketed products including Papiicare™, Libicare™, Palomacare™, Idracare™, Pronolis HD™ and Ovosicare™.

Under the terms of the agreement, which was executed on February 9th, 2021, the companies will jointly conduct a Phase I Clinical Study of BVX-0918A in Spain for late-stage ovarian cancer. BioVaxys will be responsible for the core technology and vaccine production, with Procure Health overseeing and making a US\$900,000 in-kind investment in the clinical program and regulatory planning, CRO management, patient/clinical center recruitment, marketing, and opinion leader management. Both companies have agreed to equally share costs associated with engaging a European clinical research organization ("**CRO**") to conduct the study, which are estimated at US\$2.0M. In return, Procure Health will have exclusive rights to market and distribute BVX-0918A in the European Union ("**EU**"), and the United Kingdom. Clinical data from the Spanish Phase I study will be used by BioVaxys to support

its planned IND for BVX-0918A in the US next year, as well as for all other global markets. The two companies will be working out any remaining details by end of 2Q21. Under the Agreement, Procure Health will be responsible for marketing and distribution in the EU, and will begin launch planning in late 2021/early 2022.

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

Papilocare in the US

In a major step toward transitioning to a revenue-generating company, BioVaxys has agreed to have a right of first refusal from Procure Health to market and distribute the topical gel product Papilocare™ in the US. Papilocare is the first and only product for treatment and prevention HPV-dependent cervical lesions.

Procure Health currently markets the brand in the EU as a Class II device, and has a CE mark for 28 European countries. In Procure Health's PALOMA Phase IIb clinical trial, Papilocare™ showed consistent and significant efficacy in normalizing cervical cytology at 3 months and at 6 months in the total study population with 50% to 70% of High-Risk HPV clearance at 6 months in six different international studies and more than 600 patients. HPV infection causes 528,000 cases of cervical cancer and 266,000 cervical cancer deaths each year.¹ Papilocare™ has a CE mark valid for the entire EU, and is currently marketed as a Class IIa medical device in Spain, France, Portugal, Italy, Belgium, Luxembourg, Lithuania, Latvia, Poland, Czech Republic, Hungary, Bulgaria, and Romania. Over 100,000 women have been treated with Papilocare, with no adverse events or safety issues reported. Once the FDA regulatory pathway has been determined for the US, BioVaxys will have a detailed plan in place by 3Q21 to build an appropriate capability to market and support the brand in the US, with BioVaxys providing the funding for such efforts.

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 Human Papilloma Virus ("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 a 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 2Q2021.

T-Cell Antigen Discovery Program ("TADP")

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

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

to identify novel cancer antigens eliciting a T-cell response, which will develop extensive new intellectual property for the Company.

Covid-T

Unmet Need in SARS-CoV-2 Screening

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

Covid-T Diagnostic

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

Covid-T™ uses Delayed-Type Hypersensitivity ("**DTH**") technology. DTH is known to be a measure of T cell immunity and has been used for many years for other infectious diseases including, tuberculosis, fungal diseases, and mumps. The test is performed by placing a small amount of synthesized test material, e.g. the SARS-CoV-2 spike protein, intradermally and inspecting the site for erythema and induration 24-48 hours later. The test results can be visually interpreted by a physician and measured with a ruler, or optically using a cell phone app that the Company plans to develop.

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

With the addition of s-proteins from SARS-CoV-2 variants of interest, Covid-T™ has the potential for detecting differences in T-cell responses between the original SARS-CoV-2 virus and the two new strains of SARS-CoV-2 that had originally been identified in the UK and South Africa---B.1.1.7 and 501Y.V2, respectively---but which are spreading worldwide. The Company plans to expand Covid-T's range to include the clinically concerning emerging B.1.1.7 and B.1.351 SARS2 variants. As of this AIF, the gene sequences for the variants are not yet published. Once the sequences are available, the Company will be able to produce purified s-protein for the variants.

Competitive COVID-19 Testing Environment

RNA & Antibody Screening: Currently, SARS-CoV-2 RNA detection is generally done via nasopharyngeal swab or serological testing for antibodies. All of them require specialized laboratory services and analytical techniques.

Detection of viral nucleic acid in nasal swabs takes place by real-time quantitative PCR ("RT-qPCR") method by specialized laboratories under biological safety class 2 protections. However, RT-qPCR 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\$109.00 rt-PCR nasal swab kit marketed by 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 days for results.

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 (CLIAs). 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. For the analysis, Hospital Pricing Specialists reviewed billing data from 2,862 hospitals across the U.S. to determine the average price of a nasal swab COVID-19 test. The claims reviewed had the Current Procedural Terminology code 87635. 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.

A major drawback of DNA and antibody screening is that some people who had coronavirus but tested negative for antibodies (or viral DNA) 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 then it is 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 (now owned by PerkinElmer), and Quiagen currently offer T-cell diagnostics; however, both are approved for "research use only." Oxford's *T-Spot Discovery SARS-CoV-2* kit and Quiagen's *QuantiFERON* platform are both based on diagnostics for latent tuberculosis, and assessing the immune response to cytomegalovirus infections in transplant patients. Oxford Immunotec 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.

Indoor Biotechnologies and Adaptive Biotech are both developing T-cell diagnostics, with Adaptive Biotech planning to launch their screening kit late 2021. These also require blood draws, with sera sent to central laboratories for processing. Adaptive uses a PCR test performed on peripheral blood lymphocytes (probably requires no more than 5cc blood). The Company believes it has identified a novel T cell receptor mutation that occurs after the development of a T cell response to SARS2.

Covid-T™ Development Plan Summary Time & Events:

- On-board regulatory support (12/2020).
- Clinical Development Plan (1/2021)
- Regulatory planning (1/2021)
- FDA Early Use Authorization (EUA) application filed (2/2021)
- FDA Review Group assignment (3/2021)
- License for CHO cell line and gene expression system to produce s-protein supply (3/2021)
- Pre-IND meeting with FDA (4/2021)
- Non-GMP bioproduction of SARS-CoV-2 s-protein (5/2021)
- Rabbit model acute toxicity study (5/2021)
- BLA Submission (7/2021)
- GMP bioproduction of s-protein (8/2021)
- Phase I study (3Q21)

- EUA (4Q21)

Regulatory Support: In late 2021, the Company engaged global regulatory advisory group RPS 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.

Clinical Development Plan: In January 2021, the Company completed a preliminary clinical development plan for Covid-T. Objectives of this pivotal study will be to measure the Delayed Type Hypersensitivity (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 Covid-T.

FDA Early Use Authorization (EUA) application filed: The Company approached the FDA for regulatory guidance and was asked to submit an EUA for Covid-T, 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. Although not a certainty, it is believed that Covid-T will be seen by the FDA as an *in vivo* device, with review assigned to the FDA's Center for Biologics Evaluation and Research ("CBER"). The Company anticipates hearing FDA's assignment of Covid-T by early March 2021. When BioVaxys is ready to do so, it will then request a pre-IND meeting with the FDA, which is typically granted within thirty days. In preparation for the pre-IND meeting, BioVaxys will first provide FDA with a pre-IND Briefing Package which contains all relevant product data, animal tox study plans, and bioproduction plans.

If the Company has successfully addressed FDA's questions at the pre-IND meeting, the Company will then submit its Biological License Approval application ("BLA"), approval of which is formal licensure. As the Company has requested an EUA in February 2021, it is within the realm of possibility that FDA may authorize a Research Use Only ("RUO") approval, such as that received by Oxford Immunotec for their T cell test, with only the animal tox data being required, instead of requiring the Phase I data prior to approval. There is no certainty on the outcome of any FDA decision.

Animal Toxicology: Since Covid-T requires a biological substance (the SARS-CoV-2 s-protein) to be placed intradermally, a nonclinical study will be needed to establish the risk profile prior to the start of clinical studies. The Company plans to conduct a GLP animal toxicology study of s-1 subunit of SARS2 spike protein in a rabbit model at various dose levels, with the high dose corresponding to the expected human doses. Clinical pathology on all animals will include panels for hematology, coagulation, and clinical chemistry, with histopathology evaluation performed on up to 15 tissues from all animals. The Company has received several proposals from CROs, and will be selecting a CRO for the tox study in early March 2021. Based on incoming CRO proposals, the estimated cost of the animal toxicity study will be ~US\$130,000.

Non-GMP material is acceptable for the GLP tox studies as long as there is an approved Certificate of Analysis (CoA) or a Certificate of Testing (CoT). The Company will need to have a CoA (or CoT) as well as an analytical comparison with the GMP material to show that they are comparable (not necessarily identical). A CoT is more likely since there are no specifications for the material at this point and are essentially the same.

S-Protein Sourcing: The principal material used in Covid-T is the SARS-CoV-2 s1 subprotein. There is a near-term need for a smaller quantity of the SARS-CoV-2 S1 protein for use in the animal toxicology study acceptable for a regulatory filing, and a larger quantity later for use in the planned clinical trial. A strategy to produce these materials has been devised and will be presented to the FDA during the pre-IND meeting (when scheduled by the FDA). As this

is the same synthesized protein used in BVX-0320, Company's Covid-19 candidate vaccine, bioproduction of the s-protein can be shared between the two programs.

BioVaxys will need a supply of non-GMP s-protein to conduct the animal tox study for Covid-T, as well as a supply of GMP-grade s-protein for the Phase I clinical study of Covid-T. For the Murine Model Study, the Company purchased commercially available s-protein. However, the s-protein currently available is not well-characterized, QC/QA not integrated in production, and it is not available in GMP-clinical grade. The Company will need to develop its own supply of GLP and GMP-grade s-protein. S-1 protein will be produced by inserting the gene sequence for the s-1 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, and is obtaining the license. To make the s-protein, company scientists first take a common mammalian cell, called a CHO cell, and insert DNA instructions to create the spike protein. They use the newly infused CHO cell to create a Master Cell Bank, which is then grown in large bioreactors (vats that look like those in making beer) where the spike protein is produced. The s-protein is isolated, purified and ready to be used in the diagnostic.

Production of s-protein will require obtaining a license to use a third-party proprietary cell line and expression system, with a one-time license fee anticipated of approximately US\$150,000. Bioproduction estimates for the protein will be in addition to the license fee. The Company is in discussions with a CDMO on a contract to produce the protein, and anticipates a contract signed in March 2021, and although a final cost has not been presented, it is anticipated to be ~US\$500,000 to produce the GMP-grade cell line and synthesize the s-protein in required quantities under GMP conditions.

Marketing

The Company intends to commercialize Covid-T in the United States, 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.

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 Federal Food, Drug and Cosmetic 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 EMA generally follow the same clinical development path, with the EMA 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 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 2 issued US Patents and 3 pending patent applications in the United States. These patent and patent applications include:

- 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)

- U.S. Patent Application #62/735,381 International Application No. PCT/US2019/052644- BIHAPTENIZED AUTOLOGOUS VACCINES AND USES THEREOF (original filing September 24, 2018)
- U.S patent application #62/992,722 – Hapttenized Coronavirus Spike Protein Vaccine (Filed on March 20, 2020)
- U.S patent application #63106482- METHOD AND KIT FOR DETECTION OF CELL MEDIATED IMMUNE RESPONSE (Filed on October 28, 2020)

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

The National Phase filing deadline for the above-listed International Application No. PCT/US2019/052644 entitled "Bihapttenized Autologous Vaccines and Uses Thereof" is March 24, 2021. The Company will elect those countries it would like to enter, which is typically decided on commercial interest of the invention in such a country, either by manufacture, sale or license. Generally, pharmaceutical PCT applications tend to enter at least the large jurisdictions, such as: US, Europe, Japan, China, Australia, Brazil, and India. The Company may also consider national phase filing in other markets.

National Phase filing costs (US\$) are estimated as follows (source: *MorganLewis & 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 enforceable 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 four older U.S. patents related to a haptenized cancer vaccine using a single hapten (the "**TJU License**"). The patents were previously licensed by TJU to Avax in November 1995, however Avax defaulted on its license agreement in 2012. 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\$15,000 following enrollment of the first patient in a Phase 3 clinical trial (or foreign equivalent if outside US) for a product utilizing single-hapten cancer vaccine technology;
- US\$15,000 following FDA allowance for a product utilizing single-hapten cancer vaccine technology; and
- US\$50,000 once BioVaxys Inc. has reached five million (\$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. TJU has agreed to exercise its warrant immediately prior to the completion of the Transaction. As a result, TJU received 160,000 Common Shares upon closing of the Transaction. Further, The Company bears the expense of maintaining and defending the patents that are subject to the TJU License.

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 Federal Food, Drug and Cosmetic 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 European Union ("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 Investigational New Drug application (“IND”) 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 Investigational New Drug Application (“IND”). 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): Expanded Access Program (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 Good Manufacturing Practices. To supply products for use in the U.S., foreign manufacturing facilities also must comply with current Good Manufacturing Practices, 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, 2020, the Company had zero employees. As of the date of this AIF, the Company has zero (0) employees, as management act in a consulting capacity.

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 European Union.

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

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

Preclinical and Clinical Development Risks

Third Party Risk with respect to Preclinical Studies and Clinical Trials

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

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

The Company administers the vaccine adjuvant BCG with autologous haptenized vaccines for ovarian cancer. BCG is an approved product for Bladder Cancer and can be administered by physicians as a stand-alone vaccine. There are several sources of BCG, each formulation of which differs based upon the original source of the product. If the Company is unable to continue to obtain the current strain of BCG (the "Tice" strain) used in 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 haptimized vaccines. Failure to do so will have a material adverse effect on the Company's business and financial condition.

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

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

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

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

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

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

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

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

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

Intellectual Property Risks

Risks Related to Potential Inability to Protect Intellectual Property.

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

Protection and Enforcement of the Company's Intellectual Property.

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

Third Party License Risk.

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

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

Disclosure of Proprietary Information and Trade Secrets to Third Parties.

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

General Operational Risks

Conflict of Interest

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

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 constating 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 81,574,469 Common Shares issued and outstanding as fully paid and non-assessable. In addition, 4,876,716 Common Shares are reserved for issuance under Options and 11,272,501 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 rateably 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, 2020, there were 9,490,670 Warrants outstanding and as of the date of this AIF, there are 11,272,501 Warrants outstanding with a weighted average exercise price of \$0.50 and with expiry dates ranging from August 26, 2022 to February 5, 2023.

Options

As of October 31, 2020, there were 3,876,716 Options to purchase Common Shares outstanding with a weighted average exercise price of \$0.393 and expiry dates ranging from October 6, 2021 to October 25, 2025 and as of the date of this AIF, there are 4,876,716 Options outstanding with a weighted average exercise price of \$0.433, each of which expire on dates ranging from October 6, 2021 to February 12, 2026.

MARKET FOR SECURITIES

Market

The Company's Common Shares were initially listed on the CSE under the symbol "LBM". On May 29, 2020, in connection with the Transaction, the Company's Common Shares were halted from trading. Following the close of the Transaction, the Common Shares were listed again on the CSE under the symbol "BIOV" and trade on the Frankfurt Bourse (FRA: 5LB) and US OTC: LMNGF. All numbers in the table below are shown post- Share Split.

Month	High	Low	Total Volume
October 2020	\$0.4800	\$0.3300	4,942,758
September 2020	-	-	-
August 2020	-	-	-
July 2020	-	-	-
June 2020	-	-	-
May 2020	\$0.3900	\$0.2100	4,807,744
April, 2020	\$0.3000	\$0.0500	4,561,991
March 2020	\$0.0550	\$0.0350	457,198
February 2020	\$0.0450	\$0.0425	20,052
January 2020	\$0.0600	\$0.0425	23,524
December 2019	\$0.0425	\$0.0400	40,328
November 2019	\$0.0700	\$0.0450	203,472

PRIOR SALES

The Company

During the year ended October 31, 2020, 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:

<u>Date of Grant</u>	<u>Number of Options Granted</u>	<u>Exercise Price</u>	<u>Expiry Date</u>
September 3, 2020	600,000	\$0.28	September 3, 2025
October 20, 2020	3,000,000	\$0.45	October 20, 2025

Warrants

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

<u>Date of Grant</u>	<u>Number of Warrants Granted</u>	<u>Exercise Price</u>	<u>Expiry Date</u>
August 26, 2020	5,625,699	\$0.50	August 26, 2022
September 3, 2020	1,477,291	\$0.50	September 3, 2022

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:

<u>Designation of Security</u>	<u>Number of Securities Held in Escrow or that are subject to a contractual restriction on transfer</u>	<u>Percentage of Class</u>
Common Shares	21,135,153	26%

DIRECTORS AND OFFICERS

Name, Occupation and Security Holding

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

Name and Residence	Positions with the Company	Date of Appointment	Principal Occupation Within the Past Five Years ⁽¹⁾
James Passin ⁽²⁾ <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 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, BinghamHill 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 ⁽²⁾ <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 ⁽²⁾ <i>British Columbia, Canada</i>	Director	October 20, 2020	CEO of Encounter Technology Limited. Healthcare Consultant for South America, Omron.

(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 of 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 23,427,595 Common Shares, representing approximately 28.7% 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 6 years of experience focusing on financial reporting under IFRS, governance for public companies, and technical accounting issues, including work as an auditor

at KPMG. 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)

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

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.

Conflicts of Interest

Pursuant to the Transaction, James Passin, Ken Kovan and David Berd (each of whom is now a director or officer of the Company) were issued 12,417,333 Common Shares, 6,037,800 Common Shares and 4,696,067 Common Shares respectively, and will receive compensation for services provided to the Company.

Other than otherwise disclosed above, 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 common shares, representing 15.41% 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. Pursuant to the Transaction, James Passin sold his interest in BioVaxys Inc. to the Company in exchange for the issuance of 12,417,333 Common Shares.

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, 2020, 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, 2020, 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, 2020, and October 31, 2019. 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

The Company's Audit Committee has various responsibilities as set forth in National Instrument 52-110 – *Audit Committees* ("**NI 52-110**") made under securities legislation, concerning constitution of its audit committee and its relationship with its independent auditor and among such responsibilities being a requirement that the Audit Committee establish a written charter that sets out its responsibilities.

Audit Committee Charter

The Audit Committee is a committee of the Board. The Audit Committee has a charter (the "**Audit Committee Charter**") that sets out its mandate and responsibilities. A copy of the Audit Committee Charter is attached hereto as Schedule "A".

Composition of the Audit Committee

The Audit Committee shall consist of a minimum of three directors of the Company, including the Chair of the Audit Committee, the majority of whom shall be "independent" directors as such term is defined in NI 52-110. All Audit Committee members shall, to the satisfaction of the Board, be "financially literate" as such term is defined in NI 52-110.

As of the date of this AIF, the Company's Audit Committee was composed of David Wang, Daren Hermiston and James Passin. David Wang and Daren Hermiston are independent. All current members of the Audit Committee are financially literate.

Relevant Education and Experience

In addition to each member's general business experience, the education and experience of each member that is relevant to the performance of his responsibilities as a member of the Audit Committee is as follows:

Daren Hermiston – Mr. Hermiston is a director and member of the Audit Committee of Baden Resources Inc., an issuer which has filed a preliminary prospectus and is seeking a listing on the CSE and, in such capacity in such capacity, is responsible for reviewing and approving the issuer's financial statements.

David Wang – Mr. Wang had training in an MBA program, has years of experience at finances in an Asian subsidiary of a publicly traded company, and is currently financial Co-Chair for a Vancouver nonprofit organization.

James Passin – Mr. Passin has been a director and officer of several public companies and, in such capacity, was capacity, reviewed and approved the issuer's financial statements. In addition, Mr. Passin is a former hedge fund and private equity fund manager

Reliance on Certain Exemptions

Since the commencement of the Company's most recently completed financial year, the Company has not relied on:

- (a) the exemption in section 2.4 (De Minimis Non-Audit Services) of NI 52-110;
- (b) the exemption in section 3.2 (Initial Public Offerings) of NI 52-110;
- (c) the exemption in section 3.3(2) (Controlled Companies) of NI 52-110;
- (d) the exemption in section 3.4 (Events Outside the Control of the Member) of NI 52-110;
- (e) the exemption in section 3.5 (Death, Disability or Resignation of Audit Committee Member) of NI 52-110;
- (f) the exemption in section 3.8 (Acquisition of Financial Literacy) of NI 52-110; or
- (g) an exemption from NI 52-110 in whole or in part, granted under Part 8 of NI 52-110.

At no time since the commencement of the Company's most recently completed financial year has the Company relied on the exemptions in section 2.4 (*De Minimis Non-audit Services*), section 3.2 (*Initial Public Offerings*), section 3.4 (*Events Outside Control of Member*), section 3.5 (*Death, Disability or Resignation of Audit Committee Member*), or Part 8 (*Exemptions*) of NI 52-110.

Audit Committee Oversight

At no time since the commencement of the Company's most recently completed financial year was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the Board.

Pre-Approval Policies and Procedures

The Audit Committee has adopted specific policies and procedures for the engagement of non-audit services as described in the Audit Committee Charter under the heading "*External Audit*".

External Auditor Service Fees (By Category)

In the following table, "audit fees" are fees billed by the Company's external Auditor for services provided in auditing the Company's annual financial statements for the subject year. "Audit-Related Fees" are fees not included in audit fees that are billed by the Auditor for assurance and related services that are reasonably related to the performance of the audit review of the Company's financial statements. "Tax Fees" are fees billed by the Auditor for professional services rendered for tax compliance, tax advice and tax planning. "All Other Fees" are fees billed by the Auditor for products and services not included in the foregoing categories.

The aggregate fees paid by the Company to its Auditor in the financial years ended October 31, 2019, and October 31, 2020, were as follows:

Financial Period Ending	Audit Fees (CAD\$)	Audit Related Fees (CAD\$)	Tax Fees (CAD\$)	All Other Fees (CAD\$)
October 31, 2020	25,000	5,000	Nil	Nil
October 31, 2019	12,000	146	Nil	Nil

ADDITIONAL INFORMATION

Additional information relating to the Company may be found on SEDAR at www.sedar.com. Financial information about the Company is provided in the Company's comparative annual financial statements to October 31, 2020, 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. 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 and 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.