UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

OR

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 001-37769

VBI VACCINES INC.
(Exact name of registrant as specified in its charter)

British Columbia, Canada	**N/A**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

160 Second Street, Floor 3
Cambridge, MA 02142
(Address of principal executive offices)
(Zip Code)

(617) 830-3031
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which each is registered**
Common Shares, no par value per share	**VBIV**	**The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act:

None
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2021, the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the last sale price of the common equity was $621,489,779.

As of March 3, 2022, the registrant had 258,257,494 common shares issued and outstanding, with no par value per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement on Schedule 14A to be furnished to stockholders in connection with its 2022 Annual Meeting of Stockholders, which shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates, are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

VBI VACCINES INC.
FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2021

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND OTHER INFORMATION CONTAINED IN THIS REPORT

This Annual Report on Form 10-K (this "Form 10-K") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and the provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. You can find many (but not all) of these statements by looking for words such as "approximates," "believes," "hopes," "expects," "anticipates," "estimates," "projects," "intends," "plans," "would," "should," "could," "will", "may," or other similar expressions in this Form 10-K. In particular, these include statements relating to future actions; prospective products, applications, customers, and technologies; future performance or results of anticipated products; anticipated expenses; and projected financial results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our historical experience and our present expectations or projections. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to:

- the timing of, and our ability to, obtain and maintain regulatory approvals for our clinical trials, products, and pipeline candidates;
- our ability to achieve and sustain commercial success of PreHevbrio in the U.S;
- the timing and results of our ongoing and planned clinical trials for products and pipeline candidates;
- the amount of funds we require for our prophylactic and therapeutic pipeline candidates;
- the potential benefits of strategic partnership agreements and our ability to enter into strategic partnership arrangements;
- our ability to manufacture, or to have manufactured, our 3-antigen hepatitis B vaccine and our pipeline candidates, at a commercially viable scale to the standards and requirements of regulatory agencies;
- the impact of the ongoing COVID-19 pandemic on our clinical studies, research programs, manufacturing, business plan, regulatory review including site inspections, and the global economy;
- our ability to effectively execute and deliver our plans related to commercialization, marketing, manufacturing capabilities and strategy;
- our ability to retain and maintain a good relationship with our current employees, and our ability to competitively attract new employees with relevant experience and expertise;
- the suitability and adequacy of our office, manufacturing, and research facilities and our ability to secure term extensions or expansions of leased space;
- the ability of our vendors and suppliers to manufacture and deliver materials in a timely manner that meet regulatory agency and our standards and requirements to meet planned timelines and milestones;
- any disruption in the operations of our Rehovot, Israel manufacturing facility where we manufacture all of our clinical and commercial supplies of our 3-antigen hepatitis B vaccine and clinical supplies of our hepatitis B immunotherapeutic, VBI-2601;
- our compliance with all laws, rules, and regulations applicable to our business and products;
- our ability to continue as a going concern;

- our history of losses;
- our ability to generate revenues and achieve profitability;
- emerging competition and rapidly advancing technology in our industry that may outpace our technology;
- customer demand for our 3-antigen hepatitis B vaccine and pipeline candidates;
- the impact of competitive or alternative products, technologies, and pricing;
- general economic conditions and events and the impact they may have on us and our potential customers;
- our ability to obtain adequate financing in the future on reasonable terms, as and when we need it;
- our ability to implement network systems and controls that are effective at preventing cyber-attacks, malware intrusions, malicious viruses, and ransomware threats;
- our ability to secure and maintain protection over our intellectual property;
- our ability to maintain our existing licenses with licensors of intellectual property, or obtain new licenses for intellectual property;
- changes to legal and regulatory processes for biosimilar approval and marketing that could reduce the duration of market exclusivity for our products;
- our success at managing the risks involved in the foregoing items;
- our ability to maintain compliance with the NASDAQ Capital Market’s listing standards; and
- other factors discussed in this Form 10-K.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy, and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict and many of which are outside of our control. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and actual results or events could differ materially from the plans, intentions, and expectations disclosed in the forward-looking statements we make. Therefore, you should not rely on any of these forward-looking statements. We have included important factors in the cautionary statements included in this Form 10-K, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make or collaborations or strategic partnerships we may enter into.

You should read this Form 10-K and the documents that we have filed as exhibits to this Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. Any forward-looking statement made by us in this Form 10-K is based only on information currently available to us and speaks only as of the date on which it is made. We do not assume any obligation to update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future events, or otherwise, except as required by law.

Unless otherwise stated or the context otherwise requires, the terms "VBI," "we," "us," "our," and the "Company" refer to VBI Vaccines Inc. and its subsidiaries.

Unless indicated otherwise, all references to the United States Dollar, Dollar, or $ are to the United States Dollar, the legal currency of the United States of America and all references to € mean Euros, the legal currency of the European Union. We may also refer to NIS, which is the New Israeli Shekel, the legal currency of Israel, and the Canadian Dollar or CAD, which is the legal currency of Canada.

Except for share and per share amounts or as otherwise specified, amounts presented are stated in thousands.

PART I

ITEM 1. BUSINESS

Overview

VBI Vaccines Inc. ("VBI") is a commercial stage biopharmaceutical company driven by immunology in the pursuit of powerful prevention and treatment of disease. Through its innovative approach to virus-like particles ("VLPs"), including a proprietary enveloped VLP ("eVLP") platform technology, VBI develops vaccine candidates that mimic the natural presentation of viruses, designed to elicit the innate power of the human immune system. VBI is committed to targeting and overcoming significant infectious diseases, including hepatitis B ("HBV"), COVID-19 and coronaviruses, and cytomegalovirus ("CMV"), as well as aggressive cancers including glioblastoma ("GBM"). VBI is headquartered in Cambridge, Massachusetts, with research operations in Ottawa, Canada, and a research and manufacturing site in Rehovot, Israel.

Product Pipeline

VBI's pipeline is comprised of vaccine and immunotherapeutic programs developed by virus-like particle technologies to target two distinct, but often related, disease areas – infectious disease and oncology. We prioritize the development of programs for disease targets that are challenging, underserved, and where the human immune system, when powered and stimulated appropriately, can be a formidable opponent.

VLP vaccines are a type of sub-unit vaccine, in which only the portions of viruses critical for eliciting an immune response are presented to the body. Because of their structural similarity to viruses presented in nature, including their particulate nature and repetitive structure, virus-like particles (VLPs) can stimulate potent immune responses. VLPs can be customized to present any protein antigen, including multiple antibody and T cell targets, making them, we believe, ideal technologies for the development of both prophylactic and therapeutic vaccines. However, only a few antigenic proteins self-assemble into VLPs, which limit the number of potential targets. Notably, HBV antigens are among those that are able to spontaneously form orderly VLP structures. VBI's proprietary enveloped VLP (eVLP) platform technology expands the list of potentially-viable target indications for VLPs by providing a stable core (Gag Protein) and lipid bilayer (the "envelope"). It is a flexible platform that enables the synthetic manufacture of an "enveloped" VLP, or "eVLP", which looks structurally and morphologically similar to the virus, with no infectious material.

Our product pipeline includes an approved vaccine and multiple late- and early-stage investigational programs. The investigational programs are in various stages of clinical development and the scientific information included about these therapeutics is preliminary and investigative. The investigational programs have not been approved by the United States Food and Drug Administration ("FDA"), European Medicines Agency's ("EMA"), United Kingdom Medicines and Healthcare products Regulatory Agency ("MHRA"), Health Canada, or any other health authority and no conclusion can or should be drawn regarding the safety or efficacy of these investigational programs.

In addition to our existing pipeline programs, we may also seek to in-license clinical-stage vaccines or vaccine-related technologies that we believe complement our pipeline, as well as technologies that may supplement our efforts in both immuno-oncology and infectious disease.

Key Targeted Disease Areas

Hepatitis B Virus ("HBV")

HBV infection can cause liver inflammation, fibrosis, and liver injury, resulting in potentially life-threatening conditions through acute illness and chronic disease, including liver failure, cirrhosis, and cancer. HBV remains a significant public health burden with an estimated 2.2 million chronically-infected people in the United States ("U.S.") alone. Worldwide, this number is estimated to be as high as 350 million, with approximately 800,000 deaths resulting from the consequences of HBV infection each year.

Despite the highly infectious nature of HBV, due to its often asymptomatic nature, it is estimated that as many as 67% of chronically-infected adults in the U.S. are unaware of their infection status. There is not yet a cure available for HBV infection, but while public health initiative name immunization as the most effective strategy for the prevention of HBV infections, the U.S. adult HBV vaccination rates remain persistently low at only about 25% of all adults age 19 years and older.

In November 2021, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) unanimously voted to change the adult HBV vaccine recommendations. As incorporated in the CDC's 2022 Adult Immunization Schedule, adults age 19 to 59 years are now universally recommended to be vaccinated against HBV infection. No change was made for adults age 60 years and older – those with an additional risk factor or another indication are recommended for HBV vaccination.

COVID-19 and Other Coronaviruses

Coronaviruses are a large family of enveloped viruses that cause respiratory illness of varying severities. Only seven coronaviruses are known to cause disease in humans, four of which most frequently cause symptoms typically associated with the common cold. Three of the seven coronaviruses, however, have more serious outcomes in people. These more pathogenic coronaviruses are (1) SARS-CoV-2, a novel coronavirus identified as the cause of COVID-19; (2) MERS-CoV, identified in 2012 as the cause of Middle East Respiratory Syndrome (MERS); and (3) SARS-CoV, identified in 2002 as the cause of Severe Acute Respiratory Syndrome (SARS).

Since early 2020, the disease burden of the COVID-19 pandemic has been staggering. To date, the World Health Organization ("WHO") estimates that there have been 430 million cases of COVID-19, resulting in 5.9 million deaths worldwide. In the U.S., between February 2020 and September 2021, the CDC estimates 146.6 million COVID-19 infections, 7.5 million hospitalizations, and 921,000 deaths.

The virus that causes COVID-19 continues to evolve and several SARS-CoV-2 variants have emerged and certain of these variants have been identified as having a significant public health impact. To date, notable Variants of Concern ("VOC") include:

- Alpha (B.1.1.7) – First identified as in the United Kingdom ("UK"), VOC in December 2020
- Beta (B.1.351) – First identified in South Africa, VOC in December 2020
- Gamma (P.1) – First identified in Brazil, VOC in January 2021
- Delta (B.1.617.2) – First identified in India, VOC in May 2021
- Omicron (B.1.1.529) – First identified in South Africa, VOC in November 2021

Glioblastoma ("GBM")

Glioblastoma ("GBM") is among the most common and aggressive malignant primary brain tumors in humans. In the U.S. alone, about 12,000 new GBM cases are diagnosed each year. The current standard of care for GBM is surgical resection, followed by radiation and chemotherapy. Even with intensive treatment, GBM progresses rapidly and has a high mortality rate, with median overall survival for primary GBM of about 14 months.

Cytomegalovirus ("CMV")

CMV is a common virus that is a member of the herpes family. It infects one in every two people in many developed countries. Most CMV infections are "silent", meaning the majority of people who are infected exhibit no signs or symptoms. Despite its typically asymptomatic nature in older children and adults, CMV may cause severe infections in newborn children (congenital CMV) and may also cause serious infections in people with weakened immune systems, such as solid organ or bone marrow transplant recipients. Congenital CMV infection can be treated – but not cured – and there are currently no approved vaccines available for the prevention of infection in either the congenital or the transplant setting.

Zika

Zika is a mosquito-borne virus that is spread primarily through the bite of an infected Aedes species mosquito, but can also be transmitted sexually, during pregnancy, or during childbirth. Acute infections are typically mild, but Zika has been associated with a number of neurological complications in newborns. The first formal description of Zika virus was published in 1952, but it was not until 2007 that the first Zika outbreak in humans was recorded. Over the past decade, Zika has begun to spread globally, and between January 2014 and February 2016, 33 countries reported circulation of the Zika virus, including in North America. There is currently no vaccine to prevent Zika infection.

Pipeline Programs

The table below is an overview of our commercial vaccine and our investigational programs as of January 31, 2022:

Indication	Program	Technology	Current Status
Approved Vaccine			
● Hepatitis B	PreHevbrio[1,2] *Hepatitis B Vaccine (Recombinant)*	VLP	Registration/Commercial
Prophylactic Candidates			
● Cytomegalovirus	VBI-1501	eVLP	Phase I Completed
● COVID-19 (Ancestral)	VBI-2902	eVLP	Ongoing Phase Ia

● COVID-19 (Beta variant)	VBI-2905	eVLP	Ongoing Phase Ib
● Pan-coronavirus (Multivalent)	VBI-2901	eVLP	Pre-Clinical
● Coronaviruses (Multivalent)	Undisclosed	eVLP	Pre-Clinical
● Zika	VBI-2501	eVLP	Pre-Clinical
Therapeutic Candidates			
● Hepatitis B	VBI-2601	VLP	Ongoing Phase II
● Glioblastoma	VBI-1901	eVLP	Ongoing Phase I/IIa
● Other CMV-Associated Cancers	Undisclosed	eVLP	Preclinical

[1]Approved for use in the U.S. for the prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older
[2]Approved for use in Israel, under the brand name Sci-B-Vac, for active immunization against hepatitis B virus (HBV infection)

A summary of our marketed product, lead pipeline programs and recent developments follows.

Marketed Product

PreHevbrio (Hepatitis B Vaccine [Recombinant])

PreHevbrio (Hepatitis B Vaccine [Recombinant]) was approved by the FDA on November 30, 2021 for the prevention of infection caused by all known subtypes of HBV in adults age 18 years and older. PreHevbrio contains the S, pre-S2, and pre-S1 HBV surface antigens, and is the only approved 3-antigen HBV vaccine for adults in the U.S. On February 23, 2022, following discussion at the CDC's ACIP meeting, PreHevbrio joined the list of recommended products for prophylactic adult vaccination against HBV infection. The inclusion of PreHevbrio in the ACIP recommendation will be reflected in a future CDC publication and is a notable milestone as many insurance plans and institutions require an ACIP recommendation before a vaccine is able to be reimbursed or is made available to patients. Additionally, PreHevbrio will be included in the next annual update of the CDC Adult Immunization Schedule in 2023, which will summarize changes throughout the coming year. VBI expects to commercially launch PreHevbrio in the U.S. at the end of the first quarter of 2022, with revenue generation expected to begin in the second quarter of 2022.

Commercial and regulatory activity for VBI's 3-antigen HBV vaccine outside of the U.S. include:

- *Israel:* Approved and commercially available, under the brand name Sci-B-Vac®, for active immunization against HBV infection.
- *European Union ("EU"):* On February 25, 2022, we announced that the EMA's Committee for Medicinal Products for Human Use ("CHMP") adopted a positive opinion for VBI's 3-antigen HBV vaccine for active immunization against infection caused by all known subtypes of HBV in adults, under the name PreHevbri [Hepatitis B vaccine (recombinant, adsorbed)]. The European Commission ("EC") will review the CHMP recommendation and a final decision on the Marketing Authorization Application ("MAA") for PreHevbri in the EU is expected in the coming months. If approved by the EC, the centralized marketing authorization would be valid in all EU Member States as well as in the European Economic Area ("EEA") countries – Iceland, Liechtenstein, and Norway.
- *United Kingdom ("UK"):* The MAA for VBI's 3-antigen HBV vaccine is expected to be reviewed by the MHRA as part of the EC Decision Reliance Procedure ("ECDRP"), the process for which was initiated upon receipt of positive CHMP opinion.
- *Canada:* On December 9, 2021, we completed the filing of a New Drug Submission ("NDS") to Health Canada for our 3-antigen hepatitis B vaccine candidate. Discussions are underway with regulatory agencies to determine the brand name for our 3-antigen HBV vaccine in Canada.

Prophylactic Investigational Candidates

VBI-2900: Coronavirus Vaccine Program (VBI-2901, VBI-2902, VBI-2905)

In response to the ongoing SARS-CoV-2 (COVID-19) pandemic, VBI initiated development of a prophylactic coronavirus vaccine program. Coronaviruses are enveloped viruses by nature which make them a prime target for VBI's flexible eVLP platform technology.

On August 26, 2020, we announced data from three pre-clinical studies conducted to enable selection of optimized clinical candidates for our coronavirus vaccine program. As a result of these studies, VBI selected two vaccine candidates, with the goal of bringing forward candidates that add meaningful clinical and medical benefit to those already approved: (1) VBI-2901, a multivalent pan-coronavirus vaccine candidate expressing the SARS-CoV-2, SARS, and MERS spike proteins; and (2) VBI-2902, a monovalent vaccine candidate expressing an optimized "prefusion" form of the SARS-CoV-2 spike protein.

In March 2021, a Phase I study of VBI-2902 was initiated and on June 29, 2021 we announced initial positive data from the Phase Ia portion of this study that evaluated one- and two-dose regimens of 5µg of VBI-2902 in 61 healthy adults age 18-54 years. After two doses, VBI-2902 induced neutralization titers in 100% of participants, with 4.3x higher geometric mean titer ("GMT") than that of the convalescent serum panel (n=25), and peak antibody binding GMT of 1:4,047. The study supports the assessment of a one-dose booster regimen in seropositive individuals and two-dose regimens in seronegative individuals. VBI-2902 was also well tolerated with no safety signals observed.

In response to the increased circulation of SARS-CoV-2 variants, the Phase Ib portion of the ongoing Phase I study was initiated in September 2021 and was designed to assess VBI-2905, our eVLP vaccine candidate directed against the SARS-CoV-2 Beta variant, as both a 1-dose booster in individuals previously immunized with a mRNA vaccine and as a primary 2-dose series in unvaccinated adults. Initial data from the 1-dose booster Phase Ib portion of the ongoing study is expected around the end of Q1 2022, dependent upon receipt of data from third party clinical research organizations. In addition, the first clinical study of VBI's multivalent candidate, designed to increase breadth of protection against COVID-19 and related coronaviruses, is expected to begin mid-year 2022.

The VBI-2900 program is supported by a partnership with CEPI (the "CEPI Funding Agreement"), with contributions of up to $33 million; a partnership with the Strategic Innovation Fund ("SIF"), established by the Government of Canada, with an award of up to CAD $56 million; contribution of up to CAD $1 million from the Industrial Research Assistance Program ("IRAP") of the National Research Council of Canada ("NRC"); and a collaboration with the NRC.

VBI-1501: Prophylactic CMV Vaccine Candidate

Our prophylactic CMV vaccine candidate uses the eVLP platform to express a modified form of the CMV glycoprotein B ("gB") antigen and is adjuvanted with alum, an adjuvant used in FDA-approved products.

Following the successful completion of the Phase I study in May 2018, and positive discussions with Health Canada, we announced plans for a Phase II clinical study evaluating VBI-1501 on December 20, 2018. We received similarly positive guidance from the FDA in July 2019. The Phase II study is expected to assess the safety and immunogenicity of dosages of VBI-1501 up to 20µg with alum. We are currently evaluating the timing of the Phase II study.

Therapeutic Investigational Candidates

VBI-2601: HBV Immunotherapeutic Candidate

VBI-2601 (BRII-179) is our novel, recombinant, protein-based immunotherapeutic candidate in development for the treatment of chronic HBV infection. VBI-2601 (BRII-179) is formulated to induce broad immunity against HBV, including T-cell immunity which plays an important role in controlling HBV infection.

On April 12, 2021 and June 23, 2021, we announced data from the completed Phase Ib/IIa clinical study in patients with chronic HBV infection, which was conducted by our partner Brii Biosciences Limited ("Brii Bio"). The study was a randomized, controlled study designed to assess the safety, tolerability, antiviral and immunologic activity of VBI-2601. The study was a two-part, dose-escalation study assessing different dose levels of VBI-2601 (BRII-179) with and without an immunomodulatory adjuvant, conducted at multiple study sites in New Zealand, Australia, Thailand, South Korea, Hong Kong SAR, and China.

The data from the Phase Ib/IIa for 33 evaluable patients across all study arms suggest: (1) VBI-2601 (BRII-179) is well tolerated at all dose levels with and without the adjuvant with no significant adverse events identified; (2) VBI-2601 (BRII-179) induced both B cell (antibody) and T cell responses in chronically-infected HBV patients, (3) VBI-2601 (BRII-179) induced restimulation of T cell responses to HBV surface antigens, including S, Pre-S1 and Pre-S2, in greater than 50% of the evaluable patients compared to no detectable response in the control arm; (4) the T cell responses and antibody responses were comparable across the 20µg and 40µg unadjuvanted study arms; and (5) T cell response rates between the adjuvanted and unadjuvanted cohorts were also comparable. Based on the acceptable safety profile and vaccine-induced adaptive immune responses seen in this study, VBI-2601 (BRII-179) has been advanced to Phase II studies.

On April 21, 2021, we announced that the first patient had been dosed in a Phase II clinical study evaluating VBI-2601 (BRII-179) in combination with BRII-835 (VIR-2218), an investigational small interfering ribonucleic acid (siRNA) targeting HBV, for the treatment of chronic HBV infection. To the best of our knowledge, this is the first clinical trial in the field to evaluate the combination of these two HBV mechanisms of action. The multi-center, randomized, open-label study is designed to evaluate the safety and efficacy of this combination with and without interferon-alpha as a co-adjuvant. Brii Bio has led the design and implementation of this functional cure proof-of-concept study with the support of VBI and Vir Biotechnology ("VIR"). The study will be conducted at sites in Australia, China, Taiwan, Hong Kong SAR, South Korea, New Zealand, Singapore, and Thailand. Initial data from this study is expected in the second half of 2022.

On January 5, 2022, we announced that the first patient was dosed in a second Phase IIa/IIb clinical study evaluating VBI-2601 (BRII-179). This newly announced Phase II study will assess VBI-2601 as an add-on therapy to the standard-of-care nucleos(t)ide reverse transcriptase inhibitor (nrtl) and pegylated interferon (PEG-IFN-α,) therapy. Initial data from this Phase IIa/IIb clinical study is expected in the first half of 2023.

VBI-1901: Glioblastoma (GBM)

Our cancer vaccine immunotherapeutic program, VBI-1901, targets CMV proteins present in tumor cells. CMV is associated with a number of solid tumors including glioblastoma ("GBM"), breast cancer, and pediatric medulloblastoma.

In January 2018, we initiated dosing in a two-part, multi-center, open-label Phase I/IIa clinical study of VBI-1901 in 38 patients with recurrent GBM. Phase I (Part A) of the study was a dose-escalation phase that defined the safety, tolerability, and optimal dose level of VBI-1901 adjuvanted with granulocyte-macrophage colony-stimulating factor (GM-CSF) in recurrent GBM patients with any number of prior recurrences. In December 2018, this phase completed enrollment of 18 patients across three dose cohorts, the highest of which (10 µg) was selected as the optimal dose level to test in the Phase IIa portion (Part B) of the study. Phase IIa of the study, which initiated enrollment in July 2019, is a subsequent extension of the 10 µg doses level cohort. This phase is a two-arm study that enrolled 20 first-recurrent GBM patients to receive 10 µg of VBI-1901 in combination with either GM-CSF or GlaxoSmithKline Biologicals S.A. ("GSK") proprietary adjuvant system, AS01, as immunomodulatory adjuvants. AS01 is provided pursuant to a Clinical Collaboration and Support Study Agreement ("Collaboration Agreement") we entered into with GSK on September 10, 2019. Enrollment of the 10 patients in the VBI-1901 with GM-CSF arm was completed in March 2020 and enrollment of the 10 patients in the VBI-1901 with AS01 was completed in October 2020.

Data from the ongoing Phase IIa portion of the study was announced throughout 2020 and 2021, with the latest data presented in December 2021 at the World Vaccine & Immunology Congress. The data from the Phase IIa portion of this study demonstrate: (1) improvement in 6-month, 12-month, and 18-month overall survival ("OS") data compared to historical controls; (2) 12-month OS of 60% (n=6/10) in the VBI-1901 + GM-CSF study arm and 70% (n=7/10) in the VBI-1901 + AS01 study arm, compared to historical controls of ~30%; (3) 18-month OS of 30% (3/10) in the VBI-1901 + GM-CSF study arm, 18-month OS not yet reached in the VBI-1901 + AS01 study arm; (3) 2 partial tumor responses, one of which remains on protocol past week 86 with a 93% tumor reduction relative to initiation of treatment at the start of the study, and 7 stable disease observations across both study arms; and (4) VBI-1901 continues to be safe and well tolerated at all doses tested, with no safety signals observed.

On June 8, 2021, we announced that the FDA granted Fast-Track Designation for VBI-1901 formulated with GM-CSF for the treatment of recurrent GBM patients with first tumor recurrence. The designation was granted based on data from the Phase I/IIa study.

Based on the data seen to-date, as part of the next phase of development, we anticipate assessing VBI-1901 in randomized, controlled studies in both primary and recurrent GBM patients. In the recurrent setting, we aim to expand the number of patients in the current trial and add a control arm, with the potential for accelerated approval based on tumor response rates and improvement in overall survival. Subject to discussion with the FDA, the amended protocol is expected to initiate enrollment of additional patients in Q2 2022. In the primary setting, we are exploring a randomized, controlled, clinical study with registration potential in patients first diagnosed with GBM, which, subject to approval from regulatory bodies, is expected to begin in the second half of 2022.

Impact of the COVID-19 Pandemic on Our Business

In December 2019, SARS-CoV-2 was reported to have surfaced in Wuhan, China, and on March 12, 2020, the WHO declared the global outbreak of COVID-19, the disease caused by SARS-CoV-2, to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, Canada, Israel and China, have imposed unprecedented restrictions on travel, quarantines, and other public health safety measures. The development of effective vaccines to prevent this disease has been a major global priority, and as of the date of this report, the FDA has approved two vaccines for the prevention of COVID-19, Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty, and Moderna COVID-19 Vaccine, marketed as Spikevax. Multiple vaccine candidates against SARS-CoV-2 continue to be under development, and certain large, multinational pharmaceutical companies have been granted and continue to seek authorizations for emergency approval by the FDA. The treatments for COVID-19, including symptomatic and supportive therapies, among other things, continue to be updated on a rolling basis by healthcare authorities and agencies.

Since early in the pandemic SARS-CoV-2 variants started to emerge and certain of these variants have been identified as having a significant public health impact. VBI is closely following changing SARS-CoV-2 characteristics and plans to study the impact of specific mutations that may impact vaccine efficacy and vaccine design. Further investigations are required to understand the impact of specific mutations on viral properties and the effectiveness of vaccines.

We have four ongoing clinical studies being conducted, by us or our partners, at clinical sites worldwide: 1) the Phase II study of VBI-2601 (BRII-179) and BRII-835 (VIR-2218) at multiple study sites in Asia Pacific countries; 2) the Phase IIa/IIb study of VBI-2601 (BRII-179) at multiple study sites in Asian Pacific countries; 3) the Phase I/IIa study of VBI-1901 in the United States; and 4) the Phase Ib clinical study of VBI-2902 and VBI-2905 in Canada and Mexico. In addition to the active clinical studies, we have several planned clinical studies expected to begin in 2022, including a further clinical study with VBI-1901 in the United States, and the continued clinical evaluation of our coronavirus vaccine candidates, including VBI-2901 (VBI's multivalent pan-coronavirus vaccine candidate) in Canada and potentially other countries. The enrollment of patients at some of the clinical sites in our studies has in the past been suspended, and may again be suspended in the future due to the COVID-19 pandemic, and enrollment of patients at other clinical sites may be suspended or delayed as hospitals and clinics where we are conducting or planning to conduct clinical trials may reallocate resources and limit access to or close clinical facilities due to the COVID-19 pandemic. Additionally, if our trial participants are unable to travel to or visit our clinical study sites as a result of quarantines or other restrictions resulting from the COVID-19 pandemic, we could experience higher drop-out rates or delays in our clinical studies. Government-imposed quarantines, shelter-in-place and similar restrictions may also require us to temporarily close our clinical sites, research laboratories, or manufacturing facility. Furthermore, if we determine that our trial participants may suffer from exposure to COVID-19 as a result of their participation in our clinical trials, we may voluntarily close certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. As a result, our expected development timelines for VBI-2601 (BRII-179), VBI-1901, our coronavirus vaccine candidates, and possibly our regulatory timelines for our 3-antigen HBV vaccine, in countries other than Unites States, may be negatively impacted.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition in other ways, as well. The COVID-19 pandemic has caused interruptions to global supply chains which have significantly limited the availability of raw materials, laboratory supplies, and manufacturing equipment. The extent to which the COVID-19 pandemic will continue to impact our business will depend on future developments, which are highly uncertain and cannot be predicted. We anticipate that the stress of COVID-19 on healthcare systems generally around the globe will negatively impact regulatory authorities and the third parties that we may engage in connection with the development and testing of our coronavirus vaccine candidates.

As a result of the COVID-19 pandemic, we continue to reduce exposure risk with fewer employees on site at any given time at both our manufacturing facility in Israel, where we manufacture our 3-antigen HBV vaccine and VBI-2601, and at our research and development laboratories in Ottawa, Canada. Going forward, we will continue to monitor the ongoing COVID-19 situation and will implement and enforce appropriate safety and health measures to ensure the safety of our employees.

Our manufacturing facility in Israel and contract development and manufacturing organizations ("CDMOs") that we engage to manufacture our eVLP vaccine candidates are dependent on sourcing raw materials from third party suppliers. The COVID-19 pandemic has impacted lead times and availability of many raw materials, and led to supply chain disruptions and shipping delays, all of which may adversely impact our ability to manufacture products in a timely manner. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business have limited our ability to support our operations.

The ultimate impact of the global COVID-19 pandemic or a similar health epidemic continues to be highly uncertain and subject to future developments. Relevant factors include, but are not limited to, the duration of the COVID-19 pandemic, the emergence of new variants, and any additional preventative and protective actions that regulators, or our board of directors or management may determine are needed. We do not yet know the full extent of potential delays or impacts on our business, our clinical studies, our research programs, the recoverability of our assets, and our manufacturing; however, the COVID-19 pandemic may continue to disrupt or delay our business operations, including with respect to efforts relating to potential business development transactions, and it could disrupt the marketplace which could have an adverse effect on our operations.

In addition, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the continuation of the COVID-19 pandemic may occur and could materially affect our business and the value of our common shares.

Corporate History

We were incorporated under the laws of British Columbia by Memorandum of Association on April 9, 1965 under the name "Alice Arm Molybendum Co. Ltd." On October 21, 1965, we changed our name to "Alice Arm Mining Ltd." and subsequently, on July 13, 1975, changed our name to "New Congress Resources Ltd." On January 12, 1983, we changed our name to "Levon Resources Ltd."

On July 9, 2015, we, then known as Levon Resources Ltd. (“Levon”), completed a plan of arrangement (the “Levon Merger”) pursuant to which SciVac Ltd. (“SciVac”), an Israel based company, completed a reverse takeover of Levon. Levon changed its name from Levon Resources Ltd. to SciVac Therapeutics Inc. and SciVac became our wholly-owned subsidiary.

On May 6, 2016, we completed our acquisition of VBI Vaccines (Delaware) Inc. (“VBI DE”), pursuant to which Seniccav Acquisition Corporation, a Delaware corporation and our wholly-owned subsidiary, merged with and into VBI DE, with VBI DE continuing as the surviving corporation and as our wholly-owned subsidiary (the “VBI-SciVac Merger”). Upon completion of the VBI-SciVac Merger, we (then named “SciVac Therapeutics Inc.”) changed our name to “VBI Vaccines Inc.” and received approval for the listing of our common shares on the NASDAQ Capital Market. Our common shares commenced trading on the NASDAQ Capital Market at the opening of trading on May 9, 2016 under our new name and the symbol “VBIV.” Following the effective time of the VBI-SciVac Merger, our common shares began to trade on the Toronto Stock Exchange (“TSX”) under the new symbol “VBV.” Effective as of March 23, 2018, we voluntarily delisted our common shares from the TSX.

Our registered office is located at Suite 1700, Park Place, 666 Burrard Street, Vancouver British Columbia V6C 2X8. Our principal executive offices are located at 160 Second Street, Floor 3, Cambridge, MA 02142; our manufacturing operations are located at 13 Gad Feinstein Road, POB 580, Rehovot, Israel 7610303 and our research operations are located at 310 Hunt Club Road East, Suite 201, Ottawa, Ontario Canada K1V 1C1.

Background of VBI DE

VBI DE was originally established in 1970 as Paulson Capital Corp., an Oregon corporation (“Paulson Oregon”), which began as a holding company whose operating subsidiary, Paulson Investment Company, Inc., was a full-service brokerage firm. Effective March 20, 2014, Paulson Oregon changed its state of incorporation from the State of Oregon to the State of Delaware, and as a result, Paulson Oregon became “Paulson Capital (Delaware) Corp.” and Paulson Oregon ceased to exist.

On July 25, 2014, Variation Biotechnologies (US), Inc. (“VBI US”) completed its merger with VBI Acquisition Corp. (“Merger Sub”), a Delaware corporation and wholly-owned subsidiary of Paulson Capital (Delaware) Corp., whereby Merger Sub merged with and into VBI US, with VBI US continuing as the surviving corporation. As a result of this merger, VBI US was acquired by, and became a wholly-owned subsidiary of Paulson Capital (Delaware) Corp., which changed its name to VBI Vaccines Inc. and then subsequently to VBI Vaccines (Delaware) Inc. on July 19, 2016.

Subsidiaries

SciVac, located in Rehovot, Israel, is our wholly-owned subsidiary that was incorporated on April 18, 2005 pursuant to the Israeli Companies Law (1999), as amended.

VBI DE, a Delaware corporation, is our wholly-owned subsidiary.

VBI US, a Delaware corporation, is a wholly-owned subsidiary of VBI DE and was incorporated on December 18, 2006 in the State of Delaware.

Variation Biotechnologies Inc. ("VBI Cda"), located in Ottawa, Ontario, Canada, is a wholly-owned subsidiary of VBI US, and was incorporated on August 24, 2001 under the Canada Business Corporations Act.

SciVac Hong Kong Limited, is a wholly-owned subsidiary, and was incorporated pursuant to the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) on January 29, 2019.

VBI Vaccines B.V., is a wholly-owned subsidiary, and was incorporated on October 21, 2020 in the Netherlands.

Partnerships, Collaborations, and Licensing Agreements

Our focus is to develop and deliver vaccines and therapeutics that target significant infectious diseases and aggressive cancers. As part of this strategy, we have entered into, and expect to enter into additional, partnerships, collaborations, and licensing agreements. These agreements help VBI commercialize our approved product, advance our investigational programs, and access additional expertise, capabilities, resources, and funding.

Partnership with Syneos Health ("Syneos")

On December 7, 2020, we announced a partnership for the commercialization of our 3-antigen HBV vaccine with Syneos, who was selected for their robust and innovative commercialization experience and deep vaccine expertise, including successful partnerships with leading vaccine manufacturers. VBI and Syneos have been working together on the pre-launch strategy and activity since 2019. As part of this partnership, we now have 80 fully-dedicated field team members across medical affairs, market access, and sales, as well as a highly-experienced leadership team.

The Master Commercial Services Agreement ("Commercial Agreement"), dated December 17, 2019, has an initial term of five (5) years. Details regarding activities, leaderships team, and field teams are covered in various work orders, entered into pursuant to and governed by the Commercial Agreement.

Collaboration and License Agreement with Brii Biosciences ("Brii Bio")

On December 4, 2018, we entered into the License Agreement with Brii Bio, pursuant to which, among other things, subject to terms and conditions set forth in the License Agreement, amended on April 8, 2021:

(i) we and Brii Bio agreed to collaborate on the development of a HBV recombinant protein-based immunotherapeutic in the Licensed Territory (as defined in the License Agreement), and to conduct a Phase Ib/IIa collaboration clinical trial for the purpose of comparing VBI-2601 (BRII-179), which is a recombinant protein-based immunotherapeutic developed by VBI for use in treating chronic HBV, with a novel composition developed jointly with Brii Bio (either being the "Licensed Product")

(ii) we granted Brii Bio an exclusive royalty-bearing license to perform studies, and regulatory and other activities, as may be required to obtain and maintain marketing approval for the Licensed Product, for the treatment of HBV in the Licensed Territory and to commercialize and promote the Licensed Product for the diagnosis and treatment of chronic HBV in the Licensed Territory; and

(iii) Brii Bio granted us an exclusive royalty-free license under Brii Bio's technology and Brii Bio's interest in any joint technology developed during the collaboration to develop and commercialize the Licensed Product for the diagnosis and treatment of chronic HBV in the countries of the world other than the Licensed Territory.

On December 20, 2021, we and Brii Bio further amended the License Agreement (the "Second Amendment") subject to the following additional terms and conditions:

(i) we and Brii Bio agreed to conduct an additional Phase II combination clinical trial of VBI-2601 (BRII-179), both with and without IFN-α, and BRII-835 (VIR-2218) ("Combo Clinical Trial"); and

(ii) Brii Bio granted us a non-exclusive royalty free license under the Brii Bio technology arising from the data generated in the Combo Clinical Trial solely for use in the development, manufacture or commercialization of the Licensed Product in combination with an siRNA in the countries of the words other than the Licensed Territory.

Pursuant to the Second Amendment, and the initial development plan, Brii Bio shall fund all clinical trials for the Licensed Territory. We and Brii Bio will jointly own all right, title and interest in the joint know-how development and the patents claiming joint inventions made pursuant to the Second Amendment.

As part of the initial consideration for the collaboration under the License Agreement, we received from Brii Bio a total upfront payment of $11 million. We are also eligible to receive an additional $117.5 million in potential milestone payments, along with potential low double-digit royalties on commercial sales in the Licensed Territory. In connection with the License Agreement, we and Brii Bio entered into a stock purchase agreement, dated as of December 4, 2018, pursuant to which we issued to Brii Bio an aggregate of 2,295,082 common shares in exchange for a gross contractual allocation of $7 million (included in the $11 million upfront payment), or $3.05 per share, which had a fair value of $3.6 million on the date of issuance.

There was no additional consideration contemplated in the Second Amendment.

The License Agreement will be in effect until the last-to-expire of the latest of the following terms in each region of the Licensed Territory: (i) expiration, invalidation or lapse of the last of our patent claiming a Licensed Product, (ii) 10 years from the date of first commercial sale of a Licensed Product in the applicable region, or (iii) termination or expiration of our obligation to pay third party royalties with respect to sales of a Licensed Product. Upon expiration (but not an earlier termination) of the License Agreement in each region of the Licensed Territory, we will grant Brii Bio a perpetual, non-exclusive, fully paid-up, royalty free license under our technology related to the Licensed Compounds (as defined in the License Agreement) or Licensed Products pursuant to the License Agreement in such region to make and sell Licensed Products for the diagnosis and treatment of HBV in such region. Each party may terminate the License Agreement upon a material breach of the License Agreement which has not been cured within 60 days (or 30 days for a breach payment obligations) after notice from the terminating party requesting cure of the breach, or upon bankruptcy or insolvency, either voluntary or involuntary, dissolution, or liquidation of a party. In addition, Brii Bio may terminate the License Agreement without cause upon 180 days' notice or, if the Data and Safety Monitoring Board or any regulatory authority in the Licensed Territory imposes a clinical hold on any clinical trial for a Licensed Product for six consecutive months, immediately upon notice. We may terminate the License Agreement immediately upon notice, if Brii Bio or its affiliates, directly, or indirectly through any third party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any patents owned or controlled by us related to the composition or the method of making or using Licensed Compounds or Licensed Products, or are otherwise necessary or useful to research, develop, make, or otherwise commercialize the licensed compounds or Licensed Products.

Prior to us entering into the License Agreement, we paid $6 million to terminate a distribution agreement with a third party who previously held certain distribution rights to certain Asian markets.

Collaboration Agreement with GlaxoSmithKline Biologicals S.A. ("GSK")

On September 10, 2019, we entered into the Collaboration Agreement with GSK pursuant to which we agreed to investigate the use of GSK's proprietary AS01 adjuvant in our ongoing Phase I/IIa study of VBI-1901. As a result of the Collaboration Agreement, we added a second study arm to Part B of the study and announced enrollment of patients in the $AS01_B$ arm in March 2020, as described in "Part I - Item I - Business - eVLP Platform - VBI-1901: Cancer Vaccine Immunotherapeutic Candidate".

Collaboration Agreement with the National Research Council of Canada ("NRC")

On March 31, 2020, we announced a collaboration with the NRC, Canada's largest federal research and development organization, to develop a coronavirus vaccine candidate. The collaboration combines VBI's viral vaccine expertise, eVLP technology platform, and coronavirus antigens with the NRC's uniquely designed SARS-CoV-2 antigens and assay development capabilities to select the most immunogenic vaccine candidate for further development.

On December 21, 2020, we signed an amendment to the collaboration agreement with the NRC to broaden the scope of collaboration to include certain pre-clinical evaluations, bioprocess optimization, technology transfer, and the performance of additional scale up work.

On July 8, 2021, we signed a second amendment to the collaboration agreement with the NRC to broaden the scope of the collaboration to include developing a vaccine against the Beta variant of SARS-CoV-2.

On August 27, 2021, we signed a third amendment to the collaboration agreement with the NRC to further broaden the scope to include certain stable cell line work for our vaccine candidate against the Beta variant of SARS-CoV-2.

On November 15, 2021, we signed a fourth amendment to the collaboration agreement with the NRC to further broaden the scope for our vaccine candidate against the Beta variant of SARS-CoV-2 to include additional animal studies and PRNT analysis.

On February 8, 2022, we signed a fifth amendment to the collaboration agreement with the NRC to further broaden the scope to include additional assays of new variants against SARS-CoV-2. The expiration date of the collaboration agreement, as amended, is October 31, 2022.

Partnership with the Coalition for Epidemic Preparedness Innovations ("CEPI")

On March 9, 2021, we announced a partnership with CEPI ("CEPI Funding Agreement") to develop eVLP vaccine candidates against SARS-COV-2 variants, including the Beta variant, also known as the B.1.351 variant and 501Y.V2, first identified in South Africa. CEPI agreed to provide up to $33,018 to support the advancement of VBI-2905, a monovalent eVLP candidate expressing the pre-fusion form of the spike protein from the Beta variant, through Phase I clinical development. This funding will also support preclinical expansion of additional multivalent vaccine candidates designed to evaluate the potential breadth of our eVLP technology. The preclinical expansion is intended to develop clinic-ready vaccine candidates capable of addressing emerging variants.

Contribution Agreement with the Government of Canada

On July 3, 2020, we and the NRC as represented by its IRAP signed a contribution agreement whereby the NRC agreed to contribute up to CAD $1 million for the transfer and scale-up of the technical production process for our prophylactic coronavirus vaccine program.

On August 5, 2020, we announced that VBI Cda had been awarded up to a CAD $56 million contribution from the Strategic Innovation Fund ("SIF"), established by the Government of Canada, to support our coronavirus vaccine development program through Phase II clinical studies (the "Project"). This award is governed by the terms of a Contribution Agreement (the "Contribution Agreement"), dated September 16, 2020, with Her Majesty The Queen in Right of Canada, as represented by the Minister of Industry, pursuant to which our subsidiary, Variation Biotechnologies Inc., is responsible for development of a novel, broadly reactive coronavirus vaccine against COVID-19, SARS, and MERS, and/or a monovalent vaccine targeting only COVID-19 through Phase II studies. We agreed to complete such project, to be conducted exclusively in Canada except as permitted otherwise under certain circumstances, in or before the first quarter of 2022 ("Project Completion Date"), however discussions are underway to extend the term.

Pursuant to the Contribution Agreement, the Minister will contribute an amount not exceeding the lesser of (i) 75% of VBI Cda's costs incurred in respect of the Project, subject to certain eligibility limitations as set forth in the Contribution Agreement and (ii) CAD $55,976. In consideration of such contribution, we agreed to guarantee the complete performance and fulfillment of VBI Cda's obligations under the Contribution Agreement. In the event VBI Cda fails to perform or otherwise satisfy any of its obligations related to the Contribution Agreement, we will become a primary obligor under the Contribution Agreement.

For the term of the Contribution Agreement, VBI Cda must have exclusive ownership of all intellectual property developed in connection with the Project (the "Project Intellectual Property"). Pursuant to the Contribution Agreement, we are required to obtain a consent of the Minister, not to be unreasonably withheld, prior to granting any right or license to any of the Project Intellectual Property and certain other intellectual properties that is required for the carrying out of the Project (the "Background Intellectual Property,"); subject to certain exceptions set forth in the Contribution Agreement. Furthermore, if we are unable to provide a sufficient Canadian-sourced supply of the COVID-19 vaccine, the Minister may require us to grant a license on commercially reasonable terms to use the Project Intellectual Property and the Background Intellectual Property, but only to the extent necessary to ensure such supply.

Under the terms of the Contribution Agreement, we agreed to obtain the Minister's written consent prior to (i) making significant changes in the scope, objectives, outcomes or benefits of the Project, (ii) dispose of any assets, which were, in whole or in part, funded by the Minister under the Agreement, and (iii) effecting a Change in Control (as defined in the Contribution Agreement). In addition, we will provide a written notice to the Minister of any acquisition of a business, the sale of a business or a merger or amalgamation.

In an event of default, subject to a rectification period available in certain circumstances, among other things, the Minister may (i) suspend or terminate its contribution to the Project and (ii) require repayment of all or part of the contribution paid by the Minster, together with interest from the day of demand at the interest rate set forth in the Contribution Agreement.

The Contribution Agreement will terminate no earlier than five years following the Project Completion Date unless terminated earlier in accordance with the terms of the Contribution Agreement. The Contribution Agreement also contains confidentiality and indemnification obligations of the parties.

In connection with execution of the Contribution Agreement, we obtained a consent of K2 HealthVentures LLC pursuant to the Loan Agreement defined below. Pursuant to such consent, certain events of default that result in contributions made under the Contribution Agreement in excess of $500, becoming due and payable could result in an event of default under the Loan Agreement.

Ferring and SciGen License Agreements

Our 3-antigen HBV vaccines is the subject of a license agreement between Savient Pharmaceuticals Inc. and SciGen Ltd dated June 2004, as subsequently amended (the "Ferring License Agreement"). Under the Ferring License Agreement, we are committed to pay Ferring royalties equal to 7% of net sales (as defined therein) of HBsAg "Product" (as defined therein). Under an Assignment Agreement between FDS Pharma LLP and SciGen Ltd., dated February 14, 2012 (the "SciGen Assignment Agreement"), we are required to pay royalties to SciGen Ltd. equal to 5% of net sales (as defined in the Ferring License Agreement) of Product. Under the Ferring License Agreement and the SciGen Assignment Agreement, we originally were to pay royalties on a country-by-country basis until the date 10 years after the date of commencement of the first royalty year in respect of such country. In April 2019, we exercised our option to extend the Ferring License Agreement in respect of all the countries that still make up the territory for an additional 7 years by making a one-time payment to Ferring of $100. Royalties under the Ferring License Agreement and SciGen Assignment Agreement will continue to be payable for the duration of the extended license periods.

Royalty payments under the Ferring License Agreement of $18 and $20, were recorded in cost of revenues for the year ended December 31, 2021 and 2020, respectively.

Royalty payments under the SciGen Assignment Agreement of $13 and $14 were recorded in cost of revenues for the year ended December 31, 2021 and 2020, respectively.

In addition, we are committed to pay 30% of any and all non-royalty consideration, in any form, received by us from sub-licensees (other than consideration based on net sales for which a royalty is due under the Ferring License Agreement), provided that the payment of 30% shall not apply to a grant of rights in or relating to: (i) the Territory (as such term was defined in the Ferring License Agreement prior to an amendment dated January 24, 2005); or (ii) the Berna Territory (as defined in the Ferring License Agreement).

eVLP Technology Purchase Agreement

We are engaged in the inbound licensing of key intellectual property. We identified the need for a vaccine antigen discovery and design platform and, through that certain sale and purchase agreement entered into on July 18, 2011 (the "Sale and Purchase Agreement") among VBI Cda and ePixis SA ("ePixis") and the shareholders of ePixis (collectively, the "Sellers"), acquired 100% of the outstanding shares of ePixis in order to obtain access to its exclusive rights to key intellectual property covering its eVLP vaccine platform (the "Technology"), including patents (the "Acquired Patents") covering the Technology. We paid a purchase price of €400 (approximately $450) for the ePixis shares and approximately $75 in related transaction costs. VBI Cda also agreed to make certain contingent payments to the Sellers as follows:

- Upon the earlier to occur of (i) first approval by the FDA of a new drug application (an "NDA") permitting us or any sublicensee to market and sell any pharmaceutical product or candidate pharmaceutical product that contains or can express an eVLP (a "eVLP Product") in the United States or (ii) first approval by the EMA of a Marketing Authorization Application or equivalent submission permitting us or our sublicensees to market and sell a eVLP Product candidate in one or more countries in the EU, we must pay to the Sellers €1,000, or, if there are no longer any issued and valid claims of the Acquired Patents in effect at the date such event occurs, €500.

If an eVLP Product is commercialized, we will be required to pay the Sellers the following:

- On the date that Cumulative Net Sales (as defined in the Sale and Purchase Agreement), of all eVLP Products equals or exceeds €25,000, we must pay to the Sellers €1,500, or, if there are no longer any issued and valid claims of the Acquired Patents in effect at the date such event occurs, €750; and

- On the Date that Cumulative Net Sales of all eVLP Products equals or exceeds €50,000 in the aggregate, we must pay to the Sellers €2,000 or, if there are no longer any issued and valid claims of the Acquired Patents in effect at the date such event occurs, €1,000.

If any eVLP Product is commercialized by one or more sublicensees, we have agreed to make the following payments to the Sellers:

- On the date that Cumulative Net Sales by us or any sublicensees of the eVLP Products equal or exceed €25,000 in the aggregate, we must pay to the Sellers €750, or, if there are no longer any issued and valid claims of the Acquired Patents in effect at the date such event occurs, €375;

- On the date that Cumulative Net Sales made by us or any sublicensees of the eVLP Products equal or exceed €50,000 in the aggregate, we must pay to the Sellers €750, or, if there are no longer any issued and valid claims of the Acquired Patents in effect at the date such event occurs, €375;

- On the date that Cumulative Net Sales made by us or any sublicensees of the eVLP Products equal or exceed €75,000 in the aggregate, we must pay to the Sellers €1,000, or, if there are no longer any issued and valid claims of the Acquired Patents in effect at the date such event occurs, €500; and

- On the date that Cumulative Net Sales made by us or any sublicensees of the eVLP Products equal or exceed €100,000 in the aggregate, we must pay to the Sellers €1,000, or, if there are no longer any issued and valid claims of the Acquired Patents in effect at the date such event occurs, €500.

Included in the eVLP Acquired Patents were patents (the "UPMC Patents") co-owned by L'Universite Pierre et Marie Curie, now Sorbonne Université ("UPMC"), and the Institut National de la Santé et de la Recherche Médicale ("INSERM"), both in Paris, France. In July 2006, ePixis entered into a license agreement (the "ePixis License Agreement") with UPMC, INSERM, and L'école Normale Supérieure de Lyon (collectively the "Licensor") pursuant to which the Licensor granted to ePixis an exclusive license (with the right to sublicense with written consent from UPMC) to exploit the UPMC Patents for the purpose of developing, promoting and marketing products within the United States, Japan, Canada, and Europe until the expiry of the last of the UPMC Patents, including any supplementary protection certificates. Pursuant to the ePixis License Agreement, ePixis was to pay certain fees to the Licensor based on net sales (as defined in the ePixis License Agreement) of products developed from the UPMC Patents, sublicensing income based on net sales ("Sublicensing Payments") and one-time payments ("Lump Sum Payments") for each product developed from the UPMC Patents. ePixis also agreed to reimburse UPMC for fees and costs related to filing and maintaining the patent applications.

On July 12, 2011, the parties to the ePixis License Agreement entered into the first amendment to the ePixis License Agreement (the "ePixis Amendment"). The ePixis Amendment authorized the transfer of the ePixis License Agreement to VBI Cda and laid out new financial terms and conditions for the rights granted under the ePixis License Agreement.

The ePixis Amendment provides that the fees to be paid to the Licensor by ePixis on net sales of eVLP Products based on the UPMC Patents will be 1.75% of net sales for annual sales between €0 and €50,000, 1% of net sales for annual sales between €50,000 and €100,000, and 0.75% of net sales for annual sales in excess of €100,000. Pursuant to the ePixis Amendment, Lump Sum Payments shall be made as follows:

- €50 when the results from pre-clinical studies are sufficient to allow a product to enter a regulatory filing similar to an IND or a similar entity in a country other than the United States; this milestone was met and paid during the year ended December 31, 2016 for the CMV candidate and during the year ended December 31, 2018 for the GBM candidate. During the year ended December 31, 2020, the milestone was met and was paid during the year ended December 31, 2021 for our prophylactic coronavirus vaccine program;

- €150 when the results from pre-clinical studies are sufficient to allow a product into a clinical phase, including Phase I-II clinical studies; this milestone was met and paid during the year ended December 31, 2016 for the CMV candidate; during the year ended December 31, 2018 for the GBM candidate; and during the year ended December 31, 2021 for our prophylactic coronavirus vaccine program;

- €250 when a product enters Phase II clinical studies, an event that is defined by the enrollment of the first patient;

- €500 when a product enters Phase III clinical studies; and

- €1,000 when a product is first marketed.

UPMC is also a co-owner of the patent family covering our VBI-1501 CMV vaccine and we are currently negotiating extension of our existing license to cover this patent family.

Fees on income earned from sublicenses under the ePixis Amendment were revised as follows: 25% of any amounts received by ePixis for the sublicense if the sublicense is entered into prior to the start of Phase I clinical studies; 10% of any amounts received by ePixis if the sublicense is entered into during Phase I clinical studies and prior to the start of Phase II clinical studies; 7% of any amounts received by ePixis if the sublicense is entered into during Phase II clinical studies and prior to the start of Phase III clinical studies, and 5% of any amounts received by ePixis if the sublicense is entered into after the start of Phase III clinical studies. There was no change to the requirement that ePixis reimburse UPMC for fees and costs related to filing and maintaining the patent applications and patents.

The parties may terminate the ePixis License Agreement, as amended, by mutual agreement. There is also a cancellation right that may be exercised in the event of breach. UPMC may terminate the ePixis License Agreement if we, among other things, declare bankruptcy; do not put forth reasonable effort or are unable to develop and market the products, and, in particular, if we suspend the development of the products for more than six months; our inability to make the payments required by the ePixis License Agreement; lack of sales of a product, or lack of a signed sub-license agreement within one year from the date of acquiring AMM (Autorisation de mise sur le marché – Regulation of Therapeutic Goods) authorization, or the necessary equivalent authorization for the use of the products; and lack of sales of a product for more than two years after the initial marketing has taken place. During the year-ended December 31, 2016, VBI Cda paid UPMC €200 in milestone payments related to CMV Phase I clinical trial approval and start. During the year ended December 31, 2018, VBI Cda paid UPMC €200, in milestone payments related to the GBM Phase I/IIa clinical trial approval and start. During the year ended December 31, 2021, VBI Cda paid UPMC €200 in milestone payments related to our prophylactic coronavirus vaccine program clinical trial approval and start.

Description of Operations

We are headquartered in Cambridge, Massachusetts, with our manufacturing facility in Rehovot, Israel and our research facility in Ottawa, Ontario, Canada.

The Cambridge headquarters allows us to leverage our location in a biotechnology hub, and provides us with access to experienced consultants and executive level talent.

In Rehovot, Israel, we operate a proprietary, GMP-certified, mammalian cell-derived vaccine manufacturing facility, which we use to manufacture our 3-antigen HBV vaccine, as well as clinical study supply of VBI-2601 (BRII-179). The facility was built in December 2006 and most recently received GMP certification renewal by the IMoH on February 6, 2022. It has also received IMoH authorization to release vaccine batches to export markets. In 2013, the EU entered into an agreement with Israel regarding conformity assessment and acceptance of industrial products. This agreement recognizes Israel's industrial standards as being equivalent to EU standards. It covers products for human and veterinary use (medicinal products, active pharmaceutical ingredients and excipients) and procedures related to GMP. The agreement means that Israel and the EU recognize each other's GMP inspection conclusions, manufacturing and import authorizations and certification of conformity of batches. In 2021 our facility passed a FDA Remote Interactive Evaluation as part of the Biologics License Application ("BLA") application process whereby PreHevbrio was approved for use in the United States.

The Canadian research site benefits from its location in Canada's National Capital Region, providing us with access to world-class research facilities. VBI Cda's active research collaboration with the Canadian federal government's NRC provides its staff with on-site access to the NRC's animal facility for greater control over the testing of our pipeline candidates. NRC staff manages the general animal husbandry and maintenance requirements for VBI Cda's animal research activities.

The three sites collaborate efficiently through the use of a unified information technology infrastructure and web-based video-conferencing services.

Competitors

Our pipeline candidates face, and will continue to face, intense competition from large pharmaceutical companies, specialty pharmaceutical and biotechnology companies as well as academic and research institutions. We compete in an industry that is characterized by: rapid technological change; evolving industry standards; emerging competition; and new product introductions. Competitors have existing products and technologies that will compete with our pipeline candidates and technologies and may develop and commercialize additional products and technologies that will compete with our pipeline candidates and technologies. Because several competing companies and institutions may have greater financial resources than us, they may be able to: provide broader services and product lines; make greater investments in research and development ("R&D"); and carry-on larger R&D initiatives. Competitors may also have greater development capabilities than we do and have substantially greater experience in undertaking nonclinical and clinical testing of products, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products. They may also have greater name recognition and better access to customers.

We face general market competition from several subsectors of the vaccine development field, including: large, multinational pharmaceutical companies including Sanofi S.A. ("Sanofi"), GSK, Merck, Janssen Pharmaceutical, Inc ("Janssen"), Mitsubishi Tanabe Pharma Corporation, Takeda Pharmaceutical Company Limited and Pfizer, Inc. ("Pfizer"); large and mid-size pharmaceutical companies and emerging biotechnology companies including Dynavax, Novavax Inc., Moderna, Inc., BioNTech SE, and Hookipa Biotech AG; and academic and not-for-profit vaccine researchers and developers including the National Institutes of Health. The industry is typified by extensive collaboration, licensing, and merger and acquisition activity despite the intense competition.

In the prophylactic HBV vaccine space, we have several key competitors currently commercializing single-antigen HBV vaccines, including: GSK, the manufacturer of Engerix-B and Twinrix, Merck, the manufacturer of Recombivax HB, and Dynavax, the manufacturer of Heplisav-B.

Within the therapeutic HBV space, we face both competition from and potential collaboration with other developers of innovative HBV therapeutics designed to achieve a functional cure in combination with other therapeutics. Key large pharmaceutical companies in the space include: GSK, Janssen, Gilead Sciences, Inc, and F. Hoffmann-La Roche Ltd ("Roche"). Additionally, there are a number of mid-size companies developing alternative approaches to treat HBV, including: VIR, Arbutus Biopharma Corp, Dicerna Pharmaceuticals Inc, and Aligos Therapeutics Inc. It is not yet known which modes of action, or combinations thereof, will lead to a HBV functional cure.

Given the significant unmet medical need for GBM, there are numerous competitors seeking to develop new immunotherapies to treat GBM. Among these, Immunomic Therapeutics Inc ("Immunomic"), Immatics Biotechnologies GmBH, Stemline Therapeutics Inc., Mimivax LLC, and Inovio Pharmaceuticals Inc are developing vaccines that are also currently completing clinical studies. Immunomic's approach also targets CMV antigens associated with GBM using a dendritic cell vaccine. Additional cell-based therapies and oncolytic viruses include those under clinical study by DNAtrix Inc, Transgene SA, and Ziopharm Oncology Inc.

Within the COVID vaccine space, over one hundred vaccine candidates against SARS-CoV-2 are under development; two have obtained FDA approval, from Pfizer, Inc/BioNTech SE and Moderna, Inc.; and one additional vaccine from Janssen was granted authorization for emergency use by the FDA. Additional emergency use authorizations and approvals are anticipated in 2022 and beyond. Other key companies in the space with vaccines approved for use by the WHO and/or other regulatory agencies include, Novavax, Inc., Oxford/AstraZeneca PLC, Bharat Biotech International Limited, Medicago Inc, Sinopharm, and Sinovac Biotech Ltd. Dozens of additional companies and institutions are running clinical studies, and we expect the COVID space to evolve rapidly over the next year.

Within the CMV vaccine space, we have several key competitors, some of whom are further advanced with their CMV vaccine development. Among these, Moderna's CMV vaccine is in Phase III, and Hookipa Biotech AG CMV vaccine is in Phase II.

Suppliers and Contractors

Suppliers

We rely on a single source for our supply of vials and certain raw materials required for the manufacturing of our 3-antigen HBV vaccine. We have supply agreements with these vendors intended to assure quality and flow of materials. Alternative sources from which we can obtain our supply of these materials is under assessment. We may not be able to find alternative suppliers in a timely manner that would provide supplies of these materials at acceptable quantities and prices, if at all. Additionally, critical supplies and reagents are also required by our contractors for manufacturing and release testing of our eVLP-based pipeline candidates. Any interruption in the supply of these materials would disrupt our ability to manufacture our 3-antigen HBV vaccine and our pipeline candidates and could have a material adverse effect on our business.

Contractors

We enter into contracts in the normal course of business with contract research organizations ("CROs") for clinical trials and CDMOs for manufacturing of our eVLP vaccine candidates. We also enter into contracts in the normal course of operations with vendors for research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice.

We engage CRO's to conduct our clinical programs including the ongoing GBM Phase I/IIa clinical program and our prophylactic coronavirus vaccine program. Our reliance on these CRO's reduces our control over these activities and involves certain risks. See "Risk Factors" on [page 21] for more information regarding the risks associated with our reliance on CROs.

We engage CDMOs to manufacture our eVLP vaccine candidates and these CDMOs are dependent on sourcing raw materials from third party suppliers. Our reliance on these CDMOs reduces our control over these activities and involves certain risks. See "Risk Factors" on [page 21] for more information regarding the risks associated with our reliance on CDMOs.

We rely on a number of contractors to provide services to characterize and release our 3-antigen HBV vaccine. While alternative contractors exist for these services, we may not be able to transition to alternative contractors in a manner that does not disrupt the normal course of manufacturing operations and the supply of our 3-antigen HBV vaccine.

Our novel vaccine development efforts depend on a number of key suppliers to continue our research operations. We have identified the following parties as key suppliers of reagents, technology, or expertise which impact our development plans with our eVLP pipeline candidates:

- UPMC is the owner of the eVLP vaccine platform intellectual property portfolio to which we have an exclusive license. Under the terms of the ePixis License Agreement, as amended, we are required to pay royalties for successful products developed using the intellectual property for as long as patent claims cover the period in a given jurisdiction. This patent portfolio has claims that are expected to remain in force until 2022 in the United States, after which time we are no longer obligated to compensate UPMC for development of vaccines based on the UPMC intellectual property portfolio. After that time, the remaining patent protection of the CMV vaccine candidate will be based on patents and patent applications co-owned with UPMC which, if granted, would provide patent protection extending until 2032. We are currently negotiating an agreement with UPMC to cover the CMV patents and patent applications. There can be no assurance that any pending patent applications will be granted or, if granted, will be enforceable, and the claims in pending patent applications may be amended to reduce the scope of patent claims.

- We have collaborated with NRC on various vaccine projects since 2004 and have a long history of successful partnerships including several NRC-administered industrial research grants. The NRC developed a proprietary cell line (HEK-293-NRC) that we are using for production of our eVLP-based vaccine candidates. VBI Cda and the NRC have signed a research agreement that provides VBI Cda with access to NRC facilities and expertise for the advancement of our vaccine candidate programs. Supplementary to such research agreement, we negotiated terms for a non-exclusive license to the HEK-293-NRC cell line. Under these terms, we were required to pay success-based milestone payments until the patents on the cell line expired in November of 2018. We are collaborating with NRC to develop a coronavirus vaccine candidate. The collaboration combines our viral vaccine expertise, eVLP technology platform, and coronavirus antigens with the NRC's uniquely designed SARS-CoV-2 antigens and assay development capabilities to select the most immunogenic vaccine candidate for further development. The scope of collaboration includes certain pre-clinical evaluations, bioprocess optimization, technology transfer, and the performance of additional scale up work.

- Key Reagent Suppliers: Characterization and release assays for our eVLP-based vaccines require specialized reagents. Several key reagents including reference proteins and growth media are provided by third parties and can impact development timelines. We have secured sufficient quantities of third-party reference proteins and growth media for ongoing and planned clinical studies. Supply of these key reagents remains a risk. See "Risk Factors" on [page 21] for more information regarding the risks associated with our reliance on key reagents.

- We, through our wholly-owned subsidiaries, depend on subcontractor arrangements to facilitate the completion of our research programs. Catalent Biologics, previously Paragon Bioservices, has manufactured clinical batches of our CMV vaccine candidate and our GBM immunotherapeutic vaccine candidate pursuant to the terms of a GMP-Manufacturing Services Agreement dated September 26, 2014. Resilience Biotechnologies, previously Therapure Biopharma Inc., manufactures clinical batches of our prophylactic coronavirus vaccine program and our GBM immunotherapeutic vaccine candidate pursuant to the terms of a Master Service and Supply Agreement dated November 10, 2020. The Company continues to explore alternative sources of product supply.

Employees

As of December 31, 2021, we had a total of 149 full-time and 6 part-time employees. The manufacturing site in Israel had 98 full-time employees and 2 part-time employees and the Ottawa research site employed 37 full-time and 4 part-time employees, as of December 31, 2021. The remaining 14 full-time employees worked out of our headquarters in Cambridge, MA. None of our employees are represented by unions. Our management considers its relationship with our employees to be good.

Facilities and Offices

Our registered office is located at Suite 1700, Park Place, 666 Burrard Street, Vancouver, BC V6C 2X8 with our headquarters located at 160 Second Street, Floor 3, Cambridge, MA 02142. Our manufacturing operations are located in Rehovot, Israel and our primary research facility is located in Ottawa, Ontario, Canada, refer to "Part I – Item 2. Properties."

We rent office, manufacturing and research facility space under various operating leases, and we made rent payments of $1,463 during the fiscal year ended December 31, 2021.

We believe that our office, manufacturing and research facilities are suitable and adequate for our current operations but will consider term extensions or expansion of leased space, depending on market conditions and needs.

Research and Development

We invest heavily in R&D. R&D expenses were $19.6 million and $14.9 million for the years ended December 31, 2021 and 2020, respectively. All R&D was funded by equity financings, term loan financings, collaboration agreements, funding agreements or government grants and contributions. Our most significant R&D expenses to date have been related to the development of our 3-antigen HBV vaccine, followed by the development of our GBM vaccine immunotherapeutic candidate, our prophylactic coronavirus vaccine candidates, our CMV candidate, and the related eVLP platform. Although PreHevbrio is now approved by the FDA, our R&D expenses are expected to increase as we plan to continue to invest in and advance our lead pipeline candidates. In addition, we may bring other pipeline candidates through the clinical development stage and explore other vaccine opportunities and/or collaborations.

Intellectual Property

Patents

Our intellectual property portfolio includes 19 active patent families consisting of 198 fully owned or co-owned or exclusively licensed patents and patent applications. The highlights of our patent portfolio include:

- eVLP vaccine related intellectual property: we have an exclusive license to a patent family that protect the eVLP vaccine platform and derivatives thereof. Among these patents are rights that were originally developed at the UPMC (now Sorbonne Universite), for with which we hold a world-wide exclusive license to the base technology for the design of an eVLP.

- GBM vaccine immunotherapeutic candidate related intellectual property: we own or co-own three patent families which directly address our GBM vaccine immunotherapeutic candidate. These patents and applications include claims to compositions of matter and methods of treating GBM patients.

- CMV vaccine candidate related intellectual property: we own or co-own two patent families which directly address our CMV vaccine candidate. These patents and patent applications include a composition of matter patent describing the CMV vaccine candidate as well as a proprietary assay used to provide high-throughput screening of anti-CMV vaccine candidate responses.

- HBV Immunotherapeutic candidate related intellectual property: we own or co-own two patent families which directly address our HBV immunotherapeutic candidate. These patent applications include claims to compositions of matter and methods of treating HBV patients.

- Coronavirus vaccine candidate related intellectual property: we own or co-own two patent families which directly addresses our coronavirus vaccine candidates. These patent applications include claims to compositions of matter and methods of treating a subject at risk of COVID-19 infection.

- Lipid Particle Vaccines (“LPV”) vaccine related intellectual property: we own six patent families which protect our LPV technology platform. These patents include the method for manufacturing an LPV so as to confer thermostability, the proprietary ratios of excipients and antigens that are required to give rise to a thermostable formulation, and specific parameters required to confer thermostability to several distinct classes of vaccine antigens and biologic proteins.

We have a process of continuously monitoring the competitive landscape for infectious disease vaccines to better understand the research, business, and patent activities of our academic and industrial competitors. This process helps management to understand the competitive positioning of our pipeline. This knowledge has informed and shaped our patent portfolio, which is designed to protect our proprietary vaccine technologies and establish a defense against third-party infringement claims. Our licensed patent family relating to virus like particles (7 of which have now been issued) has a patent term that extends to 2022 in the United States and have expired in other countries in 2021. Our most recently filed patent family will have a patent term that extends to 2041.

Trade Secrets

Some of our know-how and technology is not patentable. To protect our proprietary rights in unpatentable intellectual property and trade secrets, we require employees, consultants, advisors and collaborators to enter into agreements regarding intellectual property and confidential information.

Trademarks

We use the PreHevbrio, PreHevbri, and Sci-B-Vac trademarks in connection with our 3-antigen HBV vaccine. We have registered these trademarks in 12 countries – 3 of them are still pending in the United States and 1 is still pending in the EU. The trademarks are renewable indefinitely, so long as we make the appropriate filings when required. We also have a registration for the LPV mark in Canada.

Governmental Regulation and Product Approval

Vaccine development is a highly regulated field. The manufacturing and marketing of our products and product candidates and our ongoing research and development activities are subject to extensive regulation by the FDA and comparable regulatory agencies of local, state, and foreign jurisdictions, such as Health Canada in Canada, the EMA in Europe, and the MHRA in the UK. New products must go through extensive pre-clinical and clinical development prior to product launch. This process can take more than ten years from candidate identification to licensure/marketing approval by health authorities worldwide. Despite efforts to harmonize regulatory requirements in different jurisdictions, there exists a divergence of legal and regulatory requirements in different countries and territories. Delays in regulatory approval to move from one stage of development to another can potentially cause us significant delays and can affect our market capitalization.

United States, Europe, and Canada Regulatory Agencies

Before any of our products can be marketed and sold in the United States, Europe, or Canada, they must receive approval from the relevant regulatory agencies, including the FDA, EMA, UK MHRA, and Health Canada. To receive regulatory approvals to market any drug or vaccine, including those we develop, the products in development must undergo rigorous pre-clinical testing and clinical studies that demonstrate the product's safety and effectiveness for each indicated use. This extensive regulatory path includes process controls in development, testing, manufacturing, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale, and distribution of the pharmaceutical products.

In general, before any new pharmaceutical or biological product can be marketed in the mentioned geographical areas, the process typically required by the regulatory agencies includes:

- Pre-clinical toxicology, laboratory, and animal tests;
- submission of an investigational new drug application (an "IND") in the United States, which must be reviewed by the FDA before human clinical trials may begin; submission of a Scientific Advice application to EMA in Europe; or submission of a Clinical Trial Application to Health Canada;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use;
- pre-approval inspection of manufacturing facilities and selected clinical investigator sites;
- submission of a NDA, or in the case of a biologics, a BLA, to the FDA, a MAA to the EMA, or a NDS to Health Canada; and
- FDA approval of an NDA, BLA, or a supplement (for subsequent indications or other modifications, including a change in location of the manufacturing facility), EMA approval of a MAA, or Health Canada approval of a NDS.

Pre-clinical Testing

In the United States, drug candidates are tested in animals until adequate proof of safety and efficacy is established. These pre-clinical studies generally evaluate the mechanism of action and pharmacology of the product and assess the potential safety and efficacy of the product. Tested compounds must be produced according to applicable cGMP requirements and pre-clinical safety tests must be conducted in compliance with FDA and international regulations regarding good laboratory practices. The results of the pre-clinical tests, together with manufacturing information and analytical data, are generally submitted to the FDA as part of an IND, which must become effective before human clinical trials may commence. The IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA requests an extension or raises concerns about the conduct of the clinical trials as outlined in the application. If the FDA has any concerns, the sponsor of the application and the FDA must resolve those concerns before clinical trials may begin. Regulatory authorities may require additional pre-clinical data before allowing the clinical studies to commence or proceed from one phase to another, and could demand that the studies be discontinued or suspended at any time if there are significant safety issues.

Clinical Trials

Clinical trials for new vaccine drug candidates are typically conducted in three sequential phases that may overlap. In Phase I, the initial introduction of the vaccine drug candidate into human volunteers, the emphasis is on testing for safety or adverse effects, dosage, tolerance, metabolism, distribution, excretion, and clinical pharmacology. Phase II involves studies in a limited patient population to determine the initial efficacy of the vaccine drug candidate for specific targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks. Once a vaccine compound shows evidence of effectiveness and is found to have an acceptable safety profile in Phase II evaluations, pivotal Phase III trials are undertaken to more fully evaluate clinical outcomes and to establish the overall risk/benefit profile of the drug, and to provide, if appropriate, an adequate basis for product labeling. During all clinical trials, physicians will monitor patients to determine the effectiveness of the drug candidate and to observe and report any reactions or safety risks that may result from use of the vaccine drug candidate. The FDA, the trial sites internal review board, and/or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The submission of a BLA requires payment of a substantial user fee to the FDA, and the sponsor of an approved BLA is also subject to annual product and establishment user fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances. Under applicable laws and FDA regulations, each BLA submitted for FDA approval is usually given an internal administrative review within 60 days following submission of the BLA. If deemed complete, the FDA will "file" the BLA, thereby triggering substantive review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable. The FDA has established internal substantive review goals of six months for priority BLAs (for biologics addressing serious or life-threatening conditions for which there is an unmet medical need) and ten months for regular BLAs. However, these are agency proposed time frames, and so the FDA is not legally required to complete its review within these periods, and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, is not typically an actual approval, but an "action letter" that describes additional work that must be done before the BLA can be approved. The FDA's review of a BLA may involve review and recommendations by an independent FDA advisory committee. The FDA may deny approval of a BLA or BLA supplement if the applicable regulatory criteria are not satisfied, or the FDA may require additional clinical data and/or an additional pivotal Phase III clinical study. Even if such data are submitted, the FDA may ultimately decide the BLA does not satisfy its criteria for approval.

Data Review and Approval

Substantial financial resources are necessary to fund the research, clinical trials, and related activities necessary to satisfy FDA requirements or similar requirements of state, local, and foreign regulatory agencies. It normally takes many years to satisfy these various legal and regulatory requirements, assuming they are ever satisfied. Information generated in this process is susceptible to varying interpretations that could delay, limit, or prevent regulatory approval at any stage of the process. Accordingly, the actual time and expense required to bring a product to market may vary substantially. We cannot assure you that we will submit applications for required authorizations to manufacture and/or market potential products or that any such application will be reviewed and approved by the appropriate regulatory authorities in a timely manner, if at all. Success in early-stage clinical trials does not ensure success in later stage clinical trials. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages, or have conditions placed on it that restrict the commercial applications, advertising, promotion or distribution of these products.

Once issued, the FDA may withdraw product approval if ongoing regulatory standards are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized. The FDA also has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. The FDA may also request additional clinical trials after a product is approved. These so-called Phase IV studies may be made a condition to be satisfied after a drug receives approval. The results of Phase IV studies can confirm the effectiveness of a product candidate and can provide important safety information via the FDA's voluntary adverse drug reaction reporting system. Any products manufactured or distributed by us pursuant to any FDA approvals would be subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug and biologics manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future manufacturers or suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements. If our present or future manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a product from distribution, withdraw approval of the NDA for that drug, or revoke or suspend a biologics license. Furthermore, even after regulatory approval is obtained, later discovery of previously unknown negative effects of a product may result in restrictions on the product or even its complete withdrawal from the market.

The FDA closely regulates the marketing and promotion of drugs and biologics. Approval is typically subject to post-marketing surveillance and other record keeping and reporting obligations, and involves ongoing requirements such as post-marketing annual reports and labeling updates. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and/or criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturers' communications on the subject of such off-label use.

Post-Approval Requirements

Any products for which we have received, or may, in the future, receive FDA approval are subject to continuing regulation by the FDA, including, among other things, recordkeeping requirements, reporting of adverse experiences, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label" use), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the Internet. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or a supplement, which may require the applicant to develop additional data or conduct additional pre-clinical studies and clinical trials. Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or a BLA supplement, which may require the applicant to develop additional data or conduct additional pre-clinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategies (or "REMS") to assure the safe use of the product, which may require substantial commitment of resources post-approval to ensure compliance. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the quality and long-term stability of commercial products. We expect to rely on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our CMOs that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, voluntary recall and regulatory sanctions as described below.

Once an approval or clearance of a drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Coverage, Pricing and Reimbursement

The commercial success of any biopharmaceutical products approved by the FDA depends in significant part on the availability of third-party coverage and adequate reimbursement for the products.

In the United States, third-party payors include government healthcare programs, such as Medicare and Medicaid, private health insurers, managed care plans, and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. Significant uncertainty exists regarding coverage and reimbursement for newly approved healthcare products. Coverage does not ensure adequate reimbursement. It is time-consuming and expensive to seek coverage and reimbursement from third-party payors. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication or utilize other mechanisms to manage utilization (such as requiring prior authorization for coverage for a product for use in a particular patient). Limits on coverage may impact demand for our products. Even if coverage is obtained, third-party reimbursement may not be adequate to allow us to sell our products on a competitive and profitable basis. As result, we may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

Biologics Price Competition and Innovation Act of 2009 (BPCIA)

Under the Federal Patient Protection and Affordable Care Act (the "Affordable Care Act"), enacted in 2010, and specifically, the Biologics Price Competition and Innovation Act of 2009 (BPCIA) included therein, there is an abbreviated path in the United States for regulatory approval of biosimilar versions of approved biological products. The Affordable Care Act provides a regulatory mechanism that enables FDA approval of biologic drugs that are similar to (but not exact copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may not be filed until four years after marketing approval of the innovator product. Pioneer innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA will not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA.

Fast Track Approval

The Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended, and the related FDA regulations provide certain mechanisms for the accelerated "Fast Track" approval of potential products intended to treat serious or life-threatening illnesses which have demonstrated the potential to address unmet medical needs. These procedures permit early consultation and commitment from the FDA regarding the pre-clinical and clinical studies necessary to gain marketing approval. Provisions of this regulatory framework also permit, in certain cases, BLAs to be approved on the basis of valid indirect measurements of benefit of product effectiveness, thus accelerating the normal approval process. In the future, certain potential products employing our technology might qualify for this accelerated regulatory procedure. Even if the FDA agrees that these potential products qualify for accelerated approval procedures, FDA may deny approval of our drugs or may require additional studies before approval. The FDA may also require us to perform post-approval, or Phase IV, studies as a condition of such early approval. In addition, the FDA may impose restrictions on distribution and/or promotion in connection with any accelerated approval, and may withdraw approval if post-approval studies do not confirm the intended clinical benefit or safety of the potential product.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that FDA may not approve any other applications to market the same drug for the same disease, except in very limited circumstances, for seven years. These very limited circumstances are (i) an inability to supply the drug in sufficient quantities or (ii) a situation in which a new formulation of the drug has shown superior safety or efficacy. This exclusivity, however, also could block the approval of our product for seven years if a competitor obtains earlier approval of the same drug for the same indication.

Foreign Regulation

In addition to regulations in the United States, we are and will continue to be subject to a variety of laws and regulations governing clinical trials, commercial sales, and distribution of our products in foreign countries. Whether or not we obtain FDA approval, we must separately obtain approval for clinical trials or a marketing authorization by the comparable regulatory authorities of those foreign countries before we may commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Legal and compliance landscapes, as well as the policies of the FDA and foreign regulatory authorities may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our products and could also increase the cost of regulatory compliance. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Under the applicable EU regulatory regime, we may submit marketing authorization applications (MAAs) either under a centralized or decentralized procedure (which also includes the mutual recognition procedure available for companies who already hold national licenses). The decentralized procedures provide for mutual recognition of national approval decisions. These authorizations provide marketing authorizations. The centralized procedure, which is available for medicines, inter alia, produced by biotechnology, intended to treat specific illnesses, or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all EU member states (as well as in Northern Ireland and the EEA countries of Iceland, Liechtenstein, and Norway).

The procedure for obtaining marketing authorizations in the United Kingdom has been affected by Brexit, which took place on January 31, 2020. A transitional period was in place until December 31, 2020, during which time regulation of pharmaceuticals was still governed by EU law. As of January 1, 2021, the UK MHRA has implemented new procedures for MAAs. Among these new procedures is a Great Britain marketing authorization that relies on a decision taken by the European Commission (“EC”) in respect of a marketing authorization for the same product in the centralized procedure. This route – the EC decision reliance procedure (“ECDRP”) – is currently available to all authorizations approved in the centralized procedure.

Other Government Regulation

Our research and development activities use biological and hazardous materials that may be dangerous to human health and safety or the environment. We are subject to a variety of federal, provincial, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes resulting from these materials. We are also subject to regulation by the Occupational Safety and Health Administration and federal, provincial and state environmental protection agencies and to regulation under the Toxic Substances Control Act.

In addition, in the United States, we may be subject to various federal and state laws and regulations regarding fraud and abuse in the healthcare industry, as well as industry standards and guidance, such as the codes issued by the Pharmaceutical Research and Manufacturers of America (or “PhRMA Codes”), which some states reference or incorporate in their statutes and regulations. These laws, regulations, standards, and guidance may impact, among other things, our sales and marketing activities and our relationships with healthcare providers and patients. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. These federal laws include, by way of example, the following:

- The anti-kickback statute (Section 1128B(b) of the Social Security Act) which prohibits certain business practices and relationships that might affect the provision and cost of healthcare services reimbursable under Medicare, Medicaid and other federal healthcare programs, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other governmental programs;

- The physician self-referral prohibition (Ethics in Patient Referral Act of 1989, as amended, commonly referred to as the Stark Law, Section 1877 of the Social Security Act), which prohibits referrals by physicians of Medicare or Medicaid patients to providers of a broad range of designated healthcare services in which the physicians (or their immediate family members) have ownership interests or with which they have certain other financial arrangements;

- The anti-inducement law (Section 1128A(a)(5) of the Social Security Act), which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program;

- The False Claims Act (31 U.S.C. § 3729 et seq.), which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment to the federal government (including the Medicare and Medicaid programs); and

- The Civil Monetary Penalties Law (Section 1128A of the Social Security Act), which authorizes the United States Department of Health and Human Services to impose civil penalties administratively for fraudulent or abusive acts.

These laws also impose an affirmative duty on those receiving Medicare or Medicaid funding to ensure that they do not employ or contract with persons excluded from Medicare and other government programs. Due to the breadth of some of these laws, it is possible that some of our current or future practices might be challenged under one or more of these laws. In addition, there can be no assurance that we would not be required to alter one or more of our practices to comply with these laws. Evolving interpretations of current laws or the adoption of new federal or state laws or regulations could adversely affect the arrangements we may have with sales personnel, healthcare providers, and patients. Our risk of being found in violation of these laws is increased by the fact that some of these laws are open to a variety of interpretations. If our past or present operations, practices, or activities are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, damages, fines, disgorgement, contractual remedies, reputational harm, diminished profits, and future earnings, if any, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Available Information

Our Internet website can be found at www.vbivaccines.com. The information on, or that can be accessed through, our website is not part of this report. We are subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended, and, in accordance therewith, we file periodic reports, proxy statements and other information with the SEC. You may access our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, free of charge at our website as soon as reasonably practicable after the material is electronically filed with, or furnished to, the SEC.

ITEM 1A: RISK FACTORS

We are subject to various risks that may materially harm our business, prospects, financial condition and results of operations. An investment in our common shares is speculative and involves a high degree of risk. In evaluating an investment in our common shares, you should carefully consider the risks described below, together with the other information included in this Form 10-K, including the consolidated financial statements and related notes.

The risks described below are not the only risks we face. If any of the events described in the following risk factors actually occurs, or if additional risks and uncertainties later materialize, that are not presently known to us or that we currently deem immaterial, then our business, prospects, results of operations and financial condition could be materially adversely affected. In that event, the trading price of our common shares could decline, and you may lose all or part of your investment in our shares. The risks discussed below include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements.

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common shares speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Form 10-K and our other filings with the SEC, before making an investment decision regarding our common shares.

- We have a history of operating losses, and we cannot guarantee that we can ever achieve sustained profitability;
- We will need additional financing to continue our operations. If we are unable to obtain additional financing on acceptable terms, we may have to curtail or cease our development plans and operations;
- Our success is dependent on achieving and sustaining commercial success of PreHevbrio in the U.S.;
- Our success is dependent on the successful clinical development, regulatory approval and commercialization of our pipeline candidates, which will require significant time and resources;
- We may not be able to secure sufficient supplies of materials, or the services of third parties, which we require to advance the development and commercialization of our products;
- We face intense competition and rapid technological change, which may make it more difficult to achieve significant market penetration. If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer;
- We may be unable to satisfy our contractual obligations or meet expected deadlines;
- We depend or may depend on third parties to conduct clinical trials, commercialize and/or manufacture our product candidates;
- We manufacture clinical and commercial supplies of our 3-antigen HBV vaccine and VBI-2601 at a single location. Any disruption in the operations of our manufacturing facility could adversely affect our business and results of operations;
- Our success depends on our ability to maintain the proprietary nature of our technology.

Risks Related to Development and Commercialization of Product and our Pipeline Programs

The ongoing coronavirus pandemic has caused interruptions or delays of our business plan and may have a significant adverse effect on our business.

In December 2019, a strain of coronavirus, SARS-CoV-2, was reported to have surfaced in Wuhan, China, and on March 12, 2020, the World Health Organization ("WHO") declared COVID-19, disease caused by SARS-CoV-2, to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, Canada, China, and Israel, have imposed unprecedented restrictions on travel, quarantines, and other public health safety measures. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will not be put in place again due to a resurgence in COVID-19 cases.

As a result of the COVID-19 pandemic, we continue to reduce exposure risk with fewer employees on site at both our manufacturing facility in Israel, where we manufacture our 3-antigen HBV vaccine and VBI-2601, and at our research and development laboratories in Ottawa, Canada. Our manufacturing facility in Israel and CDMOs that we engage to manufacture our eVLP vaccine candidates are dependent on sourcing raw materials from third party suppliers. The COVID-19 pandemic has impacted lead times and availability of many raw materials, which may adversely impact our ability to manufacture products in a timely manner. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business have limited our ability to support our operations.

We have four ongoing clinical studies being conducted, by us or our partners, at clinical sites worldwide: 1) the Phase II study of VBI-2601 (BRII-179) and BRII-835 (VIR-2218) at multiple study sites in Asia Pacific countries; 2) the Phase IIa/IIb study of VBI-2601 (BRII-179) at multiple study sites in Asian Pacific countries; 3) the Phase I/IIa study of VBI-1901 in the United States; and 4) the Phase Ib clinical study of VBI-2902 and VBI-2905 in Canada and Mexico. In addition to the active clinical studies, we have several planned clinical studies expected to begin in 2022, including a further clinical study with VBI-1901 in the United States, and the continued clinical evaluation of our coronavirus vaccine candidates, including VBI-2901 (VBI's multivalent pan-coronavirus vaccine candidate) in Canada and potentially other countries. The enrollment of patients at some of the clinical sites in our studies has in the past been suspended, and may again be suspended in the future due to the COVID-19 pandemic, and enrollment of patients at other clinical sites may be suspended or delayed as hospitals and clinics where we are conducting or planning to conduct clinical trials may reallocate resources and limit access to or close clinical facilities due to the COVID-19 pandemic. Additionally, if our trial participants are unable to travel to or visit our clinical study sites as a result of quarantines or other restrictions resulting from the COVID-19 pandemic, we could experience higher drop-out rates or delays in our clinical studies. Government-imposed quarantines, shelter-in-place and similar restrictions may also require us to temporarily close our clinical sites, research laboratories, or manufacturing facility. Furthermore, if we determine that our trial participants may suffer from exposure to COVID-19 as a result of their participation in our clinical trials, we may voluntarily close certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. As a result, our expected development timelines for VBI-2601 (BRII-179), VBI-1901, our coronavirus vaccine candidates, and possibly our regulatory timelines for our 3-antigen HBV vaccine, in countries other than Unites States, may be negatively impacted.

We cannot predict the ultimate impact of the COVID-19 pandemic as consequences of such an event are highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical studies, our research programs, the recoverability of our assets, and our manufacturing; however, the COVID-19 pandemic may continue to disrupt or delay our business operations, including with respect to efforts relating to potential business development transactions, and it could disrupt the marketplace which could have an adverse effect on our operations.

Moreover, the various precautionary measures taken by many governmental authorities around the world in order to limit the spread of the COVID-19 has had, and may continue to have, an adverse effect on the global markets and global economy generally, including on the availability and cost of employees, resources, materials, manufacturing and delivery efforts, and other aspects of the global economy. There have been business closures, supply chain disruptions and shipping delays, an increasingly competitive labor market in the U.S. and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19, amongst others. Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on the global economy as a whole. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to pre-COVID-19 pandemic levels. The COVID-19 pandemic could disrupt our business and operations, interrupt our sources of supply, hamper our ability to raise additional funds or sell our securities, and continue to slow down the global economy.

PreHevbrio is VBI's first commercial product in the U.S. and we may not achieve and sustain commercial success in the U.S.

We received FDA approval for PreHevbrio in the U.S. in November 2021 and expect to commercially launch the vaccine in the first quarter of 2022. Successful commercialization of PreHevbrio in the U.S. will require significant resources, time, expertise, and experience. In preparation for the FDA approval, we have been working with Syneos Health on the pre-launch strategy and activity since 2019 and expanded the relationship in 2020 to build the leadership team and field teams dedicated to VBI, incorporating full-service commercialization solutions. Syneos was selected for their robust and innovative commercialization experience and deep vaccine expertise, including successful partnerships with leading vaccine manufacturers. As part of this partnership, we have established sales, marketing, market access, and medical (field and communication) capabilities. Because this is VBI's first marketed product in the United States, despite substantial sales, marketing and market access experience in the vaccine and therapeutic fields, we may not be able to successfully commercialize PreHevbrio.

Successful commercialization of PreHevbrio will also require that we enter into contracts with third-party logistics companies, wholesales, distributors, group purchasing organizations, and other institutions and potential distribution and marketing partners, and that we successfully maintain those relationships and contracts. We may not complete, or complete in a timely manner, or maintain all of these critical contracts, which may result in us not achieving successful commercialization of PreHevbrio.

Additional factors that may affect our ability to successfully commercialize PreHevbrio include:

- Our ability and the ability of Syneos to recruit and retain employees with the right expertise and experience, at sufficient numbers;
- Our ability to access and develop relationships with key healthcare providers and public health agencies;
- Our ability to compete successfully as a new entrant in established distribution channels for vaccine products; and
- Our ability to maintain sufficient funding to cover the costs and expenses associated with building and operating an effective commercial organization.

Our pursuit of coronavirus vaccine candidates is ongoing, and we may be unable to produce a vaccine that successfully provides protection against the virus in a relevant manner, if at all.

In response to the COVID-19 pandemic, and in collaboration with the NRC, ISED, and CEPI, we have worked to advance the development of our VBI-2900 program coronavirus candidates, including VBI-2901, VBI-2902, and VBI-2905. Our development of the monovalent vaccine candidates VBI-2902 and VBI-2905 is in the early clinical stage and our development of the trivalent pan-coronavirus vaccines VBI-2901 is in the pre-clinical stage, and we may be unable to develop a vaccine that successfully and safely protects against the viruses in a timely manner, if at all. In addition, the SARS-CoV-2 virus has mutated as it has spread leading to several variants, including the Alpha, Beta, Gamma, Delta, and Omicron variants, and new variants may continue to emerge. Given the evolution of the virus and the current and potential emergence of new dominant variants, the vaccine candidates that we are developing could become irrelevant if they do not work as effectively as other vaccines against then dominant variants. Furthermore, even if we successfully develop a vaccine, we may encounter difficulties developing and scaling up manufacturing processes suitable for production of sufficient supply for our clinical trials or for commercialization in a cost-effective manner. Due to the number of COVID-19 vaccine candidates in clinical trials, we may also encounter difficulty locating clinical sites with capacity to conduct clinical trials, and therefore, we may experience delays in initiating or enrolling clinical trials of our vaccine candidate. We are also committing financial resources and personnel to the development of a coronavirus vaccine, which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of coronavirus as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective.

Given the global footprint and the widespread media attention on the COVID-19 pandemic, there are efforts by public and private entities to develop vaccines against COVID-19, including large, multinational pharmaceutical companies such as AstraZeneca, GSK, Johnson & Johnson, Moderna Inc., Pfizer, and Sanofi, with vaccine candidates that are currently approved, authorized for emergency use, or at more advanced stage of development than our coronavirus vaccine candidates. In December 2020, the FDA and other similar regulatory agencies began to issue emergency use authorizations for vaccines developed by certain of these large, multinational pharmaceutical companies, and in August 2021 and January 2022, the FDA approved the first and second coronavirus vaccines, respectively. It is possible that additional vaccines developed by such large, multinational pharmaceutical companies may receive further approvals and authorizations in the near term. Those other entities may develop COVID-19 vaccines that are more effective than any vaccine we may develop, may develop a COVID-19 vaccine that becomes the standard of care, may develop a COVID-19 vaccine at a lower cost or earlier than we are able to develop any COVID-19 vaccine, or may be more successful at commercializing a COVID-19 vaccine. Many of these other organizations are much larger than we are and have access to larger pools of capital, and as such, are able to fund and carry-on larger research and development initiatives. Such other entities may have greater development capabilities than we do and have substantially greater experience in undertaking nonclinical and clinical testing of vaccine candidates, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products. Our competitors may also have greater name recognition and better access to customers. In addition, based on the competitive landscape, additional COVID-19 vaccines or therapeutics will likely be approved to be marketed. These products could reduce the commercial opportunity for our coronavirus vaccine candidates and could have a material adverse effect on our business, financial condition, results of operations and future prospects. Moreover, if we experience delayed regulatory approvals or disputed clinical claims, we may not have a commercial or clinical advantage over competitors' products. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our vaccine development efforts or for us to ultimately commercialize and market any vaccine candidate, if approved. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to biodefense products.

We rely on government and non-government organization grants or subsidies to contribute to our coronavirus vaccine development program. If we are unable to satisfy our contractual obligations or meet expected deadlines, the development of the coronavirus vaccine candidates may be extended, delayed, modified, or terminated and we may be required to repay all or part of the grants or subsidies.

On September 16, 2020, we signed the Contribution Agreement with Her Majesty the Queen in Right of Canada, as represented by Innovation, Science and Economic Development Canada ("ISED") whereby ISED agreed to contribute up to CAD $56 million from the SIF to support the development of our coronavirus vaccine program, VBI-2900, though Phase II clinical studies (the "Project"). We agreed to complete such project, to be conducted exclusively in Canada except as permitted otherwise under certain circumstances, in or before the first quarter of 2022 ("Project Completion Date"), however discussions are underway to extend the term. In an event of default, subject to a rectification period available in certain circumstances, among other things, the Minister may (i) suspend or terminate its contribution to the Project, or (ii) require repayment of all or part of the contribution paid by the Minster, together with interest from the day of demand at the interest rate set forth in the Contribution Agreement. As a result, if we default on our obligations under the Contribution Agreement, we may not have sufficient funds available to continue the development of our coronavirus vaccine program, and we cannot be certain that we will be able to obtain additional capital to fund the program. In addition, we may be required to repay the grants made under the Contribution Agreement, which would harm our business, financial condition and results of operations.

Furthermore, in connection with execution of the Contribution Agreement, we obtained a consent of K2 HealthVentures LLC, as administrative agent for the lenders and a lender, pursuant to the Loan Agreement, dated May 22, 2020. Pursuant to such consent, certain events of default that result in contributions made under the Contribution Agreement in excess of $500 becoming due and payable could result in an event of default under the Loan Agreement.

On March 9, 2021, we signed the CEPI Funding Agreement with the CEPI whereby CEPI agreed to contribute up to $33 million to support the advancement of our eVLP vaccine candidates against SARS-CoV-2 including the advancement of VBI-2905 through Phase I clinical development. We agreed to use commercially reasonable efforts to fulfill our obligations, including achieving certain objectives and timelines within the agreed timeframe laid out in the CEPI Funding Agreement. If we are unable to achieve such objectives or timelines, or if CEPI determines that we are unable to meet our obligations under the CEPI Funding Agreement, subject to certain conditions, CEPI may choose not to provide additional tranches of funding, to provide less funding, or to terminate the CEPI Funding Agreement. If CEPI terminates the CEPI Funding Agreement, CEPI will not be required to make any further payments to us and we will be required to return any CEPI funds that are unspent, subject to certain limitations. If CEPI terminates the CEPI Funding Agreement or chooses not to provide additional tranches of funding, or to provide less funding than expected, this could have a material adverse impact on our business, results of operations, financial condition and prospects; in addition, our ability to advance VBI-2905 would require alternative funding, which could significantly slow down the product development and approval process, and jeopardize our ability to commence product sales and generate revenue.

Government involvement may limit the commercial success of our coronavirus vaccine candidates.

The coronavirus pandemic has been classified as a pandemic by public health authorities, and it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities. In particular, the Government of Canada has announced that foreign investments into Canada will be subject to enhanced review under the Investment Canada Act, particularly foreign direct investments in Canadian businesses that are related to public health or involved in the supply of critical goods and services to Canadians or to the government. If we were to develop a coronavirus vaccine, the economic value of such a vaccine to us could be affected by these measures.

Various government entities, including the U.S., Israeli, and Canadian governments, are offering incentives, grants, and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against coronavirus, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share, if any, for our coronavirus vaccine even if we succeed in developing one.

Furthermore, government grants and subsidies may limit our ability to develop and manufacture our coronavirus vaccine candidates in the most efficient way. For example, under the terms of the Contribution Agreement, we are required to conduct Phase II studies of our coronavirus vaccine program in Canada, unless permitted otherwise. As a result of such limitations, we may be unable to pursue the most efficient or profitable path in developing our coronavirus vaccine program.

If we are successful in producing a vaccine against COVID-19 or more broadly, coronaviruses, we may need to devote significant resources to its scale-up and development including for use by the Canadian or the U.S. government.

In the event that the pre-clinical and clinical trials for our coronavirus vaccine candidates are perceived to be successful, we may need to work toward the large-scale technical development, manufacturing scale-up and larger scale deployment of this potential vaccine through a variety of United States government mechanisms such as an Expanded Access Program or an Emergency Use Authorization program or Canadian government programs. In this case we may need to divert significant resources to this program, which would require diversion of resources from our other programs. In addition, since the path to licensure of any vaccine against coronavirus is accelerated, if use of the vaccine is mandated by the Canadian or the United States government, we may have a widely used vaccine in circulation in Canada, the United States or another country prior to our full validation of the overall long-term safety and efficacy profile of our vaccine platform and technology. Unexpected safety issues in these circumstances could lead to significant reputational damage for us and our technology platform going forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources. Also, under the Contribution Agreement, if we are unable to provide a sufficient Canadian-sourced supply of the COVID-19 vaccine, the Minster may require us to grant a license on commercially reasonable terms to use our intellectual property to the extent necessary to ensure such supply. This provision may inhibit us from pursuing more profitable means of manufacturing and commercializing our coronavirus vaccine candidates.

Because our product development efforts depend on new and rapidly evolving technologies, we cannot be certain that our efforts will be successful.

Our product development efforts depend on new, rapidly evolving technologies and on the marketability and profitability of our products. Commercialization of our vaccines could fail for a variety of reasons, and include the possibility that:

- Our 3-antigen HBV vaccine may not be approved for sale in the Europe or Canada;
- our coronavirus vaccine candidates may not be effective or may not be developed in a timely manner, if at all;
- our eVLP vaccine technologies, any or all of the products based on such technologies or our manufacturing process will be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances or achieve commercial viability;

- we or Brii Bio may be unable to successfully carry out the development and commercialization plans under the License Agreement, as amended;
- we may be unable to develop a scale-up method for our manufacturing protocols in a cost-effective manner;
- the products, if safe and effective, will be difficult to manufacture on a large-scale or may be uneconomical to market;
- our subcontracted third-party manufacturing facilities may fail to continue to pass regulatory inspections;
- proprietary rights of third parties will prevent us or our collaborators from exploiting technologies, and manufacturing or marketing products; and
- third-party competitors will gain greater market share due to superior products or marketing capabilities.

The EMA and similar foreign regulatory agencies may require additional information or clinical trial data for our 3-antigen HBV vaccine before granting regulatory approval, if regulatory approval is granted at all.

We submitted the MAA to the EMA in the fourth quarter of 2020 for our 3-antigen HBV vaccine. On February 25, 2022, we announced that the EMA's Committee for Medicinal Products for Human Use ("CHMP") adopted a positive opinion for VBI's 3-antigen HBV vaccine for active immunization against infection caused by all known subtypes of HBV in adults, under the name PreHevbri [Hepatitis B vaccine (recombinant, adsorbed)]. However, at this time, PreHevbri is not approved in the EU. The European Commission ("EC") will review the CHMP recommendation and a final decision on the Marketing Authorization Application ("MAA") for PreHevbri in the EU is still pending. We also filed a NDS to Health Canada in the fourth quarter of 2021 for our 3-antigen HBV vaccine candidate. Our registration and commercial timelines for such vaccine candidate depend on further discussions with the respective foreign regulatory agencies. They could have requirements and requests for additional data, beyond what is included in the submissions, or completion of additional clinical trials, including a request to increase the size of the safety data set or changes to the manufacturing process or our manufacturing facility. Any such requirements or requests could:

- adversely affect our ability to timely and successfully commercialize or market our 3-antigen HBV vaccine in Europe, Canada, and other jurisdictions where our vaccine is not currently approved;
- result in significant additional costs;
- potentially diminish any competitive advantages for our 3-antigen HBV vaccine;
- potentially limit the markets for our 3-antigen HBV vaccine;
- adversely affect our ability to enter into collaborations or receive milestone payments or royalties from potential collaborators;
- cause us to abandon the further development of our 3-antigen HBV vaccine or certain of our pipeline candidates to comply with requests by the EMA, Health Canada, or similar foreign regulatory agencies in jurisdictions where it is not currently approved; or
- limit our ability to obtain additional financing on acceptable terms, if at all.

Pre-clinical and clinical trials will be lengthy and expensive. Delays in clinical trials are common for many reasons and any such delays could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales as currently contemplated.

As part of the regulatory process, we must conduct clinical trials for each vaccine candidate to demonstrate safety and efficacy to the satisfaction of the regulatory authorities, including the FDA for the United States, the EMA for the EU, the MHRA for UK, and Health Canada for Canada. Clinical trials are subject to current Good Clinical Practice regulations ("cGCP"). cGCPs are rigorous practices that are incorporated into the FDA's clinical trial regulatory requirements and are expensive and time-consuming to design and implement. We may experience delays in clinical trials for any of our pipeline candidates, and the projected timelines for continued development of the technologies and related pipeline candidates by us may otherwise be subject to delay or suspension. Our planned clinical trials might not begin on time; may be interrupted, delayed, suspended, or terminated once commenced; might need to be redesigned; might not enroll a sufficient number of patients; or might not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the following:

- delays in obtaining regulatory approval to commence a trial;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- imposition of a clinical hold because of safety or efficacy concerns by the FDA, or other regulatory authorities, a data safety monitoring board or committee, a clinical trial site's institutional review board, or us;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required institutional review board approval at each site for clinical trial protocols;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new sites;
- delays in obtaining sufficient supplies of clinical trial materials, including comparator drugs;
- delays resulting from negative or equivocal findings of a data safety monitoring board for a trial; or
- adverse or inconclusive results from pre-clinical testing or clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the investigational drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Any of these delays in completing our clinical trials could increase costs, slow down the product development and approval process, and jeopardize our ability to commence product sales and generate revenue.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required, and we may not adequately develop such protocols to support approval.

In addition to FDA requirements and those of other regulatory authorities, an independent institutional review board or an independent ethics committee at each medical institution proposing to participate in the conduct of the clinical trial generally must review and approve the clinical trial design and patient informed consent form before commencement of the study at the respective medical institution. The institutional review boards approve the clinical trial protocols and conduct periodic reviews of the clinical trials. The clinical trial protocols describe the type of people who may participate in the clinical trial, the schedule of tests and procedures, the medications and dosages to be studied, the length of the study, the study's objectives, and other details. In general, the institutional review board will consider, among other matters, ethical factors, the safety of human subjects and the possibility of liability of the institution conducting the trial. Our pre-clinical studies may not be adequate proof of safety and efficacy, and as a result, we may not be successful in developing clinical trial protocols necessary to support institutional review board approval. Any delay or failure to obtain institutional review board approval to conduct a clinical trial at a prospective site could materially impact the costs, timing, or successful completion of a clinical trial.

We rely on CROs, third-party investigators, and independent sites to conduct our clinical trials. If these third parties do not fulfill their contractual obligations or meet expected deadlines, our planned clinical trials may be extended, delayed, modified, or terminated and we may fail to obtain the regulatory approvals necessary to commercialize our pipeline candidates.

We rely on third-party CROs to conduct our clinical trials. CROs, third-party investigators, and independent sites are subject to cGCPs that include conducting, recording, and reporting the results of clinical trials and to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces cGCPs through periodic inspections. If these CROs do not perform their obligations, comply with laws or cGCPs, or meet expected deadlines, our planned clinical trials may be extended, delayed, modified, or terminated. We rely on the processes of our CROs to ensure that accurate records are maintained to support the results of the clinical trials. While we or our CROs conduct regular monitoring of clinical sites, we are dependent on the processes and quality control efforts of our third-party contractors to ensure that detailed, quality records are maintained to support the results of the clinical trials that they are conducting on our behalf. Any extension, delay, modification, or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our products and pipeline candidates and could have a material adverse effect on our business and operations.

We rely upon independent sites and investigators, such as universities and medical institutions and their faculty or staff, to conduct our clinical trials. These sites and investigators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If these investigators or collaborators fail to devote sufficient time and resources to our product development programs, do not conduct their activities in compliance with the law, or if their performance is substandard, the approval of our regulatory submissions and our introductions of new products will be delayed or prevented.

Our potential collaborators may also have relationships with other commercial entities, some of which may compete with us. If outside collaborators assist our competitors to our detriment, the approval of our regulatory submissions will be delayed and the sales from our products, if and when commercialized, will be less than expected. Even if clinical trials are completed as planned, their results may not support expectations or intended marketing claims. The clinical trials process may fail to demonstrate that our pipeline candidates are safe and effective for indicated uses. Such failure could cause us to abandon one or more pipeline candidates and could delay development of other pipeline candidates.

Additional delays to the completion of clinical studies may result from modifications being made to the protocol during the clinical trial, if such modifications are warranted and/or required by the occurrences in the given trial.

Each modification to a protocol for a clinical trial must be submitted to the FDA or foreign regulatory authorities and the institutional review boards. This submission could result in the delay or suspension of a clinical trial while the modification is evaluated. In addition, depending on the magnitude and nature of the changes made, the FDA and other regulatory authorities could take the position that the data generated by the clinical trial prior to the protocol modification cannot be pooled with the data collected after the modification because the same protocol was not used throughout the trial. This prohibition might require the enrollment of additional subjects, which could result in the extension of the clinical trial and the FDA and other regulatory authorities delaying approval of one or more pipeline candidates.

We may be required to suspend or discontinue clinical trials because of adverse side effects or other safety risks that could preclude approval of our biologic candidates.

Our clinical trials may be suspended or terminated at any time for a number of reasons. A clinical trial may be suspended or terminated by us, our collaborators, the FDA, or other regulatory authorities because of a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, presentation of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational biologic, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or negative or equivocal findings of the data safety monitoring board or the institutional review board for a clinical trial. An institutional review board may also suspend or terminate our clinical trials for failure to protect patient safety or patient rights. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. If we elect or are forced to suspend or terminate any clinical trial of any proposed product that we develop, the commercial prospects of such proposed product will be harmed and our ability to generate product revenue from such proposed product will be delayed or eliminated. Any of these occurrences may harm our business, financial condition, results of operations, and prospects significantly.

The future results of our current or future clinical trials may not support our pipeline candidates claims or may result in the discovery of unexpected adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that the results will support our pipeline candidates claims or that the FDA or foreign regulatory authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our pipeline candidates are safe and effective for the proposed indicated uses. If the FDA or foreign regulatory authorities conclude that the clinical trials for any of our pipeline candidates for which we might seek approval have failed to demonstrate safety and effectiveness, we would not receive regulatory approval to market that product in the United States or in other jurisdictions for the indications sought. In addition, such an outcome could cause us to abandon the pipeline candidates and might delay development of others. Any delay or termination of our clinical trials will delay the filing of any product submissions with the FDA or foreign regulatory authorities and, ultimately, our ability to commercialize our pipeline candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile. Adverse clinical trial results, such as death or injury due to side effects, could jeopardize regulatory approval, and if approval is granted, such results may also lead to marketing restrictions or prohibitions. In addition, the clinical trials performed for programs other than for our 3-antigen HBV vaccine involve a relatively small patient population. Because of the small sample size, their results may not be indicative of future results.

International commercialization of our 3-antigen HBV vaccine and our pipeline candidates faces significant obstacles, including obtaining regulatory approvals. Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing or selling our products in such jurisdictions.

Our 3-antigen HBV vaccine is approved for sale in the United States under the brand name PreHevbrio and in Israel under the brand name Sci-B-Vac. In countries where we do not currently have the required approvals (including EU member states, UK, and Canada), we will need to obtain separate approvals from the relevant regulatory, pricing, and reimbursement authorities to market or sell our 3-antigen HBV vaccine or any of our pipeline candidates. Pursuing regulatory approvals will be time-consuming and expensive, and we may not obtain foreign regulatory approvals on a timely basis, if at all. The regulations vary among countries, and regulatory authorities in one market may require different or additional clinical trials than those required to obtain approval in another market, and the time required to obtain approval may differ in one market from that required to obtain approval in another market. Obtaining approval in one country does not ensure approval by regulatory authorities in other countries.

In addition, we have limited international regulatory, clinical, and commercial resources. We entered into a collaborative relationship with Brii Bio for development of a HBV recombinant protein-based immunotherapeutic in China, Hong Kong, Taiwan, and Macau, and may plan to do so with other pipeline candidates in the future, and, as such, current and future partners are critical to our international success. We may not be able to maintain current, or enter into future, collaboration agreements with appropriate partners for important foreign markets on acceptable terms, if at all. Current and future collaborations with foreign partners may not be effective or profitable.

Future legislation, or regulations and policies adopted by the FDA or other regulatory authorities, may increase the time and costs required for us to conduct and complete clinical trials for our pipeline candidates.

The FDA has established regulations, guidelines, and policies to govern the pharmaceutical and biologic development and approval processes, as have foreign regulatory authorities. We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could impact our operations and business. Any change in regulatory requirements resulting from the adoption of new legislation, regulations or policies may require us to amend existing clinical trial protocols or add new clinical trials to comply with these changes. Such amendments to existing protocols or clinical trial applications or the need for new ones, may significantly and adversely affect the cost, timing, and completion of the clinical trials for our candidates.

In addition, the FDA's policies and those of other regulatory authorities may change and additional government regulations may be issued that could prevent, limit, or delay regulatory approval of our pipeline candidates, or impose more stringent product labeling and post-marketing testing and other requirements.

Developments by competitors may establish standards of care that affect our ability to conduct our clinical trials as planned.

Changes in standards related to clinical trial design could affect our ability to design and conduct clinical trials as planned. For example, regulatory authorities may not allow us to compare one or more of our pipeline candidates to a placebo, or may require a change of standard-of-care used as a comparator in a particular clinical indication where approved products are available. In that case, both the cost and the amount of time required to conduct a clinical trial could increase.

We face product liability exposure, which, if not covered by insurance, could result in significant financial liability.

The risk of product liability is inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. Our 3-antigen HBV vaccine, currently approved for sale in the United States under the brand name PreHevbrio and in Israel under the brand name Sci-B-Vac, our pipeline candidates currently in clinical trials, and any products that we may commercially market in the future may cause, or may appear to have caused, injury or dangerous drug reactions, and expose us to product liability claims. These claims might be made by patients who use the product, their families, healthcare providers, pharmaceutical companies, our corporate collaborators, or others selling such products. If our current products or any of our pipeline candidates were to cause adverse side effects, we may be exposed to substantial liabilities.

In September 2018, two civil claims were brought in the District of Court of the central district in Israel which named our subsidiary SciVac as a defendant. In one claim, two minors, through their parents, allege, among other things: defects in certain batches of Sci-B-Vac discovered in July 2015; that Sci-B-Vac was approved for use in children and infants in Israel without sufficient evidence establishing its safety; that SciVac failed to provide accurate information about Sci-B-Vac to consumers; and, that each child suffered side effects from the vaccine. The claim was filed together with a motion seeking approval of a class action on behalf of 428,000 children vaccinated with Sci-B-Vac in Israel since April 2011 and seeking damages in a total amount of NIS 1,879.5 million ($604.3 million). The second claim is a civil action brought by two minors and their parents against SciVac and IMoH alleging, among other things, that SciVac marketed an experimental, defective, hazardous, or harmful vaccine; that Sci-B-Vac was marketed in Israel without establishing its safety; and that Sci-B-Vac was produced and marketed in Israel without approval of a western regulatory body. The claim seeks damages for past and future losses and expenses as well as punitive damages. The motion seeking approval of a class action has been suspended until a ruling is given on the question of liability in the civil action. The preliminary hearings for the trial of the civil action began on January 15, 2020, with subsequent preliminary hearings held on May 13, 2020, December 3, 2020 and September 30, 2021. The next preliminary hearing is scheduled to be held on June 9, 2022.

Regardless of the merits or eventual outcome, product liability claims or other claims related to our products or pipeline candidates may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing, or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of our pipeline candidates, if approved.

We currently maintain product liability insurance, and we generally obtain clinical trial insurance once a clinical trial is initiated. However, the insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Insurance coverage is becoming increasingly expensive, and, in the future, we, or any of our collaborators, may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or at all to protect us against losses due to liability. Even if our agreements with any current or future collaborators entitle us to indemnification against product liability losses, such indemnification may not be available or adequate should any claim arise. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the commercialization of our pipeline candidates. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to extensive, ongoing post-market regulatory requirements and review in the United States, and our products may face future development and regulatory difficulties.

With regard to our 3-antigen HBV vaccine and any other product candidates for which we obtain approval in the United States or other regions (if any), the FDA or other regulatory bodies may still impose significant restrictions on a product's indicated uses or marketing, or impose conditions for approval, or impose ongoing requirements for potentially costly post-approval studies, including Phase IV clinical trials or post-marketing surveillance. As a condition to granting marketing approval of a product, the FDA or other regulatory bodies may require us to conduct additional clinical trials. The results generated in these post-approval clinical trials could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. The Food and Drug Administration Amendments Act of 2007 gives the FDA enhanced post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information and compliance with FDA-approved REMS.

We are also subject to ongoing FDA post-market requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record keeping, and reporting of safety and other post-market information. The FDA's exercise of its authority could result in delays or increased costs during product development, clinical trials, and regulatory review, increased costs to comply with additional post-approval regulatory requirements, and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable costs. Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our pipeline candidates once approved, and potentially our other marketed products. Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of our approved products. Accordingly, new data about our products could negatively affect demand because of real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

The holder of a BLA that has been approved also is subject to obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the BLA. License holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws, including, by way of example, the Federal Trade Commission Act. Any sales and promotional activities are also potentially subject to federal and state consumer protection and unfair competition laws. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA, or such other regulatory agencies as reflected in the product's approved labeling. In particular, any labeling approved by such regulatory agencies for our pipeline candidates may also include restrictions on use. Such regulatory agencies may impose further requirements or restrictions on the distribution or use of our pipeline candidates as part of a mandatory plan, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. If we receive marketing approval for one or more of our pipeline candidates, physicians may nevertheless prescribe such products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. In particular, the United States federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Depending on the circumstances, failure to meet post-approval requirements by us or our third-party collaborators can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, FDA issuance of Form 483, untitled letters, and/or warning letters, suspension or termination of any ongoing clinical trials, or refusal to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant amounts of time and resources in response, and could generate negative publicity and significantly inhibit our ability to bring to market or continue to market our products and generate revenue.

We may seek to in-license pipeline candidates or technologies to expand our product pipeline and may not succeed.

If and when we deem it to be our strategic priority, we may seek to in-license pipeline candidates or technologies to expand our product pipeline and may not succeed. The number of such candidates and technologies is limited. Competition among large pharmaceutical companies and biopharmaceutical companies for promising pipeline candidates and technologies is intense because such companies generally desire to expand their product pipelines through in-licensing. If we fail to carry out such in-licensing and expand our product pipeline, our potential future revenues may suffer especially if our current products or pipeline candidates fail to generate material revenue.

The failure by us or our current or future manufacturers to obtain FDA or other regulatory agencies' approval for manufacturing facilities could have a material adverse impact on our business, results of operations, financial condition, and prospects.

Our manufacturing facilities and any of our current and future contract manufacturers, whether the facilities are ours or third-party manufacturer facilities, must be inspected by the FDA, after we submit a BLA and before approval, and/or by the regulators in other jurisdictions for our pipeline candidates to be manufactured for commercial production. When we are approved to market a drug product in the United States, we or our third-party manufacturers must register the manufacturing facilities with the FDA and are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA's cGMP regulations. Similar rules apply in the event we are approved to market a medicinal product in the EU. Other than for our 3-antigen HBV vaccine and VBI-2601, which are currently manufactured by us at our manufacturing site in Israel, we are completely dependent on third-party manufacturers for compliance with the requirements of United States and ex-United States regulators for the manufacture of our finished products.

If we or our third-party manufacturers cannot successfully produce material that conforms to our specifications and cGMP requirements of any applicable regulatory agency, we will not be able to secure approval for our manufacturing facilities. If the FDA or another regulatory agency does not approve these facilities for commercial production, we will need to find alternative suppliers, which would result in significant delays in obtaining required regulatory approvals. In addition, if we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, requiring new warnings or other labeling changes to limit use of the drug, requiring that we conduct additional clinical trials, imposing new monitoring requirements or requiring that we establish a REMS program. These challenges may have a material adverse impact on our business, results of operations, financial condition and prospects.

We manufacture clinical and commercial supplies of our 3-antigen HBV vaccine and VBI-2601 at a single location. Any disruption in the operations of our manufacturing facility could adversely affect our business and results of operations.

We rely on our manufacturing facility in Rehovot, Israel, for the manufacture of all clinical and commercial supplies of our 3-antigen HBV vaccine and clinical supplies of VBI-2601. Our current manufacturing facility contains highly specialized equipment and materials and utilizes complicated production processes developed over a number of years, which would be difficult, time-consuming, and costly to duplicate or, though a remote risk, may be impossible to duplicate. If our facility were damaged or destroyed, or otherwise subject to disruption, including contamination, it would require substantial lead-time to replace our manufacturing capabilities and could cause costly delays. In such event, we would be forced to identify and rely entirely on third-party contract manufacturers for an indefinite period of time, which we may not be able to do in a timely manner and would further increase our production costs. Any disruptions or delays at our facility or its failure to meet regulatory compliance would significantly impair our ability to manufacture our 3-antigen HBV vaccine for sale in the jurisdictions where it is approved for sale, for future potential clinical studies of our 3-antigen HBV vaccine, and for our ongoing and future clinical studies of VBI-2601, which would result in increased costs and losses and adversely affect our business and results of operations.

If a supplier of our raw materials and certain reagents fails to provide sufficient quantities to us, we may not be able to obtain an alternative supply on a timely or acceptable basis.

We rely on a single source for our supply of some of our raw materials and certain reagents required for the manufacture our 3-antigen HBV vaccine and VBI-2601. We do not have a written or oral agreement with these single sources of supply, as all orders are handled through individual purchase orders or on an order-by-order basis. Alternative sources from which we can obtain our supply of most of these materials exist. However, we may not be able to find alternative suppliers in a timely manner that would provide supplies of these raw materials or reagents at acceptable quantities and prices, if at all. Any interruption in the supply of these materials would disrupt our ability to manufacture our 3-antigen HBV vaccine or VBI-2601 for further development, current and future clinical trials, and commercial manufacturing, and could have a material adverse effect on our business, commercialization of our 3-antigen HBV vaccine and VBI-2601 and future profit margins, if any.

We do not manufacture any of our raw materials nor do we plan to develop any capacity to do so. Instead, we rely on multiple sources to supply our raw materials so that we can manufacture sufficient quantities of our 3-antigen HBV vaccine and VBI-2601 at our manufacturing facility in Israel and sufficient quantities of our eVLP vaccine candidates at CDMOs. The COVID-19 pandemic has impacted lead times and availability of many raw materials, which may adversely impact our ability to manufacture products in a timely manner. Some of the countries of origin of our raw materials are not the same as our drug manufacturing location. Any disruption in supply of raw materials from a qualified supplier could result in significant delays with our manufacturing, clinical trials, BLA filing, BLA approval or commercial sale of the finished product due to contract delays, the need to manufacture new raw materials, out of specification raw materials, the need for import and export permits, and the failure of the newly sourced raw materials to perform to the standards of the previously sourced raw materials. These delays could have a material adverse effect on our business and future profit margins, if any.

Supply chain and shipping disruptions may result in shipping delays, a significant increase in shipping costs, and could increase product costs and result in lost sales and reputational damage, which may have a material adverse effect on our business, operating results and financial condition.

Our third-party manufacturers and suppliers have experienced, and expect to continue to experience, supply chain disruption and shipping disruptions, including disruptions or delays in loading container cargo in ports of origin or off-loading cargo at ports of destination, as a result of the COVID-19 pandemic, congestion in port terminal facilities, labor supply and shipping container shortages, inadequate equipment and persons to load, dock and offload container vessels and for other reasons. These disruptions may impact our ability to receive our raw materials and certain components required for the manufacture of our 3-antigen HBV vaccine and VBI-2601 and our other pipeline candidates, to distribute our products in a cost-effective and timely manner and to meet demand, all of which could have an adverse effect on our financial condition and results of operations. There can be no assurance that further unforeseen events impacting the supply chain will not have a material adverse effect on us in the future. Additionally, the impacts that supply chain disruptions have on our third-party manufacturers and suppliers are not within our control. It is not currently possible to predict how long it will take for these supply chain disruptions to cease or ease. Prolonged supply chain disruption that may impact us or our manufacturers and suppliers could interrupt product manufacturing, increase raw material and product lead times, increase raw material and product costs, impact our ability to meet customer demand and result in lost sales and reputational damage, all of which could have a material adverse effect on our business, financial condition and results of operations.

We expect the healthcare industry to face increased limitations on reimbursement, rebates, and other payments as a result of continued healthcare reform changes, which could adversely affect third-party coverage of our products and how much or under what circumstances healthcare providers will prescribe or administer our products.

In both the United States and other countries, sales of our products will depend in part upon the availability of reimbursement from third-party payers, which include governmental authorities, managed care organizations and other private health insurers. Third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services.

Increasing expenditures for healthcare have been the subject of considerable public attention in the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the United States healthcare system have been introduced or proposed in Congress and in some state legislatures, including reducing reimbursement for prescription products and reducing the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products.

Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. Any reduction in reimbursement that results from federal legislation or regulation may also result in a similar reduction in payments from payers. New laws may also result in additional reductions in healthcare funding, which could have a material adverse effect on our customers, which may affect our financial operations. Legislative and regulatory proposals may expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be certain whether additional legislative changes will be enacted, or whether relevant regulations, guidance, or interpretations will be changed, or what the impact of such changes on our products may be.

Although we cannot predict the full effect on our business of the implementation of existing legislation or the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for, or restrict coverage of, our products could adversely affect how much or under what circumstances healthcare providers will prescribe or administer our products. This could materially and adversely affect our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

Governments outside the United States tend to impose strict price controls, which may adversely affect our future revenues.

In some countries, particularly countries in Europe, the pricing and/or reimbursement of vaccines and therapeutics is subject to governmental control. In Canada, the prices of patented medicines are subject to price controls. In these countries, pricing negotiations with governmental, reimbursement, and coverage authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a study that compares the cost-effectiveness of our products to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

We face intense competition and rapid technological change, which may make it more difficult to achieve significant market penetration. If we cannot compete successfully for market share against other companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our products and pipeline candidates is characterized by intense competition and rapid technological advances. For example, our 3-antigen HBV vaccine will compete in the United States and Europe with other approved HBV vaccines marketed by GSK, Dynavax, and Merck and will compete outside the United States and Europe with vaccines from GSK and Merck. If competitors' existing products or new products are more effective than or considered superior to our current or future products, the commercial opportunity for our products will be reduced or eliminated. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products or may offer comparable performance at a lower cost. We face competition from fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of our competitors have products or pipeline candidates already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, are larger than us and have substantially greater financial, technical, research, marketing, sales, distribution, and other resources. Existing and potential competitors may develop or market products that are more effective or commercially attractive than any that we are developing or marketing. Competitors may obtain regulatory approvals and introduce and commercialize products before we do. These developments could have a significant negative effect on our financial condition. Even if we are able to compete successfully, we may not be able to do so in a profitable manner.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state, provincial and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, provincial, state, and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business and financial condition.

Our products and pipeline candidates may never achieve market acceptance, even if we obtain regulatory approvals.

Even if we receive regulatory approvals for the commercial sale of our products and pipeline candidates, the commercial success of these products and pipeline candidates will depend on, among other things, their acceptance by physicians, patients, third-party payers such as health insurance companies and other members of the medical community as a prophylaxis or therapeutic and a cost-effective alternative to competing products. If our products and pipeline candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of adverse side effects;
- whether our vaccines are differentiated from other vaccines based on immunogenicity or convenience;
- availability, relative cost, and relative efficacy of alternative and competing treatments;
- the effectiveness of our marketing and distribution strategy;
- publicity concerning our products or competing products and treatments; and
- our ability to obtain sufficient third-party insurance coverage or reimbursement.

If our products or pipeline candidates do not become widely accepted by physicians, patients, third-party payers and other members of the medical community, our business, financial condition and results of operations would be materially and adversely affected.

If we are unable to manufacture our pipeline candidates and products in sufficient quantities, at sufficient yields or are unable to obtain regulatory approvals for a manufacturing facility for our vaccines, we may experience delays in product development, clinical trials, regulatory approval, commercial distribution, and the In Process Research & Development ("IPR&D") assets may become impaired and be written off at some time in the future.

Completion of our clinical trials and commercialization of our pipeline candidates and products require access to, or development of, facilities to manufacture our pipeline candidates and products at sufficient yields and at commercial-scale. We have limited experience manufacturing any of our pipeline candidates and products in the volumes that will be necessary to support large-scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency, or quality.

If we are unable to manufacture our pipeline candidates and products in clinical or commercial quantities, as the case may be, in sufficient yields, with sufficient purity, potency, quality, and identity, then we must find, qualify, and rely on third parties. Any new third-party manufacturers must also receive FDA approval and/or approval from similar regulatory agencies before we may use product manufactured by them as our commercial products and pipeline candidates. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if our third-party manufacturers give other products greater priority. Any delays experienced by third-party manufacturers, whether directly or by its raw material suppliers in relation to our project, may result in delays in clinical development of our pipeline candidates and products.

As a result, any delay or interruption, could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, the IPR&D assets may become impaired and be written off at some time in the future, which could also have a material adverse effect on the financial statements.

In light of our current resources and limited commercial experience, we have and may need to continue to establish third-party relationships to successfully commercialize our pipeline candidates.

The near and long-term commercial viability of our products and pipeline candidates may depend, in part, on our ability to successfully execute current strategic collaborations and establish new strategic collaborations with contract commercial organizations, pharmaceutical and biotechnology companies, non-profit organizations, and government agencies. Establishing and maintaining strategic collaborations and obtaining government funding is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position or based on their internal pipeline or available resources; government agencies may reject contract or grant applications based on their assessment of public need, the public interest, the ability of our products to address these areas, or other reasons beyond our expectations or control. If we fail to establish or maintain collaborations or government relationships necessary for successful commercialization on acceptable terms, we may not be able to commercialize our pipeline candidates or generate sufficient revenue to fund further research and development efforts.

New or existing collaborations, including our collaborations with Syneos Health and with Brii Bio, and/or government funding may never result in the successful development or commercialization of any pipeline candidates for several reasons, including the fact that:

- we may not have the ability to control the activities of our partners and cannot provide assurance that they will fulfill their obligations to us, including with respect to the license, development, and commercialization of pipeline candidates, in a timely manner or at all;
- such partners may not devote sufficient resources to the commercialization or clinical development of our pipeline programs or properly maintain or defend our intellectual property rights (if required);
- relationships with our collaborators could also be subject to certain fraud and abuse laws if not structured properly to comply with such laws;
- any failure on the part of our partners to perform or satisfy their obligations to us could lead to delays in the development or commercialization of our pipeline candidates and affect our ability to realize product revenue; and
- disagreements, including disputes over the ownership of technology developed with such collaborators, could result in litigation, which would be time-consuming and expensive, and may delay or terminate research and development efforts, regulatory approvals, and commercialization activities.

If we or our collaborators fail to maintain our existing agreements or if we fail to establish agreements as necessary, we could be required to undertake research, development, manufacturing, and commercialization activities solely at our own expense. These activities would significantly increase our capital requirements and, given our lack of sales, marketing and distribution capabilities, significantly delay the commercialization of our pipeline candidates.

Our marketing, promotional, and business practices, including those that occur prior to the FDA's or another regulatory authority's approval of a product or pipeline candidate, are subject to extensive regulation and any material failure to comply could result in significant sanctions against us.

The marketing, promotional, and business practices of pharmaceutical and biologics companies are subject to extensive regulation, the enforcement of which may result in the imposition of civil and/or criminal penalties, injunctions, and/or limitations on marketing practices for some of our products.

There is no official FDA definition of "promotion," but FDA regulations, guidance documents, and enforcement actions make clear that the FDA takes a broad view of the term. Promotional materials include any written, oral, graphic, or broadcast material made and distributed to consumers by a company or its agents with the intent to proactively communicate certain attributes (e.g., use/indication, safety, effectiveness, etc.) of a given drug or biologic product. Examples include presentations, posters, brochures, notes, e-mail messages (external), blog postings, corporate websites, social media posts, videos, oral representations made by company representatives, product samples, reprints of scientific, and medical articles, among others. To be lawful, promotions, at a minimum, must:

- be consistent with, and not contrary to, labeling;
- present "fair balance" between risks and benefits;
- be truthful and not false or misleading;
- be adequately substantiated (when required); and
- include adequate directions for use.

Aside from off-label promotion, a lack of fair balance between risk information and benefit information has become the highest enforcement priority for the FDA in this context. We may also be subject to enforcement action in connection with any promotion of an investigational product. Under the Food, Drug, and Cosmetic Act, a sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the product candidate. The most common factors that trigger FDA enforcement actions for unauthorized promotion of an investigational drug include:

- Absence of clear and prominent statement on investigational status;
- Use of trade name pre-approval (without adequate clarification as to status);
- Lack of separation between information on investigational and approved products;
- Characterizations and descriptions of a promotional nature that are phrased as established facts (e.g., "long actions," "tamper-resistant," "next generation"); and
- Presentation of information in a manner that visually suggests it is an approved product (e.g., under a heading titled "Products").

Any enforcement action or lawsuit brought against us in connection with alleged violations of applicable promotion requirements, or prohibitions, could harm our business and our reputation, as well as the reputation of any then approved products we may promote or commercialize.

We may be subject to additional risks due to the involvement of third-party drugs, devices, or other products in clinical studies evaluating the safety and/or efficacy of our pipeline candidates and/or in connection with the commercial use of any such candidates approved by the FDA for marketing in the United States in the future.

One or more existing FDA-approved therapies may be involved in the clinical testing of a given product candidate, as such product candidate may be tested in combination with a therapy developed by another company or administered using a third-party medical device.

For example, our cancer vaccine immunotherapeutic candidate, VBI-1901, is in a two-arm Phase I/IIa clinical study where it is administered in combination with two separate adjuvants via intradermal injection. Accordingly, our clinical studies for VBI-1901, and any other study involving a third-party product, may subject us to additional risks that we may not otherwise face in connection with studies conducted without third-party products.

Among other potential risks, a third-party product we utilize could be defective, removed from the market, or otherwise rendered unavailable for the applicable use. Additionally, the safety and/or efficacy of such products may be called into question for reasons beyond our control, including, but not limited to, serious adverse events associated with the product; regulatory enforcement action against the product's manufacturer, developer, or other responsible party, as applicable; or any other circumstance or finding that negatively impacts the perceived utility or reliability of the product. The occurrence of any such events in connection with a third-party drug, device, or other product used in our clinical studies could cause the FDA and/or industry to question the validity of our clinical trial data or improperly attribute safety or efficacy issues to our pipeline candidates, either of which could have a material adverse effect on our ability to successfully develop and commercialize such candidates. We cannot predict the ultimate impact that any third-party product used in our clinical studies may have on our business, as such is dependent upon a number of factors outside of our reasonable control.

Risks Related to Our Capital Requirements and Financings

We will need additional financing to continue our operations. If we are unable to obtain additional financing on acceptable terms, we may have to curtail or cease our development plans and operations.

Our revenue generating activities include product sales and research and development services pursuant to fee for service agreements, collaboration agreements, and certain governmental research and development grants. However, our revenues have not been significant to date. Our long-term success and ability to continue as a going concern is dependent upon obtaining sufficient capital to fund the research and development of our products, to bring about their successful commercial release, if approved, to generate revenue, and, ultimately, to attain profitable operations or alternatively advance the products and technology to such a point that an acquirer would find attractive. We face substantial demand on our cash resources to fund operations and our growth plans in the future.

To date, we have been able to obtain financing; however, there is no assurance that financing will be available in the future, or if it is, that it will be available at terms acceptable to us. Additional financings may be effected through debt financing and/or the issuance of equity securities, there being no assurance that any type of financing on terms acceptable to us will be available or otherwise occur. Debt financing must be repaid regardless of whether we generate revenues or cash flows from operations and may be secured by substantially all of our assets. Any equity financing or debt financing that requires the issuance of equity securities or securities convertible into equity securities would cause the percentage ownership of our shareholders to be diluted, which dilution may be substantial. Also, any additional equity securities issued may have rights, preferences, or privileges senior to those of existing shareholders. Furthermore, if we issue additional securities, whether equity or debt, or if investors believe we may issue additional securities, the market price of our common shares could decline. If such financing is not available when required or is not available on acceptable terms, we may be required to reduce or eliminate certain pipeline candidates and development activities, and it may ultimately require us to suspend or cease operations, which could cause investors to lose the entire amount of their investment.

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We have incurred significant net losses and negative operating cash flows since inception. We incurred net losses of approximately $69.8 million and $46.2 million in 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $378.4 million. Our income generating activities have been from sales of Sci-B-Vac in Israeli markets that have generated a limited number of sales to-date, fees from research and development services, and revenue from partnership collaborations. We expect to incur significant operating losses for the next several years as we support the commercialization activities of our 3-antigen HBV vaccine and foreign regulatory agency submissions, expand our research and development, advance other pipeline candidates into and through clinical development, including our immunotherapeutic HBV candidate, GBM vaccine immunotherapeutic candidate, prophylactic coronavirus vaccine program candidates, and CMV candidate, complete clinical trials and seek regulatory approval. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, as well as those related to our expectations for the License Agreement, we are unable to predict the extent of any future losses or guarantee when, or if, our company will become profitable or cash flow positive. If we never achieve profitability or positive cash flows, or achieve either later than we anticipate, you may lose some or all of your investment in us.

Our financial statements have been prepared on a going concern basis; we must raise additional capital to fund our operations in order to continue as a going concern.

In its report dated March 7, 2022, EisnerAmper LLP, our independent registered public accounting firm, expressed substantial doubt about our ability to continue as a going concern as we have suffered recurring losses from operations and have insufficient liquidity to fund our future operations. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge out liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment. As of December 31, 2021, we had $121.7 million of cash. In order to have sufficient cash to fund our operations in the future, we will need to raise additional equity or debt capital and cannot provide any assurance that we will be successful in doing so.

Risks Related to Our Business

Adverse effects resulting from vaccines or immunotherapies or therapies could also negatively affect the perceptions by members of the health care community, including physicians, about the safety and effectiveness of our products and pipeline candidates.

There are many other companies that have developed or are currently trying to develop vaccines or immuno-oncology products for the treatment or prevention of diseases that overlap with our products and pipeline candidates. If adverse effects were to result from vaccines or immunotherapy drugs or therapies being developed, manufactured and marketed by others that overlap with our products and pipeline candidates, it could be attributed to our products or pipeline candidates or immunotherapy protocols as a whole. In fact, in the past biologics have been associated with certain safety risks and other companies developing biologics have had patients in trials suffer from serious adverse events, including death. Any such attribution could negatively affect the perceptions by members of the health care community, including physicians, about the safety and effectiveness of our products or pipeline candidates. Our industry is susceptible to rapid technological changes and there can be no assurance that we will be able to overcome any new technological challenges presented by the adverse effects resulting from vaccines or immunotherapy drugs or therapies developed, manufactured or marketed by others.

We have international operations, which subject us to risks inherent with operations outside of Canada.

We have international operations and we may seek to obtain market approvals in foreign markets that we deem to generate significant opportunities. However, even with the cooperation of a commercialization partner, conducting drug development in foreign countries involves inherent risks, including, but not limited to: difficulties in staffing, funding, and managing foreign operations; different and unexpected changes in regulatory requirements; export restrictions; tariffs and other trade barriers; different reimbursement systems; economic weaknesses or political instability in particular foreign economies and markets; compliance with tax, employment, immigration, and labor laws for employees living or travelling abroad; supply chain and raw materials management; difficulties in protecting, acquiring, enforcing, and litigating intellectual property rights; fluctuations in currency exchange rates; and potentially adverse tax consequences.

If we were to experience any of the difficulties listed above, or any other difficulties, our international development activities and our overall financial condition may suffer and cause us to reduce or discontinue our international development and market approval efforts.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to:

- comply with FDA regulations or similar regulations of comparable foreign regulatory authorities;
- provide accurate information to the FDA or comparable foreign regulatory authorities;
- comply with manufacturing standards that we have established;
- comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;
- properly protect patient information which is subject to federal and state privacy and security laws or similar laws in foreign countries;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions that we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We may be subject to federal, provincial and state healthcare laws, regulations, and policies in connection with our current and/or future activities and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

Since we have obtained FDA approval to commercialize PreHevbrio, our operations are directly, or indirectly, through our relationships with healthcare providers, customers, and third-party payors, subject to various federal and state fraud and abuse laws, including, without limitation the following:

- the federal anti-kickback statute (and state equivalents), which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or the purchase, order or recommendation of, any item or service that is reimbursable, in whole or in part, by a federal healthcare program such as the Medicare and Medicaid programs;

- the federal physician self-referral law, commonly known as the "Stark Law" (and state equivalents), which prohibits a physician from making a referral for certain designated health services covered by the Medicare program if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;

- the federal False Claims Act and related laws (and state equivalents) that prohibit and impose liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;

- the so-called qui tam provisions of the federal and state False Claims Act, which permit whistleblowers to sue in the name of the federal or state governments' healthcare providers and others for alleged violations of those laws and which permit whistleblowers to obtain a reward for bringing the case. These qui tam cases have been on the rise in recent years;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal transparency requirements under the Affordable Care Act, including the provisions commonly referred to as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

- the Prescription Drug Marketing Act, as amended, which governs the distribution of prescription drug samples to healthcare practitioners;

- the fraud and abuse provisions of the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations (collectively "HIPAA"), which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, and amendments made in 2013 to HIPAA under the Health Information Technology for Economic and Clinical Health Act, which strengthens and expands HIPAA privacy and security compliance requirements, increases penalties for violators, extends enforcement authority to state attorneys general, and imposes requirements for breach notification;

- analogous state laws and regulations, including (among others) state anti-kickback, self-referral, and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the United States federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information and that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and

- state and local law equivalents of HIPAA related to the privacy and security of patient information in certain circumstances, which are typically not preempted by HIPAA and may apply more broadly, and/or contain different, potentially more stringent, restrictions and obligations, than HIPAA thus complicating compliance efforts.

Further, the Affordable Care Act, among other things, amended the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can be found guilty of fraud or false claims under the Affordable Care Act without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. Possible sanctions for violation of the applicable fraud-and-abuse laws may include monetary fines, civil, and criminal penalties, exclusion from Medicare, Medicaid, and other government programs, forfeiture of amounts collected in violation of such prohibitions, individual imprisonment, additional reporting obligations, and oversight (if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws), and the curtailment or restructuring of our operations. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against such claims, could result in a material adverse effect on our reputation, business, results of operations, and financial condition. In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and teaching hospitals for marketing, medical directorships, and other purposes. Some states impose a legal obligation on companies to adhere to voluntary industry codes of behavior (e.g., the PhRMA Code and the AdvaMed Code of Ethics), which apply to pharmaceutical and medical device companies' interactions with healthcare providers; some mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians, and some states limit or prohibit such gifts.

Most recently, there has been a trend in federal and state legislation aimed at requiring pharmaceutical companies to disclose information about their production and marketing costs, and ultimately lowering costs for drug products. Several states have passed or introduced bills that would require disclosure of certain pricing information for prescription drugs that have no threshold amount or are above a certain annual wholesale acquisition cost. In June 2016, Vermont became the first state to pass legislation requiring certain drug companies to disclose information relating to justification of certain price increases and various others have since-followed. The United States Congress has also introduced bills targeting prescription drug price transparency, and two such bills—the Patient Right to Know Drug Prices Act (for private plans) and the Know the Lowest Price Act (for Medicare Parts C and D)—were signed into law on October 10, 2018. These laws and any other such implementation of legislation requiring publication of drug costs could materially and adversely impact our business, financial condition and results of operations by promoting a reduction in drug prices.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. We are not able to predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any state or federal regulatory review of the Company, regardless of the outcome, would be costly and time-consuming.

Our business, and our current and future activities, product candidates, or any future approved products, if any, may also be subject to equivalent healthcare-related laws and regulations of any or all of the other countries, provinces, or other applicable jurisdictions in which we currently operate or may operate in the future. There can be no assurance that the potential compliance obligations of any such foreign laws, and any corresponding consequences of noncompliance, will be similar to those of United States fraud and abuse laws.

Healthcare legislative reform measures or other changes may have a material adverse effect on our business and results of operations.

In the United States, there have been a number of legislative and regulatory initiatives focused on containing the cost of healthcare. The Affordable Care Act, for example, substantially changed the way healthcare is financed by both governmental and private insurers. The Affordable Care Act contains a number of provisions that could impact our business and operations, primarily, once we obtain FDA approval to commercialize one of our product candidates in the United States, if ever, and may also affect our operations in ways we cannot currently predict. ACA provisions that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under health insurance exchanges, expansion of the 340B program, expansion of state Medicaid programs, and fraud and abuse enforcement. Such changes may impact existing government healthcare programs, industry competition, formulary composition, and may result in the development of new programs, including Medicare payment for performance initiatives, health technology assessments, and improvements to the physician quality reporting system and feedback program.

During his time in office, former President Trump supported the repeal of all or portions of the Affordable Care Act. However, the Trump administration's relevant repeal and/or reform efforts were met with substantial opposition from various federal and state legislators and agencies and other industry stakeholders, which has contributed to the current state of uncertainty as to the validity and application of healthcare reform measures initiated thus far, the fate of the Affordable Care Act, and the current and future implications for applicable participants within the United States healthcare industry, including providers, patients, manufacturers, developers, and other relevant individuals and institutions.

In January 2017, Congress passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the Affordable Care Act and permits such legislation to pass with a majority vote in the Senate. President Trump also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Affordable Care Act and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the Affordable Care Act to the maximum extent permitted by law.

Additionally, the Tax Cuts and Jobs Act of 2017 eliminated the Affordable Care Act provision requiring individuals to purchase and maintain health coverage, or the "individual mandate," by reducing the associated penalty to zero, beginning in 2019. In December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the Affordable Care Act is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the Affordable Care Act. Substantial uncertainty remains as to the future of the Affordable Care Act after the United States Supreme Court declined to expedite its review of the Fifth Circuit's holding on January 21, 2020. Accordingly, these issues were not resolved before the election of President Biden in November 2020. There is no way to predict whether, and to what extent, if any, the Affordable Care Act will remain in-effect in the future, and it is unclear how these decisions, subsequent appeals, or other efforts to repeal and replace the Affordable Care Act will impact the United States healthcare industry or our business.

Furthermore, we cannot predict what actions the Biden administration will implement in connection with the Affordable Care Act. The adoption or implementation of new or amended legislation at the federal or state level could affect our ability to obtain regulatory approval for any of our vaccine candidates and the commercial viability of our future approved products, if any. We cannot predict the ultimate nature, timing, or effect of any changes to the Affordable Care Act or other federal and state reform efforts, and there is no assurance that such efforts will not adversely affect our future business and financial results.

Our internal computer systems, or those of our third-party vendors, collaborators, or other contractors may be subject to various federal and state confidentiality and privacy laws in the United States and abroad and could sustain system failures, security breaches, or other disruptions, any of which could have a material adverse effect on our business.

Numerous international, national, federal, provincial and state laws, including state privacy laws (such as the California Consumer Privacy Act, or "CCPA"), state security breach notification and information security laws, and federal and state consumer protection laws govern the collection, use, and disclosure of personal information. In addition, most healthcare providers who may, in future, prescribe and dispense our products in the United States and research institutions in the United States with whom we collaborate for our sponsored clinical trials are "covered entities" subject to privacy and security requirements under Health Care Insurance and Accountability Act of 1996 ("HIPAA"). Among other things, the Health Information Technology for Economic and Clinical Health Act ("HITECH") makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Certain of our clinical sites or collaborators could be subject to a wide range of penalties and sanctions under HIPAA, including criminal penalties if they knowingly obtain or disclose individually identifiable health information maintained by a covered entity in a manner that is not authorized or permitted by HIPAA. Failure to comply with current and future privacy laws and regulations could result in governmental enforcement actions (including the imposition of significant penalties), criminal and civil liability, and/or adverse publicity that negatively affects our business.

Moreover, we rely on our internal and third-party provided information technology systems and applications to support our operations and to maintain and process company information including personal information, confidential business information and proprietary information. Furthermore, we generate intellectual property that is central to the future success of the business and transmit certain amounts of confidential information. Additionally, we collect, store and transmit confidential information of collaborators, employees or other third-party contractors. We have experienced in the past, and may experience in the future, cybersecurity incidents, threats, and intrusions. Incidents, threats, and intrusions may require remediation to protect sensitive information, including our intellectual property and personal information, and our overall business. The continually changing threat landscape of cybersecurity today makes our systems potentially vulnerable to service interruptions, system errors or to security breaches from inadvertent or intentional actions by our employees, partners, and vendors, and from attacks by malicious third parties, including supply chain attacks originating at our third-party partners. Such attacks are of ever-increasing levels of sophistication. Attacks may be made by individuals or groups that have varying levels of expertise, some of which are technologically advanced and well-funded including, without limitation, nation states, organized criminal groups, and hacktivists organizations. A breach of cybersecurity, a disruption in availability, or the unauthorized alteration of systems or data could adversely affect our business, results of operations and financial condition, or lead to the loss, theft, destruction, corruption, or compromise of our information or that of our collaborators, or third-party contractors, as applicable.

While we have invested in cybersecurity and have implemented processes and procedural controls to maintain the confidentiality and integrity of such information, there can be no guarantee that our efforts will prevent all service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, and reputational harm to our business, including legal claims and proceedings, liability under laws that protect the privacy of personal information, government enforcement actions, and regulatory penalties, as well as remediation costs. While we seek to protect our information technology systems from these types of incidents, the healthcare sector continues to see a high frequency of cyberattacks and increasingly sophisticated threat actors, and our systems and the information maintained within those systems remain potentially vulnerable to data security incidents. Moreover, losses from such events may not be completely covered by insurance coverage (or may not be covered at all by any of our insurance policies depending on the circumstances). Furthermore, this insurance may not be sufficient to cover the financial, legal, or reputational losses that may result from an interruption or breach of our systems.

Any of the above-described cyber or other security-related incidents may trigger notification obligations to affected individuals and government agencies, legal claims or proceedings, and liability under foreign, federal, provincial, and state laws that protect the privacy and security of personal information. Our proprietary and confidential information may also be accessed. Any one of these events could cause our business to be materially harmed and our results of operations may be adversely impacted. Finally, as cyber threats continue to evolve, and privacy and cybersecurity laws and regulations continue to develop, we may need to invest additional resources to implement new compliance measures, strengthen our information security posture, or respond to cyber threats and incidents.

We may expand our business through the acquisition of rights to new pipeline candidates that could disrupt our business and harm our financial condition.

We may expand our product offerings, and we may seek acquisitions of pipeline candidates or technologies to do so. We may also seek to expand our business through the acquisition of businesses or companies having rights to new pipeline candidates. Acquisitions involve numerous risks, including substantial cash expenditures; potentially dilutive issuances of equity securities; incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of the acquisition; difficulties in assimilating the acquired technologies or the operations of the acquired companies; diversion of management's attention away from other business concerns; risks of entering markets in which we have limited or no direct experience; and the potential loss of key employees or key employees of the acquired companies.

There can be no assurance that any acquisition by us will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired product, company or business. In addition, future success of the combined company will depend in part on our ability to manage the rapid growth associated with some of these acquisitions. There can be no assurance that we will be able to make the combination of our business with that of any acquired products, businesses, or companies work or be successful. Furthermore, the development or expansion of our business or any acquired products, businesses, or companies may require a substantial capital investment by us. We may not have these necessary funds, or such funds might not be available on acceptable terms or at all. We may also seek to raise funds by selling capital stock or instruments convertible into or exercisable for capital stock, which could dilute each shareholder's ownership interest.

Under current United States, Canadian, and Israeli law, we may not be able to enforce covenants not to compete or to prevent the breach of confidentiality agreements, and therefore, may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

We generally enter into non-competition agreements with our employees and certain key consultants. These agreements prohibit our employees and certain key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. However, under current United States, Canadian, and Israeli law, we may be unable to enforce these agreements, in whole or in part, and therefore, we cannot be sure that these employees and key consultants will not compete with us. For example, in the past, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we are unable to demonstrate that harm would be caused to us or otherwise enforce these non-competition agreements, in whole or in part, we may be unable to prevent our competitors from benefitting from the expertise our former employees or consultants developed while working for us and our ability to remain competitive may be diminished.

We rely on confidential information that we seek to protect through confidentiality agreements with our employees and other parties. If these agreements are breached, competitors may obtain and use our confidential information to gain a competitive advantage over us or could substantially delay product development or harm our commercialization activities. We may not have any remedies against our competitors and any remedies that may be available to us may not be adequate to protect our business or compensate us for the damaging disclosure. In addition, we may have to expend resources to protect our interests from possible infringement by others, which may divert our available funds away from our business activities.

Global, market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over inflation, geopolitical issues, the U.S. financial markets, foreign exchange rates, capital and exchange controls, unstable global credit markets and financial conditions and the COVID-19 pandemic, have led to periods of significant economic instability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, and increased unemployment rates. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. In addition, there is a risk that one or more of our current or future service providers, manufacturers, suppliers, our third-party payors, and other partners could be negatively affected by difficult economic times, which could adversely affect our ability to attain our operating goals on schedule and on budget or meet our business and financial objectives.

In addition, we face several risks associated with international business and are subject to global events beyond our control, including war, public health crises, such as pandemics and epidemics, trade disputes, economic sanctions, trade wars and their collateral impacts and other international events. Any of these changes could have a material adverse effect on our reputation, business, financial condition or results of operations. There may be changes to our business if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. In February 2022, armed conflict escalated between Russia and Ukraine. The sanctions announced by the U.S. and other countries, following Russia's invasion of Ukraine against Russia to date include restrictions on selling or importing goods, services or technology in or from affected regions and travel bans and asset freezes impacting connected individuals and political, military, business and financial organizations in Russia. The U.S. and other countries could impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, currency exchange rates and financial markets, all of which could impact our business, financial condition and results of operations.

We have significant operations located in Israel and, therefore, our results may be adversely affected by political, economic, and military instability in Israel.

Our subsidiary's operations are located in Rehovot, Israel. Accordingly, political, economic, and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our business and results of operations.

Any armed conflicts, terrorist activities, or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

Since the Gaza Strip's 2007 coup, by which the terrorist organization Hamas seized control, there have been a number of armed conflicts between Hamas and Israel – in December-January 2008-9, November 2012, July-August 2014 and as recently as May 2021 – in all of which conflicts, rockets were fired from Gaza into Israeli civilian population centers. During the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party backed by Iran and controlling large swathes of Lebanon. These conflicts involved missile strikes against civilian targets in various parts of Israel, including areas in which our Rehovot facilities, employees and some of our consultants are located, and negatively affected business conditions in Israel. Civil unrest and political turbulence have occurred in other countries in the region, including Syria which shares a common border with Israel, and is affecting the political stability of those countries. Since April 2011, a civil war that has been ongoing in Syria has escalated, and evidence indicates that chemical weapons have been used in the region. This instability and any intervention may lead to additional conflicts in the region. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran also has a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, and both the Allawite regime and various rebel militia groups in Syria. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts, terrorist activities, or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital.

Commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government is currently committed to covering the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions generally and could harm our results of operations.

Political relations could limit our ability to sell or buy internationally.

We could be adversely affected by the interruption or reduction of trade between Israel and its trading partners. To date, the State of Israel and Israeli companies have been repeatedly subjected to economic boycotts. Several countries, companies and organizations continue to participate in a boycott of Israeli firms and others doing business with Israel or with Israeli companies. Also, over the past several years there have been calls in Europe and elsewhere to reduce trade with Israel. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

The operations of our subsidiary in Israel may be disrupted as a result of the obligation of Israeli citizens to perform military service.

Many Israeli citizens are obligated to perform several days, and in some cases more, of annual military reserve duty until they reach the age of 40 (or older, for reservists who are officers or who have certain special training) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity and recent armed conflicts, there have been periods of significant call-ups of military reservists. It is possible that there will be military reserve duty call-ups in the future. The operations of our subsidiary in Israel could be disrupted by such call-ups, which may include the call-up of our employees or the employees of our Israeli business partners. Such disruption could materially adversely affect our business, financial condition and results of operations.

Exchange rate fluctuations between the United States dollar, Canadian dollar and the New Israeli Shekel currencies may negatively affect our earnings cash flows.

Our functional currency is the United States dollar. We incur expenses in New Israeli Shekel, which we refer to as NIS, Canadian Dollars and United States dollars. As a result, we are exposed to the risks that the United States dollar may devalue relative to the Canadian Dollar or NIS, or, if the United States dollar appreciates relative to the Canadian Dollar or NIS, that the inflation rate in the United States may exceed such rate of devaluation of the United States dollar, or that the timing of such devaluation may lag behind inflation in the United States. The average exchange rate for the year ended December 31, 2021, was US$1.00 = NIS 3.229 and US$1.00 = CAD $1.2536. We cannot predict any future trends in the rate of inflation in the United States or the rate of devaluation, if any, of the United States dollar against the Canadian Dollar or NIS.

Risks Related to Our Intellectual Property

Our success depends on our ability to maintain the proprietary nature of our technology. We may become subject to third parties' claims alleging infringement of patents and proprietary rights or seeking to invalidate our patents or proprietary rights, which would be costly, time-consuming, and, if successfully asserted against us, delay or prevent the development of our current or future pipeline candidates or commercialization of our products.

Our success in large part depends on our ability to maintain the proprietary nature of our technology. To do so, we must, at significant cost, prosecute patent applications and maintain existing patents, obtain new patents, and pursue trade secret and other intellectual property protection. We also must operate without infringing the proprietary rights of third parties or allowing third parties to infringe our rights. We currently have rights to over 190 fully owned, co-owned, or exclusively licensed patents and patent applications. However, patent issues relating to pharmaceuticals and biologics involve complex legal, scientific, and factual questions.

To date, no consistent policy has emerged regarding the breadth of biotechnology patent claims that are granted by the United States Patent and Trademark Office or enforced by the federal courts. Therefore, we do not know whether our patent applications will result in the issuance of patents, or that any patents issued to us will provide us with any competitive advantage. We also cannot be sure that we will develop additional proprietary products that are patentable. Furthermore, there is a risk that others will independently develop similar technology or products or circumvent the patents issued to us.

Even if we are issued patents for our technologies, there is always a risk that third parties will initiate post grant review or inter parties review proceedings to challenge the validity of one or more of our patents. These proceedings can result in the loss of patent claims. Even if we are successful in defending our patents during post grant review or inter parties review proceedings, these procedures are time consuming and expensive and may have a negative impact on our results.

There is also a risk that third parties may challenge our existing patents in court or claim that we are infringing their patents or proprietary rights. We cannot assure you that the manufacture, use, sale, offer for sale, or importation of any of our products or current or future pipeline candidates will not infringe existing or future patents. Because we have not conducted a formal freedom to operate analysis for patents related to our products or pipeline candidates, we may not be aware of patents that have already been issued that a third-party might assert are infringed by one of our products or current or future pipeline candidates. Because patent applications can take many years to issue and may be confidential for eighteen months or more after filing, there also may be applications now pending of which we are unaware and which may later result in issued patents that we may infringe by commercializing any of our products or current or future pipeline candidates. We could incur substantial costs in defending patent infringement suits or in filing suits against others to have their patents declared invalid or to claim infringement of our patents. It is also possible that we may be required to obtain licenses from third parties to avoid infringing third-party patents or other proprietary rights. We cannot be sure that such third-party licenses would be available to us on acceptable terms, if at all. If we are unable to obtain required third-party licenses, we may be delayed in or prohibited from developing, manufacturing or selling products requiring such licenses.

Although our patent filings include claims covering various features of our pipeline candidates, including composition, methods of manufacture and use, our patents do not provide us with complete protection against the development of competing products. Furthermore, follow-on versions of patented biologic products (i.e., biosimilars) may have structural differences that cause them to fall outside the scope of patent claims. Some of our know-how and technology is not patentable. To protect our proprietary rights in unpatentable intellectual property and trade secrets, we require employees, consultants, advisors, and collaborators to enter into confidentiality agreements. These agreements may not provide meaningful protection for our trade secrets, know-how, or other proprietary information.

Our 3-antigen HBV vaccine is not currently protected by any pending patent application nor any unexpired patent. Accordingly, our 3-antigen HBV vaccine may be subject to competition from the sale of generic products that could adversely affect our business and operations.

Our 3-antigen HBV vaccine has no patent protection, and therefore, we will seek to rely on non-patent data exclusivity in the BPCIA and similar legislation in other countries, which is described further under "*—Risks Related to our Intellectual Property —We may not be able to obtain marketing exclusivity in the United States under the BPCIA or equivalent regulatory data exclusivity protection in other jurisdictions for our products*."

Our 3-antigen HBV vaccine is the only product we currently market or are commercializing in the United States and Israel. Failure to obtain and retain marketing exclusivity or expiration of the market exclusivity could seriously adversely affect the revenue potential for our 3-antigen HBV vaccine in the jurisdictions where it is approved for sale.

Our ability to protect and enforce our patents does not guarantee that we will secure the right to commercialize the patents.

A patent is a limited monopoly right conferred upon an inventor, and any successors in title, in return for the making and disclosing of a useful, new, and non-obvious invention. This monopoly is of limited duration but, while in force, allows the patent holder to prevent others from making and/or using his invention. While a patent gives the holder this right to exclude others, it is not a license to commercialize the invention, where other permissions may be required for permissible commercialization to occur. For example, a drug cannot be marketed in the United States without the appropriate authorization from the FDA, regardless of the existence of a patent covering the product. Further, the invention, even if patented itself, may be prohibited from commercialization if it infringes the valid patent rights of another party.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent offices, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The United States Patent and Trademark Office and various foreign governmental patent offices require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case, which could result in a material adverse effect on our business or results of operations.

We are dependent on technologies we have licensed, and we may need to license in the future, and if we fail to obtain licenses we need, or fail to comply with our payment obligations in the agreements under which we in-license intellectual property and other rights from third parties, we could lose our ability to develop our pipeline candidates.

We currently are dependent on licenses from third parties for certain of our key technologies, including the license under the Ferring License Agreement and the license from UPMC. Under the Ferring License Agreement, we are committed to pay Ferring royalties equal to 7% of net sales (as defined therein) of HbsAg "Product" (as defined therein). Under the SciGen Assignment Agreement, we are required to pay royalties to SciGen Ltd. equal to 5% of net sales (as defined in the Ferring License Agreement) of Product. Under the Ferring License Agreement and the SciGen Assignment Agreement, we originally were to pay royalties on a country-by-country basis until the date 10 years after the date of commencement of the first royalty year in respect of such country. In April 2019, we exercised our option to extend the Ferring License Agreement in respect of all the countries that still make up the territory for an additional 7 years by making a one-time payment to Ferring of $100. Royalties under the Ferring License Agreement and SciGen Assignment Agreement will continue to be payable for the duration of the extended license periods. Under our license agreement with UPMC and other licensors relating to eVLP technology, we have an exclusive license to a family of patents that is expected to expire in the United States in 2022 and have expired in other countries in 2021. Under this agreement, we are required to pay UPMC between 0.75% to 1.75% of net sales and certain lump-sum milestone payments. UPMC is also a co-owner of the patent family covering our VBI-1501 CMV vaccine and we are currently negotiating extension of our existing license to cover this patent family.

No assurance can be given that our existing license will be extended on reasonable terms or at all. In addition, we expect we will need to license intellectual property from other third parties in the future and that these licenses will be material to our business. No assurance can be given that we will generate sufficient revenue or raise additional financing to meet our payment obligations in the license agreements with Ferring, UPMC, or other license agreements we enter into with third parties in the future. Any failure to make the payments required by the license agreements may permit the licensor to terminate the license. If we were to lose or otherwise be unable to maintain these licenses for any reason, it would halt our ability to develop our pipeline candidates. Furthermore, such loss of these licenses may enable development of new products that may compete with our pipeline candidates, and our competitors may gain proprietary position. Any of the foregoing could result in a material adverse effect on our business or results of operations.

In addition, we do not own the patents or patent applications that we license, and as such, we may need to rely upon our licensors to properly prosecute and maintain those patent applications and prevent infringement of those patents. If our licensors are unable to adequately protect their proprietary intellectual property we license from legal challenges, or the Company is unable to enforce such licensed intellectual property against infringement or alternative technologies, we will not be able to compete effectively in the drug discovery and development business.

If patent laws or the interpretation of patent laws change, our competitors may be able to develop and commercialize our discoveries.

Important legal issues remain to be resolved as to the extent and scope of available patent protection for biopharmaceutical products and processes in the United States and other important markets outside the United States, such as Europe, China and Japan. As such, litigation or administrative proceedings may be necessary to determine the validity, scope and ownership of certain of our and others' proprietary rights. Any such litigation or proceeding may result in a significant commitment of resources in the future and could force us to do one or more of the following: cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our revenue; obtain a license or other rights from the holder of the intellectual property right alleged to have been infringed or otherwise violated, which license may not be available on reasonable terms, if at all; and redesign our products to avoid infringing or violating the intellectual property rights of third parties, which may be time-consuming or impossible to do. In addition, changes in patent laws in the United States and other countries may result in allowing others to use our discoveries or develop and commercialize our products. We cannot provide assurance that the patents we obtain or the unpatented technology we hold will afford us significant commercial protection.

We may not be able to enforce our intellectual property rights throughout the world. This risk is exacerbated for us because we expect that one or more of our products or pipeline candidates will be manufactured and used in a number of foreign countries.

The laws of foreign countries may not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This risk is exacerbated for us as a result of our existing and planned manufacturing operations, clinical study sites, and marketing authorizations in a number of foreign countries.

The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement or other misappropriation of our intellectual property rights. For example, several foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents and trade secrets may provide limited or no benefit.

Most jurisdictions in which we have applied for, intend to apply for or have been issued patents have patent protection laws similar to those of the United States, but some of them do not. For example, in addition to the collaboration with Brii Bio, we may do business in China, Indonesia, and India in the future, these countries may not provide the same or similar protection as that provided in the United States. Additionally, due to uncertainty in patent protection law, we have not filed applications in many countries where significant markets exist.

Proceedings to enforce patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

We may not be able to monetize intangible assets, including IPR&D and goodwill, which may result in the need to record an impairment charge.

Our consolidated balance sheet contains approximately $62.1 million of intangible assets. For IPR&D assets, which consist of the CMV and GBM programs, the risk of failure is significant, and there can be no certainty that these assets ultimately will yield successful products. The nature of our business is high-risk and requires that we invest in a large number of projects in an effort to achieve a successful portfolio of approved products. Our ability to realize value on these significant investments is often contingent upon, among other things, regulatory approvals and market acceptance. These IPR&D and goodwill assets may become impaired and be written off at some time in the future, which can have a material adverse effect on the financial statements. An example of an event that is indicative of impairment is a projection or forecast that indicates losses or reduced profits associated with an asset or the market capitalization of a company falling below the net equity value. For IPR&D projects, this could result from, among other things, a change in outlook based on clinical trial data, a delay in the projected launch date or additional expenditures to commercialize the product.

While all intangible assets can face events and circumstances that can lead to impairment, in general, intangible assets that are most at risk of impairment include IPR&D assets. IPR&D assets are high-risk, as research and development is an inherently risky activity.

We may not be able to obtain marketing exclusivity in the United States under the BPCIA or equivalent regulatory data exclusivity protection in other jurisdictions for our products.

The BPCIA, which is included in the Affordable Care Act, provides the manufacturer of innovator biologic to seek a twelve-year period of marketing exclusivity. Similar data exclusivity regimes exist in the EU and in Canada, although the term of market exclusivity is shorter than in the United States. We intend to seek the maximum period of market exclusivity for our 3-antigen HBV vaccine and our other pipeline candidates in each jurisdiction, but there is no guarantee that any of our products will receive any marketing exclusivity under the BPCIA, or under analogous legislation in other jurisdictions. Furthermore, changes in applicable law could alter any period of market exclusivity or limit its availability. Our failure to obtain exclusivity for any product that is ultimately approved by the FDA, the EMA or Health Canada may expose us to substantial competition, which could have significant adverse financial consequences.

Risks Related to Our Indebtedness

Our obligations under our credit facility are secured by substantially all of our assets, so if we default on those obligations, the lender could foreclose on our assets. As a result of these security interests, such assets would only be available to satisfy claims of our general creditors or to holders of our equity securities if we were to become insolvent at a time when the value of such assets exceeded the amount of our indebtedness and other obligations.

K2 HealthVentures LLC ("K2" or the "Lender"), pursuant to the Loan and Guaranty Agreement (the "Loan Agreement"), dated May 22, 2020, and amended on May 7, 2021 (the "First Amendment") has a security interest in substantially all of our assets other than intellectual property. As a result, if we default under our obligations to the lender, the lender could foreclose on its security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations. The principal amount of the term loan as of December 31, 2021, was $30.0 million ($32.2 million including the exit fee).

In the event of a default the Lender would have a prior right to substantially all of our assets to the exclusion of our general creditors. In that event, our assets would first be used to repay in full all indebtedness and other obligations secured by the Lender, resulting in all or a portion of our assets being unavailable to satisfy the claims of any unsecured indebtedness. Only after satisfying the claims of any unsecured creditors would any amount be available for our equity holders. These events of default include, among other things, our failure to pay any amounts due under the Loan Agreement and the First Amendment or any of the other loan documents, a breach of covenants under the Loan Agreement, our insolvency, a material adverse effect occurring, the occurrence of certain defaults under certain other indebtedness or certain final judgments against us.

The pledge of these assets and other restrictions may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged under the term loan, our ability to incur additional secured indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

If we are unable to comply with certain financial and operating restrictions in our existing credit facility, we may be limited in our business activities and access to credit or may default under our credit facility.

Provisions in the Loan Agreement impose restrictions or require prior approval on our ability, and the ability of certain of our subsidiaries to, among other things:

- incur additional debt;
- pay dividends and make distributions;
- make certain investments and acquisitions;

- guarantee the indebtedness of others or our subsidiaries;
- redeem or repurchase capital shares;
- create liens or encumbrances;
- enter into transactions with affiliates;
- engage in new lines of business;
- sell, lease or transfer certain parts of our business or property;
- incur obligations for capital expenditures;
- issue additional capital shares; and
- acquire new companies and merge or consolidate.

The Loan Agreement also contains other customary covenants. We may not be able to comply with these covenants in the future. Our failure to comply with these covenants may result in the declaration of an event of default, which, if not cured or waived, may result in the acceleration of the maturity of indebtedness outstanding under this agreement and would require us to pay all amounts outstanding. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us or at all. Our failure to repay our indebtedness would result in our lender foreclosing on all or a portion of our assets and force us to curtail or cease our operations.

Our outstanding term loan obligations may adversely affect our cash flow and our ability to operate our business.

Pursuant to the terms of Loan Agreement and the First Amendment, the Lender made a term loan to us in aggregate amount of $30.0 million. In 2021, we made average monthly payments of interest in the amount of approximately $175. We are required to pay interest only until January 1, 2023, and starting January 1, 2023 estimated monthly principal and interest payments of $1,775 until June 2024, when the entire amount is due.

The terms of our term loan could have negative consequences to us, such as:

- we may be unable to obtain additional financing to fund working capital, operating losses, capital expenditures or acquisitions on terms acceptable to us, or at all;
- the amount of our interest expense may increase because our term loan has a variable rate of interest at any time dependent on one-month London Interbank Offered Rate greater than 1%; and
- we may be more vulnerable to economic downturns and adverse developments in our industry or the economy in general.

Our ability to meet our expenses and debt obligations will depend on our future performance, which will be affected by financial, business, economic, regulatory and other factors. We will be unable to control many of these factors, such as economic conditions. We cannot be certain that we will continue to have sufficient capital to allow us to pay the principal and interest on our debt and meet any other obligations. If we do not have enough money to service our debt, we may be required, but unable to refinance all or part of our existing debt, sell assets, borrow money or raise equity on terms acceptable to us, if at all, and the lender could foreclose on its security interests and liquidate some or all of our assets.

Risks Related to Our Common Shares

The price of our common shares has been, and may continue to be, volatile. The COVID-19 pandemic has resulted in significant financial market volatility, and its impact on the global economy remains uncertain. A continuation or worsening of the pandemic could have a material adverse impact on the market price of our common shares. This may affect the ability of our investors to sell their shares, and the value of an investment in our common shares may decline.

During the 12-month period ended February 28, 2022, our common shares traded as high as $4.31 per share and as low as $1.21 per share. The market prices of our common shares may continue to be volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- future announcements about us, our collaborators or competitors, including the results of testing, technological innovations, or new products and services;
- clinical trial results;
- depletion of cash reserves;
- additions or departures of key personnel;
- operating results that fall below expectations;
- announcements by us relating to any strategic relationship;
- sales of equity securities or issuance of additional debt;
- industry developments;
- changes in state, provincial, or federal regulations affecting us and our industry;
- the continued large fluctuations in major stock market indexes which causes investors to sell our common shares;
- economic, political, and other external factors; and
- period-to-period fluctuations in our financial results.

Furthermore, the stock market in general and the market for biotechnology companies, in particular, have from time-to-time experienced extreme price and volume fluctuations that are unrelated or disproportionate to the operating performance of the affected companies. The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent months. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common shares.

We may not meet the continued listing requirements of The NASDAQ Capital Market, which could result in a delisting of our common shares.

Our common shares are listed on The Nasdaq Capital Market. We have in the past, and may in the future, be unable to comply with certain of the listing standards that we are required to meet to maintain the listing of our common shares on The Nasdaq Capital Market. We have in the past received deficiency letters from the Listing Qualifications Department of Nasdaq indicating that we did not meet the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2).

If The Nasdaq Capital Market delists our common shares from trading on its exchange for failure to meet the listing standards, an investor would likely find it significantly more difficult to dispose of or obtain our shares, and our ability raise future capital through the sale of our shares could be severely limited. We additionally may not be able to list our common shares on another national securities exchange, which could result in our securities being quoted on an over-the-counter market. If this were to occur, our shareholders could face significant material adverse consequences, including limited availability of market quotations for our common shares and reduced liquidity for the trading of our securities. In addition, we could experience a decreased ability to issue additional securities and obtain additional financing in the future. There can be no assurance that an active trading market for our common shares will develop or be sustained. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

We have no immediate plans to pay dividends.

We plan to reinvest all of our earnings, to the extent we have earnings, in order to market our products and to cover operating costs and to otherwise become and remain competitive. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common shares as a dividend. In addition, our Loan Agreement with K2 prohibits us from declaring or paying dividends or making distributions on any class of our capital stock. We currently intend to retain earnings, if any, for reinvestment in our business. Therefore, holders of our common shares should not expect to receive dividends on our common shares.

Common shares eligible for future sale may cause the price of our common shares to decline.

From time to time, certain of our shareholders may be eligible to sell all or some of their restricted common shares by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate shareholders may sell freely after six months, subject only to the current public information requirement (which disappears after one year). Of the 258,250,273 common shares outstanding as of December 31, 2021, approximately 191,323,735 common shares are held by “non-affiliates,” all of which are currently freely tradable either because those were issued in a registered offering or pursuant to Rule 144.

Any substantial sale of our common shares pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common shares.

In addition, as of December 31, 2021, we had outstanding options, awards, and warrants for the purchase of 19,958,177 common shares. Of this amount, options, awards and warrants for the purchase of 6,585,769 common shares are held by non-affiliates, who may sell these shares in the public markets from time to time, without limitations on the timing, amount or method of sale. If our share price rises, the holders may exercise their options and sell a large number of shares. This could cause the market price of our common shares to decline.

We are a "smaller reporting company" and may elect to comply with reduced public company reporting requirements, which could make our common shares less attractive to investors.

We are currently a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act. For as long as we continue to be a "smaller reporting company", we may take advantage of exemptions from various reporting requirements that are applicable to other public reporting companies that are not smaller reporting companies, including providing simplified executive compensation disclosures in our filings and having certain other decreased disclosure obligations in our filings with the Securities and Exchange Commission (the "SEC"), including being required to provide only two years of audited financial statements in our annual reports. Consequently, it may be more challenging for investors to analyze our results of operations and financial prospects.

We will remain a smaller reporting company so long as (1) the value of our common shares held by non-affiliates is less than $250 million as measured on the last business day of our second fiscal quarter, or (2) our annual revenues are less than $100 million during the most recently completed fiscal year and the value of our common shares held by non-affiliates is less than $700 million as measured on the last business day of our second fiscal quarter.

Furthermore, we are a non-accelerated filer as defined by Rule 12b-2 of the Exchange Act, and, as such, are not required to provide an auditor attestation of management's assessment of internal control over financial reporting, which is generally required for SEC reporting companies under Section 404(b) of the Sarbanes-Oxley Act. Because we are not required to, and have not, had our auditor provide an attestation of our management's assessment of internal control over financial reporting, a material weakness in internal controls may remain undetected for a longer period.

We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the price of our securities may be more volatile.

United States civil liabilities may not be enforceable against us or certain of our officers.

We are governed by the *Business Corporations Act* (British Columbia) ("BCBCA") and a substantial portion of our assets, including our manufacturing facility in Rehovot, Israel, and our research facility in Ottawa, Canada, are located outside the United States. As a result, it may be difficult for investors to effect service of process within the United States upon us or to enforce judgments obtained against us in United States courts, in any action, including actions predicated upon the civil liability provisions of United States federal securities laws or any other laws of the United States. Additionally, rights predicated solely upon civil liability provisions of United States federal securities laws or any other laws of the United States may not be enforceable in original actions, or actions to enforce judgments obtained in Unites States courts, brought in Canadian or Israeli courts. In addition, two of our officers reside outside of the United States, and all or a substantial portion of their assets may be located outside the United States, which may make effecting service of process within the United States or enforcing judgments obtained against such persons in United States courts difficult.

We are governed by the corporate laws of British Columbia which in some cases have a different effect on shareholders than the corporate laws of Delaware, United States.

We are governed by the BCBCA and other relevant laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a United States jurisdiction, and may, together with our charter documents, including the advance notice provisions in our articles for the nomination of directors, have the effect of delaying, deferring, or discouraging another party from acquiring control of our company by means of a tender offer, a proxy contest, or otherwise, or may affect the price an acquiring party would be willing to offer in such an instance. The material differences between the BCBCA and Delaware General Corporation Law, or DGCL, that may have the greatest such effect include, but are not limited to, the following: (i) for material corporate transactions (such as mergers and amalgamations, other extraordinary corporate transactions or amendments to our articles) the BCBCA generally requires a two-thirds majority vote by shareholders, whereas DGCL generally only requires a majority vote; and (ii) under the BCBCA a holder of 5% or more of our common shares can requisition a special meeting of shareholders, whereas such right does not exist under the DGCL.

The concentration of the capital stock ownership with our insiders may limit the ability of other shareholders to influence corporate matters.

As of December 31, 2021, approximately 25.9% of our outstanding common shares was controlled by our officers, directors, beneficial owners of 10% or more of our securities and their respective affiliates. As a result, these shareholders, if they acted together, may be able to determine or influence matters that require approval by our shareholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other shareholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a corporate transaction that other shareholders may view as beneficial.

General Risk Factors

We may not be successful in hiring and retaining key employees, in which case our business may be harmed.

Our business is highly dependent upon the continued services of our senior management and key scientific and technical personnel. As such, our future success depends on our ability to identify, attract, hire or engage, retain, and motivate well-qualified managerial, technical, clinical, regulatory, business, and commercial personnel. Our operations require qualified personnel with expertise in nonclinical pharmacology and toxicology, pharmaceutical development, clinical research, legal and regulatory affairs, manufacturing, sales, and marketing. We must compete for qualified individuals with numerous biopharmaceutical companies, universities, and other research institutions. Competition for such individuals is intense, and, when the need arises, we may not be able to hire the personnel necessary to support our efforts. There can be no assurance that these professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow, and manage our business. An overall tightening and increasingly competitive labor market, notably in response to the COVID-19 pandemic, has been recently observed in the U.S., Canada, and Israel. A sustained labor shortage or increased turnover rates within our employee base, caused by the COVID-19 pandemic or as a result of general macroeconomic factors, could lead to increased costs, such as increased wage rates to attract and retain employees, and could negatively affect our ability to efficiently operate our manufacturing and distribution facilities and overall business. If we are unable to hire and retain employees capable of performing at a high-level, or if mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, have unintended negative effects, our business could be adversely affected. An overall labor shortage, lack of skilled labor, increased turnover or labor inflation, caused by the COVID-19 pandemic or as a result of general macroeconomic factors, could have a material adverse impact on our operations, results of operations, liquidity or cash flows.

We could be adversely affected by violations of the United States Foreign Corrupt Practices Act and similar anti-bribery laws.

We are subject to the United States Foreign Corrupt Practices Act and similar anti-corruption laws in other jurisdictions. These laws generally prohibit companies and their intermediaries from engaging in bribery or making other prohibited payments to government officials for the purpose of obtaining or retaining business, and some have record keeping requirements. The failure to comply with these laws could result in substantial criminal and/or monetary penalties. We operate in jurisdictions that have experienced corruption, bribery, pay-offs, and other similar practices from time-to-time and, in certain circumstances, such practices may be local custom. Our Code of Business Conduct and Ethics mandates compliance with these anti-corruption laws. However, we cannot be certain that these policies and procedures will protect us against liability. There can be no assurance that our employees, other agents, or third-party manufacturers or other organizations will not engage in such conduct for which we might be held responsible. If our employees, other agents, or third-party manufacturers or other organizations are found to have engaged in such practices, we could suffer severe criminal or civil penalties and other consequences that could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

Business interruptions could limit our ability to operate our business.

Our operations, as well as those of any collaborators on which we depend, are vulnerable to damage or interruption from computer viruses, human error, natural disasters, extreme weather, electrical and telecommunication failures, international acts of terror, public health crises, such as pandemics and epidemics, and similar events. Our formal disaster recovery plan and back-up operations and business interruption insurance may not be adequate to compensate us for losses we may suffer. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

Since December 2019, the COVID-19 pandemic has resulted in government-imposed quarantines, travel restrictions and other public health safety measures worldwide. For additional discussion of the impact of the COVID-19 pandemic on our business, please see the risk factor titled *"The ongoing coronavirus pandemic has caused interruptions or delays of our business plan and may have a significant adverse effect on our business."*

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, research data, our proprietary business information and that of our suppliers, technical information about our products, clinical trial plans and employee records. Similarly, our third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost, or stolen. Any such access, inappropriate disclosure of confidential or proprietary information, or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or our product development programs, and damage to our reputation, which could adversely affect our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We are required to comply with the domestic reporting regime under the Securities Exchange Act of 1934, as amended, and incur significant legal, accounting, and other expenses, and our management are required to devote substantial time to compliance initiatives and corporate governance practices.

We are required to comply with all of the periodic disclosure and current reporting requirements of the Securities Exchange Act of 1934, as amended, applicable to a publicly traded United States domestic issuer. The obligations of being a public reporting company require significant expenditures, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of The Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and corporate governance practices, among many other complex rules that are often difficult and time consuming to implement, monitor, and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. Compliance with such requirements also places significant demands on our management, administrative, operational, internal audit, and accounting resources. As a result, we incur, and we expect to continue to incur, legal and financial compliance costs and some activities are highly time consuming and costly.

There are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected.

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act require us to identify material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Our management, including our chief executive officer and chief financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us, cause downgrades in our future debt ratings leading to higher borrowing costs and affect how our common shares trade. This could, in turn, negatively affect our ability to access public debt or equity markets for capital.

We may be subject to securities litigation, which is expensive and could divert management attention.

In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could seriously hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of our common shares and trading volume could decline.

The trading market for our common shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. Multiple securities and industry analysts currently cover us. If one or more of the analysts downgrade our common shares or publish inaccurate or unfavorable research about our business, the price of our common shares would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common shares could decrease, which could cause the price of our common shares and trading volume to decline.

ITEM 1B: UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2: PROPERTIES

We rent office and research facility space under several operating leases.

a) Our headquarters, which is currently comprised of approximately 5,874 square feet of office space, is held pursuant to a lease agreement that was entered into on September 23, 2021 with Rayjoe Limited Partnership with a base rent for the premises of $42 per month, subject to a 3% annual increase. The lease commenced on November 1, 2021, and will run through October 31, 2024. We are also responsible for the payment of additional rent, including our pro rata share of real estate taxes, operating expenses, as defined in the lease, and betterment assessments, as defined in the lease.

b) Our manufacturing facility, which is currently comprised of approximately of 3,651 square meters of manufacturing suite, laboratory and office space is held pursuant to a lease agreement that was entered into on June 16, 2006 with Eilot Hashkaot and has been amended five times since it was entered into for the purpose of revising the length of the term, providing for a new base rent and adding additional office space. The amount of the lease is approximately $37 per month and linked to the CPI. The commitments for existing space are for a term of five years ending January 31, 2027.

   On January 16, 2017, we entered into a sublease agreement for additional office space of 200 square meters with Green Power YE. The term of the sub lease has been extended twice, and on January 15, 2019, we signed a three year and 9 day extension for the sub lease agreement, the amount of the extended sub lease was for a fixed price including all rental utilities of $8 per month. This agreement was terminated as of January 1, 2022.

   On July 11, 2021, we entered into a non-cancelable sublease agreement for additional office space of 536 square meters with EMI Car Wash Systems Ltd at our manufacturing facility in Israel. The term of the lease is for 47 months, commencing January 1, 2022, with the option to extend for an additional 24 months. The amount of the lease is approximately $17 per month.

   On September 9, 2021, we entered into a non-cancelable lease agreement for additional office space of 900 square meters with Ayalot Investment at our manufacturing facility in Israel. The term of the lease is 60 months, commencing July 1, 2022, with the option to extend for an additional 60 months. The amount of the lease is approximately $12 per month. We are also responsible for the payment of additional rent, including our pro rata share of real estate taxes, operating expenses, as defined in the lease, and betterment assessments, as defined in the lease.

c) VBI Cda's research facility, which is comprised of laboratory and office space, is held pursuant to a sub-sublease that was entered into on September 1, 2014 with Iogen Corporation and subsequently amended to include some additional space with a term ending on December 31, 2022 with the option to extend the term for one additional period of three years. On September 5, 2019, the sub-sublease was assigned by Iogen Corporation to 310 Hunt Club GP Inc. ("the Assignee"). The base and additional rent for the premises is approximately $23 per month through December 31, 2022. On September 4, 2020, VBI Cda entered into a further lease agreement for additional office space at our research facility, which commenced on October 1, 2020 and expires on April 30, 2023. The base and additional rent for the additional premises is approximately $6.3 per month through December 31, 2022. VBI Cda is also responsible for its pro rata share of additional rent, payable monthly, which includes, but is not limited to, operating and maintenance costs, real estate taxes, general maintenance and repair costs, insurance and professional fees. In addition to the base rent and the additional rent, VBI Cda is responsible for the payment of a refundable harmonized sales tax as require by the Excise Tax Act (Canada). Pursuant to the sub-sublease, the additional rent per month will not exceed CAD $20.50 per square foot of rentable premises. VBI Cda was required to provide a security deposit in the amount of CAD $18.80 which the Assignee will hold until the end of the term and may, in the event of a failure by VBI Cda to pay rent as and when due, apply the security deposit to the unpaid rent obligation.

Pursuant to these leases, we made rent payments of $1,463 in 2021.

We believe that our office, manufacturing and research facilities are suitable and adequate for our current operations but will consider term extensions or expansion of leased space, depending on market conditions and needs.

ITEM 3: LEGAL PROCEEDINGS

From time to time, we may be involved in certain claims and litigation arising out of the ordinary course and conduct of business. Management assesses such claims and, if it considers that it is probable that an asset had been impaired or a liability had been incurred and the amount of loss can be reasonably estimated, provisions for loss are made based on management's assessment of the most likely outcome.

On September 13, 2018, two civil claims were brought in the District Court of the central district in Israel naming our subsidiary SciVac as a defendant. In one claim, two minors, through their parents, allege, among other things: defects in certain batches of Sci-B-Vac discovered in July 2015; that Sci-B-Vac was approved for use in children and infants in Israel without sufficient evidence establishing its safety; that SciVac failed to provide accurate information about Sci-B-Vac to consumers; and that each child suffered side effects from the vaccine. The claim was filed together with a motion seeking approval of a class action on behalf of 428,000 children vaccinated with Sci-B-Vac in Israel from April 2011 and seeking damages in a total amount of NIS 1,879.5 million ($604.3 million). The second claim is a civil action brought by two minors and their parents against SciVac and the Israel Ministry of Health alleging, among other things, that SciVac marketed an experimental, defective, hazardous or harmful vaccine; that Sci-B-Vac was marketed in Israel without sufficient evidence establishing its safety; and that Sci-B-Vac was produced and marketed in Israel without approval of a western regulatory body. The claim seeks damages for past and future losses and expenses as well as punitive damages.

SciVac believes these matters to be without merit and intends to defend these claims vigorously.

The District Court has accepted SciVac's motion to suspend reaching a decision on the approval of the class action pending the determination of liability under the civil action. Preliminary hearings for the trial of the civil action began on January 15, 2020, with subsequent preliminary hearings held on May 13, 2020, December 3, 2020 and September 30, 2021. The next preliminary hearing is scheduled to be held on June 9, 2022.

ITEM 4: MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common shares began publicly trading on The NASDAQ Capital Market on May 9, 2016, under the symbol "VBIV."

Holders

As of March 3, 2022, we had approximately 817 shareholders of record. This number does not include an indeterminate number of shareholders whose shares are held by brokers in street name.

Dividends

We have not paid cash dividends on our common shares since January 1, 2015, and do not anticipate paying any cash dividends in the foreseeable future, but intend to retain our capital resources for reinvestment in our business. In addition, our Loan Agreement prohibits us from declaring or paying dividends or making distributions on any class of our capital stock.

Recent Issuances of Unregistered Securities

All sales of unregistered securities during the year ended December 31, 2021, were previously disclosed in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

Purchase of Equity Securities

Not applicable.

ITEM 6: [RESERVED].

ITEM 7: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis summarizes the significant factors affecting our operating results, financial condition, liquidity, and cash flows as of and for the periods presented below. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the audited consolidated financial statements and related notes included elsewhere in this Form 10-K. In addition to historical information, this discussion and analysis here and throughout this Form 10-K contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

VBI Vaccines Inc. ("VBI") is a commercial stage biopharmaceutical company driven by immunology in the pursuit of powerful prevention and treatment of disease. Through its innovative approach to virus-like particles ("VLPs"), including a proprietary enveloped VLP ("eVLP") platform technology, VBI develops vaccine candidates that mimic the natural presentation of viruses, designed to elicit the innate power of the human immune system. VBI is committed to targeting and overcoming significant infectious diseases, including hepatitis B ("HBV"), COVID-19 and coronaviruses, and cytomegalovirus ("CMV"), as well as aggressive cancers including glioblastoma ("GBM"). VBI is headquartered in Cambridge, Massachusetts, with research operations in Ottawa, Canada, and a research and manufacturing site in Rehovot, Israel.

Product Pipeline

VBI's pipeline is comprised of vaccine and immunotherapeutic programs developed by virus-like particle technologies to target two distinct, but often related, disease areas – infectious disease and oncology. We prioritize the development of programs for disease targets that are challenging, underserved, and where the human immune system, when powered and stimulated appropriately, can be a formidable opponent.

VLP vaccines are a type of sub-unit vaccine, in which only the portions of viruses critical for eliciting an immune response are presented to the body. Because of their structural similarity to viruses presented in nature, including their particulate nature and repetitive structure, virus-like particles (VLPs) can stimulate potent immune responses. VLPs can be customized to present any protein antigen, including multiple antibody and T cell targets, making them, we believe, ideal technologies for the development of both prophylactic and therapeutic vaccines. However, only a few antigenic proteins self-assemble into VLPs, which limit the number of potential targets. Notably, HBV antigens are among those that are able to spontaneously form orderly VLP structures. VBI's proprietary enveloped VLP (eVLP) platform technology expands the list of potentially-viable target indications for VLPs by providing a stable core (Gag Protein) and lipid bilayer (the "envelope"). It is a flexible platform that enables the synthetic manufacture of an "enveloped" VLP, or "eVLP", which looks structurally and morphologically similar to the virus, with no infectious material.

Our product pipeline includes an approved vaccine and multiple late- and early-stage investigational programs. The investigational programs are in various stages of clinical development and the scientific information included about these therapeutics is preliminary and investigative. The investigational programs have not been approved by the United States Food and Drug Administration ("FDA"), European Medicines Agency's ("EMA"), United Kingdom Medicines and Healthcare products Regulatory Agency ("MHRA"), Health Canada, or any other health authority and no conclusion can or should be drawn regarding the safety or efficacy of these investigational programs.

In addition to our existing pipeline programs, we may also seek to in-license clinical-stage vaccines or vaccine-related technologies that we believe complement our pipeline, as well as technologies that may supplement our efforts in both immuno-oncology and infectious disease.

Pipeline Programs

The table below is an overview of our commercial vaccine and our investigational programs as of January 31, 2022:

Indication	Program	Technology	Current Status
Approved Vaccine			
● Hepatitis B	PreHevbrio[1,2] *Hepatitis B Vaccine (Recombinant)*	VLP	Registration/Commercial
Prophylactic Candidates			
● Cytomegalovirus	VBI-1501	eVLP	Phase I Completed
● COVID-19 (Ancestral)	VBI-2902	eVLP	Ongoing Phase Ia
● COVID-19 (Beta variant)	VBI-2905	eVLP	Ongoing Phase Ib
● Pan-coronavirus (Multivalent)	VBI-2901	eVLP	Pre-Clinical
● Coronaviruses (Multivalent)	Undisclosed	eVLP	Pre-Clinical
● Zika	VBI-2501	eVLP	Pre-Clinical
Therapeutic Candidates			
● Hepatitis B	VBI-2601	VLP	Ongoing Phase II
● Glioblastoma	VBI-1901	eVLP	Ongoing Phase I/IIa
● Other CMV-Associated Cancers	Undisclosed	eVLP	Preclinical

[1]Approved for use in the U.S. for the prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older

[2]Approved for use in Israel, under the brand name Sci-B-Vac, for active immunization against hepatitis B virus (HBV infection)

A summary of our marketed product, lead pipeline programs and recent developments follows.

Marketed Product

PreHevbrio (Hepatitis B Vaccine [Recombinant])

PreHevbrio (Hepatitis B Vaccine [Recombinant]) was approved by the FDA on November 30, 2021 for the prevention of infection caused by all known subtypes of HBV in adults age 18 years and older. PreHevbrio contains the S, pre-S2, and pre-S1 HBV surface antigens, and is the only approved 3-antigen HBV vaccine for adults in the U.S. On February 23, 2022, following discussion at the CDC's ACIP meeting, PreHevbrio joined the list of recommended products for prophylactic adult vaccination against HBV infection. The inclusion of PreHevbrio in the ACIP recommendation will be reflected in a future CDC publication and is a notable milestone as many insurance plans and institutions require an ACIP recommendation before a vaccine is able to be reimbursed or is made available to patients. Additionally, PreHevbrio will be included in the next annual update of the CDC Adult Immunization Schedule in 2023, which will summarize changes throughout the coming year. VBI expects to commercially launch PreHevbrio in the U.S. at the end of the first quarter of 2022, with revenue generation expected to begin in the second quarter of 2022.

Commercial and regulatory activity for VBI's 3-antigen HBV vaccine outside of the U.S. include:

- *Israel:* Approved and commercially available, under the brand name Sci-B-Vac®, for active immunization against HBV infection.
- *European Union ("EU"):* On February 25, 2022, we announced that the EMA's Committee for Medicinal Products for Human Use ("CHMP") adopted a positive opinion for VBI's 3-antigen HBV vaccine for active immunization against infection caused by all known subtypes of HBV in adults, under the name PreHevbri [Hepatitis B vaccine (recombinant, adsorbed)]. The European Commission ("EC") will review the CHMP recommendation and a final decision on the Marketing Authorization Application ("MAA") for PreHevbri in the EU is expected in the coming months. If approved by the EC, the centralized marketing authorization would be valid in all EU Member States as well as in the European Economic Area ("EEA") countries – Iceland, Liechtenstein, and Norway.
- *United Kingdom ("UK"):* The MAA for VBI's 3-antigen HBV vaccine is expected to be reviewed by the MHRA as part of the EC Decision Reliance Procedure ("ECDRP"), the process for which was initiated upon receipt of positive CHMP opinion.
- *Canada:* On December 9, 2021, we completed the filing of a New Drug Submission ("NDS") to Health Canada for our 3-antigen hepatitis B vaccine candidate. Discussions are underway with regulatory agencies to determine the brand name for our 3-antigen HBV vaccine in Canada.

Prophylactic Investigational Candidates

VBI-2900: Coronavirus Vaccine Program (VBI-2901, VBI-2902, VBI-2905)

In response to the ongoing SARS-CoV-2 (COVID-19) pandemic, VBI initiated development of a prophylactic coronavirus vaccine program. Coronaviruses are enveloped viruses by nature which make them a prime target for VBI's flexible eVLP platform technology.

On August 26, 2020, we announced data from three pre-clinical studies conducted to enable selection of optimized clinical candidates for our coronavirus vaccine program. As a result of these studies, VBI selected two vaccine candidates, with the goal of bringing forward candidates that add meaningful clinical and medical benefit to those already approved: (1) VBI-2901, a multivalent pan-coronavirus vaccine candidate expressing the SARS-CoV-2, SARS, and MERS spike proteins; and (2) VBI-2902, a monovalent vaccine candidate expressing an optimized "prefusion" form of the SARS-CoV-2 spike protein.

In March 2021, a Phase I study of VBI-2902 was initiated and on June 29, 2021 we announced initial positive data from the Phase Ia portion of this study that evaluated one- and two-dose regimens of 5µg of VBI-2902 in 61 healthy adults age 18-54 years. After two doses, VBI-2902 induced neutralization titers in 100% of participants, with 4.3x higher geometric mean titer ("GMT") than that of the convalescent serum panel (n=25), and peak antibody binding GMT of 1:4,047. The study supports the assessment of a one-dose booster regimen in seropositive individuals and two-dose regimens in seronegative individuals. VBI-2902 was also well tolerated with no safety signals observed.

In response to the increased circulation of SARS-CoV-2 variants, the Phase Ib portion of the ongoing Phase I study was initiated in September 2021 and was designed to assess VBI-2905, our eVLP vaccine candidate directed against the SARS-CoV-2 Beta variant, as both a 1-dose booster in individuals previously immunized with a mRNA vaccine and as a primary 2-dose series in unvaccinated adults. Initial data from the 1-dose booster Phase Ib portion of the ongoing study is expected around the end of Q1 2022, dependent upon receipt of data from third party clinical research organizations. In addition, the first clinical study of VBI's multivalent candidate, designed to increase breadth of protection against COVID-19 and related coronaviruses, is expected to begin mid-year 2022.

The VBI-2900 program is supported by a partnership with CEPI (the "CEPI Funding Agreement"), with contributions of up to $33 million; a partnership with the Strategic Innovation Fund ("SIF"), established by the Government of Canada, with an award of up to CAD $56 million; contribution of up to CAD $1 million from the Industrial Research Assistance Program ("IRAP") of the National Research Council of Canada ("NRC"); and a collaboration with the NRC.

VBI-1501: Prophylactic CMV Vaccine Candidate

Our prophylactic CMV vaccine candidate uses the eVLP platform to express a modified form of the CMV glycoprotein B ("gB") antigen and is adjuvanted with alum, an adjuvant used in FDA-approved products.

Following the successful completion of the Phase I study in May 2018, and positive discussions with Health Canada, we announced plans for a Phase II clinical study evaluating VBI-1501 on December 20, 2018. We received similarly positive guidance from the FDA in July 2019. The Phase II study is expected to assess the safety and immunogenicity of dosages of VBI-1501 up to 20µg with alum. We are currently evaluating the timing of the Phase II study.

Therapeutic Investigational Candidates

VBI-2601: HBV Immunotherapeutic Candidate

VBI-2601 (BRII-179) is our novel, recombinant, protein-based immunotherapeutic candidate in development for the treatment of chronic HBV infection. VBI-2601 (BRII-179) is formulated to induce broad immunity against HBV, including T-cell immunity which plays an important role in controlling HBV infection.

On April 12, 2021 and June 23, 2021, we announced data from the completed Phase Ib/IIa clinical study in patients with chronic HBV infection, which was conducted by our partner Brii Biosciences Limited ("Brii Bio"). The study was a randomized, controlled study designed to assess the safety, tolerability, antiviral and immunologic activity of VBI-2601. The study was a two-part, dose-escalation study assessing different dose levels of VBI-2601 (BRII-179) with and without an immunomodulatory adjuvant, conducted at multiple study sites in New Zealand, Australia, Thailand, South Korea, Hong Kong SAR, and China.

The data from the Phase Ib/IIa for 33 evaluable patients across all study arms suggest: (1) VBI-2601 (BRII-179) is well tolerated at all dose levels with and without the adjuvant with no significant adverse events identified; (2) VBI-2601 (BRII-179) induced both B cell (antibody) and T cell responses in chronically-infected HBV patients, (3) VBI-2601 (BRII-179) induced restimulation of T cell responses to HBV surface antigens, including S, Pre-S1 and Pre-S2, in greater than 50% of the evaluable patients compared to no detectable response in the control arm; (4) the T cell responses and antibody responses were comparable across the 20µg and 40µg unadjuvanted study arms; and (5) T cell response rates between the adjuvanted and unadjuvanted cohorts were also comparable. Based on the acceptable safety profile and vaccine-induced adaptive immune responses seen in this study, VBI-2601 (BRII-179) has been advanced to Phase II studies.

On April 21, 2021, we announced that the first patient had been dosed in a Phase II clinical study evaluating VBI-2601 (BRII-179) in combination with BRII-835 (VIR-2218), an investigational small interfering ribonucleic acid (siRNA) targeting HBV, for the treatment of chronic HBV infection. To the best of our knowledge, this is the first clinical trial in the field to evaluate the combination of these two HBV mechanisms of action. The multi-center, randomized, open-label study is designed to evaluate the safety and efficacy of this combination with and without interferon-alpha as a co-adjuvant. Brii Bio has led the design and implementation of this functional cure proof-of-concept study with the support of VBI and Vir Biotechnology ("VIR"). The study will be conducted at sites in Australia, China, Taiwan, Hong Kong SAR, South Korea, New Zealand, Singapore, and Thailand. Initial data from this study is expected in the second half of 2022.

On January 5, 2022, we announced that the first patient was dosed in a second Phase IIa/IIb clinical study evaluating VBI-2601 (BRII-179). This newly announced Phase II study will assess VBI-2601 as an add-on therapy to the standard-of-care nucleos(t)ide reverse transcriptase inhibitor (nrtl) and pegylated interferon (PEG-IFN-α,) therapy. Initial data from this Phase IIa/IIb clinical study is expected in the first half of 2023.

VBI-1901: Glioblastoma (GBM)

Our cancer vaccine immunotherapeutic program, VBI-1901, targets CMV proteins present in tumor cells. CMV is associated with a number of solid tumors including glioblastoma ("GBM"), breast cancer, and pediatric medulloblastoma.

In January 2018, we initiated dosing in a two-part, multi-center, open-label Phase I/IIa clinical study of VBI-1901 in 38 patients with recurrent GBM. Phase I (Part A) of the study was a dose-escalation phase that defined the safety, tolerability, and optimal dose level of VBI-1901 adjuvanted with granulocyte-macrophage colony-stimulating factor (GM-CSF) in recurrent GBM patients with any number of prior recurrences. In December 2018, this phase completed enrollment of 18 patients across three dose cohorts, the highest of which (10 µg) was selected as the optimal dose level to test in the Phase IIa portion (Part B) of the study. Phase IIa of the study, which initiated enrollment in July 2019, is a subsequent extension of the 10 µg doses level cohort. This phase is a two-arm study that enrolled 20 first-recurrent GBM patients to receive 10 µg of VBI-1901 in combination with either GM-CSF or GlaxoSmithKline Biologicals S.A. ("GSK") proprietary adjuvant system, AS01, as immunomodulatory adjuvants. AS01 is provided pursuant to a Clinical Collaboration and Support Study Agreement ("Collaboration Agreement") we entered into with GSK on September 10, 2019. Enrollment of the 10 patients in the VBI-1901 with GM-CSF arm was completed in March 2020 and enrollment of the 10 patients in the VBI-1901 with AS01 was completed in October 2020.

Data from the ongoing Phase IIa portion of the study was announced throughout 2020 and 2021, with the latest data presented in December 2021 at the World Vaccine & Immunology Congress. The data from the Phase IIa portion of this study demonstrate: (1) improvement in 6-month, 12-month, and 18-month overall survival ("OS") data compared to historical controls; (2) 12-month OS of 60% (n=6/10) in the VBI-1901 + GM-CSF study arm and 70% (n=7/10) in the VBI-1901 + AS01 study arm, compared to historical controls of ~30%; (3) 18-month OS of 30% (3/10) in the VBI-1901 + GM-CSF study arm, 18-month OS not yet reached in the VBI-1901 + AS01 study arm; (3) 2 partial tumor responses, one of which remains on protocol past week 86 with a 93% tumor reduction relative to initiation of treatment at the start of the study, and 7 stable disease observations across both study arms; and (4) VBI-1901 continues to be safe and well tolerated at all doses tested, with no safety signals observed.

On June 8, 2021, we announced that the FDA granted Fast-Track Designation for VBI-1901 formulated with GM-CSF for the treatment of recurrent GBM patients with first tumor recurrence. The designation was granted based on data from the Phase I/IIa study.

Based on the data seen to-date, as part of the next phase of development, we anticipate assessing VBI-1901 in randomized, controlled studies in both primary and recurrent GBM patients. In the recurrent setting, we aim to expand the number of patients in the current trial and add a control arm, with the potential for accelerated approval based on tumor response rates and improvement in overall survival. Subject to discussion with the FDA, the amended protocol is expected to initiate enrollment of additional patients in Q2 2022. In the primary setting, we are exploring a randomized, controlled, clinical study with registration potential in patients first diagnosed with GBM, which, subject to approval from regulatory bodies, is expected to begin in the second half of 2022.

Third Party License and Assignment Agreements

We currently are dependent on licenses from third parties for certain of our key technologies, including the license granted pursuant to an agreement between Savient Pharmaceuticals Inc. and SciGen Ltd dated June 2004, as subsequently amended (the "Ferring License Agreement") and a license from L'Universite Pierre et Marie Curie, now Sorbonne Université ("UPMC"), Institut National de la Santé et de la Recherche Médicale ("INSERM") and L'école Normale Supérieure de Lyon. Under the Ferring License Agreement, we are committed to pay Ferring royalties equal to 7% of net sales (as defined therein) of HBsAg "Product" (as defined therein). Under an Assignment Agreement between FDS Pharm LLP and SciGen Ltd., dated February 14, 2012 (the "SciGen Assignment Agreement"), we are required to pay royalties to SciGen Ltd. equal to 5% of net sales (as defined in the Ferring License Agreement) of Product. Under the Ferring License Agreement and the SciGen Assignment Agreement, we originally were to pay royalties on a country-by-country basis until the date 10 years after the date of commencement of the first royalty year in respect of such country. In April 2019, we exercised our option to extend the Ferring License Agreement in respect of all the countries that still make up the territory for an additional 7 years by making a one-time payment to Ferring of $0.1 million. Royalties under the Ferring License Agreement and SciGen Assignment Agreement will continue to be payable for the duration of the extended license periods. Under our license agreement with UPMC and other licensors relating to eVLP technology, we have an exclusive license to a family of patents that is expected to expire in the United States in 2022 and expired in other countries in 2021. Under this agreement, we are required to pay UPMC between 0.75% to 1.75% of net sales and certain lump-sum milestone payments. UPMC is also a co-owner of the patent family covering our VBI-1501 CMV vaccine and we are currently negotiating extension of our existing license to cover this patent family. During the year ended December 31, 2021, we made a milestone payment of €0.2 million; related to our prophylactic coronavirus vaccine program.

Financial Operations Overview

At present, our operations are focused on:

- preparing for commercial launch and thereafter ongoing commercialization of PreHevbrio in the United States;
- manufacturing our 3-antigen HBV vaccine at commercial scale to meet demand in the U.S. and Israel, where it is approved, and to prepare for supply in markets where we may obtain marketing authorization;
- preparing for commercialization of our 3-antigen HBV vaccine in Europe and Canada, where we may obtain regulatory approval;

- conducting the Phase I/IIa clinical study of our GBM vaccine immunotherapeutic candidate, VBI-1901;
- preparing for the next phase of development for our GBM vaccine immunotherapeutic candidate, VBI-1901;
- conducting the Phase I clinical study of our prophylactic COVID-19 vaccine candidates, VBI-2902 and VBI-2905 (Beta variant);
- preparing for a Phase I/II clinical study of our pan-coronavirus candidate, VBI-2901;
- continuing our development and scaling-up production processes for our prophylactic coronavirus vaccine candidates using a Contract Development and Manufacturing Organization ("CDMO") located in Canada;
- supporting the ongoing review of the regulatory submissions for our 3-antigen HBV vaccine by the EMA in the EU, MHRA in UK, and Health Canada in Canada;
- developing VBI-2601 (BRII-179), our protein-based immunotherapeutic candidate for treatment of chronic HBV, in collaboration with Brii Bio;
- preparation for further development of VBI-1501, our preventative CMV vaccine candidate;
- continuing the research and development ("R&D") of our other pipeline candidates, including the exploration and development of new pipeline candidates;
- implementing operational, compliance, financial, and management information systems, including through third party partners, to support our commercialization activities;
- maintaining, expanding, and protecting our intellectual property portfolio; and
- Developing our internal systems and processes for regulatory affairs, legal, and compliance.

VBI's revenue generating activities have been the sale of our 3-antigen HBV vaccine in Israel and through named patient programs in countries where our 3-antigen HBV vaccine is not approved, though those markets have generated a limited number of sales to-date. We have also generated revenue from various business development transactions and R&D services generating fees. To date, we have financed our operations primarily with proceeds from sales of our common stock, our long-term debt agreements, and contribution agreements and partnerships with CEPI and the Government of Canada.

VBI has incurred significant net losses and negative operating cash flows since inception and expects to continue incurring losses and negative cash flows from operations as we carry out planned clinical, regulatory, R&D, commercial, and manufacturing activities with respect to the advancement of our 3-antigen HBV vaccine and new pipeline candidates. As of December 31, 2021, VBI had an accumulated deficit of approximately $378.4 million and stockholders' equity of approximately $143.8 million. Our ability to maintain our status as an operating company and to realize our investment in our In Process Research & Development ("IPR&D") assets, which consist of our CMV and GBM programs, is dependent upon obtaining adequate cash to finance our clinical development, manufacturing, our administrative overhead and our research and development activities, and ultimately to profitably monetize our IPR&D. We plan to finance near term future operations with existing cash reserves. We expect that we will need to secure additional financing to finance our business plans, which may be a combination of proceeds from the issuance of equity securities, the issuance of additional debt, government or non-governmental organization grants or subsidies, and revenues from potential business development transactions, if any. There is no assurance we will manage to obtain these sources of financing, if required. These factors raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should we be unable to continue as a going concern.

We have incurred operating losses since inception, have not generated significant product sales revenue and have not achieved profitable operations. We incurred net losses of $69.8 million for the year ended December 31, 2021, and we expect to continue to incur substantial losses in future periods. We anticipate that we will continue to incur substantial operating expenses as we continue our research and development, clinical studies and commercialize PreHevbrio in the United States in the near term. These include expenses related to the focus of our operations highlighted above.

In addition, we have incurred and will continue to incur significant expenses as a public company, which subjects us to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the rules and regulations of the NASDAQ Capital Market, and the Canadian securities regulators.

Overall Performance

The Company had net losses of $69,753 and $46,230 for the year ended December 31, 2021 and 2020, respectively. We had an accumulated deficit of $378,371 at December 31, 2021. We had $121,694 of cash and net working capital of $97,698 as of December 31, 2021.

Revenues

Revenues consist of product sales of Sci-B-Vac in Israel, and R&D services revenue recognized as part of the License Agreement with Brii Bio and other R&D services.

In Israel, Sci-B-Vac is sold through procurement requests from the Israeli Ministry of Health's procurement organization, and four health funds ("HMOs") (collectively, the "Sci-B-Vac Customers").

Pursuant to the License Agreement with Brii Bio we provide R&D services to Brii Bio as part of the development of VBI-2601 (BRII-179).

In addition, pursuant to an agreement with the Israel Innovation Authority (formerly the Office of the Chief Scientist of Israel), we are required to make services available for the biotechnology industry in Israel. These services include relevant activities for development and manufacturing of therapeutic proteins according to international standards and cGMP quality level suitable for toxicological studies in animals. Service activities include analytics/bio analytics methods for development and process development of therapeutic proteins starting with a candidate clone through manufacturing. These R&D services are primarily marketed to the Israeli research community in academia and Israeli biotechnology companies in the life sciences industry lacking the infrastructure or experience in the development and production of therapeutic proteins to the standards and quality required for clinical trials for human use. During the year ended December 31, 2021, we provided services to biotechnology companies including analytical development.

Cost of Revenues

Cost of revenues consist primarily of costs incurred for manufacturing our 3-antigen HBV vaccine which includes cost of materials, consumables, supplies, contractors, and manufacturing salaries.

Research and Development ("R&D") Expenses

R&D expenses, net of government grants and funding arrangements, consist primarily of costs incurred for the development of our 3-antigen HBV vaccine; VBI-1901, our GBM vaccine immunotherapeutic candidate; VBI-1501, our CMV vaccine candidate; VBI-2601 (BRII-179), our hepatitis B immunotherapeutic candidate; and VBI-2900, our coronavirus vaccine program, which include:

- the cost of acquiring, developing, and manufacturing clinical study materials, and other consumables and lab supplies used in our pre-clinical studies;
- expenses incurred under agreements with contractors or CDMOs or Contract Research Organizations to advance the vaccines into and through completion of clinical studies; and
- employee-related expenses, including salaries, benefits, travel, and stock-based compensation expense.

We expense R&D costs when we incur them.

General and Administrative ("G&A") Expenses

G&A expenses consist principally of commercialization costs, salaries and related costs for executive and other administrative personnel and consultants, including stock-based compensation, and travel expenses. Other general and administrative expenses include professional fees for legal, patent protection, consulting and accounting services, travel and conference fees, board of directors meeting costs, scientific and commercial advisory board meeting costs, rent, maintenance of facilities, depreciation, office supplies, information technology costs and expenses, insurance, and other general expenses. G&A expenses are expensed when incurred.

We expect that our general and administrative expenses will increase in the future as a result of adding employees and scaling our operations commensurate with advancing clinical candidates, commercializing products, and continuing to support a public company infrastructure. These increases will likely include increased costs for insurance, hiring of additional personnel, board committees, outside consultants, investor relations, lawyers and accountants, among other expenses.

Interest Expense, Net of Interest Income

Interest expense is associated with our long-term debt as discussed in Note 10 of the Notes to the Consolidated Financial Statements.

Results of Operations

Year Ended December 31, 2021 Compared to the Year Ended December 31, 2020

All dollar amounts stated below are in thousands, unless otherwise indicated.

	Year ended December 31			
	2021	2020	**Change $**	**Change %**
Revenues	**$ 631**	$ 1,061	**$ (430)**	**(41)%**
Expenses:				
Cost of revenues	**10,770**	9,168	**1,602**	**17%**
Research and development	**19,558**	14,859	**4,699**	**32%**
General and administrative	**38,335**	20,651	**17,684**	**86%**
Total operating expenses	**68,663**	44,678	**23,985**	**54%**
Loss from operations	**(68,032)**	(43,617)	**(24,415)**	**56%**
Interest expense, net of interest income	**(4,732)**	(2,708)	**(2,024)**	**75%**
Foreign exchange gain	**3,011**	95	**2,916**	**3,069%**
Loss before income taxes	**(69,753)**	(46,230)	**(23,523)**	**51%**
Income tax expense	**-**	-	**-**	**-%**
NET LOSS	**$ (69,753)**	$ (46,230)	**$ (23,523)**	**51%**

Revenues

Revenues for the year ended December 31, 2021 were $631 as compared to $1,061 for the year ended December 31, 2020. Revenues for the year ended December 31, 2021 decreased by $430 or 41% due to a decrease in R&D services revenue for VBI-2601, our hepatitis B immunotherapeutic candidate, being developed in collaboration with Brii Bio, as fewer manufacturing and non-clinical research services were required in the year ended December 31, 2021 compared to the year ended December 31, 2020.

Revenue Composition

	2021	2020
Product revenue	**$ 262**	$ 283
R&D service revenue	**369**	778
	$ 631	$ 1,061

Revenues by Geographic Region

	Years ended December 31			
	2021	2020	**$ Change**	**% Change**
Revenue in Israel	**$ 321**	$ 284	**$ 37**	**13%**
Revenue in China/Hong Kong	**306**	724	**(418)**	**(58)%**
Revenue in Europe	**4**	53	**(49)**	**(92)%**
Total Revenue	**$ 631**	**$ 1,061**	**$ (430)**	**(41)%**

Cost of Revenues

Cost of revenues for the year ended December 31, 2021 was $10,770 as compared to $9,168 for the year ended December 31, 2020. The increase in the cost of revenues of $1,602 or 17% is due to increased outsourced testing costs, direct labor costs, and inventory related costs incurred in the year ended December 31, 2021 compared to the year ended December 31, 2020.

Research and Development Expenses

R&D expenses for the year ended December 31, 2021 were $19,558 as compared to $14,859 for the year ended December 31, 2020. R&D expenses were offset by $14,856 for the year ended December 31, 2021 and $3,157 for the year ended December 31, 2020 due to government grants and funding arrangements. The increase in R&D expenses of $4,699 or 32%, is mainly a result of the (1) the increase in the costs related to our coronavirus vaccine program, including the ongoing Phase I clinical study, that are not offset by government grants and funding arrangements; (2) an increase in R&D expenses related to continued development of our other vaccine candidates, specifically GBM our vaccine immunotherapeutic candidate, VBI-1901, as we prepare for the next phase of development; and (3) increased regulatory costs related to our 3-antigen HBV vaccine.

General and Administrative Expenses

G&A expenses for the year ended December 31, 2021 were $38,335 as compared to $20,651 for the year ended December 31, 2020. G&A expenses were offset by $859 for the year ended December 31, 2021 and $131 for the year ended December 31, 2020 due to government grants and funding arrangements. The G&A expense increase of $17,684 or 86%, excluding the effect of government grants and funding arrangements, is a result of the increase in pre-commercial activities related to our 3-antigen HBV vaccine, such as the development of our commercial and distribution infrastructure, as FDA regulatory approval of PreHevbrio occurred in late 2021, increased insurance costs, increased professional costs, and increased labor costs.

Loss from Operations

The net loss from operations for the year ended December 31, 2021 was $68,032 as compared to $43,617 for the year ended December 31, 2020. The $24,415 increase in the net loss from operations resulted from the items discussed above.

Interest Expense, Net of Interest Income

The interest expense, net of interest income increased by $2,024 for the year ended December 31, 2021, compared to year ended December 31, 2020, due to the following: (1) the conversion of $2,000 of the secured term loan to common shares, which resulted in $1,161 of additional interest accretion being recognized in interest expense, net of interest income in the consolidated statement of operations and comprehensive loss; and (2) an increase in long-term debt of $12,000.

Foreign Exchange Gain (Loss)

The foreign exchange gain for the year ended December 31, 2021 was $3,011 compared to a foreign exchange gain of $95 for the year ended December 31, 2020. The change is a result of the changes in the foreign currency exchange rates (NIS and CAD) in which the foreign currency transactions were denominated for each of those periods.

Net Loss

Net loss of $69,753 for the year ended December 31, 2021 compared to $46,230 for the year ended December 31, 2020 respectively is a result of the items discussed above.

Liquidity and Capital Resources

	Year ended December 31			
	2021	**2020**	**$ Change**	**% Change**
Cash	**$ 121,694**	$ 93,825	**$ 27,869**	**30%**
Current Assets	**130,284**	132,041	**(1,757)**	**(1)%**
Current Liabilities	**32,586**	17,348	**15,238**	**88%**
Working Capital	**97,698**	114,693	**(16,995)**	**(15)%**
Accumulated Deficit	**(378,371)**	(308,618)	**(69,753)**	**23%**

As of December 31, 2021, we had cash of $121,694 as compared to $93,825 as of December 31, 2020. As of December 31, 2021, we had working capital of $97,698 as compared to working capital of $114,693 at December 31, 2020. Working capital is calculated by subtracting current liabilities from current assets.

Net Cash Used in Operating Activities

The Company incurred net losses of $69,753 and $46,230 in the year ended December 31, 2021 and 2020, respectively. The Company used $39,908 and $47,050 in cash for operating activities during the year ended December 31, 2021 and 2020, respectively. The decrease in cash outflows is largely a result of an increase in net loss, offset by the change in operating working capital, notably the cash received in advance from the CEPI Funding Agreement.

Net Cash Used in Investing Activities

Net cash flows provided by investing activities was $23,156 for the year ended December 31, 2021 compared to cash used in investing activities of $26,000 for the year ended December 31, 2020. During the year ended December 31, 2020 we purchased short term investments, and during the year ended December 31, 2021 the short-term investments were redeemed.

Net Cash Provided by Financing Activities

Net cash flows provided by financing activities was $44,293 for the year ended December 31, 2021 compared to cash flows provided by financing activities of $122,392 during the year ended December 31, 2020. During the year ended December 31, 2021, we issued common shares for net proceeds of $32,315 and completed debt financing for net proceeds of $11,978. During the year ended December 31, 2020, we issued common shares for net proceeds of $118,713 and completed additional debt financing for net proceeds of $3,679.

Sources of Liquidity

Jefferies Open Market Sale Agreement ("ATM")

On July 31, 2020, the Company entered into an Open Market Sale Agreement with Jefferies LLC ("Jefferies"), pursuant to which the Company may offer and sell its common shares having an aggregate price of up to $125,000 from time to time through Jefferies, acting as agent or principal (the "ATM Program"). Common shares were offered pursuant to a sales agreement prospectus included in the Company's automatic shelf registration on Form S-3 filed with the United States Securities and Exchange Commission ("SEC") on July 31, 2020. During the year ended December 31, 2020, the Company issued 15,638,706 common shares under the ATM Program, for total gross proceeds of $64,685 at an average price of $4.14. We incurred $2,101 of shares issuance costs related to the common shares issued resulting in net proceeds of $62,584.

On September 3, 2021, the Company entered into a second Open Market Sale Agreement[SM] with Jefferies to act as the Company's sales agent and/or principal, for the issuance and sale of up to an additional $125,000,000 of the Company's common shares from time to time in an at-the-market public offering, which the Company could choose to use when no shares remain available for issuance under the ATM Program.

During the year ended December 31, 2021, the Company issued 9,135,632 common shares under the ATM Program, for total gross proceeds of $33,293 at an average price of $3.64. The Company incurred $1,117 of share issuance costs related to the common shares issued resulting in net proceeds of $32,176. As of December 31, 2021, $27,022 of common shares remained available for issuance under the ATM Program.

K2 HealthVentures LLC Long Term Debt

On May 22, 2020, the Company (along with its subsidiary VBI Cda) entered into the Loan and Guaranty Agreement (the "Loan Agreement") with K2 HealthVentures LLC and any other lender from time-to-time party thereto (the "Lenders") pursuant to which we received the first tranche secured term loan of $20 million (the "First Tranche Term Loan"). The Lenders originally agreed to make available the following additional tranches subject to the following conditions and upon the submission of a loan request by the Company: (1) up to $10 million available between January 1, 2021 and April 30, 2021 upon achievement of certain milestones (the "Second Tranche Term Loan"), (2) $10 million available between the closing date and December 31, 2021, subject to achievement of a certain U.S. Food and Drug Administration approval (the "Third Tranche Term Loan"), and (3) a final tranche of up to $10 million that can be made available any time prior to June 30, 2022, subject to the advance of the Third Tranche Term Loan, satisfactory review by the administrative agent of our financial and operating plan, and approval by the Lenders' investment committee (the "Fourth Tranche Term Loan"). The Company obtained the FDA on November 30, 2021 but elected not to draw down the Third Tranche Term Loan. Pursuant to the Loan Agreement, the Lenders originally had the ability to convert, at the Lenders' option, up to $4 million of the secured term loan into common shares of the Company at a conversion price of $1.46 per share ("K2 conversion feature") until the maturity date of June 1, 2024. On February 3, 2021, pursuant to the Loan Agreement, the Lenders converted $2 million of the secured term loan into 1,369,863 common shares at a conversion price of $1.46. The Lenders have the ability to convert an additional $2 million at the Lenders' option.

On May 17, 2021, the Company entered into the First Amendment with the Lenders to: (1) increase the Second Tranche Term Loan from $10 million to $12 million; (2) extend the availability period of the Second Tranche Term Loan beyond April 30, 2021, subject to certain conditions; (3) amend the Second Tranche Term Loan interest rate equal to the greater of (a) 7.75% and (b) prime rate plus 4.50%; and (4) extend the date as of which amortization of the loans under the Loan Agreement shall begin from July 1, 2022 to January 1, 2023.

In connection with the Loan Agreement, on May 22, 2020, the Company issued the Lenders a warrant to purchase up to 625,000 common shares (the "Original K2 Warrant") at an exercise price of $1.12 (the "Warrant Price"). On May 17, 2021, in connection with the First Amendment, the Company issued the Lenders an amended and restated warrant to purchase an additional 312,500 common shares for a total of 937,500 common shares (the "Restated K2 Warrant") with the same Warrant Price of $1.12. The number of common shares issuable pursuant to the Restated K2 Warrant, at any given time, is determined by dividing the Warrant Coverage Amount by the Warrant Price, where the Warrant Coverage Amount is equal to the sum of $1.1 million plus the aggregate original principal amount of the Third Tranche and Fourth Tranche Term Loan advanced at that time multiplied by 3.5%. The Restated K2 Warrant may be exercised either for cash or on a cashless "net exercise" basis and expires on May 22, 2030.

As a result of the Original K2 Warrant and K2 conversion feature, the debt was issued at a discount of $3.8 million. We also incurred $1.0 million of debt issuance costs and are required to make a final payment equal to 6.95% of the aggregate original secured term loan principal on the maturity date of the term loan, or upon earlier prepayment of the term loans in accordance with the Loan Agreement, resulting in an additional discount of $1.4 million related to the First Tranche Term Loan. The total initial debt discount was $6.2 million.

The Second Tranche Term Loan, issued pursuant to the Loan Agreement, as amended by the First Amendment, resulted in the Company incurring an additional $0.02 million of debt issuance costs, $0.2 million of third-party costs and being required to make a final payment of $0.8 million, which is equal to 6.95% of the Second Tranche Term Loan.

The total principal amount of the loan under the Loan Agreement, as amended by the First Amendment, outstanding at December 31, 2021, including the $2.2 million final payment discussed above, is $32.2 million. The principal amount of the loan made under the Loan Agreement prior to the First Amendment accrues interest at an annual rate equal to the greater of (a) 8.25% or (b) prime rate plus 5.00%. The principal amount of the Second Tranche Term Loan made under the Loan Agreement, as amended by the First Amendment, accrues interest at an annual rate equal to the greater of (a) 7.75% or (b) prime rate plus 4.50%. The interest rate as of December 31, 2021 was 8.25% for the First Tranche Term Loan and 7.75% for the Second Tranche Term Loan. The Company is required to pay only interest until January 1, 2023.

CEPI Partnership

On March 9, 2021, the Company and CEPI announced a partnership, the CEPI Funding Agreement, to develop eVLP vaccine candidates against SARS-COV-2 variants, including the Beta variant, also known as the B.1.351 variant and 501Y.V2, first identified in South Africa. CEPI agreed to provide up to $33,018 to support the advancement of VBI-2905, a monovalent eVLP candidate expressing the pre-fusion form of the spike protein from the Beta variant, through Phase I clinical development. This funding will also support preclinical expansion of additional multivalent vaccine candidates designed to evaluate the potential breadth of our eVLP technology. The preclinical expansion is intended to develop clinic-ready vaccine candidates capable of addressing emerging variants. For the year ended December 31, 2021, we received $18,363, of which there is a balance remaining of $10,183 in other current liabilities on the consolidated balance sheet.

Underwritten Public Offering

In April 2020, the Company closed an underwritten public offering of 52,272,726 common shares at a price of $1.10 per share for total gross proceeds of $57,500. The Company incurred $3,606 of share issuance costs related to the offering resulting in net cash proceeds of $53,894 and costs related to the issuance of warrants to purchase 705,000 common shares to National Securities Inc. ("National") or its designees as consideration for National providing financial advisory services in connection with the offering. The warrants issued to National or its designees ("National Warrants") are exercisable immediately upon issuance and terminate three years following issuance and have an exercise price of $1.50 per share.

Plan of Operations and Future Funding Requirements

The report of our independent registered public accounting firm on our consolidated financial statements for the year ended December 31, 2021 contains an explanatory paragraph regarding our ability to continue as a going concern. VBI has incurred significant net losses and negative operating cash flows since inception and expects to continue incurring losses and negative cash flows from operations as we carry out our planned clinical, regulatory, R&D, sales, and manufacturing activities with respect to the advancement of our 3-antigen HBV vaccine and new pipeline candidates. As of December 31, 2021, VBI had an accumulated deficit of $378,371 and stockholders' equity of $143,882.

Our ability to maintain our status as an operating company and to realize our investment in our IPR&D assets is dependent upon obtaining adequate cash to finance our clinical development, manufacturing, our commercialization activities, our administrative overhead and our research and development activities. We plan to finance near term future operations with existing cash reserves. We expect that we will need to secure additional financing to finance our business plans, which may be a combination of proceeds from the issuance of equity securities, the issuance of additional debt, structured asset financings, government grants or subsidies, and revenues from potential business development transactions, if any. There is no assurance we will manage to obtain these sources of financing. The accompanying financial statements have been prepared assuming that we will continue as a going concern; however, the above conditions raise substantial doubt about our ability to do so. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should we be unable to continue as a going concern. Our long-term success and ability to continue as a going concern is dependent upon obtaining sufficient capital to fund the research and development of our products, to bring about their successful commercial release, to generate revenue, and, ultimately, to attain profitable operations, or, alternatively, to advance our products and technology to such a point that they would be attractive candidates for acquisition by others in the industry.

We will require additional funds to conduct clinical and non-clinical trials, achieve regulatory approvals, and, subject to such approvals, commercially launch our products, and will need to secure additional financing in the future to support our operations and to realize our investment in our IPR&D assets. We base this belief on assumptions that are subject to change, and we may be required to use our available cash and cash equivalent resources sooner than we currently expect. Our actual future capital requirements will depend on many factors, including the progress and results of our ongoing clinical trials, the duration and cost of discovery and preclinical development, laboratory testing and clinical trials for our pipeline candidates, the timing and outcome of regulatory review of our products, product sales outside of Israel, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the number and development requirements of other pipeline candidates that we pursue, and the costs of commercialization activities, including product marketing, sales, and distribution.

We expect to finance our future cash needs through public or private equity offerings, debt financings, government grants or non-government funding, structured asset financings, or business development transactions. Pursuant to the Contribution Agreement, we will receive up to CAD $55,976 as a government grant to support the development of the Company's coronavirus vaccine program, though Phase II clinical studies, and pursuant to the CEPI Funding Agreement, we will receive up to $33,018 in funding to support the development of the Company's coronavirus vaccine program, specifically SARS-COV-2 variants. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. Additional equity, debt, structured asset financing, government grants or non-government funding, or business development transactions may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our R&D programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain pipeline candidates that we might otherwise seek to develop or commercialize independently.

To the extent we raise additional capital by issuing equity securities or obtaining borrowings convertible into equity, ownership dilution to existing stockholders will result and future investors may be granted rights superior to those of existing stockholders. The incurrence of indebtedness or debt financing would result in increased fixed obligations and could also result in covenants that would restrict our operations. Our ability to obtain additional capital may depend on prevailing economic conditions and financial, business, and other factors beyond our control. The ongoing COVID-19 pandemic has caused an unstable economic environment globally. Disruptions in the global financial markets may adversely impact the availability and cost of credit, as well as our ability to raise money in the capital markets. Current economic conditions have been, and continue to be, volatile. Continued instability in these market conditions may limit our ability to access the capital necessary to fund and grow our business.

The Company's long-term success and ability to continue as a going concern is dependent upon obtaining sufficient capital to fund the research and development of its products, to bring about their successful commercial release, to generate revenue and, ultimately, to attain profitable operations or, alternatively, to advance its products and technology to such a point that they would be attractive candidates for acquisition by others in the industry.

To date, the Company has been able to obtain financing as and when it was needed; however, there is no assurance that financing will be available in the future, or if it is, that it will be available at acceptable terms.

As of December 31, 2021, we have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Net Operating Loss Carryforwards

At December 31, 2021, the Company had NOLs aggregating approximately $352.6 million. The NOLs are available to reduce taxable income of future years and expire as follows:

	United States	Canada	Israel	**Total**
2024	$ -	$ 476	$ -	$ 476
2025	-	1,480	-	1,480
2026	10	3,732	-	3,742
2027	446	4,324	-	4,770
2028	718	1,674	-	2,392
2029	672	3,135	-	3,807
2030	2,556	1,015	-	3,571
2031	3,617	1,255	-	4,872
2032	2,962	-	-	2,962
2033	3,126	1,467	-	4,593
2034	5,626	5,493	-	11,119
2035	4,661	1,651	-	6,312
2036	5,323	8,762	-	14,085
2037	6,017	9,848	-	15,865
2038	-	2,446	-	2,446
2039	-	7,785	-	7,785
2040	-	16,526	-	16,526
2041	-	13,422	-	13,422
No expiration	18,234	-	214,186	232,420
Total losses	**$ 53,968**	**$ 84,491**	**$ 214,186**	**$ 352,645**

NOL and tax credit carryforwards are subject to review and possible adjustment by the tax authorities in the respective countries. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. At December 31, 2021, we recorded a 100% valuation allowance against our NOL, as we believe it is more likely than not that the tax benefits will not be fully realized. In the future, if we determine that a portion or all of the tax benefits associated with our tax carryforwards will be realized, net income would increase in the period of determination.

Critical Accounting Policies and Estimates

Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require difficult, subjective and complex judgments by management in order to make estimates about the effect of matters that are inherently uncertain. During the year ended December 31, 2021, there were no significant changes to our critical accounting policies, which are discussed in Note 2 to our Consolidated Financial Statements.

Preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual amounts could differ from the estimates made. We continually evaluate estimates used in the preparation of the consolidated financial statements for reasonableness. Appropriate adjustments, if any, to the estimates used are made prospectively based upon such periodic evaluation.

In particular, significant judgments made by management in the application of U.S. GAAP during the preparation of the consolidated financial statements and estimates with a risk of material adjustment include:

Revenue Recognition

We recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligation(s). At contract inception, we assess the goods or services promised within each contract, assess whether each promised good or service is distinct and identify those that are performance obligations.

The Company must use significant judgment to determine: a) the number of performance obligations based on the determination under step (ii) above and whether those performance obligations are distinct from other performance obligations in the contract; b) the transaction price under step (iii) above; and c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price. The transaction price is allocated to each performance obligation on an estimated stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

Where a portion of non-refundable up-front fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as contract liabilities and recognized as revenue when (or as) the underlying performance obligation is satisfied.

Product Sales

The Company recognizes revenue from product sales when obligations under the terms of the contract with the customer are satisfied; this occurs upon the transfer of control of the goods to the customers.

Collaborative Arrangements

The Company first evaluates license and/or collaboration arrangements to determine whether the arrangement (or part of the arrangement) represents a collaborative arrangement pursuant to Accounting Standards Codification ("ASC") Topic 808, Collaborative Arrangements ("ASC 808"), based on the risks and rewards and activities of the parties pursuant to the contractual arrangement. The Company then determines if the collaborative arrangements are within the scope of ASC Topic 606, Revenue Recognition ("ASC 606").

Collaborative arrangements with partners which are within the scope of ASC 606 typically include payment to us of one or more of the following: (i) license fees; (ii) research and development services to be performed as part of the contract ("R&D services") (iii) payments related to the achievement of developmental, regulatory, or commercial milestones; and (iv) royalties on net sales of licensed products.

Collaborative arrangements (or elements within the contract that are deemed part of a collaborative arrangement) with partners which represent a collaborative relationship and not a customer relationship, are accounted for outside the scope of ASC Topic 606.

License Fees

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

R&D Services

The promises under the Company's collaboration and license agreements generally include research and development services to be performed by the Company. For performance obligations that include research and development services, the Company generally recognizes revenue allocated to such performance obligations based on an appropriate measure of progress. The Company utilizes judgment to determine the appropriate method of measuring progress for purposes of recognizing revenue, which is generally an input measure such as costs incurred. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Income Taxes

In assessing the probability of realizing income tax assets, management makes estimates related to expectations of future taxable income, applicable tax opportunities, expected timing of reversals of existing temporary differences and likelihood that tax positions taken will be sustained upon examination by applicable tax authorities. The Company has recorded a full valuation allowance on its entire net deferred tax assets as it believes it is not more likely than not the tax benefits will be realized.

Intangible Assets and Goodwill

The Company's intangible assets determined to have indefinite useful lives including IPR&D and goodwill, are tested for impairment annually, or more frequently if events or circumstances indicate that the assets might be impaired. Such circumstances could include but are not limited to: (1) a significant adverse change in legal factors or in business climate, (2) unanticipated competition, or (3) an adverse action or assessment by a regulator. The Company has established August 31st as the date for its annual impairment test of IPR&D and goodwill.

The IPR&D assets, which consist of the CMV and GBM programs, were acquired in a business combination, capitalized as an intangible asset and are tested for impairment at least annually until commercialization, after which time the IPR&D will be amortized over its estimated useful life. The impairment test compares the carrying amount of the IPR&D asset to its fair value. If the carrying amount exceeds the fair value of the asset, such excess is recorded as an impairment loss. There was no IPR&D impairment determined as a result of the Company's annual testing on August 31, 2021. The fair value of the IPR&D assets included in the impairment test was determined using the income approach method and is considered Level 3 in the fair value hierarchy. Some of the more significant estimates and assumptions inherent in the estimate of the fair value of IPR&D assets include the amount and timing of costs to develop the IPR&D into viable products, the amount and timing of future cash inflows, the discount rate and the probability of technical and regulatory success applied to the cash flows. The discount rate used was 11% and the cumulative probability of technical and regulatory success to achieve approval to market the products ranged from approximately 10% to 17%.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. When evaluating goodwill for impairment, we may first perform an assessment qualitatively whether it is more likely than not that a reporting unit's carrying amount exceeds its fair value, referred to as a "step zero" approach. Subsequently (if necessary, after step zero), if the carrying value of a reporting unit exceeded its fair value an impairment would be recorded. We would perform our goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. There was no goodwill impairment determined as a result of the Company's annual testing on August 31, 2021. The fair value of the Company, which consists of a single reporting unit, included in the impairment test was determined using the closing market stock price of VBI as of August 31, 2021.

Accrued Research and Development Expenses

When preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Payments under some of the contracts we have with third parties depend on factors such as successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones.

When accruing research and development expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from our service providers. However, we may be required to estimate the cost of these services based only on information available to us. If we underestimate or overestimate the cost associated with research and development services at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued research and development expenses have approximated actual expense incurred.

Long-Term Debt

The Company accounts for long-term debt under the provisions of ASC 470-20, Debt – Debt with conversion and other options ("ASC 470"). Conversion options are accounted for at intrinsic value and other options, including warrants, are accounted for based on the relative fair value of the warrants, long-term debt, and other options (including conversion options). Conversion and other options are accounted for in additional paid-in capital and result in a debt discount. Final payments or exit fees and debt issuance costs also result in a debt discount. The debt discount is being charged to interest expense, net of interest income in the consolidated statement of operations and comprehensive loss using the effective interest method over the term of the debt.

Known Trends, Events and Uncertainties

As with other companies that are in the process of commercializing novel pharmaceutical products, we will need to successfully manage normal business and scientific risks. Research and development of new technologies is, by its nature, unpredictable. We cannot assure you that our technology will be adopted, that we will ever earn revenues sufficient to support our operations, or that we will ever be profitable. In addition, the impact of the ongoing COVID-19 pandemic, including the Omicron variant of COVID-19, which appears to be the most transmissible variant to-date, is currently indeterminable and rapidly evolving, and has adversely affected and may continue to adversely affect our operations and the global economy. Furthermore, other than as discussed in this report, we have no committed source of financing and may not be able to raise money as and when we need it to continue our operations. If we cannot raise funds as and when we need them, we may be required to severely curtail, or even to cease, our operations.

Other than as discussed above and elsewhere in this report, we are not aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition.

Recent Accounting Pronouncements

See Note 3 of Notes to the Consolidated Financial Statements.

Related Parties

During the year ended December 31, 2019, the Company agreed to pay a car loan for an officer of the Company, as part of their compensation arrangement, for $56, repayable over 3 years. The total amount of the car loan lease at December 31, 2021 and December 31, 2020, was $29 and $43, respectively.

ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risk related to changes in interest rates with respect to our cash holdings and our outstanding long-term debt.

As of December 31, 2021, and 2020, we had cash of $121.7 million and $93.8 million, respectively, and short-term investments of $0.0 and $25.3 million, respectively, which have been deposited in high interest rate bank accounts or redeemable guaranteed investment certificates, for a total of $121.7 million and $119.1 million, respectively. Our cash and short-term investments holdings are in accordance with our investment policy approved by our board of directors, which specifies the categories, allocations and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash have significant risk of default or illiquidity.

As of December 31, 2021, and 2020 we had long-term debt outstanding of $32.2 million and $21.4 million, respectively. The principal amount of the loan made under the Loan Agreement accrues interest at an annual rate equal to the greater of (a) 8.25% or (b) prime rate plus 5.00%. The principal amount of the Second Tranche Term Loan made under the Loan Agreement, as amended by the First Amendment, accrues interest at an annual rate equal to the greater of (a) 7.75% or (b) prime rate plus 4.50%. The interest rate as of December 31, 2021 was 8.25% for the First Tranche Term Loan and 7.75% for the Second Tranche Term Loan; the interest rate at December 31, 2020 was 8.25%. Our interest rate risk exposure is primarily due to prime rate fluctuations.

Based on our current interest rate risk, we do not believe that our results of operations or our financial position would be materially affected by a change in interest rates of 100 basis points.

Foreign Currency Risk

We are also exposed to market risk related to change in foreign currency exchange rates. We have operations in Israel, Canada, and the United States and therefore we incur expenses in NIS, Canadian Dollars, and United States dollars. We also contract with certain vendors that are located in Europe which have contracts denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with our foreign operations and certain agreements. We do not currently hedge our foreign exchange rate risk. As of December 31, 2021, and December 31, 2020, we had minimal liabilities to third parties denominated in foreign currencies.

ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and notes thereto required by this item begin on page F-1 of this Form 10-K, as listed in Item 15 of Part IV.

ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A: CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer and Head of Business Development (our principal financial and accounting officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Form 10-K. The evaluation was undertaken in consultation with our accounting personnel and external consultants. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer and Head of Business Development concluded that, as of December 31, 2021, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial and accounting officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and our directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, our internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our Chief Executive Officer and our Chief Financial Officer and Head of Business Development assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this assessment, management evaluated the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework (2013).*

Based on our assessment, our Chief Executive Officer and our Chief Financial Officer and Head of Business Development determined that, as of December 31, 2021, our internal control over financial reporting is effective.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fourth quarter of the last fiscal year that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B: OTHER INFORMATION

None.

ITEM 9C: DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10: DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required in response to this Item 10 is incorporated herein by reference from our definitive proxy statement on Schedule 14A for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates (the "Proxy Statement").

ITEM 11: EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated herein by reference from our Proxy Statement.

ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

The information required by this Item 12 is incorporated herein by reference from our Proxy Statement.

ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 is incorporated herein by reference from our Proxy Statement.

ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 is incorporated herein by reference from our Proxy Statement.

PART IV

ITEM 15: EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. **Financial Statements**

The following financial statements are included herein:

- Report of Independent Registered Public Accounting Firm (PCAOB: 274)
- Consolidated Balance Sheets as of December 31, 2021 and 2020
- Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2021 and 2020
- Consolidated Statements of Stockholders' Equity - For the Years Ended December 31, 2021 and 2020
- Consolidated Statements of Cash Flows - For the Years Ended December 31, 2021 and 2020
- Notes to Consolidated Financial Statements

2. **Exhibits**

See Index to Exhibits

ITEM 16: FORM 10-K SUMMARY.

Not applicable.

VBI Vaccines Inc.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
VBI Vaccines Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of VBI Vaccines Inc. and Subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2021 and 2020, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has an accumulated deficit as of December 31, 2021 and cash outflows from operating activities for the year-ended December 31, 2021 and, as such, will require significant additional funds to conduct clinical and non-clinical trials, achieve regulatory approvals, and subject to such approvals, commercially launch its products. These factors raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of In-Process Research and Development

As described in Notes 2 and 7 to the consolidated financial statements, the Company's consolidated In-Process Research & Development ("IPR&D") indefinite-lived intangible asset balance was approximately $62 million as of December 31, 2021, related to both cytomegalovirus ("CMV") and glioblastoma ("GBM") programs. The Company performs impairment testing of indefinite-lived intangible assets on August 31st each year, and tests indefinite-lived intangible assets for impairment between annual tests if events or circumstances indicate that the assets might be impaired. The impairment test compares the carrying amount of the IPR&D asset to its estimated fair value. If the carrying amounts exceeds the fair value of the asset, such excess is recorded as an impairment loss. There was no IPR&D impairment loss determined as a result of the Company's annual testing on August 31, 2021. The fair value of the IPR&D assets included in the impairment test was determined using the income approach method and is considered Level 3 in the fair value hierarchy. Some of the more significant estimates and assumptions inherent in the estimate of the fair value of IRP&D assets include the amount and timing of costs to develop the IPR&D into viable products, the amount and timing of future cash inflows, the discount rate, and the probability of technical and regulatory success applied to the cash flows. The valuation of IP&D assets was also identified as a critical accounting estimate by management.

We identified the valuation of IPR&D as a critical audit matter due to the significant judgment, assumptions and estimation required by management in determining the estimated fair value of the IPR&D. This in turn led to a high degree of auditor subjectivity relating to management's determination, and significant audit effort was required, including the use of professionals with specialized skill and knowledge, in performing our procedures and evaluating the audit evidence obtained relating to estimates made by management.

Addressing the matter involved performing procedures and evaluating audit evidence, in connection with forming our overall opinion on the consolidated financial statements. We obtained an understanding and evaluated the design of controls over the Company's valuation of IPR&D assets. Our procedures also included, among others, testing management's process and evaluating the reasonableness of significant assumptions used in estimating the fair value of IPR&D. Significant assumptions included the amount and timing of future cash flows, probability adjustments surrounding technical and regulatory success, and the discount rate. Evaluating the reasonableness of the significant assumptions involved considering consistency with third-party market and industry data, evidence obtained in other areas of the audit, historical assumptions used by the Company as well as management's representation as to its commitment to develop the IPR&D into viable products. Valuation professionals with specialized skill and knowledge were used to assist in evaluating the appropriateness of the income approach and the reasonableness of certain significant assumptions, including the discount rate, and reperforming the calculation.

Accrual for research and development expenses

As described in Note 2 to the consolidated financial statements, at each balance sheet date the Company estimates its accrued research and development expenses (including clinical trial accrued expenses) resulting from its obligations under contracts with vendors in connection with conducting clinical trials, and may depend on factors such as successful enrollment of certain numbers of patients, site initiation, and the completion of clinical trial milestones. The Company accounts for research and development expenses based on services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when an invoice has not been received or the Company has not otherwise been notified of the actual cost. The Company estimates the time period over which services will be performed and the level of effort to be expended in each period. The Company's accrual for research and development expenses of $8.2 million is included in other current liabilities on the December 31, 2021 consolidated balance sheet. The amounts recorded for research and development expenses represent the Company's estimate of the unpaid research and development expenses based on the information available to the Company at that time. The estimation of research and development expenses was also identified as a critical accounting estimate by management.

We identified the accrual for research and development expenses as a critical audit matter due to the significant judgment and estimation required by management in determining progress or state of completion of trials or services completed. This in turn led to a high degree of auditor subjectivity, and significant audit effort was required in performing our procedures and evaluating audit evidence relating to estimates made by management.

Addressing the matter involved performing procedures and evaluating audit evidence, in connection with forming our overall opinion on the consolidated financial statements. We obtained an understanding and evaluated the design of controls over the Company's estimation of the accrual for research and development expenses, including the process of estimating the expenses incurred to date based on the status of the clinical trials. Our procedures also included, among others, confirming the assumptions, described above, which were used in developing the research and development estimates, directly with the third parties involved in performing the research and development services on behalf of the Company. Our alternative procedures when confirmations were not obtained, or when differences were noted in the confirmation response, included (i) reading agreements and contract amendments with vendors in connection with conducting clinical trials, (ii) evaluating the significant assumptions described above and the methods used in developing the research and development estimates, (iii) making direct inquiries of financial and research and development client personnel regarding status and progress to completion of clinical trials and description of future commitments, and (iv) verifying amounts paid to date under each contract by vouching to invoices and payment support. For items selected for testing we also recalculated the amounts that were unpaid at the balance sheet date and compared to management's estimates.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2016.

EISNERAMPER LLP
Iselin, New Jersey
March 7, 2022

VBI Vaccines Inc. and Subsidiaries

Consolidated Balance Sheets
(in thousands, except share amounts)

	December 31, 2021	December 31, 2020
CURRENT ASSETS		
Cash	**$ 121,694**	$ 93,825
Short-term investments	**-**	25,276
Accounts receivable, net	**8**	77
Inventory, net	**2,576**	2,152
Prepaid expenses	**2,373**	1,569
Other current assets	**3,633**	9,142
Total current assets	**130,284**	132,041
NON-CURRENT ASSETS		
Other long-term assets	**1,259**	639
Property and equipment, net	**11,037**	10,721
Right of use assets	**3,344**	1,554
Intangible assets, net	**62,091**	62,156
Goodwill	**2,261**	2,261
Total non-current assets	**79,992**	77,331
TOTAL ASSETS	**$ 210,276**	$ 209,372
CURRENT LIABILITIES		
Accounts payable	**$ 4,280**	$ 3,734
Other current liabilities	**26,941**	12,415
Current portion of deferred revenues	**526**	255
Current portion of lease liability	**839**	944
Total current liabilities	**32,586**	17,348
NON-CURRENT LIABILITIES		
Lease liability, net of current portion	**2,516**	619
Long-term debt, net of debt discount	**28,441**	16,329
Liabilities for severance pay	**574**	522
Deferred revenues, net of current portion	**2,277**	2,849
Total non-current liabilities	**33,808**	20,319
COMMITMENTS AND CONTINGENCIES (NOTE 17)	-	-
STOCKHOLDERS' EQUITY		
Common shares (unlimited authorized; no par value) (2021 issued and outstanding – 258,250,273; 2020 - issued and outstanding 247,039,010)	**442,235**	403,528
Additional paid-in capital	**81,583**	75,530
Accumulated other comprehensive (loss) income	**(1,565)**	1,265
Accumulated deficit	**(378,371)**	(308,618)
Total stockholders' equity	**143,882**	171,705
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 210,276**	$ 209,372

See accompanying Notes to Consolidated Financial Statements

VBI Vaccines Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	For the Years Ended December 31	
	2021	2020
Revenues	**$ 631**	$ 1,061
Operating expenses:		
Cost of revenues	**10,770**	9,168
Research and development	**19,558**	14,859
General and administrative	**38,335**	20,651
Total operating expenses	**68,663**	44,678
Loss from operations	**(68,032)**	(43,617)
Interest expense, net of interest income (including related party - see Note 10)	**(4,732)**	(2,708)
Foreign exchange gain	**3,011**	95
Loss before income taxes	**(69,753)**	(46,230)
Income tax expense	**-**	-
NET LOSS	**$ (69,753)**	$ (46,230)
Other comprehensive (loss) income	**(2,830)**	2,017
COMPREHENSIVE LOSS	**$ (72,583)**	$ (44,213)
Net loss per share of common shares, basic and diluted	**$ (0.27)**	$ (0.21)
Weighted-average number of common shares outstanding, basic and diluted	**254,947,202**	218,268,979

See accompanying Notes to Consolidated Financial Statements

VBI Vaccines Inc. and Subsidiaries

Consolidated Statements of Stockholders' Equity
(in thousands, except number of common shares)

	Number of Common Shares	Share Capital	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
BALANCE AS OF DECEMBER 31, 2019	**178,257,199**	**$ 284,965**	**$ 66,430**	**$ (752)**	**$ (262,388)**	**$ 88,255**
Common shares issued in financing transactions, net of share issuance costs	**67,911,432**	**116,478**	-	-	-	**116,478**
Common shares issued upon exercise of warrants	**751,158**	**2,139**	-	-	-	**2,139**
Common shares issued upon exercise of options	**750**	**1**	-	-	-	**1**
Warrants issued in connection with financing transactions	-	**(453)**	**1,634**	-	-	**1,181**
Conversion feature issued in debt financing transaction	-	-	**2,577**	-	-	**2,577**
Stock-based compensation	**118,471**	**398**	**4,889**	-	-	**5,287**
Net loss	-	-	-	-	**(46,230)**	**(46,230)**
Unrealized holding gains on short-term investments	-	-	-	**71**	-	**71**
Currency translation adjustments	-	-	-	**1,946**	-	**1,946**
BALANCE AS OF DECEMBER 31, 2020	**247,039,010**	**$ 403,528**	**$ 75,530**	**$ 1,265**	**$ (308,618)**	**$ 171,705**
Common shares issued in financing transactions, net of share issuance costs	**9,135,632**	**32,176**	-	-	-	**32,176**
Common shares issued upon exercise of warrants	**56,873**	**85**	-	-	-	**85**
Common shares issued upon exercise of options	**2,638**	**4**	-	-	-	**4**
Common shares issued upon cashless exercise of warrants	**646,257**	**4,298**	**(4,298)**	-	-	-
Common shares issued upon conversion of long-term debt	**1,369,863**	**2,000**	-	-	-	**2,000**
Warrant modification in connection with debt amendment	-	-	**867**	-	-	**867**
Stock-based compensation	-	**144**	**9,484**	-	-	**9,628**
Net loss	-	-	-	-	**(69,753)**	**(69,753)**
Currency translation adjustments	-	-	-	**(2,830)**	-	**(2,830)**
BALANCE AS OF DECEMBER 31, 2021	**258,250,273**	**$ 442,235**	**$ 81,583**	**$ (1,565)**	**$ (378,371)**	**$ 143,882**

See accompanying Notes to Consolidated Financial Statements

VBI Vaccines Inc. and Subsidiaries

Consolidated Statements of Cash Flows
(in thousands)

	For the Years Ended in December 31	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	**$ (69,753)**	$ (46,230)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	**1,835**	1,652
Stock-based compensation	**9,628**	5,287
Amortization of debt discount	**2,999**	1,569
Inventory reserve	**174**	1,015
Interest accrued on short-term investments	**-**	(205)
Net change in operating working capital items:		
Change in accounts receivable	**69**	130
Change in inventory	**(513)**	(1,946)
Change in prepaid expenses	**(787)**	(511)
Change in other current assets	**5,558**	(8,409)
Change in other long-term assets	**(584)**	11
Change in operating right of use assets	**1,071**	988
Change in accounts payable	**356**	2,059
Change in deferred revenues	**(328)**	(771)
Change in other current liabilities	**11,435**	(711)
Payments made on operating lease liabilities	**(1,068)**	(978)
Net cash flows used in operating activities	**(39,908)**	(47,050)
INVESTING ACTIVITIES		
Redemption of short-term investments	**25,151**	(25,000)
Purchase of property and equipment	**(1,995)**	(1,000)
Net cash flows provided by/used in investing activities	**23,156**	(26,000)
FINANCING ACTIVITIES		
Proceeds from issuance of common shares for in financing transactions	**33,293**	122,185
Share issuance costs	**(1,067)**	(5,612)
Proceeds from issuance of common shares upon exercise of warrants	**85**	2,139
Proceeds from issuance of common shares upon exercise of stock options	**4**	1
Proceeds from debt financing	**12,000**	20,000
Debt issuance costs	**(22)**	(1,021)
Repayment of long-term debt	**-**	(15,300)
Net cash flows provided by financing activities	**44,293**	122,392
Effect of exchange rates on cash	**328**	270
CHANGE IN CASH FOR THE YEAR	**$ 27,869**	$ (49,612)
CASH, BEGINNING OF YEAR	**$ 93,825**	$ 44,213
CASH, END OF YEAR	**$ 121,694**	$ 93,825
Supplementary information:		
Interest paid	**$ 2,039**	$ 1,608
Non-cash investing and financing:		
Warrant modification in connection with debt amendment	**$ 867**	$ -
Warrants issued in connection with financing transactions	**-**	1,634
Common shares issued in connection with cashless warrant exercise	**4,298**	-
K2 conversion feature in connection with financing activities	**-**	2,577
Common shares issued upon conversion of long-term debt	**2,000**	-
Capital expenditures included in accounts payable and other current liabilities	**185**	439
Share issuance costs included in accounts payable and other current liabilities	**(50)**	(95)
Unrealized holding gains on short term investment	**-**	(71)

See accompanying Notes to Consolidated Financial Statements

1. NATURE OF BUSINESS AND CONTINUATION OF BUSINESS

Corporate Overview

VBI Vaccines Inc. (the "Company" or "VBI") was incorporated under the laws of British Columbia, Canada on April 9, 1965.

The Company and its wholly-owned subsidiaries, VBI Vaccines (Delaware) Inc., a Delaware corporation ("VBI DE"); VBI DE's wholly-owned subsidiary, Variation Biotechnologies (US), Inc., a Delaware corporation ("VBI US"); Variation Biotechnologies, Inc. a Canadian company and the wholly-owned subsidiary of VBI US ("VBI Cda"); and SciVac Ltd. an Israeli company ("SciVac"); SciVac Hong Kong Limited ("SciVac HK") and VBI Vaccines B.V a Netherlands company ("VBI BV"), are collectively referred to as the "Company", "we", "us", "our", or "VBI".

The Company's registered office is located at Suite 1700, Park Place, 666 Burrard Street, Vancouver, BC V6C 2X8 with its principal office located at 160 Second Street, Floor 3, Cambridge, MA 02142. In addition, the Company has manufacturing facilities located in Rehovot, Israel and research facilities located in Ottawa, Ontario, Canada.

Principal Operations

VBI Vaccines Inc. ("VBI") is a commercial stage biopharmaceutical company driven by immunology in the pursuit of prevention and treatment of disease. Through its innovative approach to virus-like particles ("VLPs"), including a proprietary enveloped VLP ("eVLP") platform technology, VBI develops vaccine candidates that mimic the natural presentation of viruses, designed to elicit the innate power of the human immune system. VBI is committed to targeting and overcoming significant infectious diseases, including hepatitis B ("HBV"), COVID-19 and coronaviruses, and cytomegalovirus ("CMV"), as well as aggressive cancers including glioblastoma ("GBM"). VBI is headquartered in Cambridge, Massachusetts, with research operations in Ottawa, Canada, and a research and manufacturing site in Rehovot, Israel.

The ongoing COVID-19 pandemic has materially negatively affected and continues to affect the global economy, and there is continued severe uncertainty about the duration and intensity of the impacts of the pandemic. As a result, the Company's business and results of operations have also been adversely affected and could continue to be adversely affected by COVID-19 which has necessitated restricting the number of personnel in the Company's research laboratories and manufacturing facility at any given point in time, and has slowed recruitment to clinical trials. The extent to which the COVID-19 pandemic will continue to impact our business will depend on future developments, which are highly uncertain and cannot be predicted. We do not yet know the full extent of potential delays or impacts on our business, our clinical studies, our research programs, the recoverability of our assets, and our manufacturing; however, the COVID-19 pandemic may disrupt or delay our business operations, including with respect to efforts relating to potential business development transactions, and it could disrupt the marketplace which could have an adverse effect on our operations.

Liquidity and Going Concern

The Company has a limited operating history and faces a number of risks, including but not limited to, uncertainties regarding the success of the development and commercialization of its products, demand and market acceptance of the Company's products, and reliance on major customers. The Company anticipates that it will continue to incur significant operating costs and losses in connection with the development and commercialization of its products.

The Company has an accumulated deficit of $378,371 as of December 31, 2021 and cash outflows from operating activities of $39,908, for the year-ended December 31, 2021.

The Company will require significant additional funds to conduct clinical and non-clinical trials, commercially launch our products, and achieve regulatory approvals. The Company plans to finance future operations with existing cash and cash equivalent reserves. Additional financing may be obtained from the issuance of equity securities, the issuance of additional debt, structured asset financings, and/or revenues from potential business development transactions, if any. There is no assurance the Company will manage to obtain these sources of financing, if required. The above conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

In April 2020, the Company closed an underwritten public offering of 52,272,726 common shares at a price of $1.10 per share for total gross proceeds of $57,500. The Company incurred $3,606 of share issuance costs related to the offering resulting in net cash proceeds of $53,894 and costs related to the issuance of warrants to purchase 705,000 common shares to National Securities Inc. ("National") or its designees as consideration for National providing financial advisory services in connection with the offering. The warrants issued to National or its designees ("National Warrants") are exercisable immediately upon issuance and terminate three years following issuance and have an exercise price of $1.50 per share.

In May 2020, the Company refinanced its term loan facility with Perceptive Credit Holdings, LP and entered into a Loan and Guaranty Agreement (the "Loan Agreement") with K2 HealthVentures LLC for net proceeds of approximately $4,500. The refinanced long-term debt has a maturity date of June 1, 2024. See Note 10 for more details.

On July 21, 2020, we issued 550,000 common shares upon exercise of warrants at an exercise price of $3.34 for gross proceeds of $1,837.

On July 3, 2020, the Company and the National Research Council of Canada ("NRC") signed a contribution agreement as represented by its Industrial Research Assistance Program ("IRAP") whereby the NRC agree to contribute up to CAD $1,000 for the transfer and scale-up of the technical production process for our prophylactic coronavirus vaccine program.

On September 16, 2020, the Company and Her Majesty the Queen in Right of Canada as represented by the Minister of Industry ("ISED") signed a contribution agreement (the "Contribution Agreement") for a contribution from the Strategic Innovation Fund ("SIF") whereby ISED agreed to contribute up to CAD $55,976 to support the development of the Company's coronavirus vaccine program, through Phase II clinical studies, for a period commencing on April 15, 2020 and ending in or before the first quarter of 2022, however discussions are underway to extend the term. In connection with execution of the Contribution Agreement, the Company obtained a consent of K2 HealthVentures LLC, as administrative agent for the lenders and a lender, pursuant to the Loan Agreement. Pursuant to the consent, certain events of default that result in contributions made under the Contribution Agreement in excess of $500 becoming due and payable could result in an event of default under the Loan Agreement. See Note 10 for more details on the Loan Agreement.

On July 31, 2020, the Company entered into an Open Market Sale Agreement with Jefferies LLC ("Jefferies"), pursuant to which the Company may offer and sell its common shares having an aggregate price of up to $125,000 from time to time through Jefferies, acting as agent or principal (the "ATM Program"). Common shares were offered pursuant to a sales agreement prospectus included in the Company's automatic shelf registration on Form S-3 filed with the United States Securities and Exchange Commission ("SEC") on July 31, 2020. During the year ended December 31, 2020, the Company issued 15,638,706 common shares under the ATM Program, for total gross proceeds of $64,685 at an average price of $4.14. We incurred $2,101 of share issuance costs related to the common shares issued resulting in net proceeds of $62,584.

During the year ended December 31, 2020, the Company issued 201,158 common shares upon exercise of National Warrants at an exercise price of $1.50 for gross proceeds of $302.

On March 9, 2021, the Company and the Coalition for Epidemic Preparedness Innovations ("CEPI") announced a partnership ("CEPI Funding Agreement") to develop eVLP vaccine candidates against SARS-COV-2 variants, including the Beta variant, also known as the B.1.351 variant and 501Y.V2, first identified in South Africa. CEPI agreed to provide up to $33,018 to support the advancement of VBI-2905, a monovalent eVLP candidate expressing the pre-fusion form of the spike protein from the Beta variant, through Phase I clinical development. This funding will also support preclinical expansion of additional multivalent vaccine candidates designed to evaluate the potential breadth of our eVLP technology. The preclinical expansion is intended to develop clinic-ready vaccine candidates capable of addressing emerging variants. See more information on the CEPI Funding Agreement in Note 14.

On May 17, 2021, the Company entered into the First Amendment to the Loan and Guaranty Agreement and Affirmation of Pledge and Security Agreement (the "First Amendment") with K2 HealthVentures LLC and any other lender from time-to-time party thereto. See Note 10 for more details.

In June 2021, the Company issued 646,257 common shares to Perceptive Credit Holdings, LP and PCOF EQ AIV, LP (related parties), upon exercise of 2,068,824 warrants on a cashless "net exercise" basis.

On September 3, 2021, the Company entered into a second Open Market Sale Agreement^{SM} with Jefferies to act as the Company's sales agent and/or principal, for the issuance and sale of up to an additional $125,000 of the Company's common shares from time to time in an at-the-market public offering, which the Company could choose to use when no shares remain available for issuance under the ATM Program.

During the year ended December 31, 2021, the Company issued 9,135,632 common shares under the ATM Program, for total gross proceeds of $33,293 at an average price of $3.64. The Company incurred $1,117 of share issuance costs related to the common shares issued resulting in net proceeds of $32,176. As of December 31, 2021, $27,022 of common shares remained available for issuance under the ATM Program.

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Consolidation

The consolidated financial statements include the accounts of VBI and its wholly owned subsidiaries, SciVac, SciVac HK, VBI DE, VBI US, VBI Cda, and VBI BV.

Intercompany balances and transactions between the Company and its subsidiaries are eliminated in the consolidated financial statements.

Cash and Cash Equivalents

Cash and cash equivalents include cash investments in interest-bearing accounts and term deposits which can readily be redeemed for cash or are issued for terms of three months or less from the date of acquisition.

Short-Term Investments

Short-term investments consisted of redeemable short-term investments held with Schedule 1 Canadian banks for maturity terms greater than 3 months but less than a year from the date of acquisition. Short-term investments were initially classified as available for sale and were measured at fair value whereby unrealized holding gains or losses on these investments are reported in other comprehensive income or loss and accrued interest income was recognized in interest expense, net of interest income in the consolidated statement of operations and comprehensive loss.

On September 30, 2020 we re-assessed the classification of our short-term investment and we determined that the short-term investment shall be classified as held to maturity. The transfer on September 30, 2020 occurred at fair value with the unrealized holding gains remaining in other comprehensive income or loss. Held to maturity short term investments are measured at amortized cost and the unrealized holding gains will be amortized over the remaining life of the security until April 2021.

Our short-term investments, when classified as available for sale, were measured at fair value and considered level 2 in the fair value hierarchy. The fair value of the short-term investment was determined using the market approach method and the inputs include comparable market interest rates at September 30, 2020.

Foreign Currency

The functional and reporting currency of the Company is the United States dollar. Each of the Company’s subsidiaries determines its own respective functional currency, based on the primary economic environment that it operates in, and this currency is used to separately measure each entity’s financial position and operating results.

Assets and liabilities of foreign operations with a different functional currency from that of the Company are translated at the closing rate at the end of each reporting period. Profit or loss items are translated at average exchange rates for all the relevant periods. All resulting translation differences are recognized as a component of other comprehensive loss /income.

Foreign exchange gains and losses arising from transactions denominated in a currency other than the functional currency of the entity involved, are included in operating results.

Use of Estimates

Preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual amounts could differ from the estimates made. We continually evaluate estimates used in the preparation of the consolidated financial statements for reasonableness. Appropriate adjustments, if any, to the estimates used are made prospectively based upon such periodic evaluation. The significant areas of estimation include revenue recognition, determining the deferred tax valuation allowance, estimating accrued research and development expenses, the inputs in determining the fair value of the in-process research and development ("IPR&D") and goodwill as part of the annual impairment analysis and the inputs in determining the fair value of beneficial conversion features, equity-based awards and warrants issued. Actual results may differ from those estimates.

Concentration of Credit Risk

Financial instruments that potentially subject us to significant concentrations of credit risk consist principally of cash and accounts receivable. We place our cash primarily in commercial checking accounts. Commercial bank balances may from time to time exceed federal insurance limits. However, the Company believes credit risk is low as the cash resides in large highly rated financial institutions.

The Company has not experienced any losses in cash and accounts receivable for years ended December 31, 2021 and 2020, respectively.

Inventory

Inventory components include all raw materials, work-in-progress and finished goods. Cost is determined on a specific item or first-in/first-out basis. The cost of inventories comprises costs to purchase, costs incurred in bringing the inventories to their present location and condition, and costs incurred in the manufacturing process including labor and overhead. Inventory is valued at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. On a quarterly basis, the Company evaluates the condition and age of inventories and makes provisions for slow moving inventories accordingly.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation.

The assets are depreciated by the straight-line method over the estimated useful lives of the related assets as follows:

	Number of years
Furniture and office equipment	5-14
Machinery and equipment	3-7
Computers	2-3
Leasehold improvements	shorter of useful life or the term of the lease

When assets are retired or otherwise disposed of, the cost and the related accumulated depreciation is removed from the accounts, and any resulting gain or loss is recognized in the consolidated statement of operations and comprehensive loss. The cost of maintenance and repairs is charged to expense as incurred; significant renewals and betterments are capitalized.

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment and finite-lived intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of assets to be held and used is measured by comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, then an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

The Company did not record an impairment for long-lived assets during the years ended December 31, 2021 or 2020.

In-Process Research and Development Assets and Goodwill

The Company’s intangible assets determined to have indefinite useful lives including IPR&D and goodwill, are tested for impairment annually, or more frequently if events or circumstances indicate that the assets might be impaired. Such circumstances could include but are not limited to: (i) a significant adverse change in legal factors or in business climate, (ii) unanticipated competition, or (iii) an adverse action or assessment by a regulator. The Company has established August 31st as the date for its annual impairment test of IPR&D and goodwill.

The IPR&D assets, which consist of the CMV and GBM programs, were acquired in a business combination, capitalized as an intangible asset and are tested for impairment at least annually until commercialization, after which time the IPR&D will be amortized over its estimated useful life. The impairment test compares the carrying amount of the IPR&D asset to its fair value. If the carrying amount exceeds the fair value of the asset, such excess is recorded as an impairment loss. There was no IPR&D impairment determined as a result of the Company’s annual testing on August 31, 2021 and 2020. The fair value of the IPR&D assets included in the impairment test was determined using the income approach method and is considered Level 3 in the fair value hierarchy. Some of the more significant estimates and assumptions inherent in the estimate of the fair value of IPR&D assets include the amount and timing of costs to develop the IPR&D into viable products, the amount and timing of future cash inflows, the discount rate and the probability of technical and regulatory success applied to the cash flows. For the annual impairment test performed at August 31, 2021, the discount rate used was 11% and the cumulative probability of technical and regulatory success to achieve approval to market the products ranged from approximately 10% to 17%. For the annual impairment test performed at August 31, 2020, the discount rate used was 11% and the cumulative probability of technical and regulatory success to achieve approval to market the products ranged from approximately 6% to 17%.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. When evaluating goodwill for impairment, we may first perform an assessment qualitatively whether it is more likely than not that a reporting unit’s carrying amount exceeds its fair value, referred to as a “step zero” approach. Subsequently (if necessary, after step zero), if the carrying value of a reporting unit exceeded its fair value an impairment would be recorded. We would perform our goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. There was no goodwill impairment determined as a result of the Company’s annual testing on August 31, 2021 and 2020. The fair value of the Company, which consists of a single reporting unit, included in the impairment test was determined using the closing market stock price of VBI as of August 31, 2021 and 2020.

Other Intangible Assets

The Company's other intangible assets include patents with finite lives. These assets obtained are recorded at cost less accumulated amortization and any impairment losses.

The Company amortizes intangible assets with finite lives on a straight-line basis over their estimated useful lives.

Long-Term Debt

The Company accounts for long-term debt under the provisions of ASC 470-20, Debt – Debt with conversion and other options ("ASC 470"). Conversion options are accounted for at intrinsic value and other options, including warrants, are accounted for based on the relative fair value of the warrants, long-term debt, and other options (including conversion options). Conversion and other options are accounted for in additional paid-in capital and result in a debt discount. Final payments or exit fees and debt issuance costs also result in a debt discount. The debt discount is being charged to interest expense, net of interest income in the consolidated statement of operations and comprehensive loss using the effective interest method over the term of the debt.

Research and Development

All costs of research and development are expensed as incurred.

When preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Payments under some of the contracts we have with third parties depend on factors such as successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones.

When accruing research and development expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from our service providers. However, we may be required to estimate the cost of these services based only on information available to us. If we underestimate or overestimate the cost associated with research and development services at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued research and development expenses have approximated actual expense incurred.

Government Grants

Government grants are recognized in the consolidated statement of operations and comprehensive loss in the same period as the relevant expenses, in compliance with the agreement, as a reduction in the related expense or reduce the carrying value of the asset being acquired.

Cash received from government grants related to deposits are recognized as deferred government grants, included in other current liabilities on the consolidated balance sheet, and recognized as the related deposit is used.

CEPI Funding Agreement

Cash received in advance from the CEPI Funding Agreement is included in cash on the consolidated balance sheet, however, it is restricted as to its use until the relevant expenses are incurred. The cash received is recognized as deferred funding, included in other current liabilities on the consolidated balance sheet, and recognized as a reduction in the related expense when incurred. As of December 31, 2021, the amount of cash received in advance from CEPI, not yet recognized as a reduction in expenses in the consolidated statement of operations but included in cash on the consolidated balance sheets, is $10,183. See more information on the CEPI Funding Agreement in Note 14.

Revenue Recognition

We recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligation(s). At contract inception, we assess the goods or services promised within each contract, assess whether each promised good or service is distinct and identify those that are performance obligations.

The Company must use significant judgment to determine: a) the number of performance obligations based on the determination under step (ii) above and whether those performance obligations are distinct from other performance obligations in the contract; b) the transaction price under step (iii) above; and c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price. The transaction price is allocated to each performance obligation on an estimated stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

Where a portion of non-refundable up-front fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as contract liabilities and recognized as revenue when (or as) the underlying performance obligation is satisfied.

Product Sales

The Company recognizes revenue from product sales when obligations under the terms of the contract with the customer are satisfied; this occurs upon the transfer of control of the goods to the customers.

Collaborative Arrangements

The Company first evaluates license and/or collaboration arrangements to determine whether the arrangement (or part of the arrangement) represents a collaborative arrangement pursuant to Accounting Standards Codification ("ASC") Topic 808, Collaborative Arrangements ("ASC 808"), based on the risks and rewards and activities of the parties pursuant to the contractual arrangement. The Company then determines if the collaborative arrangements are within the scope of ASC Topic 606, Revenue Recognition ("ASC 606").

Collaborative arrangements with partners which are within the scope of ASC 606 typically include payment to us of one or more of the following: (i) license fees; (ii) research and development services to be performed as part of the contract ("R&D services") (iii) payments related to the achievement of developmental, regulatory, or commercial milestones; and (iv) royalties on net sales of licensed products.

Collaborative arrangements (or elements within the contract that are deemed part of a collaborative arrangement) with partners which represent a collaborative relationship and not a customer relationship, are accounted for outside the scope of ASC Topic 606.

License Fees

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

R&D Services

The promises under the Company's collaboration and license agreements generally include research and development services to be performed by the Company. For performance obligations that include research and development services, the Company generally recognizes revenue allocated to such performance obligations based on an appropriate measure of progress. The Company utilizes judgment to determine the appropriate method of measuring progress for purposes of recognizing revenue, which is generally an input measure such as costs incurred. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Employee Benefits

The Company's liability for severance pay for the employees of its subsidiary in Israel is calculated in accordance with Israeli law based on the most recent salary paid to employees and the length of employment in the Company. The Company records its obligation with respect to employee severance payments as if it were payable at each balance sheet date.

Obligations for employee benefits are recognized as a component of operating expenses in the consolidated statement of operations and comprehensive loss in the periods during which services are rendered by employees.

Income Taxes

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities using enacted tax rates which will be in effect when the differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax asset will be realized.

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The benefit is measured as the largest amount that is more likely than not to be realized upon ultimate settlement. The Company does not have any uncertain tax positions or accrued penalties and interest as of December 31, 2021 and 2020. If such matters were to arise, the Company would recognize interest and penalties related to income tax matters in income tax expense.

The Company's claim for Scientific Research and Experimental Development ("SR&ED") deductions for income tax purposes are based upon management's interpretation of the applicable legislation in the Income Tax Act (Canada). These amounts are subject to review and acceptance by the Canada Revenue Agency and may be subject to adjustment.

Fair Value Measurements of Financial Instruments

Accounting guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The accounting guidance outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures.

The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 — Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.

Level 3 — Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

Financial instruments recognized in the consolidated balance sheet consist of cash, short-term investments, accounts receivable, other current assets, accounts payable and other current liabilities. The Company believes that the carrying value of its current financial instruments approximates their fair values due to the short-term nature of these instruments. The Company does not hold any derivative financial instruments.

The carrying amounts of the Company's long-term financial assets approximate their respective fair values.

The fair value of our outstanding debt, including the current portion, is estimated to be approximately $30,406 and $20,117 at December 31, 2021 and 2020, respectively. The fair value of the outstanding debt is considered to be Level 3 in the fair value hierarchy and was estimated by discounting to present value the scheduled coupon payments and principal repayment, using an appropriate fair market yield.

Loss Per Share

Basic loss per share is computed by dividing net loss by the weighted average number of shares outstanding during the period. Diluted loss per share is computed by dividing net loss by the weighted average number of shares outstanding after giving effect to the impact of all potentially dilutive potential shares. There was no dilutive effect on the earnings per share for all periods presented.

Leases

The Company determines if an arrangement is a lease at inception. For the Company's operating leases, the right-of-use ("ROU") assets represents the Company's right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. Since the Company's lease agreements do not provide an implicit rate, the Company estimated an incremental borrowing rate in determining the present value of its lease payments. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. Variable lease costs such as operating costs and property taxes are expensed as incurred.

Stock-Based Compensation

The Company accounts for share-based awards to employees and directors in accordance with the provisions of ASC 718, Compensation—Stock Compensation ("ASC 718"). Under ASC 718, share-based awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service period. The Company values its stock options using the Black-Scholes option pricing model. The Company accounts for forfeitures when they occur.

The Company accounts for share-based payments to non-employees issued in exchange for services based upon the fair value of the equity instruments issued. Compensation expense for stock options issued to non-employees is calculated using the Black-Scholes option pricing model and is recorded over the service performance period.

3. NEW ACCOUNTING PRONOUNCEMENTS

Recently Adopted Accounting Standards

None

Recently Issued Accounting Standards, not yet Adopted

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which will simplify the accounting for certain financial instruments with characteristics of liabilities and equity, including certain convertible instruments and contracts on an entity's own equity. Specifically, the new standard will remove the separation models required for convertible debt with cash conversion features and convertible instruments with beneficial conversion features. It will also remove certain settlement conditions that are currently required for equity contracts to qualify for the derivative scope exception and will simplify the diluted earnings per share calculation for convertible instruments.

On January 1, 2022, the Company adopted ASU 2020-06 using the modified retrospective method of transition through a cumulative-effect adjustment to opening accumulated deficit under which comparative financial information will not be restated and continue to apply the provisions of ASC 470 before the adoption of ASU 2020-06. The new guidance eliminated the beneficial conversion feature accounting model required for convertible debt. Our conversion option that was previously bifurcated and recorded as a debt discount and additional paid-in capital has now been combined as a single instrument classified as a liability.

Based on the Company's preliminary assessment of the adoption of this ASU, on January 1, 2022, the Company eliminated the beneficial conversion feature from additional paid-in capital of approximately $2,700; eliminated the interest accretion on the beneficial conversion through December 31, 2021 from opening accumulated deficit of approximately $2,000, and eliminated the debt discount of approximately $700. The Company is further evaluating the impact of the adoption of this ASU will have on its consolidated financial statements and related disclosures.

4. INVENTORY, NET

Inventory is stated at the lower of cost or market and consists of the following:

	2021	2020
Finished goods	$ -	$ -
Work-in-process	645	390
Raw materials	1,931	1,762
Inventory, net	$ 2,576	$ 2,152

The Company recorded a provision of approximately $174 and $1,015 during the years ended December 31, 2021 and 2020, respectively. The provision is for inventory largely related to excess work-in process which is no longer expected to be used in the manufacturing process.

5. OTHER CURRENT ASSETS

Other current assets consisted of the following:

	2021	2020
Government receivables	$ 1,438	$ 7,830
Other current assets	2,195	1,312
Total other current assets	$ 3,633	$ 9,142

6. PROPERTY AND EQUIPMENT

	2021		
	Cost	Accumulated Depreciation	Net Book Value
Machinery and equipment	$ 5,951	$ (2,463)	$ 3,488
Furniture and office equipment	290	(80)	210
Computer equipment and software	846	(505)	341
Leasehold improvements	8,909	(1,911)	6,998
	$ 15,996	$ (4,959)	$ 11,037

	2020		
	Cost	Accumulated Depreciation	Net Book Value
Machinery and equipment	$ 5,352	$ (1,795)	$ 3,557
Furniture and office equipment	218	(64)	154
Computer equipment and software	590	(428)	162
Leasehold improvements	8,171	(1,323)	6,848
	$ 14,331	$ (3,610)	$ 10,721

Depreciation expense for the years ended December 31, 2021, and 2020 was $1,768 and $1,588, respectively.

7. INTANGIBLE ASSETS AND GOODWILL

	2021				
	Gross Carrying Amount	**Accumulated Amortization**	**Cumulative Impairment Charge**	**Cumulative Currency Translation**	**Net Book Value**
License	**$ 669**	**$ (660)**	**$ -**	**$ 47**	**$ 56**
IPR&D assets	**61,500**	**-**	**(300)**	**835**	**62,035**
	$ 62,169	**$ (660)**	**$ (300)**	**$ 882**	**$ 62,091**

	2020				
	Gross Carrying Amount	Accumulated Amortization	Cumulative Impairment Charge	Cumulative Currency Translation	Net Book Value
License	$ 669	$ (590)	$ -	$ 44	$ 123
IPR&D assets	61,500	-	(300)	833	62,033
	$ 62,169	$ (590)	$ (300)	$ 877	$ 62,156

The license is held in Israel at SciVac. Amortization expenses for the years ended December 31, 2021 and 2020 amounted to $67 and $64, respectively. Amortization is expected to be approximately $66 per year until its fully amortized. These amounts do not include any amortization related to the IPR&D assets, which will not begin amortizing until the Company commercializes its products.

The IPR&D assets are in VBI Cda and the change in carrying value for IPR&D assets from December 31, 2020 relates to currency translation adjustments which increased by $2 for the year ended December 31, 2021. The change in carrying value from December 31, 2019 to December 31, 2020 relates to currency translation adjustments which increased IPR&D assets by $1,455.

	2021			
	Gross Carrying Amount	**Cumulative Impairment Charge**	**Cumulative Currency Translation**	**Net Book Value**
Goodwill	**$ 8,714**	**$ (6,292)**	**$ (161)**	**$ 2,261**

	2020			
	Gross Carrying Amount	Cumulative Impairment Charge	Cumulative Currency Translation	Net Book Value
Goodwill	$ 8,714	$ (6,292)	$ (161)	$ 2,261

The goodwill is in VBI Cda and the change in carrying value from December 31, 2020 relates to currency translation adjustments which increased goodwill by $0 for the year ended December 31, 2021. The change in carrying value for goodwill from December 31, 2019 relates to currency translation adjustments which increased by $53 for the year ended December 31, 2020.

8. OTHER CURRENT LIABILITIES

Other current liabilities consisted of the following:

	2021	2020
Accrued research and development expenses (including clinical trial accrued expenses)	**$ 8,196**	$ 5,842
Accrued professional fees	**2,294**	1,547
Payroll and employee-related costs	**4,805**	3,844
Deferred funding	**10,183**	-
Other current liabilities	**1,463**	1,182
Total other current liabilities	**$ 26,941**	$ 12,415

9. LOSS PER SHARE OF COMMON SHARES

Basic loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common shares outstanding during each period. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as warrants, and stock options, which would result in the issuance of incremental shares of common shares unless such effect is anti-dilutive. In computing the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remained the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation. These potentially dilutive securities are more fully described in Note 12, Stockholders' Equity and Additional Paid-in Capital.

The following potentially dilutive securities outstanding at December 31, 2021 and 2020 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	2021	2020
Warrants	**1,384,469**	3,197,666
Stock options and unvested stock awards	**18,573,708**	12,636,897
K2 conversion feature	**1,369,863**	2,739,726
	21,328,040	18,574,289

10. LONG-TERM DEBT

	2021	2020
Long-term debt, net of debt discount of $3,783 ($5,061 at December 31 2020)	**$ 28,441**	$ 16,329
Less: current portion, net of debt discount of $0 ($0 at December 31, 2020)	-	-
	$ 28,441	$ 16,329

On May 22, 2020, the Company (along with its subsidiary VBI Cda) entered into the Loan and Guaranty Agreement (the "Loan Agreement") with K2 HealthVentures LLC and any other lender from time-to-time party thereto (the "Lenders") pursuant to which we received the first tranche secured term loan of $20,000 (the "First Tranche Term Loan"). The Lenders originally agreed to make available the following additional tranches subject to the following conditions and upon the submission of a loan request by the Company: (1) up to $10,000 available between January 1, 2021 and April 30, 2021 upon achievement of certain milestones (the "Second Tranche Term Loan"), (2) $10,000 available between the closing date and December 31, 2021, subject to achievement of a certain U.S. Food and Drug Administration ("FDA") approval (the "Third Tranche Term Loan"), and (3) a final tranche of up to $10,000 that can be made available any time prior to June 30, 2022, subject to the advance of the Third Tranche Term Loan, satisfactory review by the administrative agent of our financial and operating plan, and approval by the Lenders' investment committee (the "Fourth Tranche Term Loan"). The Company obtained the FDA approval on November 30, 2021 but elected not to draw down the Third Tranche Term Loan. Pursuant to the Loan Agreement, the Lenders originally had the ability to convert, at the Lenders' option, up to $4,000 of the secured term loan into common shares of the Company at a conversion price of $1.46 per share ("K2 conversion feature") until the maturity date of June 1, 2024. On February 3, 2021, pursuant to the Loan Agreement, the Lenders, converted $2,000 of the secured term loan into 1,369,863 common shares at a conversion price of $1.46. The Lenders have the ability to convert an additional $2,000 at the Lenders' option.

On May 17, 2021, the Company entered into the First Amendment with the Lenders to: (1) increase the Second Tranche Term Loan from $10,000 to $12,000; (2) extend the availability period of the Second Tranche Term Loan beyond April 30, 2021, subject to certain conditions; (3) amend the Second Tranche Term Loan interest rate equal to the greater of (a) 7.75% and (b) prime rate plus 4.50%; and (4) extend the date as of which amortization of the loans under the Loan Agreement shall begin from July 1, 2022 to January 1, 2023.

In connection with the Loan Agreement, on May 22, 2020, the Company issued the Lenders a warrant to purchase up to 625,000 common shares (the "Original K2 Warrant") at an exercise price of $1.12 (the "Warrant Price"). On May 17, 2021, in connection with the First Amendment, the Company issued the Lenders an amended and restated warrant to purchase an additional 312,500 common shares for a total of 937,500 common shares (the "Restated K2 Warrant") with the same Warrant Price of $1.12. The number of common shares issuable pursuant to the Restated K2 Warrant, at any given time, is determined by dividing the Warrant Coverage Amount by the Warrant Price, where the Warrant Coverage Amount is equal to the sum of $1,050 plus the aggregate original principal amount of the Third Tranche and Fourth Tranche Term Loan advanced at that time multiplied by 3.5%. The Restated K2 Warrant may be exercised either for cash or on a cashless "net exercise" basis and expires on May 22, 2030.

The total proceeds attributed to the Original K2 Warrant was $1,181 based on the relative fair value of the Original K2 Warrant as compared to the sum of the fair values of the Original K2 Warrant, K2 conversion feature and debt. The effective conversion price of the K2 conversion feature of $1.52 was determined to be less than the fair value of the underlying common stock at the date of commitment, resulting in a beneficial conversion feature ("BCF") at that date. The intrinsic value of the BCF was $2,577 and recorded to additional paid-in capital. The Original K2 Warrant and the K2 conversion feature resulted in the debt being issued at a discount. The Company also incurred $1,021 of debt issuance costs and is required to make a final payment equal to 6.95% of the aggregate original secured term loan principal on the maturity date of the term loan, or upon earlier prepayment of the term loans in accordance with the Loan Agreement, resulting in an additional discount of $1,390 related to the First Tranche Term Loan. The total initial debt discount was $6,169.

The Second Tranche Term Loan, issued pursuant to the Loan Agreement as amended by the First Amendment, resulted in the Company incurring an additional $20 of debt issuance costs, $150 of third-party costs and being required to make a final payment of $834, which is equal to 6.95% of the Second Tranche Term Loan.

The Company accounted for the First Amendment as a debt modification and as a result the debt discount was increased by $1,721. This amount represents: (1) the incremental fair value of the Restated K2 Warrant of $867; (2) the increased final payment of $834 related to the Second Tranche Term Loan; and (3) debt issuance costs of $20. The third-party costs were expensed in general and administrative in the consolidated statement of operations and comprehensive loss.

The total principal amount of the loan under the Loan Agreement, as amended by the First Amendment, outstanding at December 31, 2021, including the $2,224 final payment discussed above, is $32,224. The principal amount of the loan made under the Loan Agreement accrues interest at an annual rate equal to the greater of (a) 8.25% or (b) prime rate plus 5.00%. The principal amount of the Second Tranche Term Loan made under the Loan Agreement, as amended by the First Amendment, accrues interest at an annual rate equal to the greater of (a) 7.75% or (b) prime rate plus 4.50%. The interest rate as of December 31, 2021 was 8.25% for the First Tranche Term Loan and 7.75% for the Second Tranche Term Loan. The Company is required to pay only interest until January 1, 2023. The effective interest rate on the loan of $30,000, excluding the final payment, is 15.33%.

Upon the occurrence of an Event of Default, and during the continuance of an Event of Default, the applicable rate of interest, described above, will be increased by 5.00% per annum. The secured term loan maturity date is June 1, 2024, and the Loan Agreement includes both financial and non-financial covenants. The Company was in compliance with these covenants as of December 31, 2021.

The obligations under the Loan Agreement, as amended by the First Amendment, are secured on a senior basis by a lien on substantially all of the assets of the Company and its subsidiaries other than intellectual property. The subsidiaries of the Company, other than VBI Cda and SciVac HK, and VBI BV, are guarantors of the obligations of the Company and VBI Cda under the Loan Agreement. The Loan Agreement also contains customary events of default.

Approximately $14,500 of the proceeds received were used to repay the Company's Amended Credit Facility (as defined below) with Perceptive Credit Holdings, LP, a related party ("Perceptive"), which was due on June 30, 2020. The early repayment resulted in a loss on extinguishment of debt of $84, which is included in interest expense, net of interest income on the consolidated statement of operations and comprehensive loss.

On May 6, 2016, the Company through VBI US assumed a term loan facility with Perceptive Credit Holdings, LP, a related party, ("Perceptive") in the amount of $6,000 (the "Facility"). On December 6, 2016, the Company amended the Facility (the "Amended Credit Facility") and raised Perceptive commitment amount to $13,200, which was combined with the remaining balance from the Facility of $1,800. In connection with the Amended Credit Facility, on December 6, 2016, the Company issued to Perceptive two warrants; the first warrant to purchase 363,771 shares of the Company's common shares at an exercise price of $4.13, and the second warrant to purchase 1,341,282 shares of the Company's common shares at an exercise price of $3.355. The total proceeds attributed to the warrants was $2,793 based on the relative fair value of the warrants as compared to the sum of the fair values of the warrants and debt. This resulted in the debt being issued at a discount. The Company incurred $360 of debt issuance costs and is required to pay an exit fee of $300 upon full repayment of the debt resulting in additional debt discount. Following the Amended Credit Facility and the warrant issuance, the total debt discount was $3,453.

On July 17, 2018, the Company amended the Amended Credit Facility (the "Second Amendment") to extend the period the Company is required to pay only the interest on the loan from May 31, 2018 to December 31, 2018 and to extend the expiration date of certain warrants to purchase 363,771 common shares issued to Perceptive with an original expiration date of July 25, 2019 to December 6, 2021. The Company accounted for this as a debt modification, and as a result of the extension of the warrant expiration date in connection with the Second Amendment, the debt discount was increased by $386. This amount represents the incremental fair value of the modified warrants.

On January 31, 2019, the Company further amended the Amended Credit Facility (the "Third Amendment") to i) extend the period the Company is required to pay only the interest on the loan from December 31, 2018 to January 31, 2020, ii) extend the maturity of the term loan to June 30, 2020, and iii) reduce the exercise price on certain warrants to purchase common shares issued to Perceptive to $2.75 from $4.13 for 363,771 warrants issued on July 25, 2014, and for 363,771 warrants issued on December 6, 2016, and from $3.355 for 1,341,282 warrants issued on December 6, 2016. The Company has accounted for this as a debt modification, and as a result of the amendment to the exercise price in connection with the Third Amendment, the debt discount was increased by $179. This amount represents the incremental fair value of the modified warrants.

As of December 31, 2021 and 2020, the total debt discount related to the Loan Agreement with K2 HealthVentures LLC was $7,890 and $6,169, respectively. As of December 31, 2021, and 2020 the unamortized debt discount was $3,783 and $5,061, respectively. The debt discount is being charged to interest expense, net of interest income in the consolidated statement of operations and comprehensive loss using the effective interest method over the term of the debt.

Interest expense, net of interest income recorded for the year ended December 31, 2021 and 2020 was as follows:

	2021	2020
Interest expense	**$ 2,105**	$ 1,752
Amortization of debt discount	**2,999**	1,569
Interest income	**(372)**	(613)
Total interest expense, net of interest income	**$ 4,732**	$ 2,708

During the year ended December 31, 2021, the Company amortized $2,999 of the debt discount, which comprises (1) $1,161 recognized immediately upon conversion of the K2 conversion feature and (2) $1,838 of amortization of the debt discount. Such amount is included in interest expense, net of interest income in the consolidated statement of operations and comprehensive loss.

Interest expense and amortization of debt discount for the year ended December 31, 2020 includes $723 and $461, respectively, incurred to a related party.

The following table summarizes the future payments that the Company expects to make for long-term debt:

	Principal payments on Loan Agreement and final payment
2022	$ -
2023	19,573
2024	12,651
Total	$ 32,224

11. EMPLOYEE BENEFITS

Defined Contribution Plan

The Company operates a defined contribution retirement benefit plan for all qualifying employees in accordance with corresponding federal and state/provincial law. Effective May 1, 2021, for VBI DE and VBI Cda employees, the respective companies contribute up to 3% of the employee's salary to a retirement benefit, which contribution is based on a 50% match of participating employee contributions. Prior to May 1, 2021, for VBI DE and VBI Cda employees the respective companies contributed up to 1.5% of the employee's salary to a retirement benefit, which contribution was based on a 25% match of participating employee contributions. The total expense recognized for the years ended December 31, 2021 and 2020 was $110 and de minimus, respectively.

For qualifying employees in Israel, under Israeli law, the assets of the plan are held separately from those of the Company, in funds under the control of trustees. The total expense recognized for the years ended December 31, 2021 and 2020 was $352 and $292, respectively, and represents contributions payable to these plans by the Company at rates specified in the rules of the plan.

Liability for Severance Pay

Israel's labor laws and the Law "severance pay, 1963" (the "Law"), require the Company to pay severance pay to employees during dismissal, disability and retirement. Legal retirement age under Israeli labor laws is currently 64 for women and 67 for men. Thus, under the plan, an employee who was employed by the Company for at least one year (and in the circumstances defined by the law) and was involuntarily terminated by the Company after the said period is entitled to severance pay. The rate of compensation listed in the Law is the employee's final monthly salary for each year of employment.

Under the program, the Company is obligated to deposit amounts at the rate fixed by Law (since January 1, 2008), to ensure the accrual of such a severance pay due to the employee as described above. The rate required by law is 8.33% of the employee's salary, which is deposited in a pension fund/insurance severance fund.

Included in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2021 is $16 of severance payments pursuant to the aforementioned statutory or contractual obligations. There were no severance payments pursuant to the aforementioned statutory or contractual obligations as of December 31, 2020.

12. STOCKHOLDERS' EQUITY AND ADDITIONAL PAID-IN CAPITAL

Authorized

We have an unlimited number of common shares authorized without par value.

Common Shares Issuances

2021 common shares issuances were as follows:

i. On February 3, 2021, the Company issued 1,369,863 common shares upon conversion of long-term debt

ii. On June 9, 2021, the Company issued 646,257 commons shares upon cashless exercise of warrants

iii. During the year ended December 31, 2021, as part of the ATM Program, the Company issued 9,135,632 common shares for total gross proceeds of $33,293 at an average price of $3.64. The Company incurred $1,117 of share issuance costs.

iv. During the year ended December 31, 2021, the Company issued 56,873 common shares upon exercise of National Warrants at an exercise price of $1.50 for gross proceeds of $85.

vi. During the fourth quarter of the year ended December 31, 2021, the Company issued 2,638 common shares upon exercise of options $1.66 for gross proceeds of $4.

2020 common shares issuances were as follows:

i. On March 6, 2020, the Company issued 118,471 stock awards pursuant to the 2016 Plan. Pursuant to Israeli tax requirements, the common shares were issued to a trustee on behalf of SciVac employees.

ii. On April 24, 2020, the Company closed an underwritten public offering of 52,272,726 common shares at a price of $1.10 per share for total gross proceeds of $57,500. The Company incurred $3,606 of share issuance costs.

iii. On July 21, 2020, the Company issued 550,000 common shares upon exercise of warrants at an exercise price of $3.34 for gross proceeds of $1,837.

iv. On August 11, 2020, the Company issued 750 common shares upon exercise of stock options at an exercise price of $1.64 for gross proceeds of $1.

v. During the second half of the year ended December 31, 2020, as part of the Open Market Sale Agreement with Jefferies, the Company issued 15,638,706 common shares for total gross proceeds of $64,685 at an average price of $4.14. The Company incurred $2,101 of share issuance costs.

vi. During the fourth quarter of the year ended December 31, 2020, the Company issued 201,158 common shares upon exercise of National Warrants at an exercise price of $1.50 for gross proceeds of $302.

Stock Option Plans

The Company's stock option plans are approved by and administered by the Board and its Compensation Committee. The Board designates, in connection with recommendations from the Compensation Committee, eligible participants to be included under the plan, and designates the number of options, exercise price and vesting period of the new options.

2006 VBI US Stock Option Plan

The 2006 VBI US Stock Option Plan (the "2006 Plan"), was approved by and was previously administered by the VBI US board of directors which designated eligible participants to be included under the 2006 Plan, and designated the number of options, exercise price and vesting period of the new options. The 2006 Plan was not approved by the stockholders of VBI US. The 2006 Plan was superseded by the 2014 Plan (as defined below) following the PLCC Merger and no further options will be issued under the 2006 Plan. As of December 31, 2021, there were 989,813 options outstanding under the 2006 Plan.

2014 Equity Incentive Plan

On May 1, 2014, the VBI DE board of directors adopted the VBI Vaccines Inc. 2014 Equity Incentive Plan (the "2014 Plan"). The 2014 Plan was approved by the VBI DE's shareholders on July 14, 2014. No further options will be issued under the 2014 Plan. As of December 31, 2021, there were 521,242 options outstanding under the 2014 Plan.

2016 VBI Equity Incentive Plan

The 2016 Plan, as amended, is a rolling incentive plan that sets the number of common shares issuable under the 2016 Plan, together with any other security-based compensation arrangement of the Company, at a maximum of 10% of the aggregate common shares issued and outstanding on a non-diluted basis at the time of any grant under the 2016 Plan. The 2016 Plan is an omnibus equity incentive plan pursuant to which the Company may grant equity and equity-linked awards to eligible participants in order to promote the success of the Company by providing a means to offer incentives and to attract, motivate, retain and reward persons eligible to participate in the 2016 Plan. Grants under the 2016 Plan include a grant or right consisting of one or more options, stock appreciation rights ("SARs"), restricted share units ("RSUs"), performance share units ("PSUs"), shares of restricted stock or other such award as may be permitted under the 2016 Plan. As of December 31, 2021, there were 17,023,324 options outstanding and 39,329 RSUs unvested under the 2016 Plan.

The principal features of the 2016 Plan are as follows:

Eligible Participants

Eligible participants include individuals employed (including services as a director) by the Company or its affiliates, including a service provider, who, by the nature of his or her position or job is, in the opinion of the Board, in a position to contribute to the success of the Company ("Eligible Persons").

Reservation of Shares

The aggregate number of common Shares reserved for issuance to any one participant under the 2016 Plan, together with all other security-based compensation arrangements must not exceed 5% of the total number of issued and outstanding common shares on a non-diluted basis.

The maximum number of common shares (a) issued to insiders within any one-year period; and (b) issuable to insiders at any time, under the 2016 Plan, when combined with all of the Company's other security-based compensation arrangements, must not exceed 10% of the total number of issued and outstanding common shares.

The aggregate number of common shares remaining available for issuance for awards under the 2016 Plan totaled 5,832,119 at December 31, 2021.

The source of common shares issued under the various stock option plans are new common shares.

Options and Stock Appreciation Rights

The Company may grant options to Eligible Persons on such terms and conditions consistent with the 2016 Plan. The exercise price for an option must not be less than 100% of the "market price," as that term is defined in the 2016 Plan, based on the trading price per common share, on the date of grant of such option.

With respect to SARs attached to an option, which allows the holder, upon vesting of the option and Tandem SAR, to choose to exercise the stock appreciation right or to exercise the option, the exercise price is the exercise price applicable to the option (as explained above) to which the Tandem SAR relates, subject to adjustment provisions under the 2016 Plan. For stand-alone SARs, a SAR that is granted without reference to any related Company options, the base price must not be less than 100% of the market price on the date of grant of such Stand-Alone SAR. Stock appreciation rights (and in the case of Tandem SARs, the related options) will be settled by payment in cash or common shares or a combination thereof, with an aggregate value equal to the product of (a) the excess of the market price on the date of exercise over the exercise price or base price under the applicable stock appreciation right, multiplied by (b) the number of stock appreciation rights exercised or settled. The Company has not issued any SARs under the 2016 Plan at December 31, 2021 and 2020.

Under the 2016 Plan unless otherwise designated by the Board of Directors, 25% of the options will vest on each of the first four anniversaries of the grant date. The term of options will be for a maximum of 10 years, unless exercised or terminated earlier in accordance with the terms of the 2016 VBI Plan or the applicable grant agreement.

Upon a participant's termination of employment due to death, or in the case of disability: (a) the outstanding options that were granted prior to the year that includes the participant's death or disability that have not become vested prior to such date will continue to vest and, upon vesting, be exercisable during the 36-month period following such date; and (b) the outstanding options that have become vested prior to the participant's death or disability will continue to be exercisable during the 36-month period following such date.

In the case of a participant's termination of employment or contract for services without cause: (a) the outstanding options that have not become vested prior to the participant's termination will continue to vest and, upon vesting, be exercisable during the 120-day period following such date; and (b) the outstanding options that have become vested prior to the participant's termination will continue to be exercisable during the 120-day period following such date.

In the case of a participant's termination due to resignation (including voluntary withdrawal of services by a non-employee participant): (a) the outstanding options that have not become vested prior to the date of notice of resignation will be forfeited and cancelled as of such date; and (b) the outstanding options that have become vested prior to the date of notice of resignation will continue to be exercisable during the 90-day period following such date.

In the case of a participant's termination of employment or contract for services for cause, any and all then outstanding unvested options granted to such participant will be immediately forfeited and cancelled, without any consideration therefor, as of the date such notice of termination is given.

Share Units

The Board of Directors may grant share units, which include RSUs and PSUs, to Eligible Persons on such terms and conditions consistent with the 2016 Plan.

The Board will determine the grant value and the valuation date for each grant of share units. The number of share units to be covered by each grant will be determined by dividing the grant value for such grant by the market value of a common share as of the valuation date, rounded up to the next whole number.

Share units subject to a grant will vest as specified in the grant agreement governing such grant, provided that the participant is employed on the relevant vesting date. RSUs and PSUs will be settled upon, or as soon as reasonably practicable following the vesting thereof, subject to the terms of the grant agreement. In all events, RSUs and PSUs will be settled on or before the earlier of the 90th day following the vesting date and the date that is 2 ½ months after the end of the year in which the vesting occurred. Settlement will be made by way of issuance of one common share for each RSU or PSU, a cash payment equal to the market value of the RSUs or PSUs being settled, or a combination thereof. If the share units would be settled within a blackout period, such settlement will be postponed until the earlier of the 6th trading day following the end of such blackout period and the otherwise applicable date of settlement as determined in accordance with the settlement provision set out above. The Company has not issued any PSUs under this plan at December 31, 2021 and 2020. All RSUs issued under the 2016 Plan at December 31, 2021 and 2020 contain no cash settlement provision.

If and when cash dividends are paid with respect to common shares to shareholders of record during the period from the grant date to the date of settlement of the RSUs or PSUs, a number of dividend equivalent RSUs or PSUs, as applicable, will be credited to the share unit account of such participant.

In the event a participant's employment is terminated due to resignation, share units that have not vested prior to the date of resignation will not vest and all such common shares will be forfeited immediately.

In the case of a participant's termination due to death, or in the case of disability, all share units granted prior to the year that includes the participant's death or disability, that have not vested prior to the participant's death or disability will vest at the end of the vesting period and in the case of PSUs, subject to the achievement of applicable performance conditions and the adjustment of the number of PSUs that vest to reflect the extent to which such performance conditions were achieved.

In the event a participant's employment or contract for services is terminated without cause, prior to the end of a vesting period relating to such participant's grant, the number of RSUs or PSUs, respectively, as determined by their respective formula set out in the 2016 Plan will become vested at the end of the vesting period.

In the event a participant's employment is terminated for cause, share units that have not vested prior to the date of the termination for cause will not vest and all such share units will be forfeited immediately.

Restricted Stock

Restricted stock means common shares that are subject to restrictions on such participant's free enjoyment of the common shares granted, as determined by the Board. Notwithstanding the restrictions, the participant will receive dividends paid on the restricted stock, will receive proceeds of the restricted stock in the event of any change in the common shares and will be entitled to vote the restricted stock during the restriction period.

The participant will not have rights to sell, transfer or assign, or otherwise dispose of the shares of restricted stock or any interest therein while the restrictions remain in effect. Grants of restricted stock will be forfeited if the applicable restriction does not lapse prior to such date or occurrence of such event or the satisfaction of such other criteria as is specified in the grant agreement.

No restricted stock has been issued through December 31, 2021.

Stock-Based Compensation Expense

The table below provides information, as of December 31, 2021, regarding the 2006 Plan, the 2014 Plan and the 2016 Plan under which our equity securities are authorized for issuance to officers, directors, employees, consultants, independent contractors and advisors.

Plan Category	Number of securities to be issued upon exercise/vesting of outstanding awards	Weighted average exercise price
2006 Plan	989,813	$ 4.02
2014 Plan	521,242	$ 5.09
2016 Plan	17,062,653	$ 2.47
Total	18,573,708	$ 2.63

Activity related to stock options is as follows:

	Number of Stock Options	Weighted Average Exercise Price
Balance outstanding at December 31, 2019	6,471,708	$ 2.79
Granted	6,075,900	$ 1.95
Exercised	(750)	$ 1.64
Forfeited	(39,317)	$ 2.59
Balance outstanding at December 31, 2020	12,507,541	$ 2.38
Granted	**6,215,000**	**$ 3.15**
Exercised	**(2,638)**	**$ 1.66**
Forfeited	**(185,524)**	**$ 3.09**
Balance outstanding at December 31, 2021	**18,534,379**	**$ 2.63**
Exercisable at December 31, 2021	**10,053,876**	**$ 2.49**

	Outstanding		Exercisable	
Exercise Price	Number Of Options	Weighted Average Remaining Contractual Life (Years)	Number Of Options	Weighted Average Exercise Price
$ 0.00 – 1.49	3,430,000	8.08	2,177,497	$ 1.42
$ 1.50 – 2.49	4,424,998	6.68	3,980,511	$ 1.69
$ 2.50 – 3.49	8,071,650	8.79	1,350,477	$ 3.01
$ 3.50 – 4.49	1,916,742	4.84	1,854,402	4.15
$ 4.50+	690,989	3.29	690,989	$ 5.01
	18,534,379	7.54	10,053,876	$ 2.49

The weighted average remaining contractual life of exercisable options was years 6.50 and 6.98 years at December 31, 2021 and 2020, respectively.

Information relating to restricted stock units is as follow:

	Number of Stock Awards	Weighted Average Fair Value at Grant Date
Unvested shares outstanding at December 31, 2019	157,997	2.77
Granted	125,000	$ 1.46
Vested	(140,167)	$ 2.79
Forfeited	(13,474)	$ 1.53
Unvested shares outstanding at December 31, 2020	129,356	$ 1.62
Vested	**(81,135)**	**$ 1.70**
Forfeited	**(8,892)**	**$ 1.50**
Unvested shares outstanding at December 31, 2021	**39,329**	**$ 1.47**

The intrinsic value of outstanding options at December 31, 2021 was $6,029,282 (the intrinsic value of vested options was $4,585,494 and the intrinsic value of those expected to vest was $1,443,788). The fair value of the vested RSU's was $137 for the year ended December 31, 2021. There were 2,638 options exercised for the year ended December 31, 2021 and the intrinsic value of exercised options was $4 for the year ended December 31, 2021. There were 750 options exercised for the year ended December 31, 2020 and the intrinsic value of exercised options was $2 for the year ended December 31, 2020.

In determining the amount of stock-based compensation the Company used the Black-Scholes option pricing model to establish the fair value of options granted by applying the following weighted average assumptions:

	2021	2020
Volatility	**96.87%**	91.59%
Risk free interest rate	**0.59%**	1.19%
Expected term in years	**5.85**	5.81
Expected dividend yield	**0.00%**	0.00%
Weighted average fair value per option	**$ 2.40**	$ 1.42

The volatility was based on the Company's recent historic volatility since May 6, 2016.

The risk-free rate was based on rates provided by the United States Treasury with a term equal to the expected life of the option.

The Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term due to the limited period of time its equity shares have been publicly traded. As a result, the Company uses the simplified method to determine the expected term of stock options whereby the expected term equals the average between the vesting period and the contractual life.

The fair value of the options is recognized as an expense on a straight-line basis over the vesting period, forfeitures are accounted for when they occur.

The total stock-based compensation expense recorded in the years ended December 31, was as follows:

	2021	2020
Research and development	$ 1,839	$ 1,088
General and administration	7,697	4,143
Cost of revenue	92	56
Total stock-based compensation expense	$ 9,628	$ 5,287

There is $13,700 of unrecognized compensation from all equity awards as of December 31, 2021. This expense will be recognized over a weighted average period of 1.88 years.

Warrants

In April 2020, the Company engaged National to provide financial advisory services in connection with the April 2020 underwritten public offering, discussed above. As consideration for such services, the Company issued to National or its designees warrants to purchase up to an aggregate of 705,000 common shares, subject to the terms and conditions set forth in the form of warrant agreement. The National Warrants are exercisable immediately upon issuance and terminate three years following issuance and have an exercise price of $1.50 per share.

On May 22, 2020, in connection with the Loan Agreement, as described in Note 10, the Company issued a warrant, the K2 Warrant, to purchase up to an aggregate of 625,000 common shares, subject to terms and conditions set forth in the form of warrant agreement. The K2 Warrant expires on May 22, 2030 and has an exercise price of $1.12 per share.

On July 21, 2020, the Company issued 550,000 common shares upon exercise of warrants at an exercise price of $3.34 for gross proceeds of $1,837.

During the fourth quarter of the year ended December 31, 2020, the Company issued 201,158 common shares upon exercise of National Warrants at an exercise price of $1.50 for gross proceeds of $302.

On May 17, 2021, in connection with the First Amendment, as described in Note 10, the Company issued the Lenders the Restated K2 Warrant to purchase an additional 312,500 common shares for a total of 937,500 common shares with the same Warrant Price of $1.12.

On June 9, 2021, the Company issued 646,257 common shares upon exercise of 2,068,824 warrants on a cashless “net exercise” basis.

During the year ended December 31, 2021, the Company issued 56,873 common shares upon exercise of National Warrants at an exercise price of $1.50 for gross proceeds of $85.

The value attributed to the K2 Warrant were based on the Black-Scholes option pricing model by applying the following assumptions:

	K2 Warrant
Volatility	95.00%
Risk free interest rate	1.53%
Expected term in years	9
Expected dividend yield	0.00%
Fair value per warrant	$ 2.77

Activity related to the warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance outstanding at December 31, 2019	2,618,824	$ 2.87
Issued	1,330,000	$ 1.32
Exercised	(751,158)	$ 2.85
Balance outstanding at December 31, 2020	3,197,666	$ 2.23
Issued	**312,500**	**$ 1.12**
Exercised	**(2,125,697)**	**$ 2.72**
Balance outstanding at December 31, 2021	**1,384,469**	**$ 1.24**

13. REVENUE AND DEFERRED REVENUE

Revenue comprises of the following:

	2021	2020
Product revenue	**$ 262**	$ 283
R&D Service revenue	**369**	778
	$ 631	$ 1,061

Cost of revenues for the year ended December 31, 2021 for product revenue and R&D services revenue is $10,475 and $295, respectively. Cost of revenues for the year ended December 31, 2020 for product revenue and R&D services revenue is $8,692 and $476, respectively.

The following table presents revenue expected to be recognized in the future related to performance obligations, based on current estimates, that are unsatisfied at December 31, 2021:

	Total	2022	2023 and thereafter
Product revenue	**$ 469**	**$ -**	**$ 469**
R&D Service revenue	**2,334**	**526**	**1,808**
Total	**$ 2,803**	**$ 526**	**$ 2,277**

The following table presents changes in the deferred revenue balance for the year ended December 31, 2021:

Balance at December 31, 2020	**$ 3,104**
Amounts received in 2021	**-**
Recognition of deferred revenue	**(306)**
Currency translation	**5**
Balance at December 31, 2021	**$ 2,803**
Short Term	**$ 526**
Long Term	**$ 2,277**

Collaboration and License Agreement – Brii Bio

On December 4, 2018, the Company entered into a Collaboration and License Agreement with Brii Biosciences Limited ("Brii Bio") (the "License Agreement"), amended on April 8, 2021, whereby:

- the Company and Brii Bio agreed to collaborate on the development of a HBV recombinant protein-based immunotherapeutic in the licensed territory, which consists of China, Hong Kong, Taiwan and Macau (collectively, the "Licensed Territory"), and to conduct a Phase II collaboration clinical trial for the purpose of comparing VBI-2601 (BRII-179), which is a recombinant protein-based immunotherapeutic developed by VBI for use in treating chronic HBV, with a novel composition developed jointly with Brii Bio (either being the "Licensed Product");

- the Company granted Brii Bio an exclusive royalty-bearing license to perform studies, and regulatory and other activities, as may be required to obtain and maintain marketing approval of the Licensed Product, for the treatment of HBV in the Licensed Territory and to commercialize and the Licensed Product for the diagnosis and treatment of chronic HBV in the Licensed Territory

On December 20, 2021, the Company and Brii Bio amended the License Agreement (the "Second Amendment") whereby:

- the Company and Brii Bio agreed to conduct an additional Phase II combination clinical trial of VBI-2601 (BRII-179), both with and without IFN-α, and BRII-835 (VIR-2218) ("Combo Clinical Trial"); and

- Brii Bio granted the Company a non-exclusive royalty free license under the Brii Bio technology arising from the data generated in the Combo Clinical Trial solely for use in the development, manufacture or commercialization of the Licensed Product in combination with an siRNA in the countries of the world other than the Licensed Territory.

Pursuant to the License Agreement, as amended, the Company is responsible for the R&D Services and Brii Bio is responsible for costs relating to the clinical trials for the Licensed Territory.

The initial consideration of the License Agreement consisted of an $11,000 non-refundable upfront payment. As part of the License Agreement, the Company and Brii Bio entered into a stock purchase agreement. Under the terms of the stock purchase agreement, the Company issued to Brii Bio 2,295,082 shares of its common stock valued at $3,626 (based on the Company's common stock price on December 4, 2018). The remaining $7,374, deemed to be the initial transaction price, was allocated to two performance obligations: i) the VBI-2601 (BRII-179) license and ii) R&D services. The R&D services were allocated $4,737 of the transaction price using an estimated selling price based on an expected cost plus a margin approach and the remaining transaction price of $2,637 was allocated to the VBI-2601 (BRII-179) license using the residual method.

There was no additional consideration contemplated in the Second Amendment.

In addition, the Company is also eligible to receive an additional $117,500 in potential regulatory and sales milestone payments, along with royalties on commercial sales in the Licensed Territory. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. Therefore, no variable consideration was included in the initial transaction price and no such amounts have been recognized to date.

On December 4, 2018, the Company recognized the VBI-2601 (BRII-179) license when it was granted as it was determined to be distinct and Brii Bio was able to use and benefit from the license. The R&D Services will be satisfied over time as services are rendered using the "cost-to-cost" input method as this method represents the most accurate depiction of the transfer of services based on the types of costs expected to be incurred. As of December 31, 2021, R&D services related to Brii Bio that remain unsatisfied are $2,134, out of the $2,803 total deferred revenue.

Upon termination of the License Agreement prior to the end of the term, there is no obligation for refund and any amounts in deferred revenue related to unsatisfied performance obligations will be immediately recognized.

14. COLLABORATIVE ARRANGEMENTS

GlaxoSmithKline Biologicals S.A. (“GSK”)

On September 10, 2019, the Company entered into a Clinical Collaboration Agreement (“Collaboration Agreement”) pursuant to which we will investigate the use of GSK’s proprietary $AS01_B$ adjuvant system in our ongoing study of VBI-1901. As a result of the Collaboration Agreement, a second study arm was added to Part B of the ongoing Phase Ib/IIa clinical study to accommodate the $AS01_B$ adjuvant.

This relationship is considered a collaborative relationship and not a customer relationship and is therefore accounted for outside the scope of ASC Topic 606. Costs associated with the second study arm will be expensed as incurred in Research and Development expenses; costs for the year ended December 31, 2021 and 2020 are $504 and $669, respectively.

National Research Council of Canada (“NRC”)

On March 31, 2020, the Company announced a collaboration with the NRC, Canada’s largest federal research and development organization, to develop a pan-coronavirus vaccine candidate, targeting COVID-19, SARS, and MERS. The NRC and the Company are collaborating to evaluate and select promising coronavirus vaccine candidates. The collaboration combines the Company’s viral vaccine expertise, eVLP technology platform, and modified coronavirus antigens with the NRC’s proprietary SARS-CoV-2 antigens and assay development capabilities to select the most immunogenic vaccine candidate for further development.

On December 21, 2020, the Company signed an amendment to the collaboration agreement with the NRC to broaden the scope of collaboration to include certain pre-clinical evaluations, bioprocess optimization, technology transfer, and the performance of additional scale up work.

On July 8, 2021, the Company signed a second amendment to the collaboration agreement with the NRC to broaden the scope of the collaboration to include developing a vaccine against the Beta variant of SARS-CoV-2.

On August 27, 2021, the Company signed a third amendment to the collaboration agreement with the NRC further broaden the scope to include certain stable cell line work for our vaccine candidate against the Beta variant of SARS-CoV-2.

On November 15, 2021, we signed a fourth amendment to the collaboration agreement with the NRC to further broaden the scope to include additional animal studies and PRNT analysis for our vaccine candidate against the Beta variant of SARS-CoV-2.

On February 8, 2022, we signed a fifth amendment to the collaboration agreement with the NRC to further broaden the scope to include additional assays of new variants against SARS-CoV-2.

The expiry date of the collaboration agreement, as amended, is October 31, 2022.

This relationship is considered a collaborative relationship and not a customer relationship and is therefore accounted for outside the scope of ASC Topic 606. Costs associated with the collaboration will be expensed as incurred in Research and Development expenses; costs for the year ended December 31, 2021 and 2020 are $1,152 and $454, respectively.

CEPI

On March 9, 2021, the Company and CEPI announced the CEPI Funding Agreement, to develop eVLP vaccine candidates against SARS-COV-2 variants, including the Beta variant, also known as the B.1.351 variant and as 501Y.V2, first identified in South Africa. CEPI agreed to provide up to $33,018 to support the advancement of VBI-2905, a monovalent eVLP candidate expressing the pre-fusion form of the spike protein from the Beta variant strain, through Phase I clinical development. This funding will also support preclinical expansion of additional multivalent vaccine candidates designed to evaluate the potential breadth of our eVLP technology. The preclinical expansion is intended to develop clinic-ready vaccine candidates capable of addressing emerging variants.

Under the terms of the CEPI Funding Agreement, among other things, the Company and CEPI agreed on the importance of global equitable access to any vaccines produced pursuant to the CEPI Funding Agreement. Any such vaccines, if approved, are expected to be procured and allocated through global mechanisms as part of the Access to COVID-19 Tools (ACT) Accelerator, an international initiative launched by the WHO, Gavi the Vaccine Alliance, CEPI, and other global non-governmental organizations and governmental leaders in 2021.

This relationship is considered a collaborative relationship and not a customer relationship and is therefore accounted for outside the scope of ASC Topic 606.

Costs associated with the collaboration are expensed as incurred in Research and Development and General and Administrative expenses; costs for the year ended December 31, 2021 are $8,240. Such expenses, including administrative expenses, for the year ended December 31, 2021 were reduced by the same amount. During the year ended December 31, 2021, the Company received $18,363 from CEPI and as of December 31, 2021, the Company had $10,183 recorded as deferred funding, recorded in other current liabilities on the consolidated balance sheet.

Brii Biosciences Limited

On December 4, 2018, the Company entered into a License Agreement with Brii Bio, as described in Note 13.

As described in Note 13, the Company and Brii Bio entered into the Second Amendment on December 20, 2021. The Combo Clinical Trial collaboration is considered a collaborative relationship and not a customer relationship and is therefore accounted for outside the scope of ASC Topic 606. Costs associated with the Combo Clinical Trial collaboration will be expensed as incurred in Research and Development expenses; costs for the year ended December 31, 2021 were de minimis.

15. GOVERNMENT GRANTS

Industrial Research Assistance Program (“IRAP”)

On July 3, 2020, the Company and the NRC as represented by its IRAP signed a contribution agreement whereby the NRC agreed to contribute up to CAD $1,000 for the transfer and scale-up of the technical production process for our prophylactic coronavirus vaccine program.

Costs associated with the contribution agreement are expensed as incurred in Research and Development expenses. For the year ended December 31, 2021 and 2020, the Company recognized $273 and $449, respectively, as a reduction in expenses. As of December 31, 2021 and 2020, the Company had $44 and $312, respectively, recorded as deferred government grants, recorded in other current liabilities on the consolidated balance sheet.

Strategic Innovation Fund (“SIF”)

Costs associated with the contribution agreement are expensed as incurred in Research and Development expenses and overhead charges are included in General and Administrative. On September 16, 2020, the Company and Her Majesty the Queen in Right of Canada as represented by the Minister of Industry (“ISED”) signed a contribution agreement (the “Contribution Agreement”) for a contribution from SIF whereby ISED agreed to contribute up to CAD $55,976 to support the development of the Company’s coronavirus vaccine program, through Phase II clinical studies, for a period commencing on April 15, 2020 and ending on or before the last day of the first quarter of 2022, however discussions are underway to extend the term.

For the year ended December 31, 2021 and 2020, the Company recognized $7,248 and $2,812, respectively, as a reduction in expenses. As of December 31, 2021 and 2020, the Company had $947 and $512, respectively, recorded as deferred government grants, recorded in other current liabilities on the consolidated balance sheet.

16. INCOME TAXES

Components of the Company’s loss from continuing operations before income taxes are as follows:

	2021	2020
United States	**$** (1,870)	$ (8,343)
Canada	(30,002)	(16,480)
Israel	(37,881)	(21,407)
Total	**$** (69,753)	$ (46,230)

The Company operates in United States, Israel and Canadian tax jurisdictions. Its income is subject to varying rates of tax, and losses incurred in one jurisdiction cannot be used to offset income taxes payable in another. A reconciliation of the income tax rate with the Company's effective tax rate and income tax expense are as follows:

	2021	2020
Loss before income taxes	**$ (69,753)**	$ (46,230)
Canadian statutory tax rate	**26.50%**	26.50%
Expected benefit of income tax	**(18,485)**	(12,251)
Research and development tax credits	**-**	(188)
Change in valuation allowance*	**19,099**	15,094
Difference between Canadian and foreign tax rates	**1,313**	663
Stock based compensation	**2,387**	792
Foreign exchange translation	**(4,574)**	(2,366)
Permanent statutory to GAAP difference	**480**	(1,272)
Other	**(220)**	(472)
Income tax expense	**$ -**	$ -

* A portion of the change in valuation allowance is recognized in equity, therefore the overall change in the valuation allowance will not equal the amount recognized in tax expense.

For 2021 the Canadian statutory income tax rate of approximately 26.50% is comprised of federal income tax at approximately 15% and provincial income tax at approximately 11.5%. The Israel statutory income rate is approximately 23%.

The Deferred tax asset (liability) consisted of the following:

	2021	2020
Deferred tax assets (liabilities):		
Net operating losses	**$ 86,397**	$ 70,472
Research and development tax credits	**14,102**	11,163
Property and equipment	**1,050**	641
Reserves and other	**1,996**	1,603
Intangible assets	**(16,454)**	(16,471)
Allowable capital losses	**56**	-
Debt obligations	**(1,757)**	(1,531)
Deferred financing costs	**1,779**	2,348
Net deferred tax assets	**87,169**	68,225
Less: valuation allowance	**(87,169)**	(68,225)
Net deferred tax assets (liabilities)	**$ -**	$ -

As of December 31, 2021 and 2020, the Company had United States federal net operating loss carryovers ("NOLs") of approximately $53,968 and $54,007, respectively, including $29,000 related to the acquisition of VBI DE, available to offset taxable income which expire beginning in 2026. The NOLs may be limited pursuant to Section 382 of the Internal Revenue Code and similar state statutes due to the acquisition of VBI DE in 2016 and other equity transactions through December 31, 2021. Generally, NOL utilization is limited if a corporation has a more than 50% change in ownership over a three-year period. The Company plans on undertaking a detailed analysis of any historical and/or current Section 382 ownership changes that may limit the utilization of the net operating loss carryovers.

As of December 31, 2021, the Company also had Canadian net operating loss carryovers of approximately $84,491 and 69,292, respectively, available to offset future taxable income which expire beginning in 2024.

As of December 31, 2021 and 2020, the Company had $5,868 and $5,867 respectively, of investment tax credits available to carry forward and reduce future years' Canadian income taxes which expire beginning in 2026.

As of December 31, 2021 and 2020, the Company had unclaimed research and development expenses in Canada of approximately $21,740 and $21,834, respectively, which are available to offset future taxable income indefinitely.

As of December 31, 2021 and 2020, the Company had $213 and $0, respectively, of allowable capital losses in Canada, which can be carried forward indefinitely, however can only be used against taxable capital gains.

As of December 31, 2021 and 2020, the Company also had Israel net operating loss carryovers of approximately $214,186 and $162,411, respectively, which can be carried forward indefinitely.

As of December 31, 2021, the Company had NOLs aggregating approximately $352,645. The NOLs are available to reduce taxable income of future years and expire as follows:

	United States	Canada	Israel	Total
2024	$ -	$ 476	$ -	$ 476
2025	-	1,480	-	1,480
2026	10	3,732	-	3,742
2027	446	4,324	-	4,770
2028	718	1,674	-	2,392
2029	672	3,135	-	3,807
2030	2,556	1,015	-	3,571
2031	3,617	1,255	-	4,872
2032	2,962	-	-	2,962
2033	3,126	1,467	-	4,593
2034	5,626	5,493	-	11,119
2035	4,661	1,651	-	6,312
2036	5,323	8,762	-	14,085
2037	6,017	9,848	-	15,865
2038	-	2,446	-	2,446
2039	-	7,785	-	7,785
2040	-	16,526	-	16,526
2041	-	13,422	-	13,422
No expiration	18,234	-	214,186	232,420
Total losses	**$ 53,968**	**$ 84,491**	**$ 214,186**	**$ 352,645**

17. COMMITMENTS AND CONTINGENCIES

Licensing

(a) In connection with the acquisition of the ePixis technology in 2011, VBI Cda also agreed to make certain contingent payments as follows:

Upon the completion of a “Successful Technology Transfer”, as defined in the Sale and Purchase Agreement (“SPA”), to a contract manufacturing organization, VBI Cda paid €102 (approximately $110 and referred to as the “Transfer Payment”) to the Sellers during the second quarter of 2015. The Transfer Payment related to the achievement of the first milestone, which occurred during the three months ended June 30, 2015.

The Company is committed to make further contingent payments pursuant to defined milestones in the SPA depending on whether there continue to exist any issued and valid claims on the acquired patents. Contingent payments include:

- Upon first approval in the United States or the European Union: €500 to €1,000;
- Upon commercialization when cumulative net sales equals or exceeds:
  - €25,000: €750 to €1,500; and,
  - €50,000: €1,000 to €2,000;

- Upon commercialization by one or more sublicenses when cumulative net sales equals or exceeds:
    - €25,000: €375 to €750;
    - €50,000: €375 to €750;
    - €75,000: €500 to €1,000;
    - €100,000: €500 to €1,000,
    - VBI will be obligated to pay to the Sellers the balance still owing on the total €3,500 when either cumulative net sales of €50,000 by VBI or €100,000 by VBI and its sublicenses is achieved.

The Company is further committed to pay all costs of protecting the patents and make contingent payments to the licensor of the acquired patents pursuant to defined milestones in an amendment to the related license agreement which include: royalty fees ranging between 0.75% and 1.75% depending on the level of net sales; and, lump sum payments ranging from €50 to €1,000 depending on the stage of clinical development and ultimately commercial approval. Additionally, 5% to 25% of any sublicensing fees depending on stage of clinical development are also payable to the licensor.

During the year ended December 31, 2016, VBI Cda paid €200, in milestone payments related to CMV Phase I clinical trial approval and start. During the year ended December 31, 2017 and 2018, VBI Cda paid €50 and €150, respectively, in milestone payments related to the GBM Phase I/IIa clinical trial approval and start. No payments were made in 2020. During the year ended December 31, 2021, VBI Cda paid €200, in milestone payments related to our prophylactic coronavirus vaccine program approval and start, respectively.

(b) The Company's manufactured and marketed product, a 3-antigen HBV vaccine, is a recombinant trivalent HBV vaccine that is subject to a license agreement between Savient Pharmaceuticals Inc and SciGen Ltd., dated June 2014, as subsequently amended ("Ferring License Agreement"). Under the Ferring License Agreement the Company is committed to pay Ferring royalties equal to 7% of net sales (as defined therein) of the HBsAg "Product" (as defined therein). Under an Assignment Agreement between FDS Pharm LLP and SciGen Ltd., dated February 14, 2012 (the "SciGen Assignment Agreement"), we are required to pay royalties to SciGen Ltd. equal to 5% of net sales (as defined in the Ferring License Agreement) of Product.

Royalty payments under the Ferring License Agreement of $18 and $20, were recorded in cost of revenues for the year ended December 31, 2021 and 2020, respectively.

Royalty payments under the SciGen Assignment Agreement of $13 and $14 were recorded in cost of revenues for the year ended December 31, 2021 and 2020, respectively.

In addition, the Company is committed to pay 30% of any and all non-royalty consideration, in any form, received by Company from sub-licensees (other than consideration based on net sales for which a royalty is due under the Ferring License Agreement), provided that the payment of 30% shall not apply to a grant of rights in or relating to: (i) the territory as such term was defined prior to an amendment dated January 24, 2005; or (ii) the Berna Territory (as defined in therein).

Under the Ferring License Agreement and the SciGen Assignment Agreement, we originally were to pay royalties on a country-by-country basis until the date 10 years after the date of commencement of the first royalty year in respect of such country. In April 2019, we exercised our option to extend the Ferring License Agreement in respect of all the countries that still make up the territory for an additional 7 years by making a one-time payment to Ferring of $100. Royalties under the Ferring License Agreement and SciGen Assignment Agreement will continue to be payable for the duration of the extended license periods.

Legal Proceedings

From time to time, the Company may be involved in certain claims and litigation arising out of the ordinary course and conduct of business. Management assesses such claims and, if it considers that it is probable that an asset had been impaired or a liability had been incurred and the amount of loss can be reasonably estimated, provisions for loss are made based on management's assessment of the most likely outcome.

On September 13, 2018, two civil claims were brought in the District Court of the central district in Israel naming our subsidiary SciVac as a defendant. In one claim, two minors, through their parents, allege, among other things: defects in certain batches of Sci-B-Vac discovered in July 2015; that Sci-B-Vac was approved for use in children and infants in Israel without sufficient evidence establishing its safety; that SciVac failed to provide accurate information about Sci-B-Vac to consumers; and that each child suffered side effects from the vaccine. The claim was filed together with a motion seeking approval of a class action on behalf of 428,000 children vaccinated with Sci-B-Vac in Israel from April 2011 and seeking damages in a total amount of NIS 1,879,500 ($604,341). The second claim is a civil action brought by two minors and their parents against SciVac and the Israel Ministry of Health alleging, among other things, that SciVac marketed an experimental, defective, hazardous or harmful vaccine; that Sci-B-Vac was marketed in Israel without sufficient evidence establishing its safety; and that Sci-B-Vac was produced and marketed in Israel without approval of a western regulatory body. The claim seeks damages for past and future losses and expenses as well as punitive damages.

SciVac believes these matters to be without merit and intends to defend these claims vigorously.

The District Court has accepted SciVac's motion to suspend reaching a decision on the approval of the class action pending the determination of liability under the civil action. Preliminary hearings for the trial of the civil action began on January 15, 2020, with subsequent preliminary hearings held on May 13, 2020, December 3, 2020 and September 30, 2021. The next preliminary hearing is scheduled to be held on June 9, 2022.

18. LEASES

The Company has entered into various non-cancelable lease agreements for its office, lab, and manufacturing facilities, which are classified as operating leases.

During the year ended December 31, 2021, the Company terminated the existing office facility lease agreement in the United States and entered into a new non-cancellable lease agreement for office space, the terms which commenced on November 1, 2021 running through October 31, 2024. Our manufacturing facility lease agreement in Israel has been extended for 5 years with a term now ending January 31, 2027. The lease agreement for our research facility in Canada, which comprises office and laboratory space, has a term ending on December 31, 2022 with an option to extend the term for one additional period of three years. A lease for additional office space at our research facility commenced on October 1, 2020 with a term ending April 30, 2023.

During the year ended December 31, 2021, the Company entered into two non-cancelable lease agreements for additional office at our manufacturing facility in Israel, the rent terms which will commence January 1, 2022 running through November 30, 2025 with an option to extend the term for two additional years and July 1, 2022 running through June 30, 2027 with an option to extend the term for five additional years. The Company will recognize a right of use asset and lease liability for each agreement upon the rent commencement date.

Options to extend are not recognized as part of the lease liabilities or recognized as right to use assets. There are no residual value guarantees, no variable lease payments, and no restrictions or covenants imposed by leases. The discount rate used in measuring the lease liabilities and right of use assets was determined by reviewing our incremental borrowing rate at the initial measurement date.

Lease cost:		
2021 operating lease costs:	$	1,463
2020 operating lease costs:		1,231
Other information:		
Weighted average remaining lease term		2.96 years
Weighted average discount rate		12%

Operating lease costs are included in general and administrative expenses in the statement of operation and comprehensive loss.

During the year ended December 31, 2021, the Company entered into new lease agreements and recognized a ROU asset of $3,248.

The following table summarizes future undiscounted cash payments reconciled to the lease liabilities:

Year ending December 31		
2022	**$**	**1,188**
2023		**1,057**
2024		**941**
2025		**483**
2026		**483**
2027		**40**
Total	**$**	**4,192**
Effect of discounting		**(837)**
Total lease liability	**$**	**3,355**
Less: current portion		**839**
Long term lease liability	**$**	**2,516**

19. SEGMENT INFORMATION

The Company's Chief Executive Officer ("CEO") has been identified as the chief operating decision maker. The CEO evaluates the performance of the Company and allocates resources based on the information provided by the Company's internal management system at a consolidated level. The Company has determined that it has only one operating segment.

Revenues from external customers are attributed to geographic areas based on location of the contracting customers.

	2021	2020
Revenue in Israel	**$ 321**	$ 284
Revenue in China/Hong Kong	**306**	724
Revenue in Europe	**4**	53
Total	**$ 631**	$ 1,061

There was no revenue attributed to our country of domicile, Canada, for years ended December 31, 2021 and 2020.

For the year ended December 31, 2021, the Company had 3 customers that individually accounted for 12%, 26% and 49% of revenues.

For the year ended December 31, 2020, the Company had 3 customers that individually accounted for 68%, 10% and 10% of revenues.

Tangible long-lived assets (Property and equipment and right of use assets) attributed to geographic areas are as follows:

	2021	2020
Tangible long-lived assets in Israel	**$ 12,567**	$ 10,998
Tangible long-lived assets in United States	**1,273**	644
Tangible long-lived assets in Canada (country of domicile)	**541**	633
Total	**$ 14,381**	$ 12,275

20. RELATED PARTY TRANSACTIONS

During the year ended December 31, 2019, the Company agreed to pay a car loan with an officer of the Company, as part of their compensation arrangement, for $56, repayable over 3 years. The total amount of the car loan lease at December 31, 2021 and 2020, is $29 and $43, respectively.

21. SUBSEQUENT EVENTS

On January 27, 2022, the Company approved the grant of 4,960,000 stock options to existing employees and directors pursuant to the 2016 Plan. Options granted to directors' vest monthly over 12 months. Options granted to employees vest 25% on the one-year anniversary of the grant date, with the remaining 75% vesting on a monthly basis over 24 months. All options granted automatically expire on January 27, 2032.

EXHIBIT INDEX

Exhibit No.	Description
1.1	Open Market Sale Agreement[SM], dated July 31, 2020, by and between VBI Vaccines, Inc. and Jefferies LLC (incorporated by reference to Exhibit 1.2 to the registration statement on Form S-3 (SEC File No. 333-240266), filed with the SEC on July 31, 2020).
1.2	Open Market Sale Agreement, dated September 3, 2021, by and between VBI Vaccines Inc. and Jefferies LLC (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K (SEC File No. 001-37769), filed with the SEC on September 3, 2021).
2.1	Sale and Purchase Agreement, dated as of July 18, 2011, by and between Variation Biotechnologies, Inc., EPixis SA and the Persons Listed on Schedule 1 therein (incorporated by reference to Exhibit 2.4 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).
3.1	Articles (incorporated by reference to Exhibit 3.1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on December 23, 2015).
3.2	Notice of Articles (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).
3.3	Form of Notice of Alteration (incorporated by reference to Exhibit 3.3 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761) filed with the SEC on February 5, 2016).
4.1	Warrant dated July 25, 2014 issued to PCOF 1, LLC (incorporated by reference to Exhibit 4.1 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
4.2	Form of Initial Term Note (incorporated by reference to Exhibit 4.3 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
4.3	Form of Delayed Draw Warrant (incorporated by reference to Exhibit 4.2 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
4.4	Form of Delayed Draw Note (incorporated by reference to Exhibit 4.4 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
4.5	Form of Term Note (incorporated by reference to Exhibit A to Exhibit 99.1 to the report on Form 6-K (SEC File No. 000-37769), filed with the SEC on December 16, 2016).
4.6	Form of Second Closing Effective Date Warrant held of record by Perceptive Credit Holdings, LP (incorporated by reference to Exhibit E to Exhibit 99.1 to the report on Form 6-K (SEC File No. 000-37769), filed with the SEC on December 16, 2016).
4.7	Description of Securities (incorporated by reference to Exhibit 4.7 to the Annual Report on Form 10-K SEC File No. 001-37769), filed with the SEC on March 2, 2021).
10.1(A)+	2016 VBI Vaccines Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).
10.1(B)+	2016 VBI Vaccines Equity Incentive Plan, amended and restated.
10.1(C)+	2016 VBI Vaccines Equity Incentive Plan forms of award agreements (incorporated by reference to Exhibit 10.2 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).

10.2+	VBI DE 2014 Equity Incentive Plan (incorporated by reference to Annex C to VBI DE's definitive proxy statement on Schedule 14A (SEC File No. 000-18188), filed with the SEC on June 30, 2014).
10.3	License Agreement, dated June 2004, by and between Savient Pharmaceuticals, Inc. and SciGen, Ltd., as amended (incorporated by reference to Exhibit 99.2 to the report on Form 6-K (SEC File No. 000-13248), filed with the SEC on July 20, 2015).
10.4+	Employment Agreement with Jeff Baxter, dated May 8, 2014 (incorporated by reference to Exhibit 10.5 to VBI DE's current report on form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
10.5+	Employment Agreement with David Anderson, dated May 8, 2014 (incorporated by reference to Exhibit 10.6 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
10.6	License Agreement, dated May 31, 2012, by and among University Pierre and Marie Curie, The National Institute of Health and Medical Research Public National Scientific and Technological and Ecole Normale Superieure de Lyon, and Epixis SA (incorporated by reference to Exhibit 10.45 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).
10.7	Amendment to License Agreement by and among University Pierre and Marie Curie, The National Institute of Health and Medical Research Public National Scientific and Technological and Ecole Normale Superieure de Lyon, and Epixis SA (incorporated by reference to Exhibit 10.46 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).
10.8	Sub-Sublease, dated September 1, 2014, by and between Iogen Corporation and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.48 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).
10.9	Amendment of Sub-sublease, dated March 18, 2016, by and between Iogen Corporation and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.1 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on March 21, 2016).
10.10+	Consulting Agreement with Francisco Diaz-Mitoma, dated July 1, 2016 (incorporated by reference to Exhibit 10.42 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).
10.11+	Offer letter with Nell Beattie, dated June 22, 2015 (incorporated by reference to Exhibit 10.43 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).
10.12	Amended and Restated Credit Agreement and Guaranty, dated as of December 6, 2016, by and among Variation Biotechnologies (US), Inc., the Guarantors party thereto, and Perceptive Credit Holdings, LP (incorporated by reference to Exhibit 99.1 to the report on Form 6-K (SEC File No. 000-37769), filed with the SEC on December 16, 2016).

10.13	Supplement, dated as of December 6, 2016, to the Pledge and Security Agreement, dated as of July 25, 2014, among the Grantors in favor of Perceptive Credit Holdings, LP (incorporated by reference to Exhibit 99.2 to the report on Form 6-K (SEC File No. 000-37769), filed with the SEC on December 16, 2016).
10.14	Form of Warrant, dated October 30, 2017 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (SEC File No. 001-37769) filed with the SEC on October 31, 2017).
10.15+	Form of Executive Employment Agreement (incorporated by reference to Exhibit 10.56 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on February 26, 2018).
10.16	Amendment to Sublease Lease, dated January 21, 2018, by and between Green Power YE and SciVac Ltd. (incorporated by reference to Exhibit 10.58 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on February 26, 2018).
10.17+	Employment Agreement, dated August 14, 2018, by and between VBI Vaccines (Delaware) Inc. and Christopher McNulty (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K (SEC File No. 001-37769) filed with the SEC on August 20, 2018)
10.18(1)	Collaboration and License Agreement, dated December 4, 2018, between VBI Vaccines, Inc. and Brii Biosciences Limited (incorporated by reference to Exhibit 10.62 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on February 25, 2019).
10.19	Stock Purchase Agreement, dated December 4, 2018, between VBI Vaccines, Inc. and Brii Biosciences Limited (incorporated by reference to Exhibit 10.63 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on February 25, 2019).
10.20	Amendment to Sublease Lease, dated January 15, 2019, by and between Green Power YE and SciVac Ltd. (incorporated by reference to Exhibit 10.64 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on February 25, 2019).
10.21*(3)	Collaborative Research Agreement, dated March 30, 2020, between National Research Council of Canada and Variation Biotechnologies Inc.
10.22*(3)	First Amendment to the Collaborative Research Agreement, dated December 21, 2020, between National Research Council of Canada and Variation Biotechnologies Inc.
10.23*(3)	Second Amendment to the Collaborative Research Agreement, dated July 8, 2021, between National Research Council of Canada and Variation Biotechnologies Inc.
10.24*(3)	Third Amendment to the Collaborative Research Agreement, dated August 27, 2021, between National Research Council of Canada and Variation Biotechnologies Inc.
10.25*(2)(3)	Fourth Amendment to the Collaborative Research Agreement, signed November 15, 2021, between National Research Council of Canada and Variation Biotechnologies Inc.
10.26*(2)(3)	Fifth Amendment Five to the Collaborative Research Agreement, signed February 8, 2022, between National Research Council of Canada and Variation Biotechnologies Inc.
10.27+	Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective January 1, 2020 (incorporated by reference to Exhibit 10.42 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 5, 2020).
10.28	Form of Warrant Agreement issued to National Securities Corporation or its designees (incorporated by reference to Exhibit 4.1 to the annual report on Form 8-K (SEC File No. 001-37769), filed with the SEC on April 27, 2020).
10.29(3)	Loan and Guaranty Agreement, dated as of May 22, 2020, by and among VBI Vaccines Inc., as borrower, Variation Biotechnologies Inc., as borrower representative, each of the guarantors signatory thereto, K2 HealthVentures LLC, as lender and as administrative agent, and Ankura Trust Company, LLC, as collateral trustee for lenders (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K (SEC File No. 001-37769), filed with the SEC on May 27, 2020).
10.30	Form of Warrant issued to K2 HealthVentures LLC (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K (SEC File No. 001-37769), filed with the SEC on May 27, 2020).
10.31	Lease agreement dated September 4, 2020, between 310 Hunt Club Limited and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on November 2, 2020).

10.32	Contribution Agreement, dated September 16, 2020, by and among VBI Vaccines, Inc., Variation Biotechnologies, Inc. and Her Majesty The Queen in Right of Canada as Represented by the Minister of Industry (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on November 2, 2020).
10.33+	Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective January 1, 2021 (incorporated by reference to Exhibit 10.46 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 2, 2021).
10.34	Assignment Agreement, dated February 14, 2012, between FDS Pharma LLP and SciGen Ltd (incorporated by reference to Exhibit 10.48 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 2, 2021).
10.35	Assignment Agreement, dated October 16, 2012, by and among FDS Pharma LLP, SciGen Ltd., and SciGen (LL.) Ltd (incorporated by reference to Exhibit 10.49 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 2, 2021).
10.36	Amendment to the Assignment Agreement, dated February 14, 2013, by and among SciGen Ltd., SciGen (LL.) Ltd (incorporated by reference to Exhibit 10.50 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 2, 2021).
10.37(3)	Master Commercial Services Agreement, dated December 19, 2017, between InVentiv Commercial Services, LLC and VBI Vaccines Inc. (incorporated by reference to Exhibit 10.51 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 2, 2021).
10.38*(2)(3)	Funding Agreement, by and between Variation Biotechnologies Inc., a Canadian federal corporation and a wholly-owned subsidiary of VBI Vaccines Inc., and the Coalition for Epidemic Preparedness Innovations, dated as of March 9, 2021.
10.39	Amendment to the Collaboration and License Agreement with Brii Bioscience, effective April 8, 2021 (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on May 10, 2021).
10.40+	Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective July 1, 2020 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on May 10, 2021).
10.41	First Amendment to Loan and Guaranty Agreement, dated as of May 17, 2021, by and among VBI Vaccines Inc., as borrower, Variation Biotechnologies Inc., as borrower representative, each of the guarantors signatory thereto, and K2 HealthVentures LLC, as lender and as administrative agent (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (SEC File No. 001-37769), filed with the SEC on May 21, 2021).
10.42	Form of Amended and Restated Warrant issued to K2 HealthVentures LLC (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K (SEC File No. 001-37769), filed with the SEC on May 21, 2021).
10.43	Addendum #3 to sublease agreement signed by Ayalot Investment (Ramat Vered) 1994 Ltd; EMI Car Wash Systems Ltd and SciVac Ltd effective July 11, 2021 (incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on August 2, 2021).

10.44	Sublease signed by EMI Car Wash Systems Ltd. And SciVac Ltd effective July 11, 2021(incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on August 2, 2021).
10.45	Unprotected Lease Agreement signed by Africa Israel Properties Ltd, Ayalot Investments (Ramat Vered) 1994 Ltd, Sharda Ltd and SciGen (IL) Ltd effective June 16, 2006 (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on November 8, 2021).
10.46	Addendum of Unprotected Lease Agreement dated June 16, 2006 right of use in floor protected space signed by Africa Israel Properties Ltd, Ayalot Investments (Ramat Vered) 1994 Ltd, Sharda Ltd and SciGen (IL) effective October 20, 2006 (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on November 8, 2021).
10.47	Addendum of Unprotected Lease Agreement dated June 16, 2006 signed by Africa Israel Properties Ltd, Ayalot Investments (Ramat Vered) 1994 Ltd, Sharda Ltd and SciGen (IL) Ltd Company No .513679555 effective January 2012 (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on November 8, 2021).
10.48	Addendum of Unprotected Lease Agreement dated June 16, 2006 signed by Africa Israel Properties Ltd, Ayalot Investments (Ramat Vered) 1994 Ltd, Sharda Ltd and SciVac Ltd Company No .513679555 effective February 24, 2016 (incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on November 8, 2021).
10.49	Addendum of Unprotected Lease Agreement dated June 16, 2006 signed by Africa Israel Properties Ltd, Ayalot Investments (Ramat Vered) 1994 Ltd, Sharda Ltd and SciVac Ltd. Company No 513679555 effective September 5, 2016 (incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on November 8, 2021).
10.50	Addendum to Lease Agreement for Fixed Term Rented Property dated June 16, 2006 signed by Ayalot Investment (Ramat Vered) 1994 Ltd. Private Company 512022401 and SciVac Ltd. Private Company 513679555 effective September 9, 2021 (incorporated by reference to Exhibit 10.7 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on November 8, 2021).
10.51*(2) (3)	Second Amendment to the Collaboration and License Agreement with Brii Bioscience, dated December 20, 2021.

10.52*+	Amendment to Consulting Agreement with F.Diaz-Mitoma Professional Corporation, effective January 1, 2022.
21.1	VBI Vaccines Inc. – List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Annual Report on Form 10-K SEC File No. 001-37769), filed with the SEC on March 2, 2021)
23.1*	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.
24.1*	Powers of Attorney (attached to the signature page hereto).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of Chief Financial Officer and Head of Business Development pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934.
32.1**	Certification of Chief Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
32.2**	Certification of Chief Financial Officer and Head of Business Development pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

+ Indicates a management contract or compensatory plan.

(1) Certain material has been omitted from this document pursuant to a request for confidential treatment. The omitted material has been filed separately with the SEC.

(2) Certain of the schedules (and similar attachments) to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5) of Regulation S-K under the Securities Act of 1933, as amended, because they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the Exhibit or the disclosure document. The registrant hereby agrees to furnish a copy of all omitted schedules (or similar attachments) to the SEC upon its request.

(3) Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K under the Securities Act of 1933, as amended, because they are both (i) not material and (ii) the type that the registrant treats as private or confidential. A copy of the omitted portions will be furnished to the SEC upon its request.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts, on this 7th day of March, 2022.

VBI VACCINES INC.

By: */s/ Jeffrey Baxter*
Jeffrey R. Baxter, President and Chief Executive Officer

By: */s/ Christopher McNulty*
Christopher McNulty, Chief Financial Officer and Head of Business Development (Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jeffrey Baxter and Christopher McNulty, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: March 7, 2022 */s/ Jeffrey Baxter*
Jeffrey Baxter, President, Chief Executive Officer and Director (Principal Executive Officer)

Date: March 7, 2022 */s/ Christopher McNulty*
Christopher McNulty, Chief Financial Officer and Head of Business Development and Director (Principal Financial and Accounting Officer)

Date: March 7, 2022 */s/ Steven Gillis*
Steven Gillis,
Director

Date: March 7, 2022 */s/ Michel De Wilde*
Michel De Wilde
Director

Date: March 7, 2022 */s/ Blaine McKee*
Blaine McKee
Director

Date: March 7, 2022 */s/ Joanne Cordeiro*
Joanne Cordeiro
Director

Date: March 7, 2022 */s/ Damian Braga*
Damian Braga
Director

Date: March 7, 2022 */s/ Linda Bain*
Linda Bain
Director

Exhibit 10.1B+

VBI VACCINES INC.

INCENTIVE PLAN

Effective **May 6, 2016**

As amended **December 16, 2021**

PART I – GENERAL PROVISIONS

1. PREAMBLE AND DEFINITIONS

1.1 Title.

The Plan described in this document shall be called the "VBI Vaccines Inc. Incentive Plan"

1.2 Purpose of the Plan.

The purposes of the Plan are:

(a) to promote a further alignment of interests between officers, employees and other eligible service providers and the shareholders of the Corporation;

(b) to associate a portion of the compensation payable to officers, employees and other eligible service providers with the returns achieved by shareholders of the Corporation; and

(c) to attract and retain officers, employees and other eligible service providers with the knowledge, experience and expertise required by the Corporation.

1.3 Definitions.

1.3.1 "**Affiliate(s)**" shall mean a Parent or Subsidiary of the Corporation.

1.3.2 "**Applicable Law**" means any applicable provision of law, domestic or foreign, including, without limitation, applicable securities legislation, together with all regulations, rules, policy statements, rulings, notices, orders or other instruments promulgated thereunder, and Stock Exchange Rules.

1.3.3 "**Base Price**" means the base dollar amount used to calculate the amount, if any, payable to a Participant with respect to a Share subject to a Stand-Alone SAR upon settlement thereof, which base dollar amount shall be determined in accordance with Section 10.6.

1.3.4 "**Beneficiary**" means, subject to Applicable Law, an individual who has been designated by a Participant, in such form and manner as the Board may determine, to receive benefits payable under the Plan upon the death of the Participant, or, where no such designation is validly in effect at the time of death, the Participant's legal representative.

1.3.5 "**Black-Out Period**" means a period of time when, pursuant to any policies of the Corporation, any securities of the Corporation may not be traded by certain persons as designated by the Corporation, including any holder of a Grant.

1.3.6 "**Board**" means the Board of Directors of the Corporation.

1.3.7 "**Cause**" means:

(a) subject to (b) below, "just cause" or "cause" for Termination by the Corporation or an Affiliate as determined under Applicable Law;

(b) where a Participant has a written employment agreement with the Corporation or an Affiliate, "**Cause**" as defined in such employment agreement, if applicable; or

(c) where a Participant provides services as an independent contractor pursuant to a contract for services with the Corporation or an Affiliate, any material breach of such contract.

1.3.8 "**Change in Control**" means:

(a) a successful "take-over bid" (as defined in the *Securities Act* (British Columbia), as amended, or any successor legislation thereto) pursuant to which the "offeror" acquires beneficial ownership of securities of the Corporation which, directly or following conversion or exercise thereof, would entitle the holder thereof, together with persons acting jointly or in concert with the holder thereof, to cast more than fifty percent (50%) of the votes attaching to all securities of the Corporation which may be cast to elect directors of the Corporation, other than the acquisition of beneficial ownership of additional securities of the Corporation by any person who, together with persons acting jointly or in concert with such person, was entitled prior to such "take-over bid", directly or following conversion or exercise securities of the Corporation, to cast more than fifty percent (50%) of the votes attaching to all securities of the Corporation which may be cast to elect directors of the Corporation;

(b) the issuance to, or acquisition by, any person, or group of persons acting jointly or in concert, directly or indirectly, including through an arrangement or other form of reorganization, of beneficial ownership of securities of the Corporation which, directly or following conversion or exercise thereof, would entitle the holder thereof to cast more than fifty percent (50%) of the votes attaching to all securities of the Corporation which may be cast to elect directors of the Corporation, other than the issuance of securities of the Corporation to, or acquisition of securities of the Corporation by, any person who, together with persons acting jointly or in concert with such person, was entitled prior to such issuance or acquisition, directly or following conversion or exercise securities of the Corporation, to cast more than fifty percent (50%) of the votes attaching to all securities of the Corporation which may be cast to elect directors of the Corporation;

(c) individuals who, as of a Grant Date, constitute the Board (the "Incumbent Board") cease for any reason (other than death or disability) to constitute at least a majority of the Board; provided, however, that any individual becoming a Director subsequent to the Grant Date, whose election, or nomination for election by the Corporation's shareholders, was approved by a vote of at least two-thirds of the Directors then comprising the Incumbent Board (either by a specific vote or by approval of the proxy statement of the Corporation in which such person is named as a nominee for Director, without objection to such nomination) will be considered as though such individual was a member of the Incumbent Board, but excluding for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of Directors or other actual or threatened solicitation of proxies or consents by or on behalf of a person other than the Directors then comprising the Board;

(d) an arrangement, amalgamation, merger or other form of reorganization of the Corporation where the holders of the outstanding voting securities or interests of the Corporation immediately prior to the completion of the arrangement, amalgamation, merger or reorganization will hold fifty percent (50%) or less of the votes attaching to all outstanding voting securities or interests of the continuing entity upon completion of the arrangement, amalgamation, merger or reorganization;

(e) the sale of all or substantially all of the assets of the Corporation; or

(f) the liquidation, winding-up or dissolution of the Corporation.

1.3.9 "**Code**" or "**Internal Revenue Code**" means the United States Internal Revenue Code of 1986, as amended, and any applicable United States Treasury Regulations and other binding regulatory guidance thereunder.

1.3.10 "**Corporation**" means VBI Vaccines Inc. and includes any successor corporation thereof.

1.3.11 "**Director**" means a director of the Corporation from time to time.

1.3.12 "**Disability**" means:

(a) subject to (b) below, a Participant's physical or mental incapacity that prevents him/her from substantially fulfilling his or her duties and responsibilities on behalf of the Corporation or, if applicable, an Affiliate, as determined by the Board and, in the case of a Participant who is an employee of the Corporation or an Affiliate, in respect of which the Participant commences receiving, or is eligible to receive, disability benefits under the Corporation's or Affiliate's long-term disability plan; or

(b) where a Participant has a written employment agreement with the Corporation or an Affiliate, "**Disability**" as defined in such employment agreement, if applicable.

1.3.13 "**Disability Date**" means, in relation to a Participant, that date determined by the Board to be the date on which the Participant experienced a Disability.

1.3.14 "**Eligible Person**" means an individual Employed by the Corporation or any Affiliate, including a Service Provider, who, by the nature of his or her position or job is, in the opinion of the Board, in a position to contribute to the success of the Corporation.

1.3.15 "**Employed**" means, with respect to a Participant, that:

(a) the Participant is rendering services to the Corporation or an Affiliate (including services as a Director) including as a Service Provider (referred to in Section 1.3.43 as "active Employment"); or

(b) the Participant is not actively rendering services to the Corporation or an Affiliate due to an approved leave of absence, maternity or parental leave or leave on account of Disability (provided, in the case of a US Taxpayer, that the Participant has not incurred a "Separation From Service", within the meaning of Section 409A of the Code).

For greater certainty, a Participant shall not be considered to be Employed on a Vesting Date if, prior to such Vesting Date, such Participant received a payment in lieu of notice of termination of employment, whether under a contract of employment, as damages or otherwise.

and "**Employment**' has the corresponding meaning.

1.3.16 "**Exercise Price**" means, (i) with respect to an Option, the price payable by a Participant to purchase one Share on exercise of such Option, which shall not be less than one hundred percent (100%) of the Market Price on the Grant Date of the Option covering such Share, and (ii) with respect to a Tandem SAR, the Exercise Price (as defined in paragraph (i) above) applicable to the Option to which the Tandem SAR relates, in each case subject to adjustment pursuant to Section 5.

1.3.17 "**Grant**" means a grant or right granted under the Plan consisting of one or more Options, Stock Appreciation Rights, RSUs or PSUs, shares of Restricted Stock or such other award as may be permitted hereunder.

1.3.18 "**Grant Agreement**" means an agreement between the Corporation and a Participant evidencing a Grant and setting out the terms under which such Grant is made, together with such schedules, amendments, deletions or changes thereto as are permitted under the Plan.

1.3.19 "**Grant Date**" means the effective date of a Grant.

1.3.20 "**Incentive Stock Option**" has the meaning ascribed thereto in Section 422(b) of the Code.

1.3.21 "**Insider**" means

(a) a Director or officer of the Corporation;

(b) a Director or officer of an Affiliate or a company that is an insider:

(c) a person or company that has:

(i) beneficial ownership of, or control or direction over, directly or indirectly, securities of the Corporation carrying more than 10 percent of the voting rights attached to all the Corporation's outstanding voting securities, excluding, for the purpose of the calculation of the percentage held, any securities held by the person or company as underwriter in the course of a distribution, or

(ii) a combination of beneficial ownership of, and control or direction over, directly or indirectly, securities of the Corporation carrying more than 10 percent of the voting rights attached to all the Corporation's outstanding voting securities, excluding, for the purpose of the calculation of the percentage held, any securities held by the person or company as underwriter in the course of a distribution..

1.3.22 "**Market Price**" means, with respect to any particular date:

(a) if the Shares are listed on only one Stock Exchange, the closing price per Share on such Stock Exchange;

(b) if the Shares are listed on more than one Stock Exchange, the "Market Price" as determined in accordance with paragraph (a) above for the primary Stock Exchange on which the greatest volume of trading of the Shares occurred during the immediately preceding twenty (20) Trading Days; and

(c) if the Shares are not listed for trading on a Stock Exchange, a price which is determined by the Board (acting on the advice of an independent third party, should the Board elect, in its sole discretion, to utilize an independent third party for this purpose), in good faith to be the fair market value of the Shares

1.3.23 Notwithstanding the foregoing, the determination of the Market Price shall, where applicable to a US Taxpayer, be in compliance with Section 409A of the Code. "**Option**" means an option to purchase a Share granted by the Board to an Eligible Person in accordance with Section 3 and Section 9.1.

1.3.24 "**Parent**" means any parent corporation of the Corporation within the meaning of Code Section 424(e), or any successor provision.

1.3.25 "**Participant**" means an Eligible Person to whom a Grant is made and which Grant or a portion thereof remains outstanding.

1.3.26 "**Performance Conditions**" means such financial, personal, operational or transaction-based performance criteria as may be determined by the Board in respect of a Grant to any Participant or Participants and set out in a Grant Agreement. Performance Conditions may apply to the Corporation, an Affiliate, the Corporation and its Affiliates as a whole, a business unit of the Corporation or group comprised of the Corporation and some Affiliates or a group of Affiliates, either individually, alternatively or in any combination, and measured either in total, incrementally or cumulatively over a specified performance period, on an absolute basis or relative to a pre-established target or milestone, to previous years' results or to a designated comparator group, or otherwise, provided that the performance period for measurement or achievement of any such performance criteria (or incremental element thereof) shall in all events exceed one year.

1.3.27 "**Performance Period**" means, with respect to PSUs, the period specified by the Board for achievement of any applicable Performance Conditions as a condition to Vesting.

1.3.28 "**Plan**" means this VBI Vaccines Inc. Incentive Plan, including any schedules or appendices hereto, as may be amended from time to time.

1.3.29 "**Performance Share Unit**" or "**PSU**" means a right granted to an Eligible Person in accordance with Section 3 and Section 14.1 to receive a Share or the Market Price, as determined by the Board, that generally becomes Vested, if at all, subject to the attainment of certain Performance Conditions and satisfaction of such other conditions to Vesting, if any, as may be determined by the Board.

1.3.30 "**Restricted Share Unit**" or "**RSU**" means a right granted to an Eligible Person in accordance with Section 3 and Section 14.1 to receive a Share or the Market Price, as determined by the Board, that generally becomes Vested, if at all, following a period of continuous Employment of the Participant.

1.3.31 "**Restricted Stock**" means Shares granted to a Participant that are subject to a Restriction (as defined in Section 18).

1.3.32 "**Restrictive Covenant**" means any obligation of a Participant to the Corporation or an Affiliate to (A) maintain the confidentiality of information relating to the Corporation or the Affiliate and/or its business, (B) not engage in employment or business activities that compete with the business of the Corporation or the Affiliate, (C) not solicit employees or other service providers, customers and/or suppliers of the Corporation or the Affiliate, whether during or after employment with the Corporation or Affiliate, and whether such obligation is set out in a Grant Agreement issued under the Plan or other agreement between the Participant and the Corporation or Affiliate, including, without limitation, an employment agreement, or otherwise, or (D) any other restrictive covenant contained in an applicable Grant Agreement, employment agreement or other Agreement between a Participant and the Corporation or an Affiliate.

1.3.33 "**Service Provider**" means a person or company, other than an employee, officer or director of the Corporation or an Affiliate, that:

(a) is engaged to provide, on a *bona fide* basis, for an initial, renewable or extended period of twelve (12) months or more, services to the Corporation or an Affiliate, other than services provided in relation to a distribution of securities;

(b) provides the services under a written contract between the Corporation or an Affiliate and the person or company; and

(c) in the reasonable opinion of the Corporation, spends or will spend a significant amount of time and attention on the affairs and business of the Corporation or an Affiliate;

and includes

(a) for an individual Service Provider, a corporation of which the individual Service Provider is an employee or shareholder, and a partnership of which the individual Service Provider is an employee or partner; and

(b) for a Service Provider that is not an individual, an employee, executive officer, or director of the Service Provider, provided that the individual employee, executive officer, or director spends or will spend a significant amount of time and attention on the affairs and business of the Corporation or an Affiliate.

1.3.34 "**Share**" means a common share in the capital of the Corporation or, in the event of an adjustment contemplated by Section 5.1 hereof, such other security to which a Participant may be entitled upon the exercise or settlement of a Grant as a result of such adjustment.

1.3.35 "**Share Unit**" means either an RSU or a PSU, as the context requires.

1.3.36 "**Stand-Alone SAR**" means a Stock Appreciation right that is granted without reference to any related Option.

1.3.37 "**Stock Appreciation Right**" or "**SAR**" means a right, granted to an Eligible Person, representing the right to receive payment, in cash, Shares or any combination thereof, as determined by the Board, equal to the excess of the Market Price over the Base Price or Exercise Price, whichever is applicable, on the terms and conditions and calculated in accordance with the provisions of Section 10 hereof.

1.3.38 "**Stock Exchange**" means the NASDAQ Exchange and such other stock exchange on which the Shares are listed, or if the Shares are not listed on any stock exchange, then on the over-the-counter market.

1.3.39 "**Stock Exchange Rules**" means the applicable rules of any Stock Exchange upon which Shares of the Corporation are listed.

1.3.40 "**Subsidiary**" means, any subsidiary corporation of the Corporation within the meaning of Code Section 424(f), or any successor provision.

1.3.41 "**Tandem SAR**" means a Stock Appreciation Right attached to an Option, giving the holder, upon Vesting of the Option and Tandem SAR, the right to choose to exercise the Stock Appreciation Right or to exercise the Option.

1.3.42 "**Termination**" means (i) the termination of a Participant's active Employment with the Corporation or an Affiliate (other than in connection with the Participant's transfer to Employment with the Corporation or another Affiliate), which shall occur on the earlier of the date on which the Participant ceases to render services to the Corporation or Affiliate, as applicable, and the date on which the Corporation or an Affiliate, as applicable, delivers notice of the termination of the Participant's employment or contract for services, whether such termination is lawful or otherwise, without giving effect to any period of notice or compensation in lieu of notice (except as expressly required by applicable employment standards legislation), but, for greater certainty, a Participant's absence from active work during a period of vacation, temporary illness, authorized leave of absence, maternity or parental leave or leave on account of Disability shall not be considered to be a "Termination", and (ii) in the case of a Participant who does not return to active Employment with the Corporation or an Affiliate immediately following a period of absence due to vacation, temporary illness, authorized leave of absence, maternity or parental leave or leave on account of Disability, such cessation shall be deemed to occur on the last day of such period of absence (provided, in each case, that, in the case of a US Taxpayer, the Termination constitutes a "Separation From Service", within the meaning of Section 409A of the Code), and "**Terminated**" and "**Terminates**" shall be construed accordingly.

1.3.43 "**Time Vesting**" means any conditions relating to the passage of time or continued service with the Corporation or an Affiliate for a period of time in respect of a Grant, as may be determined by the Board.

1.3.44 "**Trading Day**" means a day on which the Stock Exchange is open for trading and on which the Shares actually traded.

1.3.45 **"US Taxpayer"** means an individual who is subject to tax under the Code in respect of any amounts payable or Shares deliverable under this Plan.

1.3.46 "**Vested**" means, with respect to any Option, SAR, Share Unit, share of Restricted Stock or other award included in a Grant, that the applicable conditions with respect to Time Vesting, achievement of Performance Conditions and/or any other conditions established by the Board have been satisfied or, to the extent permitted under the Plan, waived, whether or not the Participant's rights with respect to such Grant may be conditioned upon prior or subsequent compliance with any Restrictive Covenants (and any applicable derivative term shall be construed accordingly).

1.3.47 "**Vesting Date**" means the date on which the applicable Time Vesting, Performance Conditions and/or any other conditions for an Option, SAR, Share Unit, share of Restricted Stock or other award included in a Grant becoming Vested are met, deemed to have been met or waived as contemplated in Section 3.1.

2. CONSTRUCTION AND INTERPRETATION

2.1 **Gender, Singular, Plural.**

In the Plan, references to the masculine include the feminine; and references to the singular shall include the plural and vice versa, as the context shall require.

2.2 **Severability.**

If any provision or part of the Plan is determined to be void or unenforceable in whole or in part, such determination shall not affect the validity or enforcement of any other provision or part thereof.

2.3 **Headings, Sections and Parts.**

Headings wherever used herein are for reference purposes only and do not limit or extend the meaning of the provisions herein contained. A reference to a section or schedule shall, except where expressly stated otherwise, mean a section or schedule of the Plan, as applicable. The Plan is divided into four Parts. Part I contains provisions of general application to all Grants; Part II applies specifically to Options and SARs; Part III applies specifically to Share Units; and Part IV applies specifically to Restricted Stock and other Share-based awards.

2.4 **Insiders.**

With respect to Insiders, the Plan and all transactions under the Plan are intended to comply with all applicable conditions of Rule 16b-3 promulgated under the U.S. Securities Exchange Act of 1934, as amended. To the extent any provision of the Plan or action by the Board fails to so comply, such provision or action shall be deemed null and void *ab initio*, to the extent permitted by Applicable Law and deemed advisable by the Board.

3. ADMINISTRATION

3.1 **Administration by the Board.**

The Plan shall be administered by the Board in accordance with its terms and subject to Applicable Law. Subject to and consistent with the terms of the Plan, in addition to any authority of the Board specified under any other terms of the Plan, the Board shall have full and complete discretionary authority to:

(a) interpret the Plan and Grant Agreements;

(b) prescribe, amend and rescind such rules and regulations and make all determinations necessary or desirable for the administration and interpretation of the Plan and instruments of grant evidencing Grants;

(c) determine those Eligible Persons who may receive Grants as Participants, grant one or more Grants to such Participants and approve or authorize the applicable form and terms of the related Grant Agreement;

(d) determine the terms and conditions of Grants granted to any Participant, including, without limitation, as applicable (i) Grant Value and the number of Shares subject to a Grant, (ii) the Exercise Price or Base Price for Shares subject to a Grant, (iii) the conditions to the Vesting of a Grant or any portion thereof, including, as applicable, the period for achievement of any applicable Performance Conditions as a condition to Vesting and conditions pertaining to compliance with Restrictive Covenants, and the conditions, if any, upon which Vesting of any Grant or any portion thereof will be waived or accelerated without any further action by the Board, (iv) the circumstances upon which a Grant or any portion thereof shall be forfeited, cancelled or expire, including in connection with the breach by a Participant of any Restrictive Covenant, (v) the consequences of a Termination with respect to a Grant, (vi) the manner of exercise or settlement of the Vested portion of a Grant, (vii) whether, and the terms upon which, a Grant may be settled in cash, newly issued Shares or a combination thereof, and (viii) whether, and the terms upon which, any Shares delivered upon exercise or settlement of a Grant must be held by a Participant for any specified period of time;

(e) determine whether, and the extent to which, any Performance Conditions or other conditions applicable to the Vesting of a Grant have been satisfied or shall be waived or modified;

(f) make such rules, regulations and determinations as it deems appropriate under the Plan in respect of any leave of absence or disability of any Participant. Without limiting the generality of the foregoing, the Board shall be entitled to determine:

(i) whether or not any such leave of absence shall constitute a Termination within the meaning of the Plan;

(ii) the impact, if any, of any such leave of absence on Grants issued under the Plan made to any Participant who takes such leave of absence (including, without limitation, whether or not such leave of absence shall cause any Grants to expire and the impact upon the time or times such Grants shall be exercisable);

provided that, with respect to Options that are intended to be Incentive Stock Options, the treatment of any such leave of absence shall comply with Code Section 422 and the regulations issued thereunder;

(g) amend the terms of any Grant Agreement or other documents evidencing Grants; and

(h) determine whether, and the extent to which, adjustments shall be made pursuant to Section 5 and the terms of such adjustments.

3.2 All determinations, interpretations, rules, regulations, or other acts of the Board respecting the Plan or any Grant shall be made in its sole discretion and shall be conclusively binding upon all persons.

3.3 The Board may prescribe terms for Grant Agreements in respect of Eligible Persons who are subject to the laws of a jurisdiction other than Canada in connection with their participation in the Plan that are different than the terms of the Grant Agreements for Eligible Persons who are subject to the laws of Canada in connection with their participation in the Plan, and/or deviate from the terms of the Plan set out herein, for purposes of compliance with Applicable Law in such other jurisdiction or where, in the Board's opinion, such terms or deviations are necessary or desirable to obtain more advantageous treatment for the Corporation, an Affiliate or the Eligible Person in respect of the Plan under the Applicable Law of the other jurisdiction.

Notwithstanding the foregoing, the terms of any Grant Agreement authorized pursuant to this Section 3.3 shall be consistent with the Plan to the extent practicable having regard to the Applicable Law of the jurisdiction in which such Grant Agreement is applicable and in no event shall contravene the Applicable Law of Canada, except as otherwise provided in Section 7.9 or Exhibit A or Exhibit B attached hereto.

3.4 The Board may, in its discretion, subject to Applicable Law, delegate its powers, rights and duties under the Plan, in whole or in part, to a committee of the Board, a person or persons, as it may determine, from time to time, on terms and conditions as it may determine, except that the Board shall not, and shall not be permitted to delegate any such powers, rights or duties (i) with respect to the grant, amendment, administration or settlement of any Grant to the extent delegation is not consistent with Applicable Law and any such purported delegation or action shall not be given effect, and (ii) provided that the composition of the committee of the Board, person or persons, as the case may be, shall comply with Applicable Law. In addition, provided it complies with the foregoing, the Board may appoint or engage a trustee, custodian or administrator to administer or implement the Plan or any aspect of it. Notwithstanding the foregoing, to the extent necessary to satisfy the requirements of Rule 16b-3 promulgated under the U.S. Securities Exchange Act of 1934, as amended, any function relating to an Insider shall be performed solely by the Board.

4. SHARE RESERVE

4.1 Subject to Section 4.4 and any adjustment pursuant to Section 5.1, the aggregate number of Shares that may be issued pursuant to Grants made under the Plan together with any other security-based compensation arrangement of the Corporation, shall not exceed ten percent (10%) of the aggregate issued and outstanding Shares from time to time (on a non-diluted basis).

4.2 The aggregate number of Shares reserved for issuance to any one Participant under the Plan, together with all other security-based compensation arrangements of the Corporation, must not exceed five percent (5%) of the aggregate issued and outstanding Shares (on a non-diluted basis).

4.3 The maximum number of Shares of the Corporation

(a) issued to Insiders within any one-year period, and

(b) issuable to Insiders, at any time,

under the Plan, or when combined with all of the Corporation's other security-based compensation arrangements, shall not exceed ten percent (10%) of the number of the aggregate issued and outstanding Shares.

4.4 For purposes of computing the total number of Shares available for grant under the Plan or any other security-based compensation arrangement of the Corporation, Shares subject to any Grant (or any portion thereof) that is forfeited, surrendered, cancelled or otherwise terminated prior to the issuance of such Shares shall again be available for grant under the Plan.

5. ALTERATION OF CAPITAL AND CHANGE IN CONTROL

5.1 Notwithstanding any other provision of the Plan, and subject to Applicable Law, in the event of any change in the Shares by reason of any dividend (other than dividends in the ordinary course), split, recapitalization, reclassification, amalgamation, arrangement, merger, consolidation, combination or exchange of Shares or distribution of rights to holders of Shares or any other relevant changes to the authorized or issued capital of the Corporation, if the Board shall determine that an equitable adjustment should be made, such adjustment shall, subject to Applicable Law, be made by the Board to (i) the number of Shares subject to the Plan; (ii) the securities into which the Shares are changed or are convertible or exchangeable; (iii) any Options and/or Stock Appreciation Rights then outstanding; (iv) the Exercise Price and/or Base Price, as appropriate in respect of such Options and/or Stock Appreciation Rights; and/or (v) with respect to the number of Share Units outstanding under the Plan, and any such adjustment shall be conclusive and binding for all purposes of the Plan. Notwithstanding the foregoing, no such adjustment shall be made or authorized to the extent that such adjustment would cause the Plan or any award to violate Section 422 of the Code or Section 409A of the Code.

5.2 No adjustment provided for pursuant to Section 5.1 shall require the Corporation to issue fractional Shares in satisfaction of its obligations under the Plan. Any fractional interest in a Share that would, except for the provisions of this Section 5.2, be deliverable upon the exercise of any Grant shall be cancelled and not deliverable by the Corporation.

5.3 In the event of a Change in Control prior to the Vesting of a Grant, and subject to the terms of a Participant's written employment agreement or contract for services with the Corporation or an Affiliate and the applicable Grant Agreement, the Board shall have full authority to determine in its sole discretion the effect, if any, of a Change in Control on the Vesting, exercisability, settlement, payment or lapse of restrictions applicable to a Grant, which effect may be specified in the applicable Grant Agreement or determined at a subsequent time. Subject to Applicable Law, rules and regulations, the Board shall, at any time prior to, coincident with or after the effective time of a Change in Control, take such actions as it may consider appropriate, including, without limitation: (i) provide for the acceleration of any Vesting or exercisability of a Grant; (ii) provide for the deemed attainment of Performance Conditions relating to a Grant; (iii) provide for the lapse of restrictions relating to a Grant; (iv) provide for the assumption, substitution, replacement or continuation of any Grant by a successor or surviving corporation (or a parent or subsidiary thereof) with cash, securities, rights or other property to be paid or issued, as the case may be, by the successor or surviving corporation (or a parent or subsidiary thereof); (v) provide that that a Grant shall terminate or expire unless exercised or settled in full on or before a date fixed by the Board; or (vi) terminate or cancel any outstanding Grant in exchange for a cash payment (provided that, if as of the date of the Change in Control, the Board determines that no amount would have been realized upon the exercise or settlement of the Grant, then the Grant may be cancelled by the Corporation without payment of consideration). Notwithstanding the foregoing, no such adjustment shall be made or authorized to the extent that such adjustment would cause the Plan or any award to violate Section 422 of the Code or Section 409A of the Code.

6. CLAWBACK

6.1 **Clawback.**

It is a condition of each Grant that if:

(i) the Participant fails to comply with any applicable Restrictive Covenant;

(ii) the Participant is terminated for Cause, or the Board reasonably determines after employment termination that the Participant's employment could have been terminated for Cause;

(iii) the Board reasonably determines that the Participant engaged in conduct that causes material financial or reputational harm to the Corporation or its Affiliates, or engaged in gross negligence, willful misconduct or fraud in respect of the performance of the Participant's duties for the Corporation or an Affiliate of the Corporation; or

(iv) the Corporation's financial statements (the "Original Statements") are required to be restated (other than solely as a result of a change in accounting policy by the Corporation or under International Financial Reporting Standards applicable to the Corporation) and such restated financial statements (the "Restated Statements") disclose, in the opinion of the Board acting reasonably, materially worse financial results than those contained in the Original Statements,

then the Board may, in its sole discretion, to the full extent permitted by governing law and to the extent it determines that such action is in the best interest of the Corporation, and in addition to any other rights that the Corporation or an Affiliate may have at law or under any agreement, take any or all of the following actions, as applicable:

(a) require the Participant to reimburse the Corporation for any amount paid to the Participant in respect of a Grant in cash in excess of the amount that should otherwise have been paid in respect of such Grant had the determination of such compensation been based upon the Restated Statements in the event clause (iv) above is applicable, or that was paid in the twelve (12) months prior to (x) the date on which the Participant fails to comply with a Restrictive Covenant, (y) the date on which the Participant's employment is terminated for Cause, or the Board makes a determination under paragraph (ii) or (iii) above, less, in any event, the amount of tax withheld pursuant to the *Income Tax Act* (Canada) or other relevant taxing authority in respect of the amount paid in cash in the year of payment;

(b) reduce the number or value of, or cancel and terminate, any one or more unvested Grants of Options, Share Units or SARs on or prior to the applicable maturity or Vesting Dates, or cancel or terminate any outstanding Grants which have Vested in the twelve (12) months prior to (x) the date on which the Participant fails to comply with a Restrictive Covenant, (y) the date on which the Participant's employment is terminated for Cause or the Board makes a determination under paragraph (ii) or (iii) above, or (z) the date on which the Board determines that the Corporation's Original Statements are required to be restated, in the event paragraph (iv) above applies (each such date provided for in clause (x), (y) and (z) of this paragraph (b) being a "Relevant Equity Recoupment Date"); and/or

(c) require payment to the Corporation of the value of any Shares of the Corporation acquired by the Participant pursuant to a Grant in the twelve (12) months prior to a Relevant Equity Recoupment Date (less any amount paid by the Participant to acquire such Shares and less the amount of tax withheld pursuant to the *Income Tax Act* (Canada) or other relevant taxing authority in respect of such Shares).

7. MISCELLANEOUS

7.1 Compliance with Laws and Policies.

The Corporation's obligation to make any payments or deliver (or cause to be delivered) any Shares hereunder is subject to compliance with Applicable Law. Each Participant shall acknowledge and agree (and shall be conclusively deemed to have so acknowledged and agreed by participating in the Plan) that the Participant will, at all times, act in strict compliance with Applicable Law and all other laws and any policies of the Corporation applicable to the Participant in connection with the Plan including, without limitation, furnishing to the Corporation all information and undertakings as may be required to permit compliance with Applicable Law.

7.2 Withholdings.

So as to ensure that the Corporation or an Affiliate, as applicable, will be able to comply with the applicable obligations under any federal, provincial, state or local law relating to the withholding of tax or other required deductions, the Corporation or the Affiliate shall withhold or cause to be withheld from any amount payable to a Participant, either under this Plan, or otherwise, such amount as may be necessary to permit the Corporation or the Affiliate, as applicable, to so comply. The Corporation and any Affiliate may also satisfy any liability for any such withholding obligations, on such terms and conditions as the Corporation may determine in its sole discretion, by (a) selling on such Participant's behalf, or requiring such Participant to sell, any Shares, and retaining any amount payable which would otherwise be provided or paid to such Participant in connection with any such sale, or (b) requiring, as a condition to the delivery of Shares hereunder, that such Participant make such arrangements as the Corporation may require so that the Corporation and its Affiliates can satisfy such withholding obligations, including requiring such Participant to remit an amount to the Corporation or an Affiliate in advance, or reimburse the Corporation or any Affiliate for, any such withholding obligations.

7.3 No Right to Continued Employment.

Nothing in the Plan or in any Grant Agreement entered into pursuant hereto shall confer upon any Participant the right to continue in the employ or service of the Corporation or any Affiliate, to be entitled to any remuneration or benefits not set forth in the Plan or a Grant Agreement or to interfere with or limit in any way the right of the Corporation or any Affiliate to terminate Participant's employment or service arrangement with the Corporation or any Affiliate.

7.4 No Additional Rights.

Neither the designation of an individual as a Participant nor the Grant of any Options, SARs, Share Units, Restricted Stock or other award to any Participant entitles any person to the Grant, or any additional Grant, as the case may be, of any Options, SARs, Share Units, Restricted Stock or other award under the Plan. For greater certainty, the Board's decision to approve a Grant in any period shall not require the Board to approve a Grant to any Participant in any other period; nor shall the Board's decision with respect to the size or terms and conditions of a Grant in any period require it to approve a Grant of the same or similar size or with the same or similar terms and conditions to any Participant in any other period. The Board shall not be precluded from approving a Grant to any Participant solely because such Participant may have previously received a Grant under this Plan or any other similar compensation arrangement of the Corporation or an Affiliate. No Eligible Person has any claim or right to receive a Grant except as may be provided in a written employment or services agreement between an Eligible Person and the Corporation or an Affiliate.

7.5 **Amendment, Termination.**

The Plan and any Grant made pursuant to the Plan may be amended, modified or terminated by the Board without approval of shareholders, provided that no amendment to the Plan or Grants made pursuant to the Plan may be made without the consent of a Participant if it adversely alters or impairs the rights of the Participant in respect of any Grant previously granted to such Participant under the Plan, except that Participant consent shall not be required where the amendment is required for purposes of compliance with Applicable Law. For greater certainty, the Plan may not be amended without shareholder approval in accordance with the requirements of the Stock Exchange to do any of the following:

(a) increase in the maximum number of Shares issuable pursuant to the Plan and as set out in Section 4.1;

(b) reduce the Exercise Price of an outstanding Option or the Base Price of a Stand-Alone SAR, including a cancellation of a Grant of an Option and re-grant within six (6) months of an Option in conjunction therewith constituting a reduction of the Exercise Price of the Option;

(c) extend the maximum term of any Grant made under the Plan;

(d) amend the assignment provisions contained in Section 7.11 or Section 12;

(e) increase the number of Shares that may be issued or issuable to Insiders above the restriction or deleting the restriction on the number of Shares that may be issued or issuable to Insiders contained in Section 4.3;

(f) include other types of equity compensation involving the issuance of Shares under the Plan;

(g) cause Incentive Stock Options to fail to meet the requirements of Code Section 422; or

(h) amend this Section 7.5 to amend or delete any of (a) through (h) above or grant additional powers to the Board to amend the Plan or entitlements without shareholder approval.

For greater certainty and without limiting the foregoing, shareholder approval shall not be required for the following amendments and the Board may make the following changes without shareholder approval, subject to any regulatory approvals including, where required, the approval of any Stock Exchange:

(i) amendments of a “housekeeping” nature;

(j) a change to the Vesting provisions of any Grants;

(k) a change to the termination provisions of any Grant that does not entail an extension beyond the original term of the Grant; or

(l) amendments to the provisions relating to a Change in Control.

7.6 **Currency.** Except where the context otherwise requires, all references in the Plan to currency refer to lawful United States currency. Any amounts required to be determined under this Plan that are denominated in a currency other than United States dollars shall be converted to United States dollars at the applicable Federal Reserve noon rate of exchange on the date as of which the amount is required to be determined.

7.7 **Administration Costs.**

The Corporation will be responsible for all costs relating to the administration of the Plan.

7.8 **Designation of Beneficiary.**

Subject to the requirements of Applicable Law, a Participant may designate a Beneficiary, in writing, to receive any benefits that are provided under the Plan upon the death of such Participant. The Participant may, subject to Applicable Law, change such designation from time to time. Such designation or change shall be in such form as may be prescribed by the Board from time to time. A Beneficiary designation under this Section 7.8 and any subsequent changes thereto shall be filed with the General Counsel of the Corporation.

7.9 **Governing Law.**

The Plan and any Grants pursuant to the Plan shall be governed by and construed in accordance with the laws of the Province of British Columbia and the federal laws of Canada applicable therein, and with respect to Participants who are US Taxpayers, with the Code and applicable federal laws of the US. The Board may provide that any dispute to any Grant shall be presented and determined in such forum as the Board may specify, including through binding arbitration. Any reference in the Plan, in any Grant Agreement issued pursuant to the Plan or in any other agreement or document relating to the Plan to a provision of law or rule or regulation shall be deemed to include any successor law, rule or regulation of similar effect or applicability. To the extent applicable, with respect to Participants who are US Taxpayers, this Plan shall be interpreted in accordance with the requirements of Code Sections 409A and the regulations, notices, and other guidance of general applicability issued thereunder.

7.10 **Assignment.**

The Plan shall inure to the benefit of and be binding upon the Corporation, its successors and assigns.

7.11 **Transferability.**

7.11.1 Unless otherwise provided in the Plan or in the applicable Grant Agreement in accordance with Section 7.11.2, no Grant, and no rights or interests therein, shall or may be assigned, transferred, sold, exchanged, encumbered, pledged or otherwise hypothecated or disposed of by a Participant other than by testamentary disposition by the Participant or the laws of intestate succession. No such interest shall be subject to execution, attachment or similar legal process including without limitation seizure for the payment of the Participant’s debts, judgments, alimony or separate maintenance.

7.11.2 Notwithstanding the foregoing, with respect to Participants who are not US Taxpayers, the Board may provide in the applicable Grant Agreement that a Grant is transferable or assignable (a) in the case of a transfer without the payment of any consideration, to the Participant's spouse, former spouse, children, stepchildren, grandchildren, parent, stepparent, grandparent, sibling, persons having one of the foregoing types of relationship with a Participant due to adoption and any entity in which these persons (or the Participant) own more than fifty percent (50%) of the voting interests and (b) to an entity in which more than fifty percent (50%) voting interests are owned by these persons (or the Participant) in exchange for an interest in that entity. Following any such transfer or assignment, the Grant shall remain subject to substantially the same terms applicable to the Grant while held by the Participant to whom it was granted, as modified as the Board shall determine appropriate, and, as a condition to such transfer, the transferee shall execute an agreement agreeing to be bound by such terms. Any purported assignment or transfer that does not qualify under this Section 7.11.2 shall be void and unenforceable against the Corporation.

8. EFFECTIVE DATE

8.1 The Plan is established effective **May 6, 2016**, as amended effective as of _____, 2021.

PART II – OPTIONS AND SARS

9. OPTIONS

9.1 The Corporation may, from time to time, make one or more Grants of Options to Eligible Persons on such terms and conditions, consistent with the Plan, as the Board shall determine. In granting such Options, subject to the provisions of the Plan, the Corporation shall specify,

(a) the maximum number of Shares which the Participant may purchase under the Options;

(b) the Exercise Price at which the Participant may purchase his or her Shares under the Options;

(c) the term of the Options, to a maximum of ten years from the Grant Date of the Options, the Vesting period or periods within this period during which the Options or a portion thereof may be exercised by a Participant and any other Vesting conditions (including Performance Conditions); and

(d) any Tandem SARs that are granted with respect to such Options.

9.2 The Exercise Price for each Share subject to an Option shall be fixed by the Board but under no circumstances shall any Exercise Price be less than one hundred percent (100%) of the Market Price on the Grant Date of such Option.

9.3 Unless otherwise designated by the Board in the applicable Grant Agreement, twenty five percent (25%) of the Options included in a Grant shall Vest on each of the first four anniversaries of the Grant Date and, subject to Section 9.5, any such Options shall expire on the tenth anniversary of the Grant Date (unless exercised or terminated earlier in accordance with the terms of the Plan or the Grant Agreement).

9.4 Subject to the provisions of the Plan and the terms governing the granting of the Option, and subject to payment or other satisfaction of all related withholding obligations in accordance with Section 7.2 hereof, Vested Options or a portion thereof may be exercised from time to time by delivery to the Corporation at its registered office of a notice in writing signed by the Participant or the Participant's legal personal representative, as the case may be, and addressed to the Corporation. This notice shall state the intention of the Participant or the Participant's legal personal representative to exercise the said Options and the number of Shares in respect of which the Options are then being exercised and must be accompanied by payment in full of the Exercise Price under the Options which are the subject of the exercise. On the exercise of an Option, any related Tandem SAR shall be cancelled.

9.5 If the normal expiry date of any Option, other than an Incentive Stock Option, falls within any Blackout Period or within ten business days (being a day other than a Saturday, Sunday or other than a day when banks in Vancouver, British Columbia are not generally open for business) following the end of any Blackout Period, then the expiry date of such Option shall, without any further action, be extended to the date that is ten business days following the end of such Blackout Period. The foregoing extension applies to all Options whatever the Grant Date (other than Incentive Stock Options and other than an extension beyond the original term of the Options in the case of Options held by a US Taxpayer) and shall not be considered an extension of the term of the Options as referred to in Section 7.5 hereof.

9.6 Notwithstanding anything in this Plan to the contrary, for Options that are intended to qualify as Incentive Stock Options and granted to a US Taxpayer, the following additional provisions will apply:

(a) Except as permitted by Code Section 424(a), or any successor provision, the Exercise Price per Share shall not be less than one hundred percent (100%) of the per Share Market Price on the Effective Date of the Incentive Stock Option; provided, however, that if a Participant owns shares possessing more than ten percent (10%) of the total combined voting power of all classes of shares of the Corporation or of its Parent or any Subsidiary, the Exercise Price per Share of an Incentive Stock Option granted to such Participant shall not be less than one hundred ten percent (110%) of the Market Price on the Effective Date of the Incentive Stock Option.

(b) Except as permitted by Code Section 424(a), in no event shall any Incentive Stock Option be exercisable during a term of more than ten (10) years after the Effective Date of the Incentive Stock Option; provided, however, that if a Participant owns shares possessing more than ten percent (10%) of the total combined voting power of all classes of shares of the Corporation or of its Parent or any Subsidiary, the Incentive Stock Option granted to such Participant shall be exercisable during a term of not more than five (5) years after the Effective Date.

(c) The Corporation or its Affiliate shall be entitled to withhold and deduct from any future payments to the Participant all legally required amounts necessary to satisfy any and all withholding and employment-related taxes attributable to the Participant's exercise of an Incentive Stock Option or a "disqualifying disposition" of Shares acquired through the exercise of an Incentive Stock Option as defined in Code Section 421(b) or require the Participant to remit an amount sufficient to satisfy such withholding requirements, or any combination thereof.

(d) Notwithstanding any other provision of the Plan, the aggregate fair market value (determined as of the Effective Date of the Incentive Stock Option) of the Shares with respect to which Incentive Stock Options are exercisable for the first time by a Participant during any calendar year under the Plan and any other "incentive stock option" plans of the Corporation or any Affiliate, shall not exceed US$100,000 (or such other amount as may be prescribed by the Code from time to time); provided, however, that if the exercisability or Vesting of an Incentive Stock Option is accelerated as permitted under the provisions of the Plan and such acceleration would result in a violation of the limit imposed by this Section 9.6 (d), such acceleration shall be of full force and effect but the number of Shares that exceed such limit shall be treated as having been granted pursuant to a Nonqualified Stock Option; and provided, further, that the limits imposed by this Section 9.6 (d) shall be applied to all outstanding Incentive Stock Options under the Plan and any other "incentive stock option" plans of the Corporation or any Affiliate in chronological order according to the dates of grant.

(e) The Grant Agreement in respect of any Incentive Stock Option shall contain such other limitations and restrictions upon the exercise of the Incentive Stock Option as the Board shall deem necessary to ensure that such Incentive Stock Option will be considered an "incentive stock option" as defined in Code Section 422 or to conform to any change therein.

(f) One hundred percent (100%) of the Shares reserved and available under the Plan pursuant to Section 4.1 shall constitute the maximum aggregate number of Shares that may be issued through Incentive Stock Options.

10. STOCK APPRECIATION RIGHTS

10.1 The Board may from time to time make one or more Grants of Stock Appreciation Rights to Eligible Persons on such terms and conditions, consistent with the Plan, as the Board shall determine.

10.2 Tandem SARs may be granted at or after the Grant Date of the related Options, and each Tandem SAR shall be subject to the same terms and conditions and denominated in the same currency as the Option to which it relates and the additional terms and conditions set forth in this Section 10.

10.3 On exercise of a Tandem SAR, the related Option shall be cancelled and the Participant shall be entitled to an amount in settlement of such Tandem SAR calculated and in such form as provided in Section 10.8 below.

10.4 Tandem SARs may be exercised only if and to the extent the Options related thereto are then Vested and exercisable and shall be exercised in accordance with such procedures as may be established by the Board. For greater certainty, upon the expiry or forfeiture of the Option to which a Tandem SAR is attached, including in connection with a Participant's Termination, as provided in Section 11, such Tandem SAR shall also expire or be forfeited, as the case may be.

10.5 Stand-Alone SARs granted under the Plan shall become Vested at such times, in such installments and subject to the terms and conditions of this Plan (including satisfaction of Performance Conditions and/or continued employment) as may be determined by the Board and set forth in the applicable Grant Agreement. For greater certainty, except as set out in a Grant Agreement in respect of the Stand-Along SAR, no Stand-Alone SAR granted to a Participant shall Vest after the Participant's Termination and any Stand-Alone SARs that are outstanding on the Participant's date of Termination shall be forfeited and cancelled as of such date.

10.6 The Base Price for each Stand-Alone SAR shall not be less that one hundred percent of the Market Price on the Grant Date of such Stand-Alone SAR.

10.7 Unless the Board determines otherwise, Stand-Alone SARs covered by a Grant shall, when and to the extent Vested, be settled by payment in cash of the amount determined in accordance with Section 10.8.

10.8 Upon exercise thereof, or the settlement thereof in accordance with Section 10.7, and subject to payment or other satisfaction of all related withholding obligations in accordance with Section 7.2 hereof, Stock Appreciation Rights (and, in the case of Tandem SARs, the related Options) shall be settled by payment in cash, of an amount, or the delivery of Shares or a combination of cash and Shares, as determined by the Board with an aggregate value equal to the product of:

(A) the excess of the Market Price on the date of exercise over the Exercise Price or Base Price under the applicable Stock Appreciation Right,

multiplied by

(B) the number of Stock Appreciation Rights exercised or settled.

10.9 Any cash payment in settlement of a Stand-Alone SAR shall be payable in United States dollars. Any cash payment in settlement of a Tandem SAR shall be payable in the currency as the option to which it relates. Any portion of a Stock Appreciation Right that is to be settled in Shares shall be settled by delivery of the number of Shares having a Market Price on the date of exercise equal to the portion of the amount determined in accordance with Section 10.8 being settled, rounded down to the nearest whole Share.

10.10 If the normal expiry date of any Stock Appreciation Right falls within any Blackout Period or within ten business days (being a day other than a Saturday, Sunday or other than a day when banks in Vancouver, British Columbia are not generally open for business) following the end of any Blackout Period, then the expiry date of such Stock Appreciation Right shall, without any further action, be extended to the date that is ten business days following the end such Blackout Period. The foregoing extension applies to all SARs whatever, other than Tandem SARs attached to Options of a US Taxpayer which shall be governed by the provisions of Section 9.5 that apply to the related Options, and shall not be considered an extension of the term of the SARs as referred to in Section 7.5 hereof.

11. TERMINATION OF EMPLOYMENT AND DEATH OF A PARTICIPANT – OPTIONS AND TANDEM SARS

11.1 Outstanding Options held by a Participant (or the executors or administrators of such Participant's estate, any person or persons who acquire the right to exercise Options directly from the Participant by bequest or inheritance or any other permitted transferee of the Participant under Section 12 hereof) as of the Participant's date of Termination shall be subject to the provisions of this Section 11, as applicable; except that, in all events, the period for exercise of Options shall end no later than the last day of the maximum term thereof established under Section 9.1(c), 9.5, 9.6(b) or 11.5, as the case may be.

11.2 Subject to the applicable Grant Agreement, Section 11.1 and Section 11.6, in the case of a Participant's Termination due to death, or in the case of the Participant's Disability (i) those of the Participant's outstanding Options that were granted prior to the year that includes the Participant's date of death or Disability Date, as the case may be, that have not become Vested prior to such date of death or Disability Date shall continue to Vest and, upon Vesting, be exercisable during the thirty-six (36) month period following such date of death or Disability Date, as the case may be, as if the Participant had remained Employed throughout such period and (ii) those of the Participant's outstanding Options that have become Vested prior to the Participant's date of death or Disability Date shall continue to be exercisable during the thirty-six (36) month period following the such date of death or Disability Date, as the case may be.

The number of Options granted to a Participant in the year that includes the Participant's date of death or Disability Date that remain eligible to Vest following such date of death or Disability Date (the "**Special Pro Rated Options**") shall be determined by the formula A x B/C where:

A equals the total number of Options included in the Grant that have not previously Vested,

B equals the total number of days between January 1 of the year that includes the Grant Date of such Grant and the Participant's date of death or Disability Date, and

C 365.

The Special Pro Rated Options shall continue to Vest and, upon Vesting, be exercisable during the thirty-six (36) month period following the Participant's date of death or Disability Date, as the case may be as if the Participant had remained Employed throughout such period. The balance of the Options granted to a Participant in the year that includes the Participant's date of death or Disability Date that are not Special Pro Rated Options shall be forfeited and cancelled as of the Participant's date of death or Disability Date, as the case may be.

11.3 Subject to the applicable Grant Agreement, Section 11.1 and Section 11.6, in the case of a Participant's Termination due to the termination of the Participant's employment or termination of the Participant's contract for services by the Corporation or an Affiliate without Cause, (i) those of the Participant's outstanding Options that have not become Vested prior to the Participant's Termination shall continue to Vest and, upon Vesting, be exercisable during the one hundred and twenty (120) day period following the Participant's Termination as if the Participant had remained Employed throughout such period, and (ii) those of the Participant's outstanding Options that have become Vested prior to the Participant's Termination shall continue to be exercisable during the one hundred and twenty (120) day period following the Participant's Date of Termination.

11.4 Subject to the applicable Grant Agreement and Section 11.6, in the case of a Participant's Termination due to the Participant's resignation (including the voluntary withdrawal of services by a Participant who is not an employee under Applicable Law), (i) those of the Participant's outstanding Options that have not become Vested prior to the date on which the Participant provides notice to the Corporation of his or her resignation shall be forfeited and cancelled as of such date, and (ii) those of the Participant's outstanding Options that have become Vested prior to the date on which the Participant provides notice to the Corporation of his or her resignation shall continue to be exercisable during the ninety (90) day period following the Participant's date of Termination.

11.5 Notwithstanding the foregoing, with respect to any Option that is intended to be an Incentive Stock Option, such Option shall not be exercisable for a period that is longer than (i) three (3) months from the date of the Participant's Termination for any reason other than death or disability (as defined in Code Section 22(e)), or (ii) twelve (12) months from the Participant's Termination due to disability (as defined in Code Section 22(e)) or death.

11.6 In addition to the Board's rights under Section 3.1, the Board may, at the time of a Participant's Termination or Disability Date, extend the period for exercise of some or all of the Participant's Options, but not beyond the original expiry date, and/or allow for the continued Vesting of some or all of the Participant's Options during the period for exercise or a portion of it. Options that are not exercised prior to the expiration of the exercise period, including any extended exercise period authorized pursuant to this Section 11.6, following a Participant's date of Termination or Disability Date, as the case may be, shall automatically expire on the last day of such period.

11.7 Notwithstanding any other provision hereof or in any Grant Agreement, in the case of a Participant's termination of employment or termination of the Participant's contract for services for Cause, any and all then outstanding unvested Options granted to the Participant shall be immediately forfeited and cancelled, without any consideration therefore, as of the commencement of the day that notice of such termination is given.

11.8 For greater certainty, a Participant shall have no right to receive Shares or a cash payment, as compensation, damages or otherwise, with respect to any Options that do not become Vested or that are not exercised before the date on which the Options expire**.**

12. TRANSFERABILITY OF OPTIONS – US TAXPAYER

12.1 Notwithstanding Section 7.11, with respect to Participants who are US Taxpayers, no Incentive Stock Option shall be transferable by the Participant, in whole or in part, other than by will or by the laws of descent and distribution. If the Participant shall attempt any transfer of any Incentive Stock Option, such transfer shall be void and the Incentive Stock Option shall terminate.

12.2 Further, with respect to Participants who are US Taxpayers, Options that are not Incentive Stock Options shall be transferable, in whole or in part, by the Participant by will or by the laws of descent and distribution. In addition, the Board may, in its sole discretion, permit the Participant to transfer any or all such Options to any member of the Participant's "immediate family" as such term is defined in Rule 16a-1(e), or any successor provision, of the U.S. Securities Exchange Act of 1934, as amended, or to one or more trusts whose beneficiaries are members of such Participant's "immediate family" or partnerships in which such family members are the only partners; provided, however, that the Participant cannot receive any consideration for the transfer and such transferred Stock Option shall continue to be subject to the same terms and conditions as were applicable to such Option immediately prior to its transfer.

PART III – SHARE UNITS

13. DEFINITIONS

13.1 **"Grant Value"** means the dollar amount allocated to an Eligible Person in respect of a Grant of Share Units as contemplated by Section 3.

13.2 "**Share Unit Account**" has the meaning set out in Section 15.1.

13.3 "**Valuation Date**" means the date as of which the Market Value is determined for purposes of calculating the number of Share Units included in a Grant, which unless otherwise determined by the Board shall be the Grant Date.

13.4 "**Vesting Period**" means, with respect to a Grant of Share Units, the period specified by the Board, commencing on the Grant Date and ending on the last Vesting Date for such Share Units.

14. ELIGIBILITY AND GRANT DETERMINATION.

14.1 The Board may from time to time make one or more Grants of Share Units to Eligible Persons on such terms and conditions, consistent with the Plan, as the Board shall determine, provided that, in determining the Eligible Persons to whom Grants are to be made and the Grant Value for each Grant, the Board shall take into account the terms of any written employment agreement or contract for services between an Eligible Person and the Corporation or any Affiliate and may take into account such other factors as it shall determine in its sole and absolute discretion.

14.2 The Board shall determine the Grant Value and the Valuation Date (if not the Grant Date) for each Grant under this Part III. The number of Share Units to be covered by each such Grant shall be determined by dividing the Grant Value for such Grant by the Market Value of a Share as at the Valuation Date for such Grant, rounded up to the next whole number.

14.3 Each Grant Agreement issued in respect of Share Units shall set forth, at a minimum, the type of Share Units and Grant Date of the Grant evidenced thereby, the number of RSUs or PSUs subject to such Grant, the applicable Vesting conditions, the applicable Vesting Period(s) and the treatment of the Grant upon Termination and may specify such other terms and conditions consistent with the terms of the Plan as the Board shall determine or as shall be required under any other provision of the Plan. The Board may include in a Grant Agreement under this Part III terms or conditions pertaining to confidentiality of information relating to the Corporation's operations or businesses which must be complied with by a Participant including as a condition of the grant or Vesting of Share Units.

15. ACCOUNTS AND DIVIDEND EQUIVALENTS

15.1 **Share Unit Account.**

An account, called a "**Share Unit Account**", shall be maintained by the Corporation, or an Affiliate, as specified by the Board, for each Participant who has received a Grant of Share Units and will be credited with such Grants of Share Units as are received by a Participant from time to time pursuant to Section 14 and any dividend equivalent Share Units pursuant to Section 15.2. Share Units that fail to Vest to a Participant and are forfeited pursuant to Section 16, or that are paid out to the Participant or his or her Beneficiary, shall be cancelled and shall cease to be recorded in the Participant's Share Unit Account as of the date on which such Share Units are forfeited or cancelled under the Plan or are paid out, as the case may be. For greater certainty, where a Participant is granted both RSUs and PSUs, such RSUs and PSUs shall be recorded separately in the Participant's Share Unit Account.

15.2 **Dividend Equivalent Share Units.**

Except as otherwise provided in the Grant Agreement relating to a Grant of RSUs or PSUs, if and when cash dividends (other than extraordinary or special dividends) are paid with respect to Shares to shareholders of record as of a record date occurring during the period from the Grant Date under the Grant Agreement to the date of settlement of the RSUs or PSUs granted thereunder, a number of dividend equivalent RSUs or PSUs, as the case may be, shall be credited to the Share Unit of Account of the Participant who is a party to such Grant Agreement. The number of such additional RSUs or PSUs will be calculated by dividing the aggregate dividends or distributions that would have been paid to such Participant if the RSUs or PSUs in the Participant's Share Unit Account had been Shares by the Market Value on the date on which the dividends or distributions were paid on the Shares. The additional RSUs or PSUs granted to a Participant will be subject to the same terms and conditions, including Vesting and settlement terms, as the corresponding RSUs or PSUs, as the case may be.

16. VESTING AND SETTLEMENT OF SHARE UNITS

16.1 **Continued Employment.**

Subject to this Section 16 and the applicable Grant Agreement, Share Units subject to a Grant and dividend equivalent Share Units credited to the Participant's Share Unit Account in respect of such Share Units shall Vest in such proportion(s) and on such Vesting Date(s) as may be specified in the Grant Agreement governing such Grant provided that the Participant is Employed on the relevant Vesting Date.

16.2 **Settlement.**

A Participant's RSUs and PSUs, adjusted in accordance with the applicable multiplier, if any, as set out in the Grant Agreement, and rounded down to the nearest whole number of RSUs or PSUs, as the case may be, shall be settled, by a distribution as provided below to the Participant or his or her Beneficiary, upon, or as soon as reasonably practicable following the Vesting thereof in accordance with Section 16.1 or 16.6, as the case may be, subject to the terms of the applicable Grant Agreement. In all events RSUs and PSUs will be settled on or before the earlier of the ninetieth (90^{th}) day following the Vesting Date and the date that is two and one half (2½) months after the end of the year in which Vesting occurred. Settlement shall be made by the issuance of one Share for each RSU or PSU then being settled, a cash payment equal to the Market Value of the RSUs or PSUs being settled in cash, or a combination of Shares and cash, all as determined by the Board in its discretion, or as specified in the applicable Grant Agreement, and subject to payment or other satisfaction of all related withholding obligations in accordance with Section 7.2.

16.3 **Postponed Settlement.**

If a Participant's Share Units would, in the absence of this Section 16.3 be settled within a Blackout Period applicable to such Participant, such settlement shall be postponed until the earlier of the sixth (6^{th}) Trading Day following the end of such Blackout Period and the otherwise applicable date for settlement of the Participant's Share Units as determined in accordance with Section 16.2.

16.4 **Failure to Vest.**

For greater certainty, a Participant shall have no right to receive Shares or a cash payment, as compensation, damages or otherwise, with respect to any RSUs or PSUs that do not become Vested.

16.5 **Resignation.**

Subject to the applicable Grant Agreement and Section 16.8, in the event a Participant's employment is Terminated as a result of the Participant`s resignation, no Share Units that have not Vested prior to the date of on which the Participant submits his or her resignation, including dividend equivalent Share Units in respect of such Share Units, shall Vest and all such Share Units shall be forfeited immediately.

16.6 **Death or Disability.**

Subject to the applicable Grant Agreement, in the case of a Participant`s Termination due to death, or in the case of the Participant`s Disability, all Share Units granted to the Participant that were granted prior to the year that includes the Participant's date of death or Disability Date, as the case may be, that have not Vested prior to the Participant`s date of death or Disability Date, as the case may be, and related dividend equivalent Share Units credited prior to such date of death or Disability Date, shall Vest at the end of the Vesting Period relating to such Grant(s) of such Share Units and in the case of a Grant of PSUs, subject to the achievement of the applicable Performance Conditions and the adjustment of the number of PSUs that Vest to reflect the extent to which such Performance Conditions were achieved, as if the Participant had remained Employed by the Corporation or an Affiliate until the end of the Vesting Period applicable to such Share Units.

The number of Share Units granted to a Participant in the year that includes the Participant's date of death or Disability Date that remain eligible to Vest following such date of death or Disability Date (the "**Special Pro Rated Share Units**") shall be determined by the formula A x B/C where:

A equals the total number of Share Units relating to such Grant that have not previously Vested,

B equals the total number of days between January 1 of the year that includes the Grant Date of such Grant and the Participant's date of death or Disability Date, and

C 365.

The Special Pro Rated Share Units, together with any dividend equivalent Share Units attributable thereto, shall Vest at the end of the Vesting Period relating to such Grant(s) of such Share Units and in the case of a Grant of PSUs that are subject to Performance Conditions, subject to the achievement of the applicable Performance Conditions and the adjustment of the number of Special Pro Rated PSUs and related dividend equivalent PSUs that Vest to reflect the extent to which such Performance Conditions were achieved, as if the Participant had remained Employed by the Corporation or an Affiliate until the end of the Vesting Period applicable to such Share Units. The balance of the Share Units included in a Grant made in the year that includes the Participant's date of death or Disability Date that are not Special Pro Rated Share Units shall be forfeited and cancelled as of the Participant's date of death or Disability Date, as the case may be.

16.7 **Termination of Employment without Cause.**

Subject to the applicable Grant Agreement and Section 16.8, in the event a Participant's employment or contract for services is terminated by the Corporation, or an Affiliate, as applicable, without Cause, prior to the end of a Vesting Period relating to a Grant:

(a) the number of RSUs determined by the formula A x B/C, where

A equals the total number of RSUs relating to such Grant that have not previously Vested and dividend equivalent RSUs in respect of such RSUs,

B equals the total number of days between the first day of the Vesting Period relating to such Grant and the Participant's date of Termination, and

C equals total number of days in the Vesting Period relating to such Grant,

shall become Vested RSUs at the end of the Vesting Period relating to such Grant; and

(b) the number of PSUs (if any) determined by the formula A x B/C, where

A equals the total number of PSUs relating to such Grant that have not previously Vested and dividend equivalent PSUs in respect of such PSUs that would have Vested had the Participant remained Employed until the end of the applicable Vesting Period having regard to the extent to which the applicable Performance Conditions were satisfied,

B equals the total number of days between the first day of the Performance Period relating to such Grant and the Participant's date of Termination, and

C equals total number of days in the Performance Period relating to such Grant,

shall become Vested PSUs at the end of Vesting Period relating to such Grant.

16.8 **Extension of Vesting.**

The Board may, at the time of Termination or a Disability Date, extend the period for Vesting of Share Units, but not beyond the original end of the applicable Vesting Period.

16.9 **Termination of Employment for Cause.**

In the event a Participant's employment is Terminated for Cause by the Corporation, no Share Units, that have not Vested prior to the date of the Participant's Termination for Cause including dividend equivalent Share Units in respect of such Share Units, shall Vest and all such Share Units shall be forfeited immediately.

17. SHAREHOLDER RIGHTS

17.1 **No Rights to Shares.**

Share Units are not Shares and a Grant of Share Units will not entitle a Participant to any shareholder rights, including, without limitation, voting rights, dividend entitlement or rights on liquidation.

PART IV – RESTRICTED STOCK AND OTHER AWARDS

18. DEFINITIONS

18.1 "**Restriction**" means any restriction on a Participant's free enjoyment of the Shares granted as Restricted Stock. Restrictions may be based on the passage of time or the satisfaction of Performance Conditions or the occurrence of one or more events or conditions, and shall lapse separately or in combination upon satisfaction of such conditions and at such time or times, in instalments or otherwise, as the Board shall specify.

19. RESTRICTED STOCK

19.1 **Dividends; Voting.**

While any Restriction applies to any Participant's Restricted Stock, (i) unless the Board provides otherwise, the Participant shall receive the dividends paid on the Restricted Stock and shall not be required to return those dividends to the Corporation in the event of the forfeiture of the Restricted Stock, (ii) the Participant shall receive the proceeds of the Restricted Stock in the event of any change in the Shares in respect of which the Board has determined that an equitable adjustment should be made pursuant to Section 5.1, which proceeds shall automatically and without need for any other action become Restricted Stock and be subject to all Restrictions then existing as to the Participant's Restricted Stock, and (iii) the Participant shall be entitled to vote the Restricted Stock during the Restriction period.

19.2 **Transfer Restrictions.**

The Participant shall not have the right to sell, transfer, assign, convey, pledge, hypothecate, grant any security interest in or mortgage on, or otherwise dispose of or encumber any shares of Restricted Stock or any interest therein while the Restrictions remain in effect. The Board may require, as a condition of a Grant of Restricted Stock, that the Participant deposit the shares of Restricted Stock into an escrow account.

19.3 **Forfeiture.**

Grants of Restricted Stock shall be forfeited if the applicable Restriction does not lapse prior to such date or the occurrence of such event or the satisfaction of such other criteria as is specified in the Grant Agreement. Further, unless expressly provided for in the Grant Agreement, or as otherwise determined by the Board, any Restricted Stock held by the Participant at the time of the Participant's Termination shall be forfeited by the Participant to the Corporation.

19.4 **Evidence of Share Ownership.**

Restricted Stock will be book-entry Shares only unless the Board decides to issue certificates to evidence shares of the Restricted Stock.

20. OTHER AWARDS

The Board shall have the authority to grant other equity-based awards, which may be based on one or more criteria determined by the Board, under the Plan that are consistent with the purpose of the Plan and the interests of the Corporation, including, without limitation, bonuses or similar compensation payable in the form of Shares, subject to compliance with Applicable Law.

Exhibit "A"

to

VBI Vaccines Inc. Incentive Plan

Special Provisions Applicable to US Taxpayer

This Exhibit sets forth special provisions of the VBI Vaccines Inc. Incentive Plan (the "Plan") that apply to Participants who are US Taxpayers. This Exhibit shall apply to such Participants notwithstanding any other provisions of the Plan. Terms defined elsewhere in the Plan and used herein shall have the meanings set forth in the Plan, as may be amended from time to time.

Definitions

"**Disability**" means, solely with respect to an award that constitutes deferred compensation subject to Section 409A of the Code, a "disability" as defined under Section 409A of the Code.

"**Eligible Person**" means, solely with respect to Options and SARs, an individual Employed by the Corporation or any of its subsidiaries who, by the nature of his or her position or job is, in the opinion of the Board, in a position to contribute to the success of the Corporation; provided, however, that only officers and employees shall be eligible to receive Incentive Stock Options.

"**Market Price**" means, solely with respect to the terms "Exercise Price" and "Base Price", (a) if the Shares are listed on the Stock Exchange, the closing price per Share on the Stock Exchange on the Effective Date of the Grant; (b) if the Shares are listed on more than on Stock Exchange, the fair market value as determined in accordance with paragraph (a) above for the primary Stock Exchange on which the Shares are listed, as determined by the Board; and (c) if the Shares not listed for trading on a Stock Exchange, a price which is determined by the Board in good faith to be the fair market value of the Shares in compliance with the Code Section 409A.

"**Separation From Service**" means such employment or service with the Corporation and any entity that is to be treated as a single employer with the Corporation for purposes of United States Treasury Regulation Section 1.409A-1(h) terminates such that it is reasonably anticipated that no further services will be performed.

"**Specified Employee**" means a US Taxpayer who meets the definition of "specified employee," as defined in Section 409A(a)(2)(B)(i) of the Code.

Change in Control Treatment

Notwithstanding anything to the contrary, if the Change in Control event does not constitute a change in ownership or effective control of the Company or a change in ownership of a substantial portion of the assets of the Company under Section 409A of the Code, and if the Corporation determines any award under the Plan constitutes deferred compensation subject to Section 409A of the Code, then as determined in the sole discretion of the Board, the vesting of such award may be accelerated as of the effective date of the Change in Control, but the Corporation shall pay such award on its original payment date, but in no event more than 90 days following the original payment date.

Compliance with Section 409A

The intent of the parties is that payments and benefits under this Plan comply with Section 409A of the Code, to the extent subject thereto, and accordingly, to the maximum extent permitted, this Plan shall be interpreted and administered to be in compliance therewith. Notwithstanding anything contained herein to the contrary, to the extent required in order to avoid accelerated taxation and/or tax penalties under Section 409A of the Code, a Participant shall not be considered to have terminated employment with the Company for purposes of this Plan unless the Participant would be considered to have incurred a Separation From Service from the Company. Each amount to be paid or benefit to be provided under this Plan shall be construed as a separate identified payment for purposes of Section 409A of the Code, and any payments described in this Plan that are due within the "short term deferral period" as defined in Section 409A of the Code shall not be treated as deferred compensation unless applicable law requires otherwise. Without limiting the foregoing and notwithstanding anything contained herein to the contrary, to the extent required in order to avoid accelerated taxation and/or tax penalties under Section 409A of the Code, amounts that would otherwise be payable and benefits that would otherwise be provided pursuant to this Plan (or any other plan or agreement of the Corporation) during the six-month period immediately following the Specified Employee's Separation From Service shall instead be paid on the first business day after the date that is six months following the Specified Employee's Separation From Service (or death, if earlier). The Plan and any award agreements issued thereunder may be amended in any respect deemed by the Board to be necessary in order to preserve compliance with Section 409A of the Code. The Corporation makes no representation that any or all of the payments described in this Plan will be exempt from or comply with Section 409A of the Code and makes no undertaking to preclude Section 409A of the Code from applying to any such payment. Each Participant shall be solely responsible for the payment of any taxes and penalties incurred under Section 409A of the Code.

Exhibit "B"

to

VBI Vaccines Inc. Incentive Plan

Addendum Applicable to Israeli Taxpayer

1. Purpose of the Addendum: This Israeli Addendum (the "**Addendum**") shall form an integral part of the VBI Vaccines Inc. Incentive Plan (the **"Plan"**), and it shall apply only to Participants who are deemed residents of the State of Israel for the purpose of Israeli tax laws and are employed or engaged by the Corporation's Israeli resident subsidiary ("**Israeli Participants**").

   This Addendum supplements the Plan so that it shall comply with the requirements of the Israeli Tax Ordinance (as defined below).

   The Plan and this Israeli Addendum are complimentary to each other and shall be read and deemed as one. Any requirements provided in this Addendum shall be in addition to the requirements provided in the Plan and in the Grant Agreement. In the event of conflict, whether explicit or implied, between the provisions of the Plan and this Addendum, the latter shall govern and prevail with respect to Grants to Israeli Participants.

2. Definitions:

   Unless otherwise defined herein, the terms defined in this Addendum shall have the same meaning as set out in the Plan.

   For the purposes of this Addendum, the following terms shall have the meaning set forth below:

   (a) "**Additional Rights**" means any distribution of rights, including an issuance of bonus shares granted in accordance with the terms of the Plan, in connection with Section 102 Trustee Grants (as defined below) and/or with the Shares issued thereunder.

   (b) "**Affiliate(s)**" Without derogating from the definition of Affiliate(s) in the Plan and solely with respect to to Section 102 Trustee Grants (as defined below), "Affiliate(s)" means an "employing company" within the meaning of Section 102(a) of the Tax Ordinance.

   (c) "**Controlling Shareholder**" shall have the same meaning ascribed to it in Section 32(9) of the Tax Ordinance.

   (d) "**Employee**" shall mean, solely with respect to to Section 102 Trustee Grants and Section 102 Non-Trustee Grants (as defined below), any Eligble Person who is an Israeli Participant, and office holders of the Company's Israeli resident subsidiary ("Nosei Misra" as such term is defined in the Israeli Companies Law), but exclude any person who is a Controlling Shareholder of the Corporation prior to or after the Grants.

(e) "**Fair Market Value**" means, for the purpose of determining the tax liability with respect to the grant of Capital Gain Grant Through a Trustee pursuant to Section 102(b)(3), if applicable; (i) if at the date of grant the Corporation's stock is listed on any established stock exchange or a national market system or if the Corporation's stock will be registered for trading within ninety (90) days following the date of grant, the Fair Market Value of a Share at the date of grant shall be determined in accordance with the average value of the Shares on the thirty (30) trading days preceding the date of grant or on the thirty (30) trading days following the date of registration for trading, as the case may be; (ii) if the stock is regularly quoted by a recognized securities dealer but selling prices are not reported, the Fair Market Value shall be the mean between the high bid and low asked prices for the Shares on the last market trading day prior to the day of determination.

(f) "**ITA**" means the Israeli Income Tax Authorities.

(g) "**Lock-up Period**" means the period during which the Section 102 Trustee Grants made to an Israeli Participant or, the Shares underlying the Section 102 Trustee Grants, as well as any Additional Rights issued or distributed in connection therewith are to be held by the Trustee (as defined below) on behalf of the Israeli Participant, in accordance with Section 102 pursuant to the tax route which the Corporation elects.

(h) "**Section 102**" means Section 102 of the Israeli Income Tax Ordinance, and any regulations, rules, orders or procedures promulgated thereunder, all as amended, and the Rules.

(i) "**Non-Employee**" means any Israeli Participant who is not an Employee.

(j) "**Rules**" means the Income Tax Rules (Tax Relief upon the Allotment of Shares to Employees), 2003, and any regulations, rules, orders or procedures promulgated thereunder, all as amended.

(k) "**Section 3(i)**" means Section 3(i) of the Tax Ordinance, and any regulations, rules, orders or procedures promulgated thereunder, all as amended.

(l) "**Section 3(i) Grant**" means a Grant made to Israeli Participant pursuant to Section 3(i).

(m) "**Section 102 Trustee Grant**" means a Grant of Options and/or RSU made to Israeli Participant that by its terms qualifies and is intended to qualify under the provisions of Section 102(b) of the Tax Ordinance (including the Section 102(b) Route Election (as defined below)), as either:

1) "**Ordinary Income Grant Through a Trustee**" for the special tax treatment under Section 102(b)(1) and the "Ordinary Income Route", or

2) "**Capital Gain Grant Through a Trustee**" for the special tax treatment under Section 102(b)(2) or Section 102(b)(3) and the "Capital Route".

(n) "**Section 102(b) Route Election"** means the right of the Corporation to choose either the "Capital Route" (as set under Section 102(b)(2)), or the "Ordinary Income Route" (as set under Section 102(b)(1)), subject to the provisions of Section 102(g) of the Tax Ordinance.

(o) "**Section 102 Non-Trustee Grant**" means a Grant made not through a trustee under the terms of Section 102(c) of the Tax Ordinance.

(p) "**Tax Ordinance**" means the Israeli Income Tax Ordinance, 1961.

(q) "**Tax Ruling**" shall mean any ruling or authorization which the Corporation or the Corporation's Israeli resident subsidiary, at its sole and absolute discretion, may obtain from the ITA in connection with the Plan or the Grants made thereunder, including any terms and conditions and restrictions set forth therein.

(r) "**Trustee**" means a person or an entity, appointed by the Board and approved in accordance with the provisions of Section 102, to hold in trust on behalf of the Employees the Section 102 Trustee Grants, or the Shares issued thereunder, as well as all Additional Rights granted in connection therewith, in accordance with the provisions of Section 102.

(s) "**Trust Agreement**" means a written agreement between the Corporation or any Affiliate and the Trustee, which sets forth the terms and conditions of the trust and is in accordance with the provisions of Section 102.

3. Administration: Further to the authorities of the Board, as detailed in the Plan, with regard to this Addendum, the Board shall have full power and authority to: (i) designate Grants made under this Addendum as either a Section 102 Trustee Grant, Section 102 Non-Trustee Grant or Section 3(i) Grant; (ii) make a Section 102(b) Route Election; (iii) adapt the forms of Grant Agreements to include provisions regarding Grants in accordance with this Addendum and any applicable law; and (iii) determine any other matter and execute any document which are necessary or desirable for, or incidental to, the administration of the Addendum and the Grants made hereunder and the issuance and delivery of any underlying Shares, including without limitation the appointment of a Trustee, the execution of a Trust Agreement and any other document necessary for submission of the Plan and this Addendum to the ITA, including, if so decided by the Corporation at its sole discretion, the filing of a Tax Ruling.

4. Eligibility:

4.1 Subject to the terms and conditions of the Plan, Section 102 Trustee Grants and Section 102 Non-Trustee Grants may only be made to Employees. Section 3(i) Grants may be made only to Non-Employees.

4.2 Subject to the terms and conditions of the Plan, Grants made under this Addendum to Israeli Participants may only consist of Options and/or RSU.

4.3 Grants made under this Addendum to Israeli Participants who are Employees are intended to qualify as Section 102 Trustee Grants.

5. Section 102(b) Route Election: No Section 102 Trustee Grant may be made under this Addendum, unless and until, the Corporation's election of the type of Section 102 Trustee Grants, either as "Ordinary Income Grant Through a Trustee" or as "Capital Gain Grant Through a Trustee", is appropriately filed with the Income Tax Authorities before the first date of grant of Section 102 Trustee Grant. The Section 102(b) Route Election shall obligate the Corporation in accordance with the provisions of Section 102(g) of the Tax Ordinance. For avoidance of doubt, it is clarified that the Corporation does not obligate itself to file a Section 102(b) Route Election, and in any case, such Section 102(b) Route Election shall be at the sole discretion of the Corporation. It is further clarified that such Section 102(b) Route Election shall not prevent the Corporation from granting Section 102 Non-Trustee Grants simultaneously.

6. Trustee:

6.1 Section 102 Trustee Grant, which shall be made under the Addendum and any Shares issued upon exercise or vesting thereof shall be issued to and in the name of the Trustee who shall hold the same in trust for the benefit of the Employees at least for the applicable Lock-up Period. Upon the expiration of the Lock-up Period and subject to any further period included in the Plan and/or in the Grant Agreement, the Trustee may release Section 102 Trustee Grant or Shares issued upon exercise or vesting thereof only after the Employee's full payment of his or her tax liability in connection therewith due pursuant to the Tax Ordinance and the Rules and any applicable Tax Ruling.

6.2 Notwithstanding the above, in the event that an Employee shall elect to release Section 102 Trustee Grants or the Shares issued thereunder prior to the expiration of the Lock-up Period, the sanctions under Section 102 shall apply to and shall be borne solely by the Employee.

6.2 Any Additional Rights distributed to Employees shall be deposited with and/or issued to the Trustee for the benefit of the Employees, and shall be held by the Trustee for the applicable Lock-up Period in accordance with the provisions of Section 102 and the Rules and any applicable Tax Ruling.

6.3 As a condition to any Grant of Section 102 Trustee Grant, the Israeli Participants shall provide the Corporation and the Trustee with a written undertaking and confirmation under which each Israeli Participant confirms that he/she is aware of the provisions of Section 102 and the applicable Section 102(b) Route Election and agrees to the provisions of the Trust Agreement (including the ancillary trust note thereto) between the Corporation and the Trustee and agrees to comply with the Tax Ordinance, the Rules and the provisions of the Trust Agreement and any applicable Tax Ruling, and undertakes not to release, by sale or transfer, the Section 102 Trustee Grant, and the Shares issued thereunder, and all rights attached thereto (including Additional Rights) prior to the lapse of the applicable Lock-up Period. The Israeli Participants shall not be entitled to sell or release from trust the Section 102 Trustee Grant, nor the Shares issued thereunder, nor any right attached thereto (including Additional Rights), nor to request the transfer or sale of any of the same to any third party, before the lapse of the Lock-up Period. The Israeli Participants shall further agree to exempt the Trustee from any liability in respect of any action or decision duly taken and *bona fide* executed in relation with the Plan, the Addendum and any Grant, Shares or other rights received in connection therewith.

6.4 For as long as the Trustee holds Shares in trust for the benefit of the Employees, the Trustee shall not use the voting rights vested in such Shares, and shall not exercise such rights in any way whatsoever. In the event the right to vote such Shares is held by the Trustee pursuant to Section 102, then upon the exercise of any Option the Trustee shall execute a voting proxy in such form as may be prescribed by the Board, subject to the provisions of Section 102.

7. The Corporation may make Section 102 Trustee Grants only after the passage of thirty (30) days' following the delivery, to the appropriate Israeli Income Tax Authorities, of a request for approval of the Plan and the Addendum as well as the Trustee according to Section 102, or after a shorter period, if approved by the Israeli Income Tax Authorities. Notwithstanding the above, if within ninety (90) days' following the delivery of such request, the tax officer notifies the Corporation of its decision not to approve the Plan and/or the Addendum, the Grants, which were intended to be made as Section 102 Trustee Grants, shall be deemed to be Section 102 Non-Trustee Grants, unless otherwise was approved by the tax officer.

8. Tax Consequences: Any tax consequences arising from the grant or exercise of a Grant, from the issuance or sale of Shares covered thereby or from any other event or act (of the Israeli Participant, the Corporation, its Affiliate or the Trustee) hereunder, shall be borne solely by the Israeli Participant. The Corporation and/or its Affiliates and/or the Trustee shall withhold all applicable taxes according to the requirements under the Tax Ordinance, the Rules, any applicable Tax Ruling and any other applicable laws, rules, and regulations, including withholding taxes at source. The Corporation and/or the Trustee shall not be required to release any Grants or issue or transfer any underlying Shares until all required payments have been fully made.

8.1 The Corporation may require, as a condition to any Grants or the issuance or delivery of underlying Shares, that an Israeli Participant provide a security or guarantee to the satisfaction of the Corporation, to secure payment of all taxes which may become due upon the future transfer of his/her Shares to be issued under any Section 3(i) Grants.

8.2 Furthermore, the Employee shall agree to indemnify the Corporation and/or its Affiliates and/or the Trustee and hold them harmless against and from any and all liability for any such tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax from any Grants or underlying Shares issued to the Israeli Participant thereunder.

8.3 In the event that an Employee shall cease to be employed by the Corporation or its Affiliate for any reason, the Employee shall be obligated, upon the Corporation's, the Affiliate's or the Trustee's first demand to provide the Corporation, its Affiliate and the Trustee with a security or guarantee, in the degree and manner satisfactory to them, to cover any future tax obligation resulting from the disposition of the Grants and/or the Shares acquired thereunder.

8.4 To the extent that Section 102 and/or the tax officer's approval and/or any Tax Ruling require the Plan and/or this Addendum and/ or the Grant Agreement to contain specified provisions in order to qualify the Grants for the tax treatment under Section 102, such provisions shall be deemed to be stated herein and/or in the Grant Agreement, as applicable, and to be binding upon the Corporation, any Affiliate and the Israeli Participant.

8.5 The provisions in the Plan (i) relating to Preformance Conditions; and (ii) in Section 6.1(a) and 6.1(c) of the Plan, shall not apply to Grants made under this Addendum.

9. Currency Exchange Rates: Except as otherwise determined by the Board, all monetary values with respect to Grants granted pursuant to this Addendum, including without limitation the Fair Market Value and the Exercise Price of any Option, shall be stated in United States Dollars. In the event that the exercise price is in fact to be paid in New Israeli Shekels, at the sole discretion of the Board, the conversion rate shall be the last known representative rate of the United States Dollar to the New Israeli Shekels on the date of payment.

10. Subordination to the Ordinance: The Grants, the Plan, this Addendum and any applicable Grant Agreements are subject to the applicable provisions of the Ordinance, which shall be deemed an integral part of each, and which shall prevail over any term that is inconsistent therewith.

11. Additional Documents: Israeli Participants may be required to execute, in addition to the Grant Agreement, any and all other documents required by the Corporation or any Affiliate, (including without limitation any customary documents and undertakings towards the Trustee, if applicable, and/or any tax authorities). Notwithstanding anything to the contrary in the Plan or in this Addendum, no Grant shall be deemed made unless all documents required by the Corporation or any Affiliate to be signed by the Israeli Participant prior to or upon such Grant, shall have been duly signed and delivered to the Corporation or such Affiliate.

12. Non-Transferability: Notwithstanding anything in the Plan to the contrary, with regard to Section 102 Trustee Grants and the Shares issued thereunder, as long as such Grants and/or Shares are held by the Trustee on behalf of the Employee, all rights of the Employee with respect thereto are personal and cannot be transferred, assigned, pledged or mortgaged, other than by will or by the laws of descent and distribution.

13. Governing Law: Solely for tax purposes, this Addendum and all instruments issued thereunder or in connection therewith shall be governed by and construed and enforced in accordance with the applicable laws of the state of Israel, without giving effect to the principles of conflict of laws.

[***] Certain information has been excluded pursuant to Regulation S-K, Item 601(b)(10)(iv) from this Document because it is both not material and is the type that the registrant treats as private or confidential.

Exhibit 10.21

National Research Council Canada | Conseil national de recherches Canada

Collaborative Research Agreement

Business Confidential – Protected ***B***

Non-Exclusive Licence Included ☑
Exclusive Licence Included ☑

BETWEEN: **NATIONAL RESEARCH COUNCIL OF CANADA**
a departmental corporation of the Government of Canada whose head office address is:
1200 Montreal Road
Ottawa, Ontario K1A 0R6 (called the **"NRC"**)

AND: **VARIATION BIOTECHNOLOGIES INC.**

A company incorporated under the *Canada Business Corporations Act* under number 393728-3 whose Registered Office Address is located in:
310 Hunt Club Road East, 2nd Floor
Ottawa, Ontario K1V 1C1 (called the **"Collaborator" or "VBI")**

(Collectively known as the **"Parties"**)

In consideration of the mutual covenants hereunder, the Parties agree as follows:

1. This Agreement concerns scientific research and development, called the "Project", described as: **COVID-19 vaccine evaluation.**

2. The Collaborator chooses to work with the NRC because of the NRC's unique capabilities, and does not expect the NRC to perform work that would be in competition with Canadian firms. Except as otherwise specified in this Agreement, the name of the NRC, or any reference to the NRC, shall not be used in promotional activities of the Collaborator without the NRC's prior written consent.

3. The Parties will contribute to the Project by the performance of work as described in the attached "Statement of Work and Deliverables", or by payments, or both. This Agreement is subject to the terms in the attached "General Conditions".

4. The total value of the Project is estimated to be minimum of $[***] (no option) to a maximum of $[***] (with option).

5. The Collaborator is a Canadian Small and Medium Enterprise (SME), and benefits from a Fee Reduction of minimum of $[***] (no option) to a maximum of $[***] (with option). The Customer hereby warrants that, at the time of signing this Agreement, it is a SME with 500 or fewer full-time equivalent employees, or it is a Canadian educational institution.

6. The Collaborator shall pay to the NRC in cash the sum of minimum of $[***] (no option) to a maximum of $[***] (with option) according to the attached "Schedule of Payments". The Collaborator shall also pay applicable sales taxes.

7. The Collaborator has initiated work to design monovalent & multivalent coronavirus constructs, at its own costs, using their eVLP platform and will include, in its constructs, up to 4 protein antigens provided by NRC.

8. The NRC shall make a co-investment to the Project by performing, at its own cost, work described in the Statement of Work and Deliverables at an estimated value of $[***].

9. This Agreement shall become effective when the last Party has signed and expires on 15 November 2020, except for the following terms and conditions which shall survive the termination or expiration of this Agreement:

(a) payment obligations which accrued while this Agreement was in force, or upon its termination, and the interest provisions of this Agreement; and

(b) the terms and conditions with respect to Intellectual Property which are found in the attached Annex **IU** entitled "Intellectual Property" that forms part of this Agreement; and

(c) terms and conditions with respect to exclusion of certain liability, limited warranties, and dispute resolution, all of which are found in the attached General Conditions that form part of this Agreement.

10. This Agreement shall be interpreted according to the laws of the Province of Ontario and the laws of Canada in force there. Subject to section GC-15, for any litigation concerning this Agreement, including litigation arising from arbitration, the Parties hereby irrevocably and unconditionally attorn to the exclusive jurisdiction of the Courts of the Province of Ontario, and all courts competent to hear appeals therefrom. The Parties expressly exclude any conflict of laws rules or principles that might refer disputes under this Agreement to the laws of another jurisdiction.

11. This Agreement may be executed in one or more counterparts and by the different parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one valid and binding Agreement. A portable document format (PDF) copy of an executed counterpart signature page will be as valid as an originally executed counterpart for purposes of signing this Agreement.

SIGNED by the Collaborator

VARIATION BIOTECHNOLOGIES INC.

Date: March 30, 2020

Per: */s/ Jeff Baxter*
Jeff Baxter
CEO

SIGNED by the NRC at Ottawa, Ontario

NATIONAL RESEARCH COUNCIL OF CANADA

Date: March 30, 2020

Per: */s/ Lakshmi Krishnan*
Lakshmi Krishnan, Ph.D.
Human Health Therapeutics

ANNEX SP – SCHEDULE OF PAYMENTS TO THE NRC

Billing address: See page 1

Billing contact:

Name: Andrea McCrae
Title: Project Manager
Telephone: 613 749 4200
Email: amccrae@vbivaccines.com

SP-1 The Collaborator shall be invoiced as follows:

Schedule of Payments:

Work Task	Proposed Schedule of Payments	Task Value	NRC Co-investment	CAN SME Fee Reduction	NRC Pricing*	Final Price Amount Due*
Task 1: Assay development		[***]	[***]			
Task 2: Immunogenicity in vivo	Invoiced upon completion of task	[***]		[***]	[***]	[***]
Task 3: PRNT assay	Invoiced upon completion of task	[***]		[***]	[***]	[***]
Task 4: Reporter assay	Invoiced upon completion of task	[***]		[***]	[***]	[***]
Total Minimum (without options)*		**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
Total Maximum (with options)*		**[***]**	**[***]**	**[***]**	**[***]**	**[***]**

* Plus applicable taxes

SP-2 All amounts shall be due 30 days from the date of the invoice.

SP-3 Payments must be made to: “Receiver General - National Research Council of Canada” and addressed to:

Accounts Receivable
National Research Council of Canada
1200 Montreal Road
Ottawa, Ontario, K1A 0R6
CANADA

SP-4 Payments can be made by cheque; MasterCard, Visa or American Express; or by wire transfer. Wire transfer information is available upon request. The Collaborator is responsible for all bank charges associated with wire transfers. Any inquiries may be directed to: AccountsReceivable@nrc-cnrc.gc.ca.

SP-5 The Collaborator shall provide any Invoicing Reference Number at the time of Agreement signature or promptly thereafter. The NRC will not delay or cancel invoicing nor defer accrual of interest due to the Collaborator’s failure to provide an Invoicing Reference Number.

SP-6 The NRC may suspend its performance of any obligations under this Agreement so long as any payment is overdue for any reason.

SP-7 If this Agreement is amended to increase the scope of the Project, the NRC reserves the right to calculate costing for its additional Project activities at its rates that are in effect at that time. Any such cost increases shall be approved, in writing, by both Parties.

SP-8 If a Party expects that the value of its estimated contribution will be exceeded by more than 10%, it shall promptly notify the other Party. The Parties shall then negotiate a further agreement on costs or payments, and either Party may suspend the performance of any obligations, other than confidentiality, intellectual property and accrued obligations to pay, until a further agreement is reached. If the Parties fail to agree on an amendment within 60 days of the notice, then this Agreement shall terminate on the 60th day after the notice, unless the Parties agree otherwise in writing.

SP-9 If a surplus of prepayment remains as a result of premature termination, it will be refunded.

SP-10 If an instrument tendered in payment or settlement of an amount due to the NRC is dishonoured for any reason, the NRC will invoice an additional administrative charge of CAD 25 and this amount will be due as invoiced.

SP-11 Interest is payable on all overdue amounts. Interest is calculated and compounded monthly at the average bank rate plus 3% and accrues during the period beginning on the due date and ending on the day before the day on which payment is received by the NRC. For purposes of this paragraph "**bank rate**" means the rate of interest established periodically by the Bank of Canada as the minimum rate at which the Bank of Canada makes short term advances to members of the Canadian Payments Association, and "**average bank rate**" means the weighted arithmetic average of the bank rates that are established during the month before the month in respect of which interest is being calculated.

(Rate information may be found at http://www.tpsgc-pwgsc.gc.ca/recgen/txt/tipp-ppir-eng.html. *This site provides information on the rate used by departments of the Government of Canada to calculate the interest on overdue accounts payable and is the same rate used by the NRC to charge interest on overdue accounts receivable under the Interest and Administrative Charges Regulations, SOR/96-188. This web site address, and the information set out there, is provided here for convenience. In case of rate discrepancy, the rates quoted by the Bank of Canada shall prevail.)*

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ANNEX GC: GENERAL CONDITIONS

GC-1 **INTERPRETATION OF AGREEMENT:** This Agreement supersedes all prior communications, negotiations and agreements concerning the Project. Notwithstanding any language in a purchase order that is sent to the NRC by the Collaborator in respect of the Project, the purchase order is for administrative purposes only of the Collaborator and does not constitute an offer, a counter-offer, or an amendment to this Agreement nor does it create a new agreement in respect of the Project. The NRC shall include on the face of its invoice for the Project any purchase order number issued by the Collaborator for the Project. No amendment or waiver of terms in this Agreement, including the annexes thereto, is effective unless it is in writing, signed by all Parties, except that the Parties agree that the Agreement may be extended by an exchange of email from their authorized representatives. In case of inconsistency between the STATEMENT OF WORK AND DELIVERABLES and the rest of this Agreement, the rest of this Agreement prevails. No forbearance by a Party implies any broader, continuing, or future forbearance. If a court finds part of this Agreement invalid, the remainder is valid in accordance with its most reasonable interpretation. This Agreement does not create a relationship of agency, employment, partnership, or joint venture.

GC-2 **ASSIGNMENT:** This Agreement, and any licence granted pursuant to it, is personal to the Parties, so that neither its assignment, nor its assumption by a corporation formed by amalgamation of a Party with a third party, is valid except by written consent of all Parties, which consent shall not be unreasonably withheld.

GC-3 **EXCLUSION OF CERTAIN LIABILITY:** No Party shall be liable for failure or delay in performance caused by circumstances beyond its reasonable control, or for incorrectness or inaccuracy of data supplied, advice given, or opinions expressed unless directly attributable to gross negligence or willful misconduct. No claim may be made for indirect, consequential, or incidental damages. No claim shall exceed the cost of the Project.

GC-4 **LIMITED WARRANTIES:** Each Party warrants that it will conduct the Project work in a professional manner conforming to generally accepted practices for scientific research and development. However, because of the nature of such work, no specific result is promised.

(a) No Party warrants that technical information conveyed in the deliverables does not infringe the rights of third parties under a present or future patent.

(b) No Party warrants the validity of patents under which rights may be granted pursuant to this Agreement, or makes any representation as to the scope of patents or that those inventions may be exploited without infringing the rights of others.

GC-5 **TERMINATION OF AGREEMENT FOR COST OVERRUNS**: If following notification by one Party that costs expressed as estimates will be exceeded by more than 10%, if the Parties do not amend this Agreement to modify the total cost of the Project or the Statement of Work and Deliverables or both within sixty (60) days, then upon the expiration of that period this Agreement shall be terminated and upon such termination:

(a) the Collaborator shall pay to the NRC any costs pre-dating the effective date of the termination that were intended to be reimbursable to the NRC under this Agreement;

(a) any licence or option granted under this Agreement to any Party is also terminated;

(b) confidentiality obligations of each Party regarding the information that is part of its Arising IP are terminated except with respect to the Jointly Created Arising IP, both Parties continuing to be bound by all other confidentiality obligations under this Agreement.

GC-6 **TERMINATION OF AGREEMENT:** This Agreement may be terminated as follows:

(a) by either Party if the other Party defaults in performance of any obligation under this Agreement and fails to cure the default within thirty (30) days after receipt of written notice of default, and termination will take effect at the expiration of the cure period;

(b) by the NRC forthwith if the Collaborator becomes bankrupt or has a receiver appointed to continue its operations, or passes a resolution for winding up;

(c) by the NRC forthwith if the Collaborator has made a false or misleading representation or warranty;

(d) upon termination:

(i) the Collaborator shall pay to the NRC any costs pre-dating the effective date of the termination that were intended to be reimbursable to the NRC under this Agreement;

(ii) the Collaborator shall also pay to the NRC any incurred costs by the NRC that result directly from the cancellation of obligations and from uncancellable obligations;

(iii) any licence or option granted under this Agreement is terminated;

(iv) confidentiality obligations of each Party regarding the information that is part of its Arising IP are terminated, both Parties continuing to be bound by all other confidentiality obligations under this Agreement.

GC-7 **NOTICES:** Any notice related to this Agreement, including a notice of change of address, must be sent to the addresses stated at the beginning of this Agreement, either by registered mail, which is deemed to be effective notice five days after mailing, or by courier or email, which are effective notices only when acknowledged by a courier's delivery receipt or by a specific non-automatic return transmission.

GC-8 **CONDITIONS:** The Collaborator agrees that if there is any research work in the Project involving human subjects, human tissues, laboratory animals, or animal tissues, it shall not proceed without prior approval of the NRC's Human Subjects Research Ethics Committee or Animal Care Committee and shall not be conducted in contravention of the respective Committee's conditions of approval.

GC-9 **NO BRIBES:** The Collaborator represents and warrants to the NRC that no bribe, gift, reward, benefit or other inducement has been or will be paid, given, promised or offered directly or indirectly to any federal government official or employee or to a member of the family of such person, with a view to influencing the entry into this Agreement or the administration of this Agreement.

GC-10 **NO DIRECT BENEFIT:** The Collaborator represents and warrants to the NRC that the following individuals shall not derive a direct benefit from this Agreement:

(a) a current or former public office holder who is not in compliance with the *Conflict of Interest Act*, 2006, c.9, s.2;

(b) a current or former member of the House of Commons who is not in compliance with the Conflict of Interest Code for Members of the House of Commons;

(c) a current or former public servant who is not in compliance with the *Values and Ethics Code for the Public Sector*; or

(d) a current or former the NRC employee who is not in compliance with the NRC's *Conflict of Interest Policy*.

GC-11 **NO MISREPRESENTATION:** The Collaborator represents and warrants to the NRC that it, including its Directors, officers, employees or agents, has made no material misrepresentation, whether by omission or commission, with a view to the obtaining of this Agreement.

GC-12 **NO CONTINGENCY FEE:** The Collaborator represents and warrants to the NRC that it has not directly or indirectly paid or agreed to pay and that it will not directly or indirectly pay a contingency fee for the solicitation, negotiation or obtaining of this Agreement to any person, other than an employee acting in the normal course of the employee's duties. In this section, "contingency fee" means any payment or other compensation that depends or is calculated based on the degree of success in soliciting, negotiating or obtaining this Agreement and "person" includes any individual who is required to file a return with the registrar pursuant to the *Lobbying Act*, R.S.C.,1985,c. 44 (4th Supplement) as amended.

GC-13 **VISITS:** Subject to reasonable notice of the number and names and status of personnel, including employees, students and other persons working on behalf of the other Party and other requirements under this Agreement, a Party may, in its discretion, permit visits to its premises by one or more of the other Party's personnel, if relevant to the Project and not likely to interfere with regular operations.

GC-14 **PERSONNEL:** The Collaborator shall be liable for the actions of its personnel, including its employees, contractors, agents or students and shall ensure that while working on the NRC premises, they are required to comply with the following requirements:

(a) regulations, policies and directives that the NRC may adopt from time to time to address access to the NRC facilities and activities thereon, and without limiting the generality of the foregoing, regulations, policies and directives addressing:

(i) protection of confidential information;

(ii) information management and information technology (IM/IT);

(iii) harassment and code of conduct in the NRC facilities;

(iv) protection of safety and health of the NRC employees, the Collaborator's personnel and others; and

(v) security and emergency procedures;

(b) any and all security policies that the Government of Canada may promulgate from time to time including:

(i) any and all security conditions and requirements the NRC may request from time to time including, without limitation, undergoing a security screening, which may include a fingerprint check and if, following a security screening, an employee of the Collaborator is unable to obtain or maintain a level of security clearance that, in the sole opinion of the NRC, is adequate, such employee of the Collaborator will be denied access to the NRC facilities and IT Resources;

(ii) the requirement to display an identification badge as a condition of access to the NRC facilities with or without restrictions on hours of access;

(iii) restrictions on access to the NRC's IT Resources; the "NRC's IT Resources" include, but are not limited to, all computers, telecommunications systems, workstations, PCs, laptops, storage, software, peripheral devices, servers, network equipment, transmission equipment, Remote Access Systems, and internal and external communications systems—such as the Internet, e-mail and Intranet—e-mail accounts, messages and associated files created, sent received, or stored on the NRC IT resources; and

(iv) the requirement to follow security procedures at all times and not to do anything that may compromise the integrity of the NRC facilities or the NRC IT Resources, with the NRC reserving the right to modify or terminate the access privileges of the Collaborator's personnel at any time;

(c) all confidentiality obligations under this Agreement.

The NRC shall provide the Collaborator with access to all relevant legislation, regulations, policies and procedures as well as notice of any changes, and shall provide security, health and safety training to the Collaborator's personnel as soon as possible following permitted access to the NRC facilities.

GC-15 **DISPUTE RESOLUTION:** Disputes concerning this Agreement shall not be litigated. All disputes arising in connection with this Agreement which cannot be resolved through negotiations to the mutual satisfaction of both Parties within thirty (30) days, or such longer period as may be mutually agreed upon, may be submitted by either Party to arbitration in accordance with the *Commercial Arbitration Act* of Canada, R.S.C., 1985, c. 17 (2nd Supp.), as amended, and shall be subject to the following:

(a) The Party requesting such arbitration shall do so by written notice to the other Party.

(b) The arbitration shall take place in Ottawa, Ontario before a single arbitrator to be chosen jointly by the Parties. Failing agreement of the Parties on a single arbitrator within thirty (30) days of such notice requesting arbitration, either party may apply to a judge of a court having jurisdiction in Ottawa, Ontario for the appointment of a single arbitrator.

(c) Each Party shall pay its own costs and an equal share of all of the costs of the arbitration and the fees of the arbitrator, except for the exceptional circumstance in which an arbitral award may require the payment of all costs by a Party who has brought a plainly frivolous dispute.

(d) The arbitrator shall issue a written decision as soon as practicable after the conclusion of the final hearing, but in any event no later than sixty (60) days thereafter, unless that time period is extended for a fixed period by the Arbitrator on written notice to each Party because of illness or other cause beyond the Arbitrator's control. The decision shall be rendered in such form that judgment may be entered thereon in any court having jurisdiction.

(e) The decision shall be final and binding on the Parties in accordance with the *Commercial Arbitration Act* of Canada.

Neither Party may request arbitration in respect of a breach of this Agreement after the fourth anniversary of the day on which the requesting Party first discovered that breach, unless the other Party has agreed in writing to extend the period.

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ANNEX IU: INTELLECTUAL PROPERTY (Uncertain)

IU-1 **NATURE OF THE PROJECT:** By the nature of the Project, Arising Intellectual Property that may arise is difficult to predict, and the Parties consider it desirable to defer settling the terms on which it will be available until the Arising Intellectual Property is known.

IU-2 **DEFINITIONS:**

2.1 "**Arising Intellectual Property**" or "**Arising IP**" is Intellectual Property that is developed in the Project and that is disclosed in the Deliverables. The possessive adjective "the NRC's" or "other Party's" or "VBI's" indicates ownership or control by that Party.

(a) "**Jointly Created Arising IP**" is Intellectual Property created by employees of both Parties while carrying out the Project that is not NRC Arising IP or VBI Arising IP and shall include any Arising IP that relates to the combination of NRC-designed protein antigens and virus like particles produced by VBI.

(b) "**NRC Arising IP**" is any Arising Intellectual Property relating specifically to assays developed solely by NRC as described in Task 1 of the Workplan, or relating specifically to protein antigens designed solely by NRC but it does not include Intellectual Property owned or controlled by VBI prior to the date of this Agreement, VBI Arising IP or the Jointly Created IP.

(c) "**VBI Arising IP**" is any Arising Intellectual Property relating specifically to antigens designed solely by VBI, and to eVLPs and vaccines solely developed by VBI, which incorporate only those antigens solely developed by VBI, for use in the Project and any improvements to the Intellectual Property owned or controlled by VBI prior to date of this Agreement made during the course of carrying out the Project but it does not include Intellectual Property owned or controlled by NRC prior to the date of this Agreement, the NRC Arising IP or the Jointly Created IP.

2.2 **"Commercially Exploit**" is to use, reproduce and modify Arising IP, and to manufacture, use, import, and sell articles embodying or made by use of any Deliverables and to provide services by the use of any Deliverables.

2.3 **"Confidential Non-Project Information"** means any confidential or proprietary information, either of a business or technical nature, other than Arising Intellectual Property, disclosed by one Party to the other Party pursuant to this Agreement.

2.4 **"Deliverables"** are the tangible results of the Project, such as reports, physical models, samples, data records, drawings, and machine-readable software that are specifically mentioned in the Statement of Work and Deliverables as being deliverable.

2.5 **"Intellectual Property"** or **"IP"** is all rights in inventions (whether patentable or not), patents, copyright material, trade secrets, confidential information and bacterial, viral, plant, human, or animal material that has new genetic or other characteristics first produced by a Party..

IU-3 **ARISING INTELLECTUAL PROPERTY:** The Parties represent that, by law or contract, they will own any Arising IP created by their employees. A Party who is the sole owner of Arising IP is responsible for patenting and licensing its Arising IP, but is not obliged by this Agreement to patent its Arising IP. VBI has the right to seek patent protection for the Jointly Created Arising IP at its own expense. However, if VBI is unwilling to patent the Jointly Created Arising IP, NRC may do so at its own expense. Notwithstanding the foregoing, ownership of Arising IP shall be determined as follows:

(a) Any NRC Arising IP shall be owned by NRC, and shall be subject to the license terms described in IU-5 (a).

(b) Any VBI Arising IP shall be owned by VBI, and no license shall be granted under this Agreement except as is required to permit NRC to complete the Workplan.

(c) Any Jointly Created Arising IP shall be owned jointly by NRC and VBI, and shall be subject to the license terms described in IU-5 (b).

(d) If the Parties cannot come to an unanimous agreement on each Party's contribution regarding inventorship of the Jointly Created Arising IP, the Parties shall both agree to refer the matter in good faith to an inventorship analysis by an independent unbiased third party ("**Un-Biased Expert"**) to provide a non-binding expert opinion to assess each researcher's contribution to the invention and determine which researchers should be named as inventors on any patent applications for the Jointly Created Arising IP.

IU-4 **SHARING INFORMATION:** The Parties shall keep each other promptly informed of Arising IP. Each Party shall give the other, for information only, a copy of any patent application for Jointly Created Arising IP immediately upon filing the application, and a copy of related correspondence with a patent office if requested, and the information contained in such documents and correspondence will be maintained in confidence until they become publicly available through no breach of this Agreement.

IU-5 **LICENCE OF THE ARISING IP:** Upon request by VBI no later than six (6) months after the end of the Project, the NRC undertakes to negotiate with VBI in good faith to settle the terms of a licence which will allow VBI to Commercially Exploit the NRC Arising IP and Jointly Created Arising IP on the following terms:

(a) NRC Arising IP: NRC hereby grants VBI a non-exclusive option for a license to Commercially Exploit the NRC Arising IP, such license to include standard commercial terms to be negotiated between the Parties.

(b) Jointly Created Arising IP: NRC hereby grants VBI an exclusive option for an exclusive license to Commercially Exploit the Jointly Created Arising IP, such license to include standard commercial terms to be negotiated between the Parties

(c) In the event that VBI exercises its option pursuant to subsection (a) or (b), the Parties shall negotiate the terms of a license agreement in good faith for a period of three months, which period may be extended upon mutual agreement of the Parties. If the Parties are unable to reach an agreement on the terms of the non-exclusive license referred to in subsection (a) within the aforementioned period, the option shall expire and NRC shall have no further obligations with respect thereto. If the Parties are unable to reach an agreement on the terms of the exclusive license referred to in subsection (b), neither Party shall be permitted to Commercially Exploit or licence its share of the Jointly Created Arising IP without the permission of the other Party. Notwithstanding the foregoing, each Party shall grant to the other Party a royalty-free, exclusive license to use its share of the Jointly Created Arising IP solely for internal research purposes and as required to perform the Project and any amendments or additions thereto which are agreed upon between the Parties in writing.

In addition, subject to the confidentiality provisions herein the NRC hereby licenses the other Party under Crown copyright, free and without time limit, to use and reproduce all documents and drawings that are deliverable under this Agreement.

IU-6 **INTENTIONALLY OMITTED :**

IU-7 **NON-PROJECT TECHNOLOGY:** If, in order to perform work in the course of the Project, a Party needs another Party's IP that is not part of the Arising IP, a licence for that limited purpose is granted by this Agreement and terminates at the end of the Project. Any other licence must be negotiated and agreed to in writing.

IU-8 **CONFIDENTIAL NON-PROJECT INFORMATION RESTRICTIONS:** Unless otherwise stipulated in a separate agreement, the following provisions apply to Confidential Non-Project Information that is in electronic, written, graphic or other tangible form, including a physical object, that is clearly marked "Proprietary" or "Confidential" or with an equivalent legend, or that is oral information provided that at the time of disclosure the disclosing Party clearly identifies the confidential nature of such information and confirms such confidential nature by transmitting the information, in a written version that is marked as above, to the receiving Party within 20 days of disclosure. The receiving Party agrees not to disclose any Confidential Non-Project Information, including to any director, officer or employee of the receiving Party unless that individual needs the information to perform work in the course of the Project and is legally bound to keep confidences. In protecting Confidential Non-Project Information, the receiving Party must use at least the same degree of care as it uses to protect its own information of a similar nature, but not less than a reasonable degree of care. Unless specifically licensed, Confidential Non-Project Information may only be used by the receiving Party to perform work in the course of the Project. These obligations of confidentiality and protection will initially apply to Confidential Non-Project Information in the form of oral information but will cease to apply if the information is not provided in a written version within 20 days of disclosure. Notwithstanding the foregoing, the receiving Party may disclose the particulars of this Agreement to others of its officers and employees for internal administrative and business purposes, to the extent that such disclosure does not result in a public release of such information.

IU-9 **END OF CONFIDENTIAL NON-PROJECT INFORMATION RESTRICTIONS:** Unless otherwise stipulated in a separate agreement, all obligations of confidentiality and restrictions on the use of Confidential Non-Project Information in this Agreement cease to apply five (5) years after the expiration of this Agreement and such obligations and restrictions do not apply to information that can be proved to be:

9.1 independently developed by the receiving Party without reference to or use of the confidential information of the other Party;

9.2 received from a third party without breach of any obligation of confidentiality;

9.3 in the public domain at the time of its disclosure or that later enters the public domain without breach of this Agreement; or

9.4 required to be disclosed by law, including, in the case of the NRC, the *Access to Information Act*, provided that the receiving Party first provides the other Party with notice of such requirements and of its intent to disclose the information.

IU-10 **CONFIDENTIALITY AND USE OF ARISING IP:** All Deliverables and Arising IP will be maintained in confidence and protected by both Parties with at least the same degree of care as they use to protect their own confidential information, but not less than a reasonable degree of care. Arising IP shall not be disclosed except:

10.1 as required for a patent application or, where permitted by this Agreement, for a licence to a third party including disclosure to prospective licensees;

10.2 if the Arising IP has entered the public domain without breach of this Agreement;

10.3 as required to be disclosed by law, including, in the case of the NRC, the *Access Information Act*, provided that the receiving Party first provides the other Party with notice of such requirements and of its intent to disclose information;

10.4 NRC may disclose the NRC Arising IP and VBI may disclose the VBI Arising IP to the extent that such disclosure does not lead to disclosure of the Jointly Created Arising IP; or

10.5 As is permitted by Section IU-12 or as otherwise agreed to by the Parties.

IU-11 **PUBLICITY**: No Party will publicly suggest that the other Party endorses or recommends any product or process or results of the Project.

IU-12 **PUBLICATION**: The Parties may jointly publish, or jointly agree in writing to allow one Party to publish, Confidential Information arising from the Project. If a Party requests in writing permission to publish and the other Party does not respond within thirty (30) days, permission is assumed. Such publications must fairly assign credit to the individual researchers involved. Any publication can be delayed by a period reasonable to allow the Parties to file for intellectual property protection. If a license is granted by NRC to VBI for the Jointly Created IP, VBI shall be expressly permitted to publish information regarding the Jointly Created IP without further permission.

IU-13 **PRESS RELEASE**: The Parties hereby acknowledge that VBI is a publicly traded entity and subject to Securities and Exchange Commission regulation on disclosure within five (5) days of execution without disclosing any confidential information protected under this Agreement. VBI will draft a press release for the NRC's contributions, review and approval within a timely manner, which approval will not be unreasonably withheld and will be assumed if no response if received within four (4) business days of receipt.

IU-14 **NO IMPLIED WARRANTIES:** The NRC's Arising IP is supplied and licensed on a "as is" basis, and there are no representations, warranties or conditions, express or implied by statute, including without limitation any with respect to:

14.1 market readiness, merchantability, or fitness for any use or purpose;

14.2 operational state, character, quality, or freedom from defects;

14.3 validity of patents;

14.4 non-infringement of rights of third parties under present or future patents.

IU-15 **NO CONTESTATION OF VALIDITY:** The Parties acknowledge the validity of the patents and copyright, if any licensed hereunder and agrees not to contest such validity, either directly or indirectly by assisting other parties.

IU-16 **INDEMNITY:** The NRC rejects all liability and responsibility relating to the consequences of using the NRC's Arising IP. The other Party shall indemnify and save harmless the NRC, its employees and agents from and against, and be responsible for:

16.1 all claims, demands, losses, damages, costs including solicitor and client costs, actions, suits or proceedings brought by any third party, that are in any manner based upon, arising out of, related to, occasioned by, or attributable to:

(a) the use by the other Party of the NRC's Arising IP including without limitation, the manufacturing, distribution, shipment, offering for sale, sale, or use of products and services derived from the NRC's Arising IP; and

(b) product liability and infringement of Intellectual Property rights other than copyright, if any, licensed hereunder;

16.2 other costs, including extra-judicial costs, of the NRC defending such any action or proceeding, which the NRC shall have the right to defend with counsel of its choice.

This clause shall survive expiration or termination of this Agreement.

(the rest of this page was intentionally left blank)

STATEMENT OF WORK AND DELIVERABLES

Multivalent Coronavirus vaccine development

VBI and the NRC are proposing a collaborative effort to develop a multivalent Coronavirus vaccine (with the goal to cross-protect against known strains of SARS-2, SARS & MERS) which would have utility against current known and potential new strains of Coronavirus.

VBI has initiated work to design monovalent & multivalent coronavirus constructs using their eVLP platform and will include 3-4 protein antigens provided by NRC.

Phase 1 Objective: To establish the potency of VBI monovalent and multivalent Coronavirus eVLP vaccine preparations

Task 1: Assay Development – NRC ($[***] co-investment)

SARS-CoV-2 requires novel assays to evaluate immunogenicity. NRC is developing [***]. Depending on the time to development, [***]will be used to evaluate the immunogenicity of the vaccine candidates. The [***]assays to be developed are a PRNT assay [***] (using pseudovirus).

Task 2: Preclinical Potency Testing (per construct) – Price: $[***] (Task value: $[***])

Group assignments (n=[***]**):

1) [***]
2) [***]vaccine*
3) [***]vaccine*
4) [***]vaccine*
5) [***] vaccine*

**dose and* [***]*vs* [***]*to be determined by VBI*

***choice of* [***]*to be discussed with VBI*

Mice will be [***]. Blood will be sampled [***]after each immunization to conduct immunogenicity assays ([***] at VBI and [***]at NRC). [***]will only be done on serum samples [***].

Future Anticipated Work: It is anticipated that additional animal studies can be added as separate experiments as required. VBI anticipates developing [***] but these will be tested at a later date. VBI also remains open to testing [***]designs as [***]are available for coding in eVLP.

Task 3: PRNT Assay (per iteration of Task 1) – Price $[***] (Task value: $[***])

Task 4: Reporter assay using pseudovirus (per iteration of Task 1) – Price $[***] (Task value: $[***])

Total Estimated Budget (first iteration of Tasks 2-4): $[***]

Budget Summary: VBI Multivalent eVLP vaccine candidate against coronaviruses

Work Task	Task Value	NRC Co-investment	CAN SME Fee Reduction	NRC Task Price*
Task 1: Assay development	[***]	[***]		
Task 2: Immunogenicity in vivo	[***]		[***]	[***]
Task 3: PRNT assay	[***]		[***]	[***]
Task 4: Reporter assay	[***]		[***]	[***]
Total Minimum (without options)*	[***]	[***]	[***]	[***]
Total Maximum (with options)*	[***]	[***]	[***]	[***]

* Plus applicable taxes

OPTION: VBI may wish to exercise the option to execute another iteration of Tasks 1-3. This option is [***] in total ($[***]).

Assumptions:

1) Availability of sufficient material from VBI and suppliers to conduct experiments.
2) Resource availability
3) Relevant PRNT and reporter assays are established in-house.

Deliverables

- Experimental protocols and results, including raw data in Microsoft Office file format.
- A summary report for each study.

Contacts:

For the NRC:

Paul Payette, Ph.D., MBA, Client Relationship Leader
Email: [***]

Anh Tran, Ph.D., Assistant Research Officer - HHT
Email: [***]

Rhonda Kuo Lee, Project Manager, HHT
Email: [***]

For the Collaborator:

Adam Buckley, VP – Business Development
Email: [***]

[***] Certain information has been excluded pursuant to Regulation S-K, Item 601(b)(10)(iv) from this Document because it is both not material and is the type that the registrant treats as private or confidential.

Exhibit 10.22

National Research Council Canada | Conseil national de recherches Canada

Amendment One to Collaborative Research Agreement

Business Confidential – Protected *B*

THIS IS AN AMENDING AGREEMENT

BETWEEN: **NATIONAL RESEARCH COUNCIL OF CANADA**
a departmental corporation forming part of the Government of Canada
created by the *National Research Council Act* (R.S.C. 1985, c. N-15), and
an agent of Her Majesty the Queen in Right of Canada
whose head office address is:
1200 Montreal Road
Ottawa, Ontario K1A 0R6 (called the **"NRC"**)

AND: ***VARIATION BIOTECHNOLOGIES INC.***
a *Company incorporated under the Canada Business Corporations Act under number 393728-3 whose Registered Office Address is located in:*

300 Hunt Club Road East, 2nd Floor
Ottawa, Ontario K1V 1C1 (called the **"Collaborator" or "VBI"**)

(Collectively known as the "**Parties**")

WHEREAS the parties entered into an Agreement signed by the NRC on 3*0 March 2020* (called the **"Original Agreement"**) by which the Parties agreed to collaborate in a "Project", described as: ***COVID-19 vaccine evaluation***.

WHEREAS the parties wish to amend the Original Agreement. In consideration of the mutual covenants hereunder, the parties agree as follows

1. The Original Agreement shall be read with the amended terms stated below. With respect to all other terms, the Parties confirm the Original Agreement.

2. The Budget attached hereto includes the work scheduled to be performed pursuant to the Original Agreement (Tasks 1, 2, 3 and 4) and additional work related to vaccine evaluation which was not included in the Original Agreement.

3. The attached "**SCHEDULE OF PAYMENTS**" is in addition to the "**SCHEDULE OF PAYMENTS"** from the Original Agreement.

4. The attached "**NEW STATEMENT OF WORK AND DELIVERABLES"** is in addition to the "**STATEMENT OF WORK AND DELIVERABLES**" in the Original Agreement.

5. The estimated total value of this Project amendment is: **minimum of $[***](Tasks 1.5, 1.6 1.8 and 1.9)** (immediate priority) to a **maximum of $[***] (Tasks 1.5 – 1.9)** (includes [***] tasks) as stated in the Statement of Work.

6. The Collaborator is a Canadian Small and Medium Enterprise (SME) or a Canadian educational institution, including a community college, CEGEP, polytechnic or university, and benefits from a Fee Reduction of **minimum of $[***] (Tasks 1.5, 1.6, 1.8 and 1.9) to a maximum of $[***] (Tasks 1.5 - Tasks 1.9)**. The Collaborator hereby warrants that, at the time of signing this Agreement, it is a SME and has 500 or fewer full-time equivalent employees, or it is a Canadian educational institution.

7. The amount that the Collaborator will pay to the NRC in cash for this amendment is: **minimum of $[***] (Tasks 1.5, 1.6 1.8 and 1.9)** (immediate priority) to a **maximum of $[***] (Tasks 1.5 – 1.9)** (includes [***] tasks) as stated in the Statement of Work.

8. The estimated value of the NRC's in-kind contribution for this amendment is: ***minimum $[***] (Tasks 2.1, 2.2, 2.3, 2.4 and Task 2.6) to a maximum $[***] (Tasks 2.1 - Tasks 2.6)***.

9. The expiry date as stated in the Original Agreement as "30 November 2020" is now amended to be "15 March 2022".

10. This Agreement may be executed in one or more counterparts and by the different parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one valid and binding Agreement. A portable document format (PDF) copy of an executed counterpart signature page will be as valid as an originally executed counterpart for purposes of signing this Agreement.

SIGNED by the Collaborator at Ottawa, Ontario

VARIATION BIOTECHNOLOGIES INC.

Date: 21 DEC 2020

Per: */s/ Jeff Baxter*
Jeff Baxter
CEO

SIGNED by the NRC at Ottawa, Ontario

NATIONAL RESEARCH COUNCIL OF CANADA

Date: 21 DEC 2020

Per: */s/ Lakshimi Krishnan*
Lakshmi Krishnan, Ph.D.
A/Vice President, Life Sciences

ANNEX SP – SCHEDULE OF PAYMENTS TO NRC

Billing address: See page 1

Billing contact:

Name: Andrea McRae
Title: Project Manager
Telephone: [***]
Email: [***]

SP-1 The Collaborator shall be invoiced as follows:

Invoicing Schedule (Estimated Dates)	**Amount Due***
1. Invoice to be issued on ***signature of this amendment for Tasks 1.5 – 1.6***	**$[***]**
2. Invoice to be issued on ***completion of Tasks 1.8 – 1.9***	***$[***]***
3. Invoice to be issued upon **confirmation by client – Task 1.7**	***$[***]***

*Plus applicable taxes

SP-2 All amounts shall be due 30 days from the date of the invoice.

SP-3 Payments must be made to: "Receiver General - National Research Council of Canada" and addressed to:

Accounts Receivable
National Research Council of Canada
1200 Montreal Road
Ottawa, Ontario, K1A 0R6
CANADA

SP-4 Payments can be made by cheque, MasterCard, Visa or American Express; or by wire transfer. Wire transfer information is available upon request. The Collaborator is responsible for all bank charges associated with wire transfers. Any inquiries may be directed to: AccountsReceivable@nrc-cnrc.gc.ca.

SP-5 The Collaborator shall provide any Invoicing Reference Number at the time of Agreement signature or promptly thereafter. The NRC will not delay or cancel invoicing nor defer accrual of interest due to the Collaborator's failure to provide an Invoicing Reference Number.

SP-6 The NRC may suspend its performance of any obligations under this Agreement so long as any payment is overdue for any reason.

SP-7 If this Agreement is amended to increase the scope of the Services, the NRC reserves the right to calculate costing for its additional Project activities at its rates that are in effect at that time. Any such cost increases shall be approved, in writing, by both Parties.

SP-8 If the NRC expects that the value of its estimated contribution will be exceeded by more than *10%*, it shall promptly notify the other Party. The Parties shall then negotiate a further agreement on costs or payments, and either Party may suspend the performance of any obligations, other than confidentiality, intellectual property and accrued obligations to pay, until a further agreement is reached. If the Parties fail to agree on an amendment within 60 days of the notice, then this Agreement shall terminate on the 60th day after the notice, unless the Parties agree otherwise in writing.

SP-9 If a surplus of prepayment remains as a result of premature termination, it will be refunded.

SP-10 If an instrument tendered in payment or settlement of an amount due to the NRC is dishonoured for any reason, the NRC will invoice an additional administrative charge of CAD 25 and this amount will be due as invoiced.

SP-11 Interest is payable on all overdue amounts. Interest is calculated and compounded monthly at the average bank rate plus 3% and accrues during the period beginning on the due date and ending on the day before the day on which payment is received by the NRC. For purposes of this paragraph "**bank rate**" means the rate of interest established periodically by the Bank of Canada as the minimum rate at which the Bank of Canada makes short term advances to members of the Canadian Payments Association, and "**average bank rate**" means the weighted arithmetic average of the bank rates that are established during the month before the month in respect of which interest is being calculated.

(Rate information may be found at http://www.tpsgc-pwgsc.gc.ca/recgen/txt/tipp-ppir-eng.html. *This site provides information on the rate used by departments of the Government of Canada to calculate the interest on overdue accounts payable and is the same rate used by the NRC to charge interest on overdue accounts receivable under the Interest and Administrative Charges Regulations, SOR/96-188. This web site address, and the information set out there, is provided here for convenience. In case of rate discrepancy, the rates quoted by the Bank of Canada shall prevail.)*

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REVISED & EXPANDED STATEMENT OF WORK AND DELIVERABLES

Amendment to VBI-NRC Collaborative Research Agreement A-0035546: Multivalent Coronavirus vaccine development

The Client and NRC hereby agree to amend the workplan from the Original Agreement and expand to include a broader workplan relating to evaluation and manufacture of Client's COVID-19 vaccines as set out below.
With the completion of the Stage 1 (Establish potency of VBI monovalent and multivalent coronavirus eVLP vaccine preparations) in the original workplan, VBI and NRC have agreed to expand the R&D collaboration to include follow-on pre-clinical evaluation, bioprocess optimization and scale-up work as well as additional productions for clinical trials.

The following activities, Stage 2, are meant to encompass the further scope for the workplan. Indicated budget figures are high-level estimates. Follow-on discussions between NRC and VBI will further refine the scope and associated budget. However, no increases to the amounts shown in the Budget will be effective unless agreed in writing by Client.

Note: VBI will be responsible to provide the plasmids needed for all productions.

Stage 1: Candidate Identification & Immunogenicity

The Client and NRC have agreed that the original workplan has been modified to accommodate 3 larger studies (29B609, 29B619 and 29B621) which included additional PRNT and ELISPOT work. The final price for these 3 studies is equivalent to the full maximum price for agreement A-00355546: [***]. The parties also agree to amend and extend this stage of work as follows:

1.5 Task 1.5: 29B634 **estimated budget: $[***]** (anticipated duration: [***]weeks)
1.6 Task 1.6: Additional [***]: [***]for [***]work done at [***]**estimated budget: $[***]** (anticipated duration: [***]weeks)
1.7 Task 1.7: Optional [***] studies for immunogenicity to be conducted at the request of Client (up to [***]mouse studies, n=[***]) $[***] per study x [***] = ***estimated budget: $[***]*** *(anticipated duration: [***] weeks for each study)*
1.8 Task 1.8 Phase I Clinical sample testing [***]for clinical samples

- n= [***]***estimated budget $[***]*** *(anticipated duration [***] weeks)*

1.9 OPTION: Task 1.9 Phase II Clinical sample testing [***] for clinical samples

- n= [***]***estimated budget $[***]*** *(anticipated duration [***] weeks)*

Total estimated budget for new and amended tasks in Stage 1: $[***]

Stage 2: Tech Transfer & Process Development Activities

The approach for the following activities is to transfer the existing VBI manufacturing process to NRC at [***], and also to scale up the modified process to [***] (implementing [***] developed in Task 2.1 below) to produce product for use in later stage clinical trials. NRC will discuss approach together with VBI and further discussion may, with the agreement of the parties, change the scope for process modification. Nevertheless, process modification will be kept to a minimum in order to accelerate timelines. Given the at risk nature of this development, NRC is proposing to complete these development activities at risk and in consideration of future Retained Doses as per Exhibit B.

2.1. Task 2.1: [***] (SOW already submitted but additional work is already anticipated) – See Annex C
Revised estimated budget: $[***] (anticipated duration: [***]weeks)

2.2. Task 2.2 Process transfer to [***]: Transfer of current process for [***]. This includes: 2.2.1. [***].
Estimated budget: $[***] *(anticipated duration: [***]weeks [***])*

2.3. Task 2.3 Analytics:
[***]**Estimated budget:** $[***].

2.4 Task 2.4 Modified process scale up [***]**.**

2.5 Task 2.5 Optional - [***]

Total estimated budget for core tasks: $[***]

Given the COVID situation, there are a number of constraints on timelines in particular:

1) *With current procurement challenges, many items for larger scale and Clinical material production may need to be purchased at-risk in an attempt to reduce long lead times for some consumables (media, columns, etc). Despite best efforts, some items may have lead times which impact timelines for the described work. VBI may choose to procure these directly in order to expedite timelines.*
2) *There are public health and NRC Corporate restrictions on the number of people permitted to work on-site and this may impact timelines although NRC and VBI will endeavour to minimize this wherever possible.*

Budget Summary: VBI-2900 eVLP vaccine candidates against coronaviruses

Work Task	Task Value	NRC Co-investment	CAN SME Fee Reduction	NRC Task Price*
STAGE 1: Candidate Identification				
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
Stage 1 - Total Minimum (without option)	[***]	[***]	[***]	[***]
Stage 1 – Total Maximum (with option)	[***]	[***]	[***]	[***]

Work Task	Task Value	NRC Co-investment	CAN SME Fee Reduction	NRC Task Price*
STAGE 2: Tech Transfer & Process Devt				
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
Stage 2 Total Minimum	[***]	[***]	[***]	[***]
Stage 2 Total Maximum (with options)*				
Clinical Trial Material – ANNEX A				
[***]	TBD			TBD
[***]	TBD			TBD
ANNEX A Subtotal	TBD	0		TBD

Annex A - Production of Clinical Trial Material

Annex B – Stage 4 - Additional Production

Annex C: Scope of Work for the Polishing Step for eVLP Purification.

[***] Certain information has been excluded pursuant to Regulation S-K, Item 601(b)(10)(iv) from this Document because it is both not material and is the type that the registrant treats as private or confidential.

Exhibit 10.23

National Research Council Canada | Conseil national de recherches Canada

Amendment Two to Collaborative Research Agreement

Business Confidential – Protected B

THIS IS AN AMENDING AGREEMENT

BETWEEN: NATIONAL RESEARCH COUNCIL OF CANADA

a departmental corporation forming part of the Government of Canada
created by the *National Research Council Act* (R.S.C. 1985, c. N-15), and
an agent of Her Majesty the Queen in Right of Canada
whose head office address is:

1200 Montreal Road
Ottawa, Ontario K1A 0R6 (called the **"NRC"**)

AND: VARIATION BIOTECHNOLOGIES INC.

a Company incorporated under the Canada Business Corporations Act under number 393728-3 whose Registered Office Address is located in:

300 Hunt Club Road East, 2nd Floor
Ottawa, Ontario K1V 1C1 (called the **"Collaborator" or "VBI"**)

(Collectively known as the "**Parties**")

WHEREAS the parties entered into an Agreement signed by the NRC on 30 March 2020 (called the **"Original Agreement"**) and an Amendment One signed by NRC on 21 December 2020 (called "Amendment One") by which the Parties agreed to collaborate in a "Project", described as: **COVID-19 vaccine evaluation**. Original and Amendment One Agreements are now called "The Agreements".

WHEREAS this Amending Agreement includes certain special obligations which relate solely to Tasks performed for the purpose of developing a vaccine against the South Africa (Beta) variant of COVID-19, which project is being funded by the Coalition for Epidemic Preparedness Innovations (CEPI). These special obligations are required by the terms of the funding agreement between Collaborator and CEPI.

WHEREAS the parties wish to amend the Agreements. In consideration of the mutual covenants hereunder, the parties agree as follows

1. The Agreements shall be read with the amended terms stated below. With respect to all other terms, the Parties confirm the Agreements.

2. The attached "**SCHEDULE OF PAYMENTS**" is in addition to, the "**SCHEDULE OF PAYMENTS"** from the Agreements except that the amount shown for Task 1.7 shall replace the amount shown for Task 1.7 in Amendment One and the amount shown for Task 1.8 shall replace the amount shown for Task 1.8-1.9 in Amendment One. Furthermore, Annex B to Amendment One has been cancelled.

3. The attached "**NEW STATEMENT OF WORK AND DELIVERABLES"** is in addition and, in the case of Tasks 1.7, 1.8 and 1.9 and Annex B is an amendment to the "**STATEMENT OF WORK AND DELIVERABLES**" in the Agreements.

4. The estimated total value of this Project amendment two is: **minimum of $[***] (without options)** to a **maximum of $[***] (with options)** as stated in the Statement of Work.

5. The Collaborator is a Canadian Small and Medium Enterprise (SME) or a Canadian educational institution, including a community college, CEGEP, polytechnic or university, and benefits from a Fee Reduction of **minimum of $[***] (without options) to a maximum of $[***] (with options).** The Collaborator hereby warrants that, at the time of signing this Agreement, it is a SME and has 500 or fewer full-time equivalent employees, or it is a Canadian educational institution.

6. The amount that the Collaborator will pay to the NRC in cash for this amendment two is: **minimum of $[***] (without options)** to a **maximum of $[***] (with options)** as stated in the Statement of Work.

7. The estimated value of the NRC's in-kind contribution for this amendment is: **$[***].**

8. The following special provisions apply to Tasks carried out pursuant to this Amending Agreement:

(a) NRC shall exert reasonable efforts to retain records of its activities regarding the work performed pursuant to this Amending Agreement for a period of at least 5 years from the date of completion of the work, to the extent that it does not contradict with any applicable laws, regulations, or policies of the NRC and can provide a copy of such documentation to Collaborator upon request.

(b) NRC shall exert reasonable efforts to retain, for a period of at least 5 years (to the extent that it does not contradict with any applicable laws, regulations, or policies of the NRC) from the date of completion of the work described in this Amending Agreement, documentation supporting the amounts invoiced to and paid by Collaborator pursuant to this Amending Agreement and can provide a copy of such documentation to Collaborator upon request.

(c) Each of NRC and Collaborator agree that it shall carry its obligations hereunder in accordance with laws and regulations that are applicable to its activities and operations.

(d) Section IU-8 of the Original Agreement is amended to add the following last paragraph:

Collaborator shall be permitted to disclose Confidential Non-Project Information to CEPI solely to the extent required to comply with its obligations pursuant to its funding agreement with CEPI, including its obligations pursuant to the CEPI Third Party Code. NRC will have the right to review the Confidential Information prior to any disclosure to CEPI;

(e) The NRC is part of the Government of Canada and confirms that it is in compliance with laws, regulations, and policies whose goals are aligned with the goals of the CEPI Third Party Code.

9. This Amending Agreement may be executed in one or more counterparts and by the different parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one valid and binding agreement. A portable document format (PDF) copy of an executed counterpart signature page will be as valid as an originally executed counterpart for purposes of signing this Amending Agreement.

SIGNED by the Collaborator at Ottawa, Ontario

VARIATION BIOTECHNOLOGIES INC.

Date: July 6, 2021

Per: */s/ Jeff Baxter*
Jeff Baxter
CEO

SIGNED by the NRC at Ottawa, Ontario

NATIONAL RESEARCH COUNCIL OF CANADA

Date: July 8, 2021

Per: */s/ Lakshmi Krishnan*
Lakshmi Krishnan, Ph.D.
A/Vice President, Life Sciences

ANNEX SP – SCHEDULE OF PAYMENTS TO NRC

Billing address: See page 1

Billing contact:

Name: Andrea McRae
Title: Project Manager
Telephone: [***] Email: [***]

SP-1 The Collaborator shall be invoiced as follows:

Invoicing Schedule (Estimated Dates)	**Amount Due***
STAGE 1	
1. Invoice to be issued on **signature of this amendment for Task 1.7**	[***]
2. Invoice to be issued upon **completion of Task 1.8**	[***]
3. Invoice to be issued on **completion of Task 1.10**	[***]
4. Invoice to be issued upon **completion of Task 1.11**	[***]
5. Invoice to be issued upon **completion of Task 1.12**	[***]
6. Invoice to be issued upon **completion of Task 1.13**	**[***]**
7. Invoice to be issued upon **completion of Task 1.14**	[***]
8. Invoice to be issued upon approval to exercise **Optional Task 1.9.1**	[***]
9. Invoice to be issued upon approval to exercise **Optional Task 1.9.2**	**[***]**
10. Invoice to be issued upon approval to exercise **Optional Task 1.15.1**	[***]
11. Invoice to be issued upon approval to exercise **Optional Task 1.15.2**	[***]
12. Invoice to be issued upon approval to exercise **Optional Task 1.16.1**	[***]
13. Invoice to be issued upon approval to exercise **Optional Task 1.16.2**	[***]
STAGE 2	
14. Invoice to be issued **on signature of this amendment for Tasks 2.6 and 2.7.1**	[***]
15. Invoice to be issued on **completion of Tasks 2.7.2, 2.7.3 and 2.7.4**	[***]
16. Invoice to be issued upon approval to exercise **Optional Task 2.7.5.1**	[***]
17. Invoice to be issued upon approval to exercise **Optional Task 2.7.5.2**	[***]

*Plus applicable taxes

SP-2 All amounts shall be due 30 days from the date of the invoice.

SP-3 Payments must be made to: “Receiver General - National Research Council of Canada” and addressed to:

Accounts Receivable
National Research Council of Canada
1200 Montreal Road
Ottawa, Ontario, K1A 0R6 CANADA

SP-4 Payments can be made by cheque, MasterCard, Visa or American Express; or by wire transfer. Wire transfer information is available upon request. The Collaborator is responsible for all bank charges associated with wire transfers. Any inquiries may be directed to: AccountsReceivable@nrc-cnrc.gc.ca.

SP-5 The Collaborator shall provide any Invoicing Reference Number at the time of Agreement signature or promptly thereafter. The NRC will not delay or cancel invoicing nor defer accrual of interest due to the Collaborator's failure to provide an Invoicing Reference Number.

SP-6 The NRC may suspend its performance of any obligations under this Agreement so long as any payment is overdue for any reason.

SP-7 If this Agreement is amended to increase the scope of the Services, the NRC reserves the right to calculate costing for its additional Project activities at its rates that are in effect at that time. Any such cost increases shall be approved, in writing, by both Parties.

SP-8 If the NRC expects that the value of its estimated contribution will be exceeded by more than 10%, it shall promptly notify the other Party. The Parties shall then negotiate a further agreement on costs or payments, and either Party may suspend the performance of any obligations, other than confidentiality, intellectual property and accrued obligations to pay, until a further agreement is reached. If the Parties fail to agree on an amendment within 60 days of the notice, then this Agreement shall terminate on the 60th day after the notice, unless the Parties agree otherwise in writing.

SP-9 If a surplus of prepayment remains as a result of premature termination, it will be refunded.

SP-10 If an instrument tendered in payment or settlement of an amount due to the NRC is dishonoured for any reason, the NRC will invoice an additional administrative charge of CAD 25 and this amount will be due as invoiced.

SP-11 Interest is payable on all overdue amounts. Interest is calculated and compounded monthly at the average bank rate plus 3% and accrues during the period beginning on the due date and ending on the day before the day on which payment is received by the NRC. For purposes of this paragraph "**bank rate**" means the rate of interest established periodically by the Bank of Canada as the minimum rate at which the Bank of Canada makes short term advances to members of the Canadian Payments Association, and "**average bank rate**" means the weighted arithmetic average of the bank rates that are established during the month before the month in respect of which interest is being calculated.

(Rate information may be found at http://www.tpsgc-pwgsc.gc.ca/recgen/txt/tipp-ppir-eng.html*. This site provides information on the rate used by departments of the Government of Canada to calculate the interest on overdue accounts payable and is the same rate used by the NRC to charge interest on overdue accounts receivable under the Interest and Administrative Charges Regulations, SOR/96-188. This web site address, and the information set out there, is provided here for convenience. In case of rate discrepancy, the rates quoted by the Bank of Canada shall prevail.)*

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Statement of Work

Covid-19 Vaccine Evaluation – Amendment two

1. Workplan

Stage 1: Candidate Identification & Immunogenicity

Tasks 1.5 and 1.6 in Amendment 1 have been completed and invoiced.

The following tasks are amended/added to the workplan:

Work related to ISED funding (Products: VBI-2901; VBI -2902)

Task 1.7: [***]

[***]

Estimated budget: $[***]

Task 1.8 Phase I clinical sample testing by PRNT (R&D assay) for both Wuhan and South African:

[***]

Estimated budget: $[***]

OPTIONAL: Task 1.9 Phase II clinical sample testing by PRNT (R&D assay) to be conducted upon Collaborator request.

[***]

Estimated budget: $[***]

Tasks captured below are new work added and relate to new variants under project funded by CEPI

Task 1.10 Study 29B688: Mouse study (72 mice, 2 doses) and PRNT (R&D assay) for both Wuhan and South African

[***]

Estimated budget: $[***]

Task 1.11 Study *TBD1*: Mouse study (48 mice, 2 doses) and PRNT (R&D assay) for both Wuhan and South African

[***]

Estimated budget: $[***]

Task 1.12 Study *TBD2*: Mouse study (48 mice, 2 doses) and PRNT (R&D assay)

[***]

Estimated budget: $[***]

Task 1.13 PRNTs (R&D assay) for both Wuhan and South African strain on samples from Hamster Challenge Study 1 done at VIDO.

[***] ***Estimated budget: $***[***]

Task 1.14 PRNTs (R&D assay) for both Wuhan and South African on samples from Hamster Challenge Study 2 done at VIDO

[***]

Estimated budget: $[***]

OPTIONAL: Task 1.15 Phase I clinical sample testing by PRNT (R&D assay) to be conducted upon Collaborator request.

[***]

Estimated budget: $[***]

OPTIONAL: Task 1.16 Phase II clinical sample testing by PRNT (R&D assay) to be conducted upon client request.

[***]

Estimated budget: $[***]

[***]

Stage 2: Tech Transfer & Process Development Activities

The following Tasks have been completed:

Task 2.1 - [***] eVLP Purification

Task 2.4.1 [***] production of [***]

The following tasks are amended/added to the workplan:

Task 2.2 Process transfer [***]. This includes:

Subtasks [***] are cancelled ([***]).

Task 2.3

Task 2.4 [***] process scale up (including new IEX step) No changes to subtasks 2.4.1 and 2.4.2

2.4.3 [***]

Estimated budget: $[***]

Work related to new variants under project funded by CEPI

Task 2.6 [***]

[***]

Estimated budget: $[***]

Task 2.7 Upstream Optimization

[***]

[***]

Estimated budget: **[***]**

Stage 4: At Risk Domestic Production during Stage 4 and Prior to Approval

Task 4.1: [***]

Task 4.2: [***]

Task 4.3: [***]

[***]

- **Deliverables**[***]

2. Assumptions

- [***]

3. Estimated Budget

Budget Summary: VBI Covid-19 Vaccine Evaluation-
Amendment 2 – STAGE 1

Work Task	Task Value	CAN SME Fee Reduction	NRC Task Price*
[***]	[***]	[***]	[***]
[***]			

4. Project Schedule

[***]

5. Responsibilities

NRC Responsibilities

- Perform the above work according to high standards of quality;
- The NRC will repeat, at its own cost, any portion of work whose failure was due to error by the NRC personnel or to power or equipment failure;
- Maintain good lines of communication with *Variation Biotechnologies Inc.*;
- To report any problems encountered to *Variation Biotechnologies Inc.* immediately;
- NRC cannot guarantee that a specific amount/level of purity or of product will be obtained.
- Samples will be stored within an NRC facility for the duration of the project, unless stated otherwise. NRC will dispose of any remaining samples or may transfer to *Variation Biotechnologies Inc.* upon request.

Variation Biotechnologies Inc. Responsibilities

- Provide to the NRC all of the necessary information;
- Provide to the NRC a copy of the Informed Consent Form for the clinical trial samples;
- Provide to NRC the plasmids needed for all productions;
- Maintain good lines of communication with the NRC;
- Shipment of product will be charged to Variation Biotechnologies Inc.'s courier account.

[***] Certain information has been excluded pursuant to Regulation S-K, Item 601(b)(10)(iv) from this Document because it is both not material and is the type that the registrant treats as private or confidential.

Exhibit 10.24

National Research Council Canada | Conseil national de recherches Canada

Amendment 3 to Collaborative Research Agreement

Business Confidential – Protected *B*

THIS IS AN AMENDING AGREEMENT

BETWEEN: **NATIONAL RESEARCH COUNCIL OF CANADA**
a departmental corporation forming part of the Government of Canada
created by the *National Research Council Act* (R.S.C. 1985, c. N-15), and
an agent of Her Majesty the Queen in Right of Canada
whose head office address is:

1200 Montreal Road
Ottawa, Ontario K1A 0R6 (called the **"NRC"**)

AND: ***VARIATION BIOTECHNOLOGIES INC.***
a *Company incorporated under the Canada Business Corporations Act under number 393728-3 whose Registered Office Address is located in:*

300 Hunt Club Road East, 2nd Floor
Ottawa, Ontario K1V 1C1 (called the **"Collaborator" or "VBI"**)

(Collectively known as the "**Parties**")

WHEREAS the parties entered into an Agreement signed by the NRC on 3*0 March 2020* (called the **"Original Agreement"**) and Amendment One signed by NRC on 21 December 2020 (called "Amendment One"), as well as Amendment Two signed by NRC on July 8, 2021 (called "Amendment Two") by which the Parties agreed to collaborate in a "Project", described as: ***COVID-19 vaccine evaluation***. The Original Agreement, Amendment One and Amendment Two are now called "The Agreements".

WHEREAS this Amending Agreement includes certain special obligations which relate solely to Tasks performed for the purpose of developing a vaccine against the South Africa (Beta) variant of COVID-19, which project is being funded by the Coalition for Epidemic Preparedness Innovations (CEPI). These special obligations are required by the terms of the funding agreement between Collaborator and CEPI.

WHEREAS the parties wish to amend the Agreements.

IN CONSIDERATION of the mutual covenants hereunder, the parties agree as follows:

1. The Agreements shall be read with the amended terms stated below. With respect to all other terms, the Parties confirm the Agreements.

2. The attached "**SCHEDULE OF PAYMENTS**" is in addition to the "**SCHEDULE OF PAYMENTS"** from the Agreements.

3. The attached "**NEW STATEMENT OF WORK AND DELIVERABLES"** is in addition to the "**STATEMENT OF WORK AND DELIVERABLES**" in the Agreements.

4. The estimated total value of this Project amendment three is: **minimum of $*** (Task 2.8.1) to a maximum of $ *** (All Tasks)** as stated in the Statement of Work.

5. The Collaborator is a Canadian Small and Medium Enterprise (SME) or a Canadian educational institution, including a community college, CEGEP, polytechnic or university, and benefits from a Fee Reduction of **minimum of $*** (Task 2.8.1) to a maximum of $*** (All Tasks).** The Collaborator hereby warrants that, at the time of signing this Agreement, it is a SME and has 500 or fewer full-time equivalent employees, or it is a Canadian educational institution.

6. The amount that the Collaborator will pay to the NRC in cash for this amendment two is: **minimum of $*** (Task 2.8.1)** to a **maximum of $*** (All Tasks)** as stated in the Statement of Work.

7. The following special provisions apply to Tasks carried out pursuant to this Amending Agreement:

(a) NRC shall exert reasonable efforts to retain records of its activities regarding the work performed pursuant to this Amending Agreement for a period of at least 5 years from the date of completion of the work, to the extent that it does not contradict with any applicable laws, regulations, or policies of the NRC and can provide a copy of such documentation to Collaborator upon request.

(b) NRC shall exert reasonable efforts to retain, for a period of at least 5 years (to the extent that it does not contradict with any applicable laws, regulations, or policies of the NRC) from the date of completion of the work described in this Amending Agreement, documentation supporting the amounts invoiced to and paid by Collaborator pursuant to this Amending Agreement and can provide a copy of such documentation to Collaborator upon request.

(c) Each of NRC and Collaborator agree that it shall carry its obligations hereunder in accordance with laws and regulations that are applicable to its activities and operations.

(d) Section IU-8 of the Original Agreement is amended to add the following last paragraph:

Collaborator shall be permitted to disclose Confidential Non-Project Information to CEPI solely to the extent required to comply with its obligations pursuant to its funding agreement with CEPI, including its obligations pursuant to the CEPI Third Party Code. NRC will have the right to review the Confidential Information prior to any disclosure to CEPI;

(e) The NRC is part of the Government of Canada and confirms that it is in compliance with laws, regulations, and policies whose goals are aligned with the goals of the CEPI Third Party Code.

8. This Amending Agreement may be executed in one or more counterparts and by the different parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one valid and binding agreement. A portable document format (PDF) copy of an executed counterpart signature page will be as valid as an originally executed counterpart for purposes of signing this Amending Agreement.

SIGNED by the Collaborator at Ottawa, Ontario

VARIATION BIOTECHNOLOGIES INC.

Date: *August 6, 2021*

Per: */s/ Jeff Baxter*
Jeff Baxter
CEO

SIGNED by the NRC at Ottawa, Ontario

NATIONAL RESEARCH COUNCIL OF CANADA

Date: *August 27, 2021*

Per: */s/ Roman Szumski*
Roman Szumski
Vice President, Life Sciences

ANNEX SP – SCHEDULE OF PAYMENTS TO NRC

Billing address: See page 1

Billing contact:

Name:	Andrea McRae
Title:	Project Manager
Telephone:	613 749 4200
Email:	amcrae@vbivaccines.com

SP-1 The Collaborator shall be invoiced as follows:

Invoicing Schedule (Estimated Dates)		**Amount Due***
1. Invoice to be issued upon ***signature of this amendment for Task 2.8.1***	$	***
2. Invoice to be issued upon approval from Collaborator (Task 2.8.2)	$	***
3. Invoice to be issued upon approval from Collaborator (Task 2.8.3)	$	***
TOTAL MAXIMUM PAYABLE AMOUNT	**$**	*******

*Plus applicable taxes

SP-2 All amounts shall be due 30 days from the date of the invoice.

SP-3 Payments must be made to: “Receiver General - National Research Council of Canada” and addressed to:

Accounts Receivable
National Research Council of Canada
1200 Montreal Road
Ottawa, Ontario, K1A 0R6 CANADA

SP-4 Payments can be made by cheque, MasterCard, Visa or American Express; or by wire transfer. Wire transfer information is available upon request. The Collaborator is responsible for all bank charges associated with wire transfers. Any inquiries may be directed to: AccountsReceivable@nrc-cnrc.gc.ca.

SP-5 The Collaborator shall provide any Invoicing Reference Number at the time of Agreement signature or promptly thereafter. The NRC will not delay or cancel invoicing nor defer accrual of interest due to the Collaborator’s failure to provide an Invoicing Reference Number.

SP-6 The NRC may suspend its performance of any obligations under this Agreement so long as any payment is overdue for any reason.

SP-7 If this Agreement is amended to increase the scope of the Services, the NRC reserves the right to calculate costing for its additional Project activities at its rates that are in effect at that time. Any such cost increases shall be approved, in writing, by both Parties.

SP-8 If the NRC expects that the value of its estimated contribution will be exceeded by more than *10%*, it shall promptly notify the other Party. The Parties shall then negotiate a further agreement on costs or payments, and either Party may suspend the performance of any obligations, other than confidentiality, intellectual property and accrued obligations to pay, until a further agreement is reached. If the Parties fail to agree on an amendment within 60 days of the notice, then this Agreement shall terminate on the 60th day after the notice, unless the Parties agree otherwise in writing.

SP-9 If a surplus of prepayment remains as a result of premature termination, it will be refunded.

SP-10 If an instrument tendered in payment or settlement of an amount due to the NRC is dishonored for any reason, the NRC will invoice an additional administrative charge of CAD 25 and this amount will be due as invoiced.

SP-11 Interest is payable on all overdue amounts. Interest is calculated and compounded monthly at the average bank rate plus 3% and accrues during the period beginning on the due date and ending on the day before the day on which payment is received by the NRC. For purposes of this paragraph "**bank rate**" means the rate of interest established periodically by the Bank of Canada as the minimum rate at which the Bank of Canada makes short term advances to members of the Canadian Payments Association, and "**average bank rate**" means the weighted arithmetic average of the bank rates that are established during the month before the month in respect of which interest is being calculated.

(Rate information may be found at http://www.tpsgc-pwgsc.gc.ca/recgen/txt/tipp-ppir-eng.html. *This site provides information on the rate used by departments of the Government of Canada to calculate the interest on overdue accounts payable and is the same rate used by the NRC to charge interest on overdue accounts receivable under the Interest and Administrative Charges Regulations, SOR/96-188. This web site address, and the information set out there, is provided here for convenience. In case of rate discrepancy, the rates quoted by the Bank of Canada shall prevail.)*

(the rest of this page was intentionally left blank)

STATEMENT OF WORK AND DELIVERABLES

1. PROJECT OBJECTIVES

The goal of this project is to generate a stable cell line secreting murine leukemia virus Gag protein (Gag) based Virus-like-Particles (VLPs) expressing the SARS-CoV-2 Spike protein (Spike).

***

National Research Council Canada | Conseil national de recherches Canada

Amendment 4 to Collaborative Research Agreement

[***] Certain information has been excluded pursuant to Regulation S-K, Item 601(b)(10)(iv) from this Document because it is both not material and is the type that the registrant treats as private or confidential.

Business Confidential – Protected *B*

THIS IS AN AMENDING AGREEMENT

BETWEEN: **NATIONAL RESEARCH COUNCIL OF CANADA**
a departmental corporation forming part of the Government of Canada
created by the *National Research Council Act* (R.S.C. 1985, c. N-15), and
an agent of Her Majesty the Queen in Right of Canada
whose head office address is:
1200 Montreal Road
Ottawa, Ontario K1A 0R6 (called the **"NRC"**)

AND: ***VARIATION BIOTECHNOLOGIES INC.***
a *Company incorporated under the Canada Business Corporations Act under number 393728-3 whose Registered Office Address is located in:*
300 Hunt Club Road East, 2nd Floor
Ottawa, Ontario K1V 1C1 (called the **"Collaborator" or "VBI"**)

(Collectively known as the "**Parties**")

WHEREAS the parties entered into an Agreement signed by the NRC on 3*0 March 2020* (called the **"Original Agreement"**) and Amendment One signed by NRC on 21 December 2020 (called "Amendment One"), Amendment Two signed by NRC on July 8, 2021 (called "Amendment Two") and Amendment Three (called "Amendment Three") signed by NRC on 28 August 2021, by which the Parties agreed to collaborate in a "Project", described as: ***COVID-19 vaccine evaluation***. The Original Agreement, Amendment One, Amendment Two and Amendment Three are now called "The Agreements".

WHEREAS this Amending Agreement includes certain special obligations which relate solely to Tasks performed for the purpose of developing a vaccine against the South Africa (Beta) variant of COVID-19, which project is being funded by the Coalition for Epidemic Preparedness Innovations (CEPI). These special obligations are required by the terms of the funding agreement between Collaborator and CEPI.

WHEREAS the parties wish to amend the Agreements.

IN CONSIDERATION of the mutual covenants hereunder, the parties agree as follows:

1. The Agreements shall be read with the amended terms stated below. With respect to all other terms, the Parties confirm the Agreements.

2. The attached "**SCHEDULE OF PAYMENTS**" is in addition to the "**SCHEDULE OF PAYMENTS"** from the Agreements.

3. The attached "**NEW STATEMENT OF WORK AND DELIVERABLES"** is in addition to the "**STATEMENT OF WORK AND DELIVERABLES**" in the Agreements.

4. The estimated total value of this Project amendment four is: **minimum of $[***] (Tasks 1.17 – 1.22) to a maximum of $[***] (Tasks and Optional tasks)** as stated in the Statement of Work.

5. The Collaborator is a Canadian Small and Medium Enterprise (SME) or a Canadian educational institution, including a community college, CEGEP, polytechnic or university, and benefits from a Fee Reduction of **minimum of $[***] (Tasks 1.17 – 1.22) to a maximum of $[***] (Tasks and Optional tasks).** The Collaborator hereby warrants that, at the time of signing this Agreement, it is a SME and has 500 or fewer full-time equivalent employees, or it is a Canadian educational institution.

6. The amount that the Collaborator will pay to the NRC in cash for this amendment four is: **minimum of $[***] (Tasks 1.17 – 1.22)** to a **maximum of $[***] (Tasks and Optional tasks)** as stated in the Statement of Work.

7. The following special provisions apply to Tasks carried out pursuant to this Amending Agreement:

(a) NRC shall exert reasonable efforts to retain records of its activities regarding the work performed pursuant to this Amending Agreement for a period of at least 5 years from the date of completion of the work, to the extent that it does not contradict with any applicable laws, regulations, or policies of the NRC and can provide a copy of such documentation to Collaborator upon request.

(b) NRC shall exert reasonable efforts to retain, for a period of at least 5 years (to the extent that it does not contradict with any applicable laws, regulations, or policies of the NRC) from the date of completion of the work described in this Amending Agreement, documentation supporting the amounts invoiced to and paid by Collaborator pursuant to this Amending Agreement and can provide a copy of such documentation to Collaborator upon request.

(c) Each of NRC and Collaborator agree that it shall carry its obligations hereunder in accordance with laws and regulations that are applicable to its activities and operations.

(d) Section IU-8 of the Original Agreement is amended to add the following last paragraph:

Collaborator shall be permitted to disclose Confidential Non-Project Information to CEPI solely to the extent required to comply with its obligations pursuant to its funding agreement with CEPI, including its obligations pursuant to the CEPI Third Party Code. NRC will have the right to review the Confidential Information prior to any disclosure to CEPI;

(e) The NRC is part of the Government of Canada and confirms that it is in compliance with laws, regulations, and policies whose goals are aligned with the goals of the CEPI Third Party Code.

8. The expiry date of The Agreements is extended from 15 March 2022 to 30 June, 2022.

9. This Amending Agreement may be executed in one or more counterparts and by the different parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one valid and binding agreement. A portable document format (PDF) copy of an executed counterpart signature page will be as valid as an originally executed counterpart for purposes of signing this Amending Agreement.

-signature page follows-

SIGNED by the Collaborator at Ottawa, Ontario

VARIATION BIOTECHNOLOGIES INC.

Date: November 2, 2021

Per: */s/ Jeff Baxter*
Jeff Baxter
CEO

SIGNED by the NRC at Ottawa, Ontario

NATIONAL RESEARCH COUNCIL OF CANADA

Date: November 15, 2021

Per: */s/ Roman Szumski*
Roman Szumski
Vice President, Life Sciences

ANNEX SP – SCHEDULE OF PAYMENTS TO NRC

Billing address: See page 1

Billing contact:

Name:	Andrea McRae
Title:	Project Manager
Telephone:	613 749 4200
Email:	[***]

SP-1 The Collaborator shall be invoiced as follows:

Invoicing Schedule (Estimated Dates)	**Amount Due***
Upon Signature of Amendment 4 (Tasks 1.18)	[***]
Upon completion of Task 1.19	[***]
Upon completion of Task 1.20	[***]
Upon completion of Task 1.21	[***]
Upon completion of Task 1.22	[***]
Upon exercising Optional Task 1.23.1	[***]
Upon exercising Optional Task 1.23.2	[***]
Upon exercising Optional Task 1.23.3	[***]
Upon exercising Optional Task 1.23.4	[***]
TOTAL MAXIMUM PAYABLE AMOUNT	**[***]**

*Plus applicable taxes

SP-2 All amounts shall be due 30 days from the date of the invoice.

SP-3 Payments must be made to: “Receiver General - National Research Council of Canada” and addressed to:

Accounts Receivable
National Research Council of Canada
1200 Montreal Road
Ottawa, Ontario, K1A 0R6 CANADA

SP-4 Payments can be made by cheque, MasterCard, Visa or American Express; or by wire transfer. Wire transfer information is available upon request. The Collaborator is responsible for all bank charges associated with wire transfers. Any inquiries may be directed to: AccountsReceivable@nrc-cnrc.gc.ca.

SP-5 The Collaborator shall provide any Invoicing Reference Number at the time of Agreement signature or promptly thereafter. The NRC will not delay or cancel invoicing nor defer accrual of interest due to the Collaborator’s failure to provide an Invoicing Reference Number.

SP-6 The NRC may suspend its performance of any obligations under this Agreement so long as any payment is overdue for any reason.

SP-7 If this Agreement is amended to increase the scope of the Services, the NRC reserves the right to calculate costing for its additional Project activities at its rates that are in effect at that time. Any such cost increases shall be approved, in writing, by both Parties.

SP-8 If the NRC expects that the value of its estimated contribution will be exceeded by more than *10%*, it shall promptly notify the other Party. The Parties shall then negotiate a further agreement on costs or payments, and either Party may suspend the performance of any obligations, other than confidentiality, intellectual property and accrued obligations to pay, until a further agreement is reached. If the Parties fail to agree on an amendment within 60 days of the notice, then this Agreement shall terminate on the 60th day after the notice, unless the Parties agree otherwise in writing.

SP-9 If a surplus of prepayment remains as a result of premature termination, it will be refunded.

SP-10 If an instrument tendered in payment or settlement of an amount due to the NRC is dishonored for any reason, the NRC will invoice an additional administrative charge of CAD 25 and this amount will be due as invoiced.

SP-11 Interest is payable on all overdue amounts. Interest is calculated and compounded monthly at the average bank rate plus 3% and accrues during the period beginning on the due date and ending on the day before the day on which payment is received by the NRC. For purposes of this paragraph "**bank rate**" means the rate of interest established periodically by the Bank of Canada as the minimum rate at which the Bank of Canada makes short term advances to members of the Canadian Payments Association, and "**average bank rate**" means the weighted arithmetic average of the bank rates that are established during the month before the month in respect of which interest is being calculated.

(Rate information may be found at http://www.tpsgc-pwgsc.gc.ca/recgen/txt/tipp-ppir-eng.html. *This site provides information on the rate used by departments of the Government of Canada to calculate the interest on overdue accounts payable and is the same rate used by the NRC to charge interest on overdue accounts receivable under the Interest and Administrative Charges Regulations, SOR/96-188. This web site address, and the information set out there, is provided here for convenience. In case of rate discrepancy, the rates quoted by the Bank of Canada shall prevail.)*

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STATEMENT OF WORK AND DELIVERABLES

[***]

National Research Council Canada | Conseil national de recherches Canada

Amendment Five to Collaborative Research Agreement

[***] Certain information has been excluded pursuant to Regulation S-K, Item 601(b)(10)(iv) from this Document because it is both not material and is the type that the registrant treats as private or confidential.

Business Confidential – Protected *B*

THIS IS AN AMENDING AGREEMENT (referred to herein as "Amendment Five")

BETWEEN: **NATIONAL RESEARCH COUNCIL OF CANADA**
a departmental corporation forming part of the Government of Canada
created by the *National Research Council Act* (R.S.C. 1985, c. N-15), and
an agent of Her Majesty the Queen in Right of Canada
whose head office address is:
1200 Montreal Road
Ottawa, Ontario K1A 0R6 (called the **"NRC"**)

AND: ***VARIATION BIOTECHNOLOGIES INC.***
a *Company incorporated under the Canada Business Corporations Act under number 393728-3 whose Registered Office Address is located in:*
300 Hunt Club Road East, 2nd Floor
Ottawa, Ontario K1V 1C1 (called the **"Collaborator" or "VBI"**)

(Collectively known as the "**Parties**")

WHEREAS the parties entered into an Agreement signed by the NRC on 3*0 March 2020* (called the **"Original Agreement"**) and Amendment One signed by NRC on 21 December 2020 (called "Amendment One"), Amendment Two signed by NRC on July 8, 2021 (called "Amendment Two"), Amendment Three (called "Amendment Three") signed by NRC on 28 August 2021 and Amendment Four (called "Amendment Four"), signed by NRC on 15 November 2021, by which the Parties agreed to collaborate in a "Project", described as: ***COVID-19 vaccine evaluation***. The Original Agreement, Amendment One, Amendment Two, Amendment Three, Amendment Four and this Amendment Five are now called "The Agreement".

WHEREAS this Amendment Five includes certain amendments to Tasks related to the assays of new variants performed for the purpose of developing a vaccine against COVID-19, which project is being funded by the Coalition for Epidemic Preparedness Innovations (CEPI).

WHEREAS the parties wish to add a definition and clauses for Contractors as well as add a list of Contractors for the Collaborator.

WHEREAS the Parties wish to amend the Agreements.

IN CONSIDERATION of the mutual covenants hereunder, the Parties agree as follows:

1. The Agreement shall be read with the amended terms stated below. With respect to all other terms, the Parties confirm the Agreement.

2. **"Contractors"** means contract manufacturing organizations ("**CMOs**") and contract research organization ("**CROs**") to be used by the Collaborator to perform research and/or manufacturing services on behalf of the Collaborator in the performance of certain obligations arising out of the Agreement. Except for the preapproved Contractors listed in **Annex - List of Approved Contractors** of this Amendment Five, the Collaborator shall obtain the prior written approval from the NRC for each applicable Contractor. For clarity, the NRC shall, subject to any relevant legal theories or defenses, treat any breach of the Agreement by a Contractor as a breach of the Agreement by the Collaborator.

3. The attached "**SCHEDULE OF PAYMENTS**" is in addition to the "**SCHEDULE OF PAYMENTS"** from the Agreements.

4. The attached "**NEW STATEMENT OF WORK AND DELIVERABLES"** is in addition to the "**STATEMENT OF WORK AND DELIVERABLES**" in the Agreements.

5. The estimated total value of this Project Amendment Five is: **minimum of $ *** (Task 1.22 and Task 2.9.1) to a maximum of $*** (Tasks and Optional tasks)** as stated in the Statement of Work.

6. The Collaborator is a Canadian Small and Medium Enterprise (SME) or a Canadian educational institution, including a community college, CEGEP, polytechnic or university, and benefits from a Fee Reduction of **minimum of $*** (Task 1.22 and Task 2.9.1) to a maximum of $*** (Tasks and Optional tasks).** The Collaborator hereby warrants that, at the time of signing this Agreement, it is a SME and has 500 or fewer full-time equivalent employees, or it is a Canadian educational institution.

7. The amount that the Collaborator will pay to the NRC in cash for this Amendment Five is: **minimum of $*** (Task 1.22 and Task 2.9.1)** to a **maximum of $*** (Tasks and Optional tasks)** as stated in the Statement of Work.

8. The expiry date of The Agreement is extended from 30 June, 2022 to 31 October, 2022.

9. This Amendment Five may be executed in one or more counterparts and by the different parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one valid and binding agreement. A portable document format (PDF) copy of an executed counterpart signature page will be as valid as an originally executed counterpart for purposes of signing this Amending Agreement.

SIGNED by the Collaborator at Ottawa, Ontario

VARIATION BIOTECHNOLOGIES INC.

Date: January 31, 2022

Per: */s/ Jeff Baxter*
Jeff Baxter
CEO

SIGNED by the NRC at Ottawa, Ontario

NATIONAL RESEARCH COUNCIL OF CANADA

Date: February 8, 2022

Per: */s/ Lakshmi Krishnan*
Lakshmi Krishnan, Ph.D.
Acting Vice President, Life Sciences

ANNEX SP – SCHEDULE OF PAYMENTS TO NRC

Billing address: See page 1

Billing contact:

Name:	Andrea McRae
Title:	Project Manager
Telephone:	613 749 4200
Email:	***

SP-1 The Collaborator shall be invoiced as follows:

Invoicing Schedule (Estimated Dates)	**Amount Due***
Upon signature by both Parties of Amendment 5 Task 2.9.1	**$ *** **
Upon completion of Task 1.22	**$ *** **
Upon completion of Task 2.9.2 Go/No Go	**$ *** **
Upon completion of Task 2.9.3 Go/No Go	**$ *** **
Upon completion of Task 2.9.4 Go/No Go	**$ *** **
Upon exercising Optional Task 2.9.5	**$ *** **
TOTAL MAXIMUM PAYABLE AMOUNT	**$ *** **

*Plus applicable taxes

SP-2 All amounts shall be due 30 days from the date of the invoice.

SP-3 Payments must be made to: “Receiver General - National Research Council of Canada” and addressed to:

Accounts Receivable
National Research Council of Canada
1200 Montreal Road
Ottawa, Ontario, K1A 0R6 CANADA

SP-4 Payments can be made by cheque, MasterCard, Visa or American Express; or by wire transfer. Wire transfer information is available upon request. The Collaborator is responsible for all bank charges associated with wire transfers. Any inquiries may be directed to: AccountsReceivable@nrc-cnrc.gc.ca.

SP-5 The Collaborator shall provide any Invoicing Reference Number at the time of Agreement signature or promptly thereafter. The NRC will not delay or cancel invoicing nor defer accrual of interest due to the Collaborator’s failure to provide an Invoicing Reference Number.

SP-6 The NRC may suspend its performance of any obligations under this Agreement so long as any payment is overdue for any reason.

SP-7 If this Agreement is amended to increase the scope of the Services, the NRC reserves the right to calculate costing for its additional Project activities at its rates that are in effect at that time. Any such cost increases shall be approved, in writing, by both Parties.

SP-8 If the NRC expects that the value of its estimated contribution will be exceeded by more than *10%*, it shall promptly notify the other Party. The Parties shall then negotiate a further agreement on costs or payments, and either Party may suspend the performance of any obligations, other than confidentiality, intellectual property and accrued obligations to pay, until a further agreement is reached. If the Parties fail to agree on an amendment within 60 days of the notice, then this Agreement shall terminate on the 60th day after the notice, unless the Parties agree otherwise in writing.

SP-9 If a surplus of prepayment remains as a result of premature termination, it will be refunded to Collaborator.

SP-10 If an instrument tendered in payment or settlement of an amount due to the NRC is dishonored for any reason, the NRC will invoice an additional administrative charge of CAD 25 and this amount will be due as invoiced.

SP-11 Interest is payable on all overdue amounts. Interest is calculated and compounded monthly at the average bank rate plus 3% and accrues during the period beginning on the due date and ending on the day before the day on which payment is received by the NRC. For purposes of this paragraph "**bank rate**" means the rate of interest established periodically by the Bank of Canada as the minimum rate at which the Bank of Canada makes short term advances to members of the Canadian Payments Association, and "**average bank rate**" means the weighted arithmetic average of the bank rates that are established during the month before the month in respect of which interest is being calculated.

(Rate information may be found at http://www.tpsgc-pwgsc.gc.ca/recgen/txt/tipp-ppir-eng.html. *This site provides information on the rate used by departments of the Government of Canada to calculate the interest on overdue accounts payable and is the same rate used by the NRC to charge interest on overdue accounts receivable under the Interest and Administrative Charges Regulations, SOR/96-188. This web site address, and the information set out there, is provided here for convenience. In case of rate discrepancy, the rates quoted by the Bank of Canada shall prevail.)*

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STATEMENT OF WORK AND DELIVERABLES

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ANNEX - LIST OF APPROVED CONTRACTORS

1. Resilience Biotechnologies Inc.
2. VVector BIO

[***] Certain information has been excluded pursuant to Regulation S-K, Item 601(b)(10)(iv) from this Document because it is both not material and is the type that the registrant treats as private or confidential.

Exhibit 10.38

COVID-19 Outbreak Response Agreement (ver 3.1)
Agreement Summary

AWARDEE INFORMATION

Name:	Variation Biotechnologies Inc. ("**Awardee**")
Mailing Address:	
Project Lead:	David Anderson
Management Contact:	Adam Buckley
Bank Account Details:	Account Name: USD Account Number: ** Routing/ABA Number: ** Swift Code: ** Bank: ** Bank Address: **

CEPI INFORMATION

Mailing Address:	Coalition for Epidemic Preparedness Innovations, PO Box 123 Torshov, N-0412 Oslo, Norway
Project Lead:	
Management Contact:	

AGREEMENT INFORMATION

Project Name	Development of SA-Variant Monovalent & Multivalent SARS-CoV2 Vaccine Candidates
CEPI Programme Name	Outbreak Response To Novel Coronavirus (COVID-19)
Effective Date	Date of last signature below
Expiry Date	As described in Clause 20.1 of the Terms and Conditions in Annex A.
This Agreement includes and incorporates by reference:	The agreement (the "**Agreement**") means this Agreement Summary together with the following: - Terms and Conditions *(*Annex A*)* - Team Charter *(*Annex B*)* - iPDP for Work Package(s) *(*Annex C*)* - Budget for Work Package(s) *(*Annex D*)* - List of AMC Countries, UMICs and HICs as at the Effective Date (Annex E) - List of Sub-Contractors (Annex F) - List of Pre-existing Agreements (Annex G)

THIS AGREEMENT (the "Agreement") is between Awardee and the Coalition for Epidemic Preparedness Innovations ("**CEPI**") and is effective as of the date of the last signature, below (the "**Effective Date**"). Each party to this Agreement may be referred to individually as a "**Party**" and together as the "**Parties.**" This Agreement sets out the terms and conditions governing the performance and funding of the Project (as defined herein). It also reflects the Parties' mutual commitment to develop a safe and effective vaccine against SARS-CoV-2, to test and obtain regulatory approval for the vaccine as rapidly as possible, consistent with patient safety and achieving vaccine quality, and to ensure the manufacture and distribution of sufficient quantities of the vaccine to meet global demand at affordable prices in the country of use. As a condition of this funding award, the Parties enter into this Agreement by having their authorised representatives sign below.

Signed for and on behalf of:

COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS

Signature:	*/s/ Richard Hatchett*
Name:	Richard Hatchett
Title:	Chief Executive Officer
Date.	March 9, 2021

VBI Vaccines Inc.

Signature:	*/s/ Jeffrey Baxter*
Name:	Jeffrey Baxter
Title:	Chief Executive Officer
Date:	March 8, 2021

Annex A: Terms and Conditions

Definitions:

1.1 "**Additional COVID-19 Candidate**" means any of Awardee's vaccine candidates against SARS-CoV-2 containing antigens from only SARS-CoV-2 and not from any other viruses, other than the Project Vaccine or VBI-2902 (as defined herein), in any form or dosage of pharmaceutical composition or preparation.

1.2 "**Additional COVID-19 Candidate Notice**" has the meaning described in Clause 14.1.

1.3 "**Affiliate**" means any business entity controlled by, controlling or under common control with, a Party. For clarity, "control" shall exist through the ability to directly or indirectly control the management and/or business of the other entity, whether through ownership of voting stock or the power to appoint a majority of the Party's governing board.

1.4 "**Agreement Summary**" means the signature page that identifies the Parties and to which this Annex A and other annexes are attached.

1.5 "**AMC Countries**" means those countries which are eligible to participate in the COVAX AMC from time to time (listed in Annex E as at the Effective Date).

1.6 "**Background Intellectual Property**" (or "**Background IP**") means any and all Intellectual Property that is owned or controlled by Awardee during the Term of this Agreement, whether existing as of the Effective Date or later developed or acquired independently of the Project. For clarity, Background IP includes commercial freedom-to-operate licences obtained by Awardee.

1.7 "**Budget**" means the schedule of funds identified in Annex D to be paid by CEPI to the Awardee for the Project activities in the Work Packages, as may be amended from time to time by the written agreement of both Parties.

1.8 "**Business Days**" means any day, other than (a) a Saturday or Sunday; and (b) any public holiday in London England, Oslo Norway or Massachusetts United States.

1.9 "**Canada Agreement**" means the agreements between the Strategic Innovation Fund of Canada and Variation Biotechnologies Inc. executed Sept 16th 2020 including any extensions or amendments thereto, provided that any such amendment is consistent with CEPI's rights hereunder.

1.10 "**CEPI Service Provider**" means a third party contracted and funded directly by CEPI, which CEPI, at its discretion, may make available to Awardee to support its activities under the Project.

1.11 "**Commercial Benefits"** means any economically quantifiable benefits that arise from the commercial exploitation of the Project Results (including the Project Vaccine).

1.12 "**Commercially Reasonable Efforts**" means the carrying out of such obligations or tasks with a level of efforts and resources (including departmental budget resources) consistent with the efforts and resources that Awardee commits to other products at a similar stage of development, life cycle and potential for impacting subject outcomes, taking into account all relevant factors, including issues of safety and efficacy, product profile, difficulty in developing or manufacturing products, the regulatory requirements involved (including the likelihood of receipt of approval by the relevant governmental authorities) and the potential marketability for a product intended to address the global urgent medical need, serious public health issues and economic impact created by the COVID-19 pandemic and potential market demand of the product.

1.13 "**Cost Guidance**" means CEPI's explanatory document regarding eligible direct and indirect costs, non-eligible costs, and valuation of in-kind contributions, as further described in Clause 11.2.

1.14 "**Cost of Goods**" (or "**COGs**") means the actual costs of manufacturing and supplying the Project Vaccine incurred by Awardee or its designee, the scope of which shall be determined pursuant to Section 15.3 and shall include the following costs to the extent attributable to the manufacture and supply of the Project Vaccine (unless otherwise agreed by the Parties):

(a) direct costs of raw materials, intermediates and components, reference materials or standards required for release testing and materials necessary to support stability studies (including methods and consumables);

(b) fully loaded direct labour costs;

(c) direct costs of drug substance and drug product manufacturing, quality assurance and stability testing, characterisation testing, quality control release testing of drug substance and drug product, quality assurance batch record review and release;

(d) costs of interim packaging and labelling;

(e) direct costs of insurance, storage and freight and shipping costs;

(f) tariffs, sales and excise taxes, customs and duty and charges levied by governmental entities (including export fees) on the Project Vaccine;

(g) a fair and reasonable allocation of identifiable internal and indirect costs incurred by Awardee in connection with and attributable to such manufacturing of the Project Vaccine, including, at a minimum, for process development, project management, manufacturing oversight, facilities, depreciation, utilities, insurance, and quality control and assurance, in conformity with relevant U.S. GAAP, IFRS or other local GAAP accounting principles, in each case, calculated by Awardee in a manner consistent with its treatment of such costs (including idle capacity) with respect to other products and without disadvantaging the Project Vaccine on account of the terms of this Agreement or otherwise;

(h) royalties, licensing fees, milestone fees and other costs and expenses directly attributable to rights to use the Intellectual Property and technology associated with the Project Vaccines and the Project Materials;

(i) costs of compliance with regulatory requirements including reporting, audits and updates;

(j) direct costs of product liability insurance, if not otherwise provided; and

(k) costs and expenses for pharmacovigilance and medical affairs directly incurred for, or fairly allocable to, the Project Vaccine supplied pursuant to this Agreement.

1.15 "**COVID-19 Global Vaccine Access Facility**" or "**COVAX**" means the global umbrella mechanism developed and managed under the auspices of the Vaccine Task Force, a component of the Access to COVID-19 Tools (ACT) Accelerator, that shall pool funding commitments and incentivise scale-up of research and development, clinical trial investments, and manufacturing for a portfolio of vaccine candidates.

1.16 "**Enabling Rights**" means rights to Background Intellectual Property, Project Intellectual Property and Project Results that could be asserted by Awardee or a Subawardee to block CEPI from exercising the Public Health Licence to make, have made, use, have used, import, sell or otherwise exploit the Project Vaccine. For purposes of this Agreement, Enabling Rights also includes the contractual rights that control the use of such items as, for example, rights to use biological materials covered in material transfer agreements entered into between Awardee and third parties.

1.17 "**Equitable Access**" has the meaning given to it in Clause 15.1.

1.18 "**Equitable Access Plan**" means the principles of Equitable Access under this Agreement including those set out in Clause 15 and the Equitable Access Policy (as defined in Clause 15.1).

1.19 "**Field**" means the public health response to the Outbreak and to other coronaviruses against which a Project Vaccine may be at least partially cross-protective or as otherwise agreed by the Parties from time to time in accordance with Clause 22.6.

1.20 "**Financial Report**" has the meaning described in Clause 3.9.

1.21 "**Further Funding Notice**" has the meaning described in Clause 4.1.

1.22 "**Gavi**" means the Gavi Vaccine Alliance, an independent non-profit foundation within the meaning of Articles 80 *et seq.* of the Swiss Civil Code with a registered address at Chemin du Pommier 40, 1218 Le Grand-Saconnex, Geneva, Switzerland and any procurement agent that may be appointed by Gavi from time to time.

1.23 "**HICs**" or "**Higher Income Countries**" means the countries identified in Annex E.

1.24 "**Integrated Product Development Plan**" (or "**iPDP**") means the document setting out details of one or more Work Packages that collectively describe the various activities, deliverables, milestones, phases, risks and timelines associated with the Project, as may be amended from time to time by the written agreement of both Parties. The initial iPDP is set forth as Annex C.

1.25 "**Intellectual Property**" or "**IP**" means (a) inventions, patents, utility models, and rights in the foregoing; (b) trade marks, trade names, geographical indications and appellations of origin, rights under the law of passing off, unfair competition and equivalents; (c) copyright, rights in software, rights in performances and in recordings, moral rights, and database rights; (d) designs, design patents, registered and unregistered designs and design rights; (e) confidential information consisting of trade secrets and rights under the law of breach of confidence and equivalents; and all other intellectual property rights of any kind however designated that may subsist anywhere in the world whether arising by operation of law, treaty, contract, conduct or otherwise, together with all registrations, applications, rights to priority, renewals, extensions, continuations, divisions or reissues thereof and all rights to bring action for infringement past, present and future.

1.26 "**Joint Monitoring and Advisory Group**" or "**JMAG**" has the meaning described in Clause 2.3.

1.27 "**LMICs**" or "**Low and Middle Income Countries**" means the countries identified by the Organisation for Economic Co-operation and Development (or "**OECD**") as having low-income or middle-income economies, as may be updated from time-to-time by the OECD.

1.28 "**Lowest Tier Countries**" means in the case of any matter relating to COVID-19, the AMC Countries and in the case of all other diseases, the Low and Middle Income Countries.

1.29 "**NRC Agreement"** means the Collaboration Agreement with the NRC dated March 30, 2020 and the first Amendment dated December 21, 2020, as may be amended from time to time provided that any such amendment is consistent with CEPI's rights hereunder.

1.30 "**Outbreak**" means the COVID-19 outbreak caused by the SARS-CoV-2 virus or any strain, mutations and related recurrences of such virus.

1.31 "**Pandemic Period**" means the period of time beginning on 30 January 2020, when the World Health Organization (or "**WHO**") declared COVID-19 to be a Public Health Emergency of International Concern (or "**PHEIC"**), and ending on the earlier of (1) the date on which WHO declares that the COVID-19 PHEIC is over or (2) the date determined by CEPI, in its reasonable discretion in consultation with the Awardee and based on epidemiological data published by WHO, including.

1.32 "**Pre-existing Agreements**" means the agreements entered into by the Awardee prior to the Effective Date details of which are set out in Exhibit H.

1.33 "**Project**" means the activities under this Agreement, as are described in the Team Charter, iPDP and Budget, to be performed by or on behalf of the Awardee and/or any Subawardee.

1.34 "**Project Continuity Plan**" has the meaning described in Clause 13.2.

1.35 "**Project Data**" has the meaning described in Clause 9.1.

1.36 "**Project Intellectual Property**" (or "**Project IP**") means the Intellectual Property discovered or made by or on behalf of the Awardee and/or any Subawardee in the performance of the Project.

1.37 "**Project Materials**" has the meaning described in Clause 9.2.

1.38 "**Project Results**" means all of the tangible materials and other results that are made or developed by or on behalf of Awardee and/or any Subawardee under the Project, including the Project Vaccine and assays developed by or on behalf of the Awardee or any Subawardee that are necessary for Project Vaccine production, whether in whole or in components, serum samples collected, protocols used in clinical or non-clinical evaluation of the Project Vaccine, Project Data, and Project Materials.

1.39 "**Project Vaccine**" means one or more of Awardee's vaccine candidates *** (as described in the iPDP) and any other of the Awardee's vaccine candidates expressly identified in the iPDP, in any form or dosage of pharmaceutical composition or preparation (including any *** candidate vaccines of any of the foregoing which are included in the iPDP and Budget from time to time).

1.40 "**Public Health Licence**" means a grant by Awardee to CEPI of all relevant Enabling Rights for use in the Field by CEPI as described in Clause 13.4.

1.41 "**Ready Reserve of Clinical Trial Material**" has the meaning described in Clause 12.1.

1.42 "**Stage Gate**" means a mutually agreed "go/no go" decision point to continue a given Work Package or to commence activities in another Work Package, as set out in the iPDP.

1.43 "**Stage Gate Review Committee**" has the meaning described in Clause 2.5.

1.44 "**Subawardee**" means a third party that is contracted by and receives CEPI funds from Awardee to perform activities or provide support under the Project. For clarity, Subawardees include both "Sub-Grantees" and "Sub-Contractors" described in Clauses 3.3 and 3.2, respectively.

1.45 **"Sub-Contractor"** has the meaning described in Clause 3.2.

1.46 "**Team Charter**" has the meaning described in Clause 2.1.

1.47 "**Technical Report(s)**" has the meaning described in Clause 2.4.

1.48 "**Term**" has the meaning described in Clause 20.1.

1.49 "**Third Party Code**" (or "**Code**") means the periodically updated, consolidated statement of CEPI's values and of the policies, practices and principles described in Clause 11.2.

1.50 "**Trusted Collaborator**" is a component of the Project Continuity Plan and has the meaning described in Clause 13.2.

1.51 "**Trusted Manufacturer**" is a component of the Project Continuity Plan and has the meaning described in Clause 13.2.

1.52 "**UMICs**" or "**Upper and Middle Income Countries**" means the countries identified in Annex E.

1.53 **"VBI-2902"** means Awardee's clinical stage monovalent vaccine against the L-strain of reference for SARS-COV2.

1.54 **"Volume Commitment Percentage"** means the relevant percentage of the Awardee's capacity to produce Project Vaccine together with Trusted Manufacturer, where the relevant percentage shall be calculated as follows: **% for any Project Vaccine for which CEPI provides preclinical funding, **% for any Project Vaccine for which CEPI funds through Phase 1 clinical study, **% for any Project Vaccine for which CEPI funds through Phase 2 clinical study, **% for any Project Vaccine for which CEPI funds through Phase 3 clinical study, and **% for any Project Vaccine for which CEPI funds through to (i) approval and registration as set out in the iPDP; (ii) WHO pre-qualification or emergency use listing; and (ii) reasonably sufficient commercial manufacturing capabilities as required to meet Awardee's obligations hereunder. In the event that CEPI co-funds with a third party organization, VBI, CEPI and the third party organization will negotiate an appropriate Volume Commitment Percentage commensurate with the respective interests of the party, funding contributions and stage of investment (provided always that such Volume Commitment Percentage shall be no lower than the Volume Commitment Percentage applicable to the funding stage immediately prior to the latest stage to which CEPI has provided funding).

1.55 "**Work Package(s)**" means a discrete set of Project activities described in the iPDP.

2 <u>Project Organisation and Management</u>:

2.1 **Team Charter**. The Project shall be managed by the Parties as described in the Team Charter in Annex B.

2.2 **iPDP and Work Packages**. Awardee shall use Commercially Reasonable Efforts to undertake the Project as described in the iPDP, including achieving the milestones and timelines of each Work Package and achieving each Stage Gate within the agreed timeframe, it being understood that neither Party can assure a positive technical outcome for any Work Package. The Project is organised into one or more Work Packages and each Work Package has an associated budget as set out in the Budget. The Work Packages shall be pursued and performed by Awardee in accordance with the Budget and the iPDP. CEPI will pay the Awardee in accordance with the Budget and the iPDP and, where applicable, upon completion of a Stage Gate (as determined pursuant to Clause 2.5). Additional Work Package(s) may be agreed in writing by the Parties after the Effective Date, which, upon execution by both Parties, shall be annexed to and become a part of this Agreement. Work Packages may also be modified or extended with the mutual written consent of both Parties in accordance with Clause 22.6.

2.3 **Joint Monitoring and Advisory Group**. Promptly following the Effective Date, the Parties will establish a joint monitoring and advisory group ("**JMAG**") that shall meet regularly as specified in the Team Charter to monitor progress of and advance the Project. The JMAG shall coordinate the efforts of CEPI and Awardee to:

(a) facilitate communications between the Parties;

(b) review the progress of the Project;

(c) discuss substantial proposed changes in the scope or conduct of applicable clinical and animal studies;

(d) discuss clinical trial protocols, publications and regulatory submissions;

(e) coordinate the sharing of any Project Results identified in a Work Package as intended for use by other CEPI awardees;

(f) review and update the Project Continuity Plan;

(g) review and update the Equitable Access Plan; and

(h) discuss plans, as appropriate, for the development of manufacturing and its scale-up and scale-out.

2.4 **Technical Reports and Access to Project Results**. Awardee shall disclose all Project Results to CEPI's Project Lead, at meetings of the JMAG and shall provide written reports of progress made under the iPDP using a template provided by CEPI ("**Technical Reports**"), within twenty (20) Business Days of the end of each calendar quarter during the term of the Project as set out in the iPDP. In addition, the Awardee shall make Project Results available to CEPI as described in the iPDP or otherwise as may reasonably be requested from time to time by CEPI.

2.5 **Stage Gate Review**. Unless otherwise addressed in a Work Package for a given Stage Gate, when Awardee believes that a Stage Gate in a Work Package will be achieved in the near term, Awardee shall notify the JMAG promptly and provide relevant information (including the completion of a form provided by CEPI) and request a meeting of CEPI's committee authorised to assess whether Stage Gates have been completed (the "**Stage Gate Review Committee**"). Awardee's Project Manager shall coordinate with CEPI's Project Manager to schedule a Stage Gate Review Committee meeting as early as possible, but no later than fifteen (15) Business Days before the planned meeting date. CEPI shall notify Awardee of the Stage Gate Review Committee's decision as soon as possible, but no later than twenty (20) Business Days after the meeting date.. If the Stage Gate Review Committee determines that the Stage Gate was not completed, CEPI shall promptly discuss with Awardee potential actions to be taken in order to complete such Stage Gate.

2.6 **Subawardees**. Project activities may be undertaken by Subawardees that are identified in a Work Package and associated Budget as of the Effective Date or are proposed by Awardee and reasonably approved by CEPI in writing after the Effective Date.

2.7 **CEPI Service Providers**. CEPI has entered into certain service agreements with CEPI Service Providers that have agreed to provide preferential charging to CEPI awardees. CEPI shall make available various laboratory services or other support to Awardee provided by a CEPI Service Provider, for example, by providing testing of clinical serum samples, evaluation of immunity of Project Vaccine in animal models and various analytical services. Awardee agrees to make Commercially Reasonable Efforts to utilise any CEPI Service Provider for the provision of services as may be specified in a Work Package and agreed in writing between the Parties. Awardee and the CEPI Service Provider may, at their own discretion, enter directly into an appropriate agreement between themselves setting out the terms on which the services will be provided. CEPI shall, through the JMAG or otherwise, discuss with Awardee protocols and data management related to any services provided by any CEPI Service Provider.

3 Use of Funds; Procurement; Project Records:

3.1 **Use and Management of Funds**. The Budget sets out the total funding to be provided by CEPI to Awardee for each Work Package. Awardee shall use this funding only in accordance with a Work Package unless otherwise agreed in writing by CEPI in advance. Awardee shall manage all funds received by Awardee for the Project (whether CEPI funds or funds provided by a third party) with financial controls and practices consistent with U.S. GAAP, IFRS or local GAAP, and further in compliance with applicable CEPI policies and procedures as described in Clause 11.2 of this Agreement.

3.2 **Use of Sub-Contractors**.

(a) Awardee may use sub-contractors to undertake work pursuant to the Work Packages on its behalf provided that such sub-contractors are listed in Annex F or they have been approved by CEPI in advance in writing ("**Sub-Contractors**"). Such Sub-Contractors may be retained without a tender process.

(b) The use of any Sub-Contractors that are not included in the iPDP and Budget as of the Effective Date must be approved in advance in writing by CEPI and managed by Awardee in compliance with Clause 11.2. Awardee's selection and use of Sub-Contractors must be undertaken in compliance with Section 14 of the Third Party Code and Cost Guidance.

(c) If Awardee is using a Sub-Contractor to undertake work pursuant to a Work Package, the funding allocated for the Sub-Contractor will be determined based on costs pre-approved in writing by CEPI, which may include a modest profit.

(d) Awardee shall ensure that each Sub-Contractor is subject to all of the obligations, as between the Awardee and the Sub-Contractor, applicable to Awardee under this Agreement, including the obligations relating to auditing, inspection, record keeping, use of funds, compliance obligations analogous to those in the Third Party Code and Cost Guidance, and all other compliance obligations as are applicable to Awardee under this Agreement. Awardee shall be responsible for the acts and omissions of its Sub-Contractors that participate in the Project as if such acts and omissions were those of the Awardee itself.

(e) Awardee shall ensure that each Sub-Contractor (i) assigns or grants a licence in respect of all Enabling Rights to the Awardee in order to enable the grant of the Public Health License to CEPI pursuant to Clause 13.4 of this Agreement; or (ii) directly grants the Public Health License to CEPI pursuant to Clause 13.4 of this Agreement.

(f) Awardee shall notify CEPI promptly in writing if any Sub-Contractor is not in compliance with the representations and warranties in Clause 17 or any other terms of this Agreement.

3.3 **Use of Sub-Grantees**.

(a) Subawardees that are "**Sub-Grantees**" will be identified as such in the iPDP and will be funded using the same grant structure as the grant received by Awardee under this Agreement.

(b) Awardee shall ensure that Sub-Grantees only appoint Sub-Contractors in accordance with the provisions of Clause 3.2.

(c) The funding allocted to a Sub-Grantee will be based on actual costs incurred in line with a budget approved by CEPI in writing and determined on a without-profit basis.

(d) The use of any Sub-Grantees that are not included in the iPDP and Budget as of the Effective Date must be approved in writing in advance by CEPI and managed by Awardee in accordance with Clause 11.2 of this Agreement, Section 15 of the Third Party Code, and Cost Guidance.

(e) Awardee shall ensure that each Sub-Grantee agrees in writing to be subject to all of the obligations applicable to Awardee under this Agreement, including the obligations relating to auditing, inspection, record keeping, use of funds, compliance with the Third Party Code and Cost Guidance, and all other compliance obligations as are applicable to Awardee under this Agreement. Awardee shall be responsible for the acts and omissions of its Sub-Grantees that participate in the Project as if such acts and omissions were those of the Awardee itself.

(f) Awardee shall ensure that each Sub-Grantee (i) assigns or grants a licence in respect of all Enabling Rights to the Awardee in order to enable the grant of the Public Health License to CEPI pursuant to Clause 13.4 of this Agreement; or (ii) directly grants the Public Health License to CEPI pursuant to Clause 13.4 of this Agreement.

(g) Awardee shall notify CEPI promptly in writing if any Sub-Grantee is not in compliance with the representations and warranties in Clause 17 or any other terms of this Agreement.

3.4 **Payments.** Payments to Awardee under this Agreement shall be made in U.S. dollars (US$) to Awardee's bank account identified on the Agreement Summary. CEPI shall make payments in tranches covering six (6) month periods as set out in the Budget. Awardee shall be entitled to submit a payment request form to CEPI upon execution of this Agreement and thereafter at the same time as the semiannual financial reporting. Tranches of funding for each payment request submitted under this Agreement in accordance with the Budget shall be paid by CEPI within twenty (20) Business Days after receipt and approval by CEPI of all of the following: (i) payment request by Awardee; (ii) any quarterly Technical Report due at the time of the payment request; and (iii) any quarterly Financial Report due at the time of the payment request; each to be submitted using templates provided by CEPI. Payments may be adjusted by CEPI to reflect any underspend as well as any interest earned on unutilised funds as noted in the Financial Report.

3.5 **Delayed Payments**. CEPI may delay or condition a payment if:

(a) Awardee has not achieved a material milestone in accordance with the iPDP by the agreed time, unless such delay has been approved in writing by the JMAG in accordance with the Team Charter or otherwise by CEPI;

(b) The Awardee or any Subawardees are no longer in compliance with the representations and warranties in Clause 17 at the time the payment tranche is requested; or

(c) Awardee has not reasonably completed the payment request form or submitted reasonably satisfactory Technical Reports and Financial Reports.

3.6 **Hold on Payment During a Material Breach**. CEPI is not obliged to pay any tranches of funding for any Work Package for so long as Awardee is in breach of a material obligation under this Agreement.

3.7 **Retained Final Payment**. CEPI shall retain ten percent (10%) of the payment tranche in respect of the final 6 months' of the term of the Project and release it within twenty (20) Business Days after approving Awardee's final Technical Report and Financial Report for the final Work Package.

3.8 **Financial Reports**. Awardee shall provide reports of its expenditure under the Budget with supporting documentation and using a template provided by CEPI ("**Financial Reports**") within thirty (30) Business Days of the end of each calendar quarter during the term of the Project or such other date(s) as may be identified in the Budget. Awardee shall submit a final Financial Report for a Work Package within sixty (60) days after the completion of any Work Package.

3.9 **Project Records**. Awardee shall keep accurate records of its Project activities and expenditure under each Work Package and retain them for a period of five (5) years from the end of the term of the applicable Project.

3.10 **Access to Financial Records**. During the Term and for a period of five (5) years after expiration or termination of this Agreement, CEPI, or its designee (which shall be an internationally recognised certified public accounting firm, not engaged on a contingent basis), and at CEPI's reasonable cost, shall have on-site access to inspect Awardee's Project-related financial records once annually upon at least fifteen (15) Business Days' advance written notice. Such inspections shall be conducted during normal operating hours in a manner to minimise disruption to Awardee's and/or Sub-Grantee's business. For clarity, access to such records also shall be provided to records related to Cost of Goods as described in Clause 15.

3.11 **Project Financial Audits**. During the Term and for a period of five (5) years after expiration or termination of this Agreement, if requested by CEPI, and at CEPI's reasonable cost, once annually upon at least fifteen (15) Business Days' notice, Awardee's external auditors shall conduct a Project audit in accordance with ISA800 and/or ISA805 and like standards and provide CEPI with audited statements. Such inspections shall be conducted during normal operating hours in a manner to minimise disruption to Awardee's business.

4 Further Funding:

4.1 **First Right to Fund.** Where practicable CEPI likes to continue to participate in its programmes throughout their life cycle. In the event that (a) Awardee reasonably requires any funding for the development, manufacture and/or deployment of a Project Vaccine in addition to the funding to be provided by CEPI pursuant to the Budget; or (b) Awardee receives any offer or indication of interest from a third party to provide funding support for the development, manufacture and/or deployment of a Project Vaccine; Awardee shall provide prompt written notice to CEPI, including a summary of the amount of funding required or offered and the terms (if any) offered by any potential third party funder (each a "**Further Funding Notice**"). CEPI shall have the first right (but not the obligation), at CEPI's sole discretion, to provide such further funding support to the Awardee for the development, manufacture and deployment of the Project Vaccine and shall provide written notice to the Awardee of any such election within thirty (30) days of receipt by CEPI of a Further Funding Notice. The Awardee shall not accept any third party funding support in respect of the development, manufacture and/or deployment of a Project Vaccine unless and until the earlier of (i) CEPI has provided written notice that it does not wish to provide such further funding; or (ii) Awardee has not received an election from CEPI to provide such further funding within thirty (30) days of receipt by CEPI of a Further Funding Notice.

4.2 **Participation By Other Funders**. Each Party acknowledges that additional third party funding support for the Project may become available to either Party. For example, other funders may offer to fund certain activities under a Work Package or the scale-up and scale-out of Project Vaccine production. Subject to Clause 4.1 and Awardee's representations in Clause 17.2, the Parties shall, in good faith, use reasonable endeavours to facilitate such participation and make appropriate revisions to relevant Work Packages and the Budget, as well as managing any potentially conflicting commitments.

5 **Ownership of Project Results; Intellectual Property:**

5.1 **Awardee's Background IP**. Awardee shall retain ownership of its Background IP. Nothing in this Agreement shall be deemed to assign any ownership interest in such Background IP to CEPI, without prejudice to the licence rights of CEPI expressly set out in this Agreement.

5.2 **Ownership of Project Intellectual Property**. Awardee shall own any Intellectual Property invented by either Party and arising under the Project, subject to the rights of CEPI to use Project Intellectual Property expressly set out in this Agreement. Awardee shall have the right, but not the obligation, to seek IP protection in respect of any Project Intellectual Property at its own cost. Upon request, but no less than annually, Awardee shall provide a written update to CEPI regarding the status of Project Intellectual Property rights sought and obtained.

5.3 **Ownership of Project Results**. Awardee shall own the Project Results, subject to the rights of CEPI to use Project Results expressly set out in this Agreement.

5.4 **Third Party IP**. The Parties shall notify each other promptly regarding any third party IP they become aware of that might impact Awardee's ability to perform its obligations under this Agreement and activities contemplated under the Project Continuity Plan and Equitable Access Plan. The Parties shall cooperate in good faith to resolve any such matters.

6 **Clinical Trials:**

6.1 **Clinical Trials**. Awardee shall undertake the clinical trials as described in the clinical development plan in the iPDP (the "**Project Clinical Trials**"), in compliance with all applicable laws and regulations, including requirements related to use of clinical data outside of the country in which a given Project Clinical Trial is conducted. Awardee shall ensure that all Project Clinical Trials comply with CEPI's Clinical Trial Policy referred to in Clause 11.2.

6.2 **Clinical Trial Protocols**: **Preparation**. Awardee shall be responsible for the preparation of clinical trial protocols for the Project Clinical Trials. Awardee shall provide CEPI and/or CEPI's designee with a draft of each clinical trial protocol for the Project Clinical Trials and shall consult with and consider any reasonable suggestions made by CEPI and/or its designee regarding the clinical trial protocols reasonably in advance of finalising the relevant clinical trial protocol and submitting it to the institutional review boards, ethics committees, and/or regulatory authorities.

6.3 **Clinical Trial Protocols**: **Reporting of Submitted Versions**. Awardee shall provide to CEPI a copy of all clinical trial protocols as submitted to institutional review boards, ethics committees and regulatory authorities in respect of the Project Clinical Trials.

6.4 **Clinical Data**. Informed consent shall be obtained from each clinical trial subject to allow, to the extent permitted by law:

(a) the transfer of anonymised or pseudonymised data to CEPI and/or CEPI's designee; and

(b) the collection and use of biological samples and the use of data (duly anonymised or pseudonymised (at CEPI's discretion) and, at CEPI's request, blinded) derived from such samples by CEPI or its designated Assessors (as defined herein) for the purposes of this Agreement.

6.5 **Sponsorship and Management of Clinical Trials**.

(a) Awardee shall be the sponsor of any clinical trial (unless CEPI and Awardee otherwise agree in writing), and shall be responsible for obtaining and maintaining all regulatory and ethical committee approvals necessary or reasonably useful for the conduct of the Project Clinical Trials.

(b) In respect of each Project Clinical Trial, Awardee shall establish an internal Trial Steering Committee ("**TSC**") and either a Safety Monitoring Committee or Data Safety Monitoring Board, as applicable (each, a "**DSMB**"). CEPI shall be entitled to appoint, and Awardee shall permit, a CEPI representative or designee to attend all meetings of each Project Clinical Trial's TSC and/or DSMB as an observer (either in person or by telephone, video or other electronic means). Subject to Clause 6.5(c) below, Awardee shall provide a copy to CEPI of all papers that a member of the TSC and/or DSMB would be entitled to receive at the same time as any such papers are provided to the members of the TSC and/or DSMB (as applicable).

(c) In the event that CEPI's attendance at a meeting of the TSC and/or DSMB or receipt of papers would, in the Awardee's reasonable discretion acting in good faith, jeopardise the integrity/blinded nature of an ongoing Project Clinical Trial, the Awardee shall promptly notify CEPI of such fact and CEPI shall not be entitled to, and Awardee shall not be required to permit CEPI to, attend such meeting or receive such papers at that time. During an ongoing Project Clinical Trial, Awardee will continue to provide CEPI with all open session DSMB documents, DSMB recommendation forms and other "open" documents identified by both Parties in the iPDP and/or protocol for such Project Clinical Trial. After a Project Clinical Trial l is unblinded, Awardee shall provide a copy of all papers that were provided to the members of the TSC and/or DSMB and/or that a member of the TSC and/or DSMB would be entitled to receive.

6.6 **Safety Notifications**. Awardee shall notify the JMAG in writing promptly following any single safety event of concern or a series of safety events considered by the DSMB as relevant in relation to the Project Vaccine and within 48 hours from the time when such event or series of events becomes known to Awardee.

6.7 **Records and Reporting.** Awardee shall ensure that all data in relation to the Project Clinical Trials and any other clinical trials undertaken by or on behalf of Awardee or Subawardee with respect to the Project Vaccine are appropriately recorded and that all such records are kept up to date and maintained in accordance with applicable laws and regulations. Awardee will ensure that CEPI is able to review and verify all anonymised or pseudonymised data at the end of the relevant Project Clinical Trial or other clinical trial and will promptly following the end of such Project Clinical Trial or such other clinical trial provide a copy of, or access to, such anonymised or pseudonymised data to CEPI in such form as CEPI may reasonably require.

6.8 **Priority for Clinical Trials**. Awardee acknowledges that the pool of subjects available in areas of Outbreak to participate in a clinical trial to test the Project Vaccine may be limited. Accordingly, if WHO, CEPI or a regulatory authority in the area where the clinical trial is to be conducted determines that a product other than a Project Vaccine has substantially greater potential and should be prioritised instead for a particular clinical trial, Awardee shall not unreasonably proceed with a clinical trial of such Project Vaccine unless required to do so by a relevant regulatory authority or a Pre-existing Agreement. Awardee shall be reimbursed for its reasonable, non-cancellable costs incurred resulting from such determination to not proceed.

6.9 **Potential WHO Clinical Trials**.

(a) Awardee shall not unreasonably decline to participate in a Phase IIb or III clinical trial as requested and funded by WHO and/or CEPI to compare the Project Vaccine with other COVID-19 vaccine candidates.

(b) In the event of such participation by Awardee, Awardee will, promptly following the end of such clinical trial, provide a copy of the final study report to CEPI.

7 <u>Regulatory Activities</u>:

7.1 **Regulatory Activities**. Awardee shall pursue the regulatory activities described in the iPDP.

7.2 **Meetings with Regulatory Authorities**. Awardee shall notify CEPI in writing of any material meetings with regulatory authorities at least five (5) Business Days in advance of such meetings, or if Awardee itself receives less than five (5) Business Days notice of such a meeting, as soon as practicable. CEPI or its designee may, at CEPI's option, observe all material interactions between Awardee and regulatory authorities relating to the Project Vaccine. At CEPI's reasonable request, Awardee shall request a meeting with regulatory authorities to address any significant unresolved issues.

7.3 **Regulatory Filings**. Awardee shall consult regularly with CEPI regarding regulatory strategy for a Project Vaccine and shall provide advance copies of all material regulatory submissions for review and comment by CEPI no later than ninety-six (96) hours prior to their contemplated submission to a regulatory authority. If a final version is not available by ninety-six (96) hours prior to submission, then a mature draft version may be electronically delivered to CEPI for review at that time. Additionally, Awardee shall upload copies of the following to a confidential electronic archiving service designated by CEPI:

(a) all submissions to regulatory authorities and regulatory filings in respect of a Project Vaccine together with all data included or referenced therein (other than ministerial or routine submissions that do not involve safety or efficacy issues); and

(b) material documents and information exchanged between any regulatory authority and the Awardee relating to a Project Vaccine including official meeting minutes.

8 Animal Studies:

8.1 **Animal Studies**. Awardee shall pursue studies involving animals as described in the iPDP, in compliance with all applicable laws and regulations and further in compliance with Clause 11.2.

9 Dissemination of Project Results; Publication:

9.1 **Dissemination of Project Data**. Awardee shall disseminate pre-clinical and clinical trial data (including any negative results, model animal Project Vaccine-related deaths and any toxicology study issues) produced under the Project (collectively, "**Project Data**"), as described in the iPDP and this Agreement or as otherwise agreed by the JMAG.

9.2 **Dissemination of Project Materials.** Awardee shall disseminate biological samples, Project Vaccines, and other tangible materials produced under the Project (collectively, "**Project Materials**") as described in the iPDP and this Agreement or as otherwise agreed by the JMAG. If Awardee develops animal models under the Project, they shall also be considered Project Materials and disseminated as described in the iPDP and this Agreement or as otherwise agreed by the JMAG.

9.3 **Publication of Project Data for the Outbreak Research Community**. Project Data shall be shared by the Awardee and CEPI openly and rapidly with the broader community to inform the public health response and help save lives. Key principles of this sharing of data have been agreed to by funders, research organisations, government agencies, civil society organisations and for-profit life science enterprises, as described in the Wellcome Trust's Statement on Sharing Research Data and Findings Relevant to the Coronavirus (COVID-19) Outbreak to which CEPI is a signatory. Additional guidance is provided in (i) WHO's 2016 Guidance for Managing Ethical Issues in Infectious Disease Outbreaks; and (ii) WHO's 2016 Guidance on Good Participatory Practices in Trials of Interventions Against Emerging Pathogens.

9.4 **Clinical Trial Registration and Results**:

(a) Clinical trials must be registered through an easily discoverable existing public route such as clinicaltrials.gov, The EU Clinical Trials Register, and/or the International Clinical Trials Registry Platform, in accordance with all applicable laws and regulations. The information provided shall follow the current WHO Trial Registration Data Set. The clinical trial ID or registry identifier code/number shall be included in all publications of clinical trials.

(b) Clinical trial results (including negative results) must be disclosed publicly following database lock in as close to real time as is possible. Publication should be made through an easily discoverable existing public route (website or system) that includes a metadata description, where patient privacy is upheld, and the system follows a request-for-information approach (where requests are fulfilled subject to an independent review and approval step). Clinical trial data shall be submitted for publication within four (4) months after each final study report or comparable report is submitted to CEPI. During the same time period, Awardee shall make the results available to the national Ministry of Health or equivalent in the countries where trials are held. Related clinical trial data shall be deposited in an open sharing platform such as ClinicalStudyDataRequest.com, Vivli Center for Global Clinical Research Data, or an equivalent service.

9.5 **Open Access**. CEPI requires "Open Access" for all Project Results. This means that the Awardee must ensure that a copy of the final manuscript of all research publications, journal articles, scholarly monologues and book chapters published under this Clause 9 is deposited into PubMed Central (or Europe PubMed Central) or otherwise made freely available upon acceptance for publication or immediately after the publisher's official date of final publication. Moreover, Awardee shall ensure that all peer-reviewed published research that is funded, in whole or in part, by CEPI shall be published in accordance with the principles of Plan S ("Accelerating the transition to full and immediate Open Access to scientific publications"), a UK and European data sharing initiative for research funded by public grants. Awardee shall comply with CEPI's reasonable requests to share information in a preprint service such as bioRxiv.

9.6 **Statement of Support in Publications**. All such publications shall include a statement that the work was "supported, in whole or in part, by funding from CEPI" (or such other words to the same effect) and shall credit, where appropriate, the country in which any clinical trials were performed.

10 **Independent Assessors:**

10.1 **Independent Assessors**. As required in a Work Package or as otherwise reasonably requested by CEPI, Awardee shall cooperate with and provide reasonable assistance to independent third-party laboratories or consultants ("**Assessors**") (which may include but is not limited to the Task Force for Global Health and its Safety Platform for Emergency vACcines (SPEAC) Project), retained in confidence and at CEPI's expense, to consult on development of clinical trial protocols, explore development strategies, and evaluate Project Results, including the Project Vaccine. Awardee acknowledges that such Assessors may provide CEPI with directly comparable evaluations of similar materials developed under CEPI's portfolio of awarded projects. The results of the testing, analysis, meta-analysis or other assessments by such Assessor(s) shall be subject to the confidentiality obligations of this Agreement. At Awardee's reasonable request, CEPI shall provide Awardee with access to the results of any evaluation of Project Results by an Assessor solely to the extent such assessment directly relates to the Project Results and Project Vacine. For clarity, CEPI shall not be required to grant access to any information regarding CEPI's portfolio of other awarded projects.

10.2 Awardee and the Assessor(s) may, at their own discretion, enter directly into an appropriate agreement between themselves to the extent necessary to facilitate any Assessor's activities under Clause 10.1, such as a non-disclosure agreement or material transfer agreement. CEPI shall, through the JMAG or otherwise, discuss with Awardee protocols and data management related to any Assessor's activities under Clause 10.1.

10.3 **Awardee Cooperation**. Awardee shall provide reasonable assistance to CEPI and any designated Assessor to facilitate any Assessor's activities under Clause 10.1, including:

(a) ensuring that any samples to be transferred or exported by or on behalf of Awardee from a clinical trial site or sample storage site are transferred and/or exported pursuant to the terms and conditions of a material transfer agreement to be entered into between Awardee and the Assessor in a form reasonably acceptable to CEPI, the Awardee and the Assessor, in addition to any other applicable laws and regulations.

(b) cooperating with regard to any data analysis, to the extent relevant under a given Work Package or otherwise reasonably requested by CEPI by:

(i) providing data or other information generated under this Agreement to CEPI's designated Assessor as CEPI may instruct, including data regarding CMC, formulation or the results of any of its pre-clinical or clinical trials (duly anonymised and, upon CEPI's request, blinded) and other documents and information such as study protocols, case report forms needed to develop standardised approaches and tools for safety data management;

(ii) providing CEPI's designated Assessor with other data (duly anonymised and, upon CEPI's request, blinded) as CEPI may reasonably request in order to conduct comparative assessments; and

(iii) providing CEPI's designated Assessor with clinical trial data (duly anonymised and, at CEPI's request, blinded) for the purposes of signal detection or meta-analyses of safety data (including across product candidates).

11 <u>Compliance</u>:

11.1 **Compliance with applicable laws**. Awardee shall comply with all laws and regulations that are applicable to its activities, operations and use of CEPI funds under the Project.

11.2 **CEPI's Third Party Code and Cost Guidance**. The Third Party Code is a statement of CEPI's values and of the policies, practices and principles applicable to recipients of CEPI funding. CEPI shall notify Awardee of material changes to the Code without undue delay. CEPI's Cost Guidance provides additional information regarding the treatment of costs.

(a) Awardee acknowledges the statement of CEPI's values in Section 1 of the Code.

(b) Awardee shall adhere to business practices, ethical principles and legal requirements that are at least substantially similar to those described in Sections 2 to 10 of the Code.

(c) Awardee confirms that it has understood and will comply with the provisions of the 'Accurate Records and Documentation' paragraph in Section 10 of the Code, which may entail obtaining records and financial documentation from Sub-Contractors and Sub-Grantees to be provided to CEPI or its designated auditor.

(d) Awardee shall comply with the requirements for reporting compliance concerns and misconduct to CEPI subject to applicable law (Sections 4 and 11 of the Code).

(e) Awardee shall cooperate as may be requested by CEPI in the submission of information related to Project activities and expenditures in accordance with the International Aid Transparency Initiative (Section 12 of the Code).

(f) Awardee shall comply with CEPI's Equitable Access Policy, which is further described in Clause 14 of this Agreement.

(g) To the extent applicable to the Project, Awardee shall comply with CEPI's Animals in Research Policy.

(h) To the extent applicable to the Project, Awardee may rely upon its own substantially similar policies and principles so as to comply with: (i) CEPI's Clinical Trials Policy; (ii) CEPI's Managing Conflicts of Interest Policy; (iii) CEPI's Scientific Integrity Policy; and (iv) CEPI's Travel and Expenses Policy.

(i) Awardee shall comply with the provisions of the Third Party Code related to Sub-Contracts (Section 14 of the Code) and to Sub-Grants (Section 15 of the Code).

11.3 **Compliance Audit**. During the Term and for a period of five (5) years after expiration or termination of this Agreement, CEPI, or an auditor appointed by CEPI, shall be entitled to audit Awardee's performance of its compliance obligations under this Agreement, upon reasonable notice. Such audits may include requests for documentation concerning Awardee's own costs as well as Subawardees' costs in connection with the Project, and Awardee shall use all reasonable endeavours to provide such documentation to CEPI without undue delay.

11.4 **Compliance by Sub-Contractors and Sub-Grantees**. CEPI's Third Party Code and Cost Guidance apply to all third parties which receive funds from CEPI, either directly or indirectly. The compliance obligations in this Clause 11 of the Agreement therefore also apply to all Sub-Contractors and Sub-Grantees and Awardee shall ensure that all such Sub-Contractors and Sub-Grantees comply in full with the obligations set out in this Clause 11.

12 <u>Ready Reserve of Clinical Trial Material</u>:

12.1 **Ready Reserve.** CEPI may instruct and fund Awardee to undertake the manufacturing and maintenance of a Ready Reserve of Clinical Trial Material through an additional Work Package, which may include doses from consistency batches if so directed by CEPI. For purposes of this Agreement, a "Ready Reserve of Clinical Trial Material" means a quantity of doses for potential use in a clinical trial, which Project Vaccine has not yet received a marketing approval. Such Ready Reserve of Clinical Trial Material may be used for further clinical trials, to advance product development and for emergency use subject to obtaining all necessary regulatory approvals and consents, in each case in emergency situations based on national or international guidance (such as from WHO) or in such other manner, in each case as CEPI may reasonably determine. If required by CEPI, an additional Work Package covering such activities shall be negotiated expeditiously and in good faith by the Parties.

12.2 **Management of Ready Reserve**. The Parties agree that CEPI may delegate the management of the Ready Reserve of Clinical Trial Material to WHO or another CEPI designee, at its discretion.

13 Project Continuity:

13.1 **Awardee Contingency Plan**. Awardee shall prepare and maintain a contingency plan to minimise any potential disruption to the Project, and provide a copy of the plan to CEPI in confidence as it relates to the Project as required under the iPDP.

13.2 **Project Continuity Plan**. Because of the exigent nature of the Outbreak, the iPDP shall include a Project Continuity Plan that, at a minimum, shall address the following items:

(a) responsibilities and level of access on the part of other collaborators, Subawardees and consortium members, if any, to Project Results and Enabling Rights;

(b) management of key Project Materials through participants in the Project and other entities such as the BioEscrow® deposit service of the American Type Culture Collection;

(c) identification of a proposed third party, within a timeframe to be established in the iPDP, such as a Subawardee, under contract to Awardee, which is capable of performing the activities in agreed Work Packages, any additional Work Packages or a Project expansion ("**Trusted Collaborator**"), in the event that Awardee is unable to continue its activities under this Agreement or declines CEPI's request to undertake additional Work Packages or a Project expansion. Awardee's Subawardee agreement(s) with Trusted Collaborator shall expressly permit Awardee to assign the agreement to CEPI if so requested by CEPI pursuant to Clause 13.6; and

(d) requirement for the Awardee to use its reasonable endeavours to sign Subawardee agreement(s) with one or more operational manufacturing facilities at one or more geographically dispersed manufacturing sites located in LMICs, within a timeframe to be established in the iPDP, or within such other time period as may be set out in the iPDP from time to time, which Awardee will contract with as described in the iPDP to produce Project Vaccine for use in the Field ("**Trusted Manufacturer**"). Awardee's Subawardee agreement(s) with Trusted Manufacturer(s) shall (i) comply with the relevant requirements of this Agreement; (ii) enable Awardee to use the Trusted Manufacturers to produce the Project Vaccine for supply in accordance with Clause 15.5 (Volume Commitment); (iii) shall include a right for CEPI to reserve manufacturing capacity with the Trusted Manufacturer; and (iv) shall expressly permit Awardee to assign the agreement to CEPI if so requested by CEPI pursuant to Clause 13.6. The terms of such Subawardee agreement shall be subject to CEPI's prior written consent. Awardee shall notify CEPI of the identity of the Trusted Manufacturer(s) and provide a copy of the relevant final Subawardee agreement(s) to CEPI without undue delay after the entry into the Subawardee agreement(s).

13.3 **Alternative Designations by CEPI**. If Awardee does not designate a Trusted Collaborator and/or Trusted Manufacturer, or a designated Trusted Collaborator and/or Trusted Manufacturer notifies Awardee that they are no longer available, then CEPI may propose a Trusted Collaborator or Trusted Manufacturer to Awardee. Neither Party may unreasonably decline to accept the designation of a proposed Trusted Collaborator under Clause 13.2 or this Clause 13.3. Once designated and under contract to pursue Project activities, a Trusted Collaborator and Trusted Manufacturer shall be a Subawardee for the purposes of this Agreement.

13.4 **Public Health Licence**. Subject to the terms of this Agreement, Awardee hereby grants (and shall ensure that each Subawardee grants) a worldwide, non-exclusive, irrevocable, fully paid up, royalty free Public Health Licence to CEPI, on the condition that CEPI may only exercise the rights granted under the Public Health Licence in the event that:

(a) CEPI is not in material breach of its obligations under this Agreement; and

(b) one or more of the triggers set out in Clause 13.5 has occurred.

CEPI shall be entitled to sublicense Project Results and Enabling Rights included in the Public Health Licence in accordance with this Clause 13. Each sublicence shall be in writing and CEPI shall require that each sublicensee complies with the terms of the Public Health Licence.

13.5 **Public Health Licence Triggers**. Consistent with Clause 13.4, CEPI shall have the right to exercise the Public Health Licence in the event that any one or more of the following events occurs:

(a) Awardee declines to participate in an additional Work Package or Project expansion that CEPI has offered to fund, either directly or indirectly through a Subawardee;

(b) CEPI and Awardee agree, in good faith, that Awardee shall not be able to perform the activities under an agreed Work Package, either directly or indirectly through a Subawardee;

(c) Awardee is in material breach of this Agreement or the Equitable Access Plan and has not cured such breach within thirty (30) Business Days of notification of such breach by CEPI, unless otherwise mutually agreed in writing; or

(d) the Agreement is terminated by CEPI pursuant to Clause 20.2(a)-(b) (default or insolvency) or 20.3(c) – (e) (unavailability to perform Project activities, failure to satisfy payment criteria or fraud).

For clarity, CEPI shall only have the right to exercise the Public Health Licence in the events set out in Clauses 13.5(a) and (b) during the Term.

In the event that CEPI exercises the Public Health Licence, CEPI shall provide prompt written notice of such exercise to VBI and shall use its reasonable endeavours to exploit the rights granted to it under such Public Health Licence. On expiry of the later of (i) the Term; (ii) the date that is five years from the end of the Pandemic Period; or (ii) ten years from the Effective Date; and provided that CEPI has not exercised its rights under the Public Health License in accordance with this Clause 13.5, the Public Health License granted pursuant to Clause 13.4 shall lapse and be of no further force and effect.

13.6 **Agreement between CEPI and the Trusted Collaborator or Trusted Manufacturer**. In the event that the Public Health Licence is exercised, CEPI may request assignment of the relevant Trusted Collaborator or Trusted Manufacturer contracts from Awardee to CEPI or, at CEPI's discretion, CEPI may endeavour to reach agreement directly with the Trusted Collaborator and/or Trusted Manufacturer, as the case may be, to perform such activities as CEPI may deem necessary. At CEPI's request, Awardee shall use all reasonable endeavours to facilitate the conclusion of a direct contractual relationship between the Trusted Collaborator or Trusted Manufacturer, as the case may be, and CEPI. If those negotiations do not result in an agreement within twenty (20) Business Days from the initiation of negotiations, then CEPI may grant rights under its Public Health Licence to a third party unilaterally designated by CEPI as a Trusted Collaborator or Trusted Manufacturer, without approval from Awardee.

13.7 **Effects of Exercise of the Public Health Licence**. Upon exercise of the Public Health Licence by CEPI and provision of written notice to Awardee, Awardee shall promptly:

(a) provide CEPI with an up-to-date list of Enabling Rights and applicable Background IP, along with an invoice for any payments due under any licence agreement for Third Party Background IP attributable to the grant of the Public Health Licence to CEPI or a sublicensee;

(b) provide CEPI with a good faith schedule of key technology transfer activities and estimated direct costs for the technology transfer in Clause 13.6;

(c) promptly and diligently transfer to the Trusted Collaborator and/or Trusted Manufacturer, as the case may be, all Project Results, Project Materials described in Clause 13.2(b), all guidance, information, materials and assistance reasonably required to accomplish the Project activities identified by CEPI. Such transfer shall be (i) in the event the Public Health Licence is exercised by CEPI pursuant to Clause 13.5(a) or (b), at CEPI's reasonable cost; or (ii) in the event the Public Health Licence is exercised by CEPI pursuant to Clause 13.5(c) or (d), at Awardee's cost; and

(d) and Awardee hereby does undertake not to sue CEPI or its designee for the exercise of the Public Health Licence.

14 Further Development Projects:

14.1 **Additional COVID-19 Candidate.** During the Term (including any period of continued funding), CEPI shall have the first right (but not the obligation), at CEPI's sole discretion, to elect to contribute funding to support the Awardee for the development, manufacture and deployment of any Additional COVID-19 Candidate. In the event that Awardee identifies any Additional COVID-19 Candidate, Awardee shall provide prompt written notice to CEPI of the existence of such Additional COVID-19 Candidate (an "**Additional COVID-19 Candidate Notice**") and shall provide to CEPI a summary of all material information and data regarding such Additional COVID-19 Candidate available to Awardee. Awardee shall further provide to CEPI all such information as CEPI may reasonably request regarding such Additional COVID-19 Candidate in order for CEPI to evaluate its interest in providing funding support for the development, manufacture and/or deployment of such Additional COVID-19 Candidate. Within thirty (30) days of receipt by CEPI of any Additional COVID-19 Candidate Notice, CEPI shall provide written notice to Awardee of its desire to provide funding support to Awardee for the development, manufacture and deployment of such Additional COVID-19 Candidate. If CEPI elects to provide such funding support to Awardee, Awardee and CEPI shall discuss and agree, in good faith, a Work Package detailing the rapid development, manufacture and deployment of the Additional COVID-19 Candidate and, following the written agreement of both Parties to the Work Package and updated iPDP, such Additional COVID-19 Candidate shall become a Project Vaccine. If CEPI does not elect to provide funding support in respect of any Additional COVID-19 Candidate within thirty (30) days of receipt by CEPI of any Additional COVID-19 Candidate Notice, then Awardee shall be free to develop and seek funding from any third party for such development of the relevant Additional COVID-19 Candidate.

14.2 **Disease X Project**. During the Term and for a period of five (5) years after expiration or termination of this Agreement, CEPI may provide written notice to the Awardee at any time if it wishes to discuss the funding of a further project to be performed by Awardee for the development, manufacture and/or deployment of a platform technology which could be used in respect of any unknown "disease X" that poses (or has the potential to pose) an increased public health risk due to its epidemic potential, as may be identified by CEPI or listed on the WHO Blueprint from time to time. For a period of five (5) years after expiration or termination of this Agreement, CEPI may also provide written notice to the Awardee at any time if it wishes to discuss the funding of any Additional COVID-19 Candidate. Following receipt of any such written notice by Awardee, CEPI and Awardee shall negotiate expeditiously and in good faith the terms of a new agreement for any such further project, and any funding to be provided by CEPI to Awardee in respect of such project for a period of up to ninety (90) days. Both Parties shall use their reasonable endeavours to agree to terms relating to any such further project within ninety (90) days but neither party shall be obligated to enter into an agreement. For clarity, neither Party shall be deemed to have defaulted under or to be in breach of this Section 14.2 for failure to agree such terms within the ninety (90) day period, provided that the relevant Party has used its commercially reasonable endeavours to do so.

15 **Equitable Access:**

15.1 **Commitment to Equitable Access**. The Awardee and CEPI each confirm that they are committed to achieving "Equitable Access" to the results of all CEPI-supported programmes whether in an outbreak or pandemic situation in accordance with the "Equitable Access Policy" referenced in CEPI's Third Party Code and in Clause 11.2. Equitable Access means that a Project Vaccine will be made available first to populations at risk when and where they are needed at affordable prices.

15.2 **Project Vaccine Registration**. Awardee shall cooperate with CEPI or CEPI's designee to take such actions as are reasonably agreed and funded as agreed between the Parties in the Budget to register Project Vaccines in countries identified as priorities which are set out in the iPDP or as may be mutually agreed by the Parties in an advanced purchase agreement or otherwise. If Awardee is not the licence holder for the purposes of registration in a given country, then Awardee shall be responsible for ensuring that any applicable Subawardee facilitates such registrations as instructed by and funded as agreed between the Parties in the Budget. As soon as practicable, Awardee shall liaise with WHO to apply for WHO pre-qualification or a similar registration system to the extent available and shall implement such systems as soon as they have been approved by WHO.

15.3 **Global Allocation and Purchase**. It is the Parties' expectation that Gavi, pursuant to COVAX (or a similar purchasing entity as otherwise reasonably directed by CEPI), shall provide funding to purchase the Project Vaccine and be responsible for its allocation. Awardee shall respond promptly to any Gavi or UNICEF or CEPI identified Request for Proposal for a COVID-19 vaccine. Awardee shall negotiate in good faith with Gavi (or as otherwise reasonably directed by CEPI) to sign a purchase commitment or purchase order to supply Project Vaccine as may be required by Gavi, CEPI or any designee of Gavi or CEPI whether during or after a Pandemic Period, in accordance with and subject to the provisions of Clauses 15.5 and 15.7. As part of the good faith negotiation, the Parties shall negotiate and settle the costs, expenses and other factors to be used in the calculation of COGs, such negotiation and settlement to, at all times, be guided by and reflect the principle that Awardee shall not suffer financial losses when supplying Project Vaccine to any market and take into account the amount of funding provided by CEPI and any other grants or public funding received by Awardee or Subawardee from third parties.

15.4 **Pandemic Period Production Reporting**. During the Pandemic Period, Awardee shall:

(a) provide the JMAG with a regularly updated quarterly statement of its actual capacity and a forecast of its planned capacity for the following four (4) calendar quarters for the manufacturing of Project Vaccine under this Agreement and otherwise;

(b) provide the JMAG with advance notice in writing of all manufacturing runs for the Project Vaccine in accordance with agreed forcasting;

(c) discuss in good faith with the JMAG how to achieve its requirements for doses of Project Vaccine, including any potential increase in Awardee's manufacturing capacity.

15.5 **Volume Commitment**. Awardee shall:

(a) during the Pandemic Period, produce Project Vaccine in quantities which shall be at least equal to the quantities described in the Work Package(s);

(b) during the Pandemic Period, subject only to the Awardee's supply obligations under the Pre-existing Agreements (including Section 6.3.1 of the Canada Agreement) which have been communicated to CEPI as required under the iPDP, offer the Volume Commitment Percentage of the Project Vaccine produced pursuant to Clause 15.5(a) for purchase by Gavi, CEPI or their respective designees pursuant to Clause 15.3 during the Pandemic Period. For clarity, Awardee may not allocate or agree to supply such Project Vaccine doses to other third parties, other than as required pursuant to the Pre-existing Agreements, during the Pandemic Period without the express written permission of Gavi, CEPI or their respective designee;

(c) After the Pandemic Period, for a period lasting until the later of (i) five years from the end of the Pandemic Period; or (ii) ten years from the Effective Date; subject to the same limitations as Section 15.5(b), if CEPI determines in its reasonable discretion in consultation with the Awardee that a regional but not a global Outbreak exists, then Awardee shall offer a percent of the total quantity of the Project Vaccine produced for purchase by Gavi, CEPI or their respective designees pursuant to Clause 15.3 equal to the Volume Commitment Percentage multiplied by the percentage of the world population that resides in the region in which the Outbreak exists; *save that* where a regional Outbreak exists in a relatively small population (as reasonably determined by CEPI), the Parties shall discuss in good faith an increase in the Volume Commitment Percentage in order to adequately address such an Outbreak. For example, if the Volume Commitment Percentage was ** and there was an Outbreak in Africa, then, based on 2020 census data, approximately ** of Project Vaccine would be offered for purchase by Gavi;

(d) supply Project Vaccine doses to COVAX in a timely manner that enables COVAX represented economies to receive Project Vaccine in a similar timeframe to other third party customers;

(e) consistent with the commitments in Clauses 15.4 to 15.6, subject only to the Awardee's supply obligations under the Pre-existing Agreements (including Section 6.3.1 of the Canada Agreement) which have been communicated to CEPI as required under the iPDP, sell the Project Vaccine doses to Gavi, CEPI or their respective designees during and after the Pandemic Period pursuant to Clause 15.3; and

(f) upon receipt of written request from CEPI, provide reasonable information to CEPI about its production, supply, pricing and sales of Project Vaccine which is sufficient for CEPI to evaluate whether such activities are in accordance with Awardee's obligations under this Agreement;

(g) subject only to the Awardee's supply obligations under the Pre-existing Agreements (including Section 6.3.1 of the Canada Agreement) which have been communicated to CEPI as required under the iPDP, use its Commercially Reasonable Efforts to provide an amount of doses to be reasonably determined by CEPI based on the Awardee's worldwide supply capacity and the level and timing of CEPI's funding contribution to the global initiative "Access to COVID-19 Tools (act) Accelerator" so as to ensure availability for all, subject to the inclusion of satisfactory liability protection (which may include participation in the Gavi no fault compensation programme) and regulatory conditions. This Agreement does not cover specific details with regard to the provision of doses to the COVID-19 Tools (act) Accelerator to be concluded and agreed separately with the relevant parties involved.

15.6 **Commercially Reasonable Efforts**. With regard to its obligations under this Agreement, Awardee shall use its Commercially Reasonable Efforts to address the urgent medical need created by the COVID-19 pandemic by fulfilling such obligations, including achieving the objectives and timelines of each Work Package (including each Stage Gate in a Work Package) within the agreed timeframe, it being agreed that Awardee does not represent or warrant any particular outcome for any Work Package or any activity described in a Work Package or this Agreement.

15.7 **Post-Pandemic Period Production and Supply**. After the Pandemic Period, for a period lasting until the later of (i) five years from the end of the Pandemic Period; or (ii) ten years from the Effective Date, Awardee shall continue to produce and supply the Project Vaccine for purchase by Gavi, CEPI or their respective designees pursuant to Clause 15.3, as is required by Gavi, CEPI or their respective designees to meet the needs of AMC Countries for so long as there is demand for such supply, which quantity shall be set out in an advanced purchase agreement between the Awardee and Gavi, CEPI or their respective designees. Awardee shall negotiate and agree on the terms of any such advanced purchase agreement with Gavi, CEPI or their respective designees expeditiously and in good faith but Awardee shall not, for greater certainty, be subject to any commitments regarding volume save as otherwise set forth in Clause 15.5(c). Awardee undertakes to continue to sell Project Vaccine after the Pandemic Period for a period lasting until the later of (i) five years from the end of the Pandemic Period; or (ii) ten years from the Effective Date, to AMC Countries and to public sector entities that procure the Project Vaccine for use in AMC Countries (if there is a demand for such supply), at a reasonable price to achieve Equitable Access for populations in need of a Project Vaccine as well as an appropriate return on investment for vaccine manufacturers, and ensuring that on-going supply is commercially sustainable.

15.8 **Re-emergence of Pandemic:** In the event that the Pandemic Period has ended but there is a re-emergent pandemic caused by SARS-CoV-2, then the Parties shall negotiate in good faith to amend the agreement to address the Parties obligations during that period, in a manner consistent with the principles of Equitable Access applicable to the Pandemic Period set out in this Clause 15 (including in respect of timelines, supply volume and access).

15.9 **Pricing Objectives**. The Parties acknowledge that the price of the Project Vaccine is critical to achieving Equitable Access. Accordingly, Awardee agrees that its pricing shall be as reasonably required to achieve both Equitable Access for populations in need of a Project Vaccine as well as an appropriate return on investment for vaccine manufacturers, and ensuring that on-going supply is commercially sustainable. The Parties acknowledge that the availability of pandemic insurance as described in Clause 18.7 shall be relevant to pricing. For clarity the following shall be considered to have satisfied the Equitable Access Plan for the relevant doses of Project Vaccine:

(a) the purchase of Project Vaccine by Gavi, CEPI or their respective designee during the Pandemic Period as described above in this Clause 15;

(b) during the Pandemic Period, and in respect of any region in which an epidemic is determined to exist according to Section 15.5(c), the sale of the Project Vaccine to Gavi, CEPI or their respective designee at no more than (i) ** for allocation to LMICs; (ii) ** for allocation to UMICs and (iii) ** for allocation to HICs; provided always that in each case the sale of the Project Vaccine to Gavi, CEPI or their respective designee shall be at a price that is no higher than the lowest price at which Awardee sells the Project Vaccine to any third party in respect of the relevant country other than as contemplated by the Canada Agreement;

(c) after the Pandemic Period for a period ending on the later of (i) five years from the end of the Pandemic Period; or (ii) ten years from the Effective Date, the sale of the Project Vaccine to Gavi, CEPI or their respective designee at no more than ** for allocation to LMICs, provided always that in each case the sale of the Project Vaccine to Gavi, CEPI or their respective designee shall be at a price that is no higher than the lowest price at which Awardee sells the Project Vaccine to any third party in respect of the relevant country; and

(d) during the Pandemic Period and after the Pandemic Period for a period ending on the later of (i) five years from the end of the Pandemic Period; or (ii) ten years from the Effective Date, the sale of the Project Vaccine not acquired by Gavi, CEPI or their respective designee at no more than ** for allocation to LMICs.

15.10 **Costs and Sales**. Consistent with the commitments and limitations in Clauses 15.4 to 15.9, Awardee shall:

(a) provide written quarterly updates to the JMAG during the Term and to CEPI during any period after the expiry of the Term that Awardee is making sales of Project Vaccine pursuant to Section 15.3 regarding its COGs for Project Vaccines and discuss relevant product development decisions that could affect COGs; and

(b) sell the Project Vaccine doses to Gavi, CEPI, or CEPI's designee during and after the Pandemic Period pursuant to Clause 15.3.

15.11 **Information about Production, Supply, Pricing and Sales**. At any time during the Term, and during any period after expiry of the Term that Awardee is making sales of Project Vaccine pursuant to Section 15.3, upon written request by CEPI, Awardee shall provide reasonable information about its COGs, production, supply, pricing and sales of Project Vaccine sufficient to enable CEPI to evaluate whether such activities meet the Equitable Access Policy.

15.12 **Audit of Cost of Goods**. At any time during the Term, and during any period after expiry of the Term until the date that is five (5) years after the expiry of any pricing obligations pursuant to Clause 15.9, no more than once per twelve (12) month period and at CEPI's reasonable cost, CEPI shall have the right to review or to designate an external auditor (which shall be an internationally recognised certified public accounting firm, not engaged on a contingent basis) to review Awardee's financial records relevant to the information provided in Clause 15.9. Such audits will be conducted during normal operating hours in a manner which minimises disruption to Awardee's business. In the event that the audit concludes that the COGs and production, allocation, supply or pricing of Project Vaccine doses are not substantially in accordance with the pricing obligations in Clause 15, then Awardee shall: (i) reimburse the reasonable costs of the audit; and (ii) take immediate steps, as advised by the auditors, to comply with the requirements of this Clause 5. The provisions of this Clause 15.12 shall also apply to any Subawardees and Trusted Collaborators.

15.13 **Equitable Access Plan**. The Equitable Access Plan shall be reviewed by JMAG no less than every six (6) months and shall take into account changes in COGs over time, production yield and volume and production economics. The Equitable Access Plan shall be regularly updated during the Term of this Agreement.

15.14 **Alternative to Purchase by Gavi**. In the event that Gavi does not procure Project Vaccine as set out by the Parties in Clause 15.3, or does not continue such activities after the Pandemic Period relevant to this Clause 15, then CEPI, or its designee or their designated purchasing agent(s), shall have the rights accorded to Gavi in this Clause 15.

16 Commercial Benefits:

16.1 **Commercial Benefits**. CEPI is required by its own funders to obtain a share of any Awardee's Commercial Benefits as a contribution to support CEPI's programme activities. For clarity, examples of Commercial Benefits include the sales of a Project Vaccine at market prices, commercial licensing of Project IP, receipt of government-granted incentives such as Priority Review Vouchers and revenue from the commercialisation of combination, derivative or follow-on products (including antibody products, assays and vaccines) or application of production technology resulting in whole or part from CEPI funding.

16.2 **Waiver of Commercial Benefits**. In consideration for Awardee's acceptance and compliance with the provisions of Clause 15, CEPI agrees to forgo any share of potential Commercial Benefits otherwise applicable under Sub-Clause 16.1 during the Pandemic Period. Following the Pandemic Period and except during a period of regional Outbreak pursuant to Section 15.5.(c), the Awardee shall promptly notify CEPI of any Commercial Benefits in respect of any sales of a Project Vaccine for which CEPI provides funding through Phase 2 clinical studies (or any Project Vaccine if (i) this Agreement is terminated by CEPI pursuant to Clause 20.2 or Clause 20.3(c) – (e); or (ii) Awardee does not accept further funding from CEPI offered on similar terms to those set out in this Agreement) in any country other than an AMC Country. Following receipt by CEPI of any such notice, Awardee and CEPI shall discuss the sharing of such Commercial Benefits in the Field, commensurate with CEPI's funding contributions and stage of investment, through an appropriate mechanism agreed in good faith by the Parties within ninety (90) days.

17 **Representations and Warranties:**

17.1 **Awardee Warranties**. Awardee warrants that the following statements are true and correct to its reasonable knowledge and belief in so far as they relate to the Project as of the Effective Date:

(a) it has the full power and authority to enter into and assume its obligations under this Agreement;

(b) this Agreement has been duly executed and is legally binding and enforceable in accordance with its terms:

(c) it is in material compliance with all statutes, regulations, directives and requirements of any governmental entity;

(d) it does not infringe, misappropriate or violate the intellectual property, privacy or publicity rights of any third party;

(e) it is not under any obligation, contractual or otherwise, to any person or third party in respect of the Enabling Rights that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the complete fulfillment of its obligations under this Agreement;

(f) it has disclosed in writing to CEPI any actual or contemplated commitments or obligations to third parties for Project Vaccine doses;

(g) it has identified Enabling Rights in writing to CEPI;

(h) neither Awardee nor agreed Subawardees, if any, nor any officer or employee of the foregoing has been debarred or is subject to debarment by a regulatory authority or funding agency anywhere in the world;

(i) all financial and other information submitted to CEPI in relation to this Agreement is true, complete and accurate in all material respects; and

(j) to the extent that Awardee relies upon its own processes, procedures and policies to the extent specifically permitted for purposes of compliance with Clause 11.2, such processes, procedures and policies are substantially similar to those of CEPI.

17.2 **Awardee Representations**. During the Term of this Agreement, Awardee shall:

(a) notify CEPI promptly in writing in the event that any of the warranties set out in Sub-Clause 17.1 are no longer true and correct, and shall so notify CEPI at least at the time that Awardee requests any disbursement of Project funds;

(b) provide written updates to the JMAG regarding Enabling Rights acquired or created during the course of the Project;

(c) notify CEPI before accepting third-party funds related to the Project (not including public financings on a stock exchange, receipt of funds pursuant to the Canada Agreement or receipt of funds pursuant to the Loan and Guaranty Agreement dated May 22, 2020 between Variation Biotechnologies Inc., the Awardee and K2 Health Ventures LLC);

(d) make no encumbrances over, dispose of, or otherwise deal with the Project Results, Project Intellectual Property and/or Enabling Rights in any way that could be reasonably deemed inconsistent with this Agreement, including the Public Health Licence, or that could impede the complete fulfillment of its obligations under this Agreement, without the express written permission of CEPI; and

(e) notify CEPI promptly if it becomes aware that any actions are likely or have already been taken by the government of any country in which Awardee shall conduct Project activities that may adversely affect Awardee’s commitments in this Agreement, including Equitable Access. For clarity, such government actions may relate, for example, to the exercise of eminent domain or sovereign rights over Project Vaccine doses.

17.3 **Additional Awardee Representation**. In the event that the Public Health Licence becomes exercisable and irrespective of whether the Agreement has expired or been terminated, Awardee shall make no encumbrances over, dispose of, or otherwise deal with the Project Results, Project Intellectual Property and/or Enabling Rights, in any way that may be inconsistent with the Public Health Licence, without the express written permission of CEPI.

17.4 **CEPI Warranties**. CEPI warrants that the following statements are true and correct to its reasonable knowledge and belief, in so far as they relate to the Project:

(a) it has the full power and authority to enter into and assume its obligations under this Agreement;

(b) it is in material compliance with all statutes, regulations, directives and requirements of any governmental entity; and

(c) it has not granted rights to any third party in respect of Project Results (other than in accordance with the terms of this Agreement).

17.5 **No Other Warranties**. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NO PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF PATENTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

18 **Insurance, Liability and Indemnification:**

18.1 **Insurance**. Awardee shall maintain insurance sufficient to cover the activities, risks, and potential omissions relevant to the Project, including clinical trial liability insurance cover, in accordance with generally accepted industry standards and as required by law. Awardee shall provide CEPI with a certificate confirming such insurance upon request. In the event that the Public Health Licence becomes exercisable and CEPI exercises such rights, CEPI shall maintain comparable insurance protection.

18.2 **Indemnification for Third Party Claims**. Awardee shall indemnify and defend CEPI, its Affiliates, officers, directors, third party contractors, and employees, from and against any and all damages, and liabilities arising from claims asserted by third parties (including claims for negligence) which arise directly or indirectly out of or in connection with: (i) a breach of Awardee's, or its Affiliate's or Subawardee's obligations under this Agreement; (ii) the research, development, manufacture, promotion or use of any Project Vaccine, Project Results or Enabling Rights (including for clarity, the use of any Project Results in development activities and clinical studies) conducted by Awardee, or its Affiliates or Subawardees; or (iii) any claim that the use of Awardee's Intellectual Property Rights infringe the intellectual property rights of any third party, except to the extent such claim, damage or liability is caused by CEPI's negligence or intentional misconduct. In the event that the Public Health Licence becomes exercisable and CEPI exercises such rights, the obligations of this Clause 18.2 shall apply to CEPI *mutatis mutandis*.

18.3 **Conduct of Responses to Third Party Claims**. Each Party shall use all reasonable endeavours to inform the other Party promptly of any circumstances that are likely to give rise to a third party claim which may be covered by Clause 18.2 together with copies of all relevant papers and official documents. The indemnified party shall not take any material action in respect of any third party claim which is covered by Clause 18.2 without the consent of the indemnifying party, including any settlement of any such third party claim, provided such consent is not unreasonably conditioned, withheld or delayed. The indemnifying party shall have the right to assume control of defence of the claim and shall keep the indemnified party fully informed of the progress of all relevant third party claims which are covered by Clause 18.2 and shall fully consult with the indemnified party on the nature of any defence to be advanced in advance. The indemnified party may have its counsel participate in (but not control) the defence of a claim, at the indemnified party's own expense.

18.4 **Exclusions**. Except in the event of a breach of a Party's confidentiality obligations under Clause 19, neither Party shall be liable to the other Party for any loss of profits or economic loss; or indirect, incidental or consequential damages, whether in contract, warranty, negligence, tort, strict liability or otherwise, arising out of or in connection with any breach of or failure to perform any of the provisions of this Agreement.

18.5 **Liability Cap**. CEPI's maximum liability in aggregate to Awardee arising out of this Agreement shall not exceed the aggregate of the total Work Package budget unless CEPI has exercised the Public Health Licence in which event CEPI's maximum liability to Awardee arising out of this Agreement shall not exceed the greater of: (i) the aggregate of the total Work Package budget or (ii) CEPI's total insurance cover for any clinical trials or provision of Project Vaccine under the Public Health Licence.

18.6 **Exclusions from Liability Cap**. Notwithstanding the foregoing, nothing in this Agreement shall limit the liability of either Party in respect of: (i) personal injury or death arising out of that Party's negligence or intentional misconduct; or (ii) fraud or fraudulent misrepresentation or intentional misconduct.

18.7 **Pandemic Insurance**. The Parties acknowledge that, as of the Effective Date, WHO is considering an insurance mechanism that would provide insurance cover for the suppliers of investigational products for use in the case of a PHEIC declared by WHO. The Parties agree that, if and when this mechanism is established, they shall discuss in good faith the impact of such arrangements on the Parties' obligations under this Agreement and how it would apply to the supply of Project Vaccines.

19 **Confidentiality:**

19.1 **Confidential Information**. Confidential Information means non-public information disclosed by one Party to the other and includes, in the case of Awardee, non-public information relating to its products, inventions, clinical trials and data. For avoidance of doubt, for so long as none of the exceptions in Clause 19.2 apply, COGs, production, supply, pricing and sales of Project Vaccine shall be deemed Confidential Information of Awardee, provided however that CEPI shall have the right to use and disclose such Confidential Information in a manner that anonymises Awardee's identity by aggregating it with similar information from other of CEPI's awardees or third parties. Each Party undertakes that during the Term of this Agreement as defined in Sub-Clause 20.1 and for five (5) years after its expiry or termination, it shall keep confidential and not disclose the other Party's Confidential Information to any person other than its employees, agents, consultants, contractors, professional advisers, Subawardees and regulatory authorities and, in the case of CEPI, Gavi, COVAX, its funders and Assessors, who have a need to know and agree to respect its confidentiality. Each Party shall take commercially reasonable precautions to protect against unauthorised disclosure and shall use the other Party's Confidential Information only for the purposes of carrying out is obligations under, and achieving this objectives of, this Agreement. For clarity, Project Results may be disclosed and utilised by the Parties as set out in and subject to the terms of this Agreement.

19.2 **Confidentiality Limitations**. Confidential Information shall not include:

(a) information already known to the receiving Party or its Affiliates and which is not subject to pre-existing obligations of confidentiality;

(b) information that is independently developed by the receiving Party or its Affiliates;

(c) information that is or becomes part of the public domain other than by unauthorised disclosure by receiving Party;

(d) information properly obtained by the receiving Party or its Affiliates from a source that, to the best knowledge of the receiving Party, is not bound by a confidentiality obligation to the disclosing Party; and

(e) information to the limited extent that is required to be disclosed by a competent legal authority; provided that, where it is free to do so, the receiving Party shall give notice of such disclosure requirement to the disclosing Party as soon as reasonably practicable.

20 <u>Term and Termination:</u>

20.1 **Term**. This Agreement shall commence on the Effective Date identified in the Agreement Summary and shall continue in full force and effect until the earlier of: (i) five (5) years from the Effective Date; (ii) the time that all activities set out in any active Work Packages, including any additional Work Packages, have been completed including delivery of any payments; and (iii) the termination of this Agreement pursuant to this Clause 20 (the "**Term**").

20.2 **Termination by Either Party for Default or Insolvency**. Either Party (the "**Terminating Party**") may terminate this Agreement by giving written notice of termination, effective immediately, if the other Party (the "**Defaulting Party**"):

(a) breaches a material obligation in this Agreement and either fails to cure that breach within a cure period of thirty (30) Business Days after notice from the Terminating Party or such longer time if agreed in writing or, if the breach is not reasonably capable of cure within thirty (30) Business Days, fails to take prompt and reasonable steps to cure the breach and maintain such diligent efforts until cure is achieved; or

(b) makes any statutory arrangement with its creditors, resolves to or undergoes any insolvency proceeding anywhere in the world (except for the purpose of solvent amalgamation or reconstruction).

20.3 **Other Termination by CEPI**. CEPI shall be entitled, in its sole discretion, to terminate this Agreement by providing written notice of termination to Awardee in the following circumstances:

(a) with immediate effect if CEPI notifies Awardee that there are material safety, regulatory, scientific misconduct or ethical issues associated with continuing the Project, as reasonably determined by CEPI and, if such issue is capable of remedy, Awardee has failed to remedy such issue within ten (10) Business Days;

(b) upon thirty (30) Business Days' prior notice in writing, if CEPI determines that the Project must be materially limited in scope or terminated;

(c) CEPI reasonably determines that Awardee is unable to discharge its obligations under this Agreement, for example if key personnel or technology resources required for successful completion of the Project become unavailable to Awardee permanently or for a material period of time, and Awardee does not reasonably alleviate CEPI's concerns within a cure period of thirty (30) Business Days or such longer time as may be agreed by the Parties in writing;

(d) Awardee does not satisfy the criteria in Clause 3.4 required for CEPI to pay funding tranches under a Work Package and fails to satisfy those criteria in full within a cure period of forty (40) Business Days or such longer time as may be agreed by the Parties in writing; or

(e) Awardee has committed fraud or a Financial Irregularity. For purposes of this Agreement, "**Financial Irregularity**" includes any and all kinds of corruption, including bribery, nepotism and illegal gratuities; misappropriation of cash, inventory and all other kinds of assets; and making fraudulent financial and non-financial statements to CEPI.

20.4 **Payments After Certain Terminations by Awardee**. If this Agreement is terminated by Awardee pursuant to Clause 20.2(a) - (b) (default or insolvency on the part of CEPI) or terminated by CEPI pursuant to Clause 20.3(a) – (b) (issues precluding continuation of the Project or limiting of Project Scope by CEPI), then CEPI shall reimburse Awardee for all reasonably incurred expenses through termination and any non-cancellable expenses relating to Project activities that were included in the iPDP and/or authorised in writing by CEPI and including those that arise through termination and after the termination date, solely to the extent they are not otherwise covered by CEPI funding and provided always that Awardee uses all reasonable endeavours to minimise and mitigate any such expenses.

20.5 **Effects of Termination by CEPI under Clause 20.2(a) - (b) or 20.3(c) - (d).** If this Agreement is terminated by CEPI pursuant to Clause 20.2(a) - (b) (default or insolvency on the part of Awardee) or 20.3(c) - (d) (inability to proceed or financial issues with Awardee), then CEPI shall reimburse Awardee for all expenses reasonably incurred prior to termination and any non-cancellable expenses relating to the Project activities that were included in the iPDP and/or authorised in writing by CEPI and that arise either before or after the date of termination, provided always that Awardee uses all reasonable endeavours to minimise and mitigate any such expenses. Additionally, Awardee shall use all reasonable endeavours to, and only to the extent required to practice CEPI Public Health License, at CEPI's expense:

(a) make all Project Data publicly available in such manner as CEPI may direct, except to the extent that to do so would result in the public disclosure of Enabling Rights or Awardee Confidential Information or Confidential Information of a third party that would not otherwise reasonably be publicly disclosed;

(b) at CEPI's sole discretion, either authorize access to or dispatch to CEPI (or its designee) by registered post or reputable courier services all Project Materials within twenty (20) Business Days of CEPI requesting such Project Materials in writing;

(c) grant rights to CEPI (or its designee) to any regulatory approvals and applications for regulatory approvals relating to the Project Vaccine;

(d) within twenty (20) Business Days of the date of termination, provide CEPI with an up-to-date list of all sublicence, contract manufacturing agreements and other third party agreements and arrangements to which Awardee is a party that solely relate to the development of the Project Vaccine and have deliverables or work outstanding as at the date of termination (the "**Contracts**");

(e) as requested by CEPI, and to the extent it has the legal right to do so (i) assign the benefit (subject to the assumption of the burden) of one or more Contracts to CEPI (or its designee) and, where consent of a third party is required, seek to obtain such consent; (ii) novate one or more Contracts to CEPI (or its designee); or (iii) terminate one or more Contracts in accordance with its terms at Awardee's cost;

(f) as requested by CEPI, perform technology transfer, on an expedited basis, to a Trusted Collaborator or Trusted Manufacturer, as the case may be; and

(g) as requested by CEPI, provide written confirmation or ratification in the event that CEPI exercises the Public Health Licence.

20.6 **Additional Effects of Termination**. Irrespective of the grounds for CEPI's termination of the Agreement:

(a) CEPI shall not be required to make any further payments to Awardee under this Agreement or any Work Package other than as specified in this Clause 20;

(b) Awardee shall return any CEPI funds within twenty (20) Business Days from the date of termination that are unspent, if any, after deducting reimbursement to Awardee for all reasonably incurred expenses incurred prior to the termination date and any non-cancellable expenses relating to the Project activities that were included in the iPDP and/or authorised in writing by CEPI and that arise before or after the date of termination, provided always that Awardee uses all reasonable endeavours to minimise and mitigate any such expenses;

(c) each Party shall return or destroy, as requested by the other Party, the Confidential Information of the other Party, except that: (i) CEPI may retain the Project Results subject to the obligations of confidentiality set out in Clause 19, (ii) each Party may keep one (1) copy of such Confidential Information for monitoring compliance, and (iii) solely in the event that the Public Health Licence has been exercised, CEPI may retain such other Confidential Information reasonably required by CEPI to exercise and benefit from the Public Health Licence. Neither Party shall be required to delete copies of Confidential Information stored on automatic electronic backup systems;

(d) if there is an on-going clinical trial, unless agreed otherwise by the Parties in writing, Awardee shall ensure that no additional trial subjects are enrolled and the Parties shall work together to plan and implement a wind-down of the study in an orderly fashion, with due regard for patient safety and the rights of any participating subjects.

20.7 **Repayment of Funds for Financial Irregularity**. Where termination is due to any Financial Irregularity or fraudulent or illegal activity by Awardee, Awardee shall repay to CEPI the amount of funds related to such Financial Irregularity or fraudulent or illegal activity within twenty (20) Business Days of the notice of termination.

20.8 **Survival of Rights and Identified Clauses**. Termination of this Agreement shall be without prejudice to the rights and duties of either Party accrued prior to termination or expiry of the Agreement. The following sections shall continue to be enforceable notwithstanding termination or expiry: Clauses 3.8-3.11, 5.1-5.3, 6.7, 6.9(b), 9, 11.2 (solely to the extent applicable to any surviving obligations under this Agreement), 11.3, 11.4, 13.4, 13.5, 13.6, 13.7, 14.2, 15.1, 15.3, 15.4, 15.5, 15.6, 15.7, 15.8, 15.9, 15.10, 15.11, 15.12, 15.14, 16, 17.3, 18, 19, 20, 21, 22.1, 22.2, 22.3, 22.4, 22.5, 22.7, 22.9, 22.10, 22.11, 22.12, 22.14, 22.16, 22.17 as well as any other provision, which by its nature, is intended to survive termination.

21 <u>Resolving Differences</u>:

21.1 **Resolution by the JMAG**. Awardee and CEPI shall cooperate in good faith to resolve differences and disputes about the Project (including any disputes under Clause 15.3) at the JMAG.

21.2 **Escalation to Senior Management of the Parties**. Any difference or dispute that cannot be resolved by the JMAG shall be submitted to the Parties' respective Chief Executive Officers or designees for resolution. If the Parties remain unable to resolve such dispute within sixty (60) days of referral to the Chief Executive Officers or designees for resolution (or such additional time as mutually agreed in writing), then, with the exception of disputes relating to intellectual property, the Parties irrevocably submit to arbitration for its resolution upon referral of such dispute by either Party pursuant to Clause 21.3.

21.3 **Arbitration**. Any disputes to be resolved by binding arbitration (including any question regarding its existence, validity or termination or this Agreement), shall be referred to and finally resolved by arbitration under the Rules of the London Court of International Arbitration, which Rules are incorporated by reference into this Clause. The number of arbitrators shall be three (3). The seat, or legal place, of arbitration shall be London, England. The language to be used in the arbitral proceedings shall be English. Notwithstanding the foregoing, any Party may seek specific performance, interim or final injunctive relief or any other relief of similar nature or effect in any court of competent jurisdiction. This Clause shall be governed by and construed in accordance with the law of England and Wales without giving effect to any choice of law or conflict of law provisions or rules that would cause the application of the laws of any other jurisdiction.

21.4 **Public Health Licence**. If CEPI invokes its rights under a Public Health Licence under Clause 13, then the Parties shall pursue an expedited resolution of any differences under Clause 21.2 within fourteen (14) days. However, because of the exigent circumstances in the Outbreak, Awardee agrees that CEPI may proceed under a Public Health Licence and the ultimate resolution of any dispute shall be limited to the recovery of monetary damages by Awardee under Clause 21.3 rather than any injunctive relief except to the extent that the dispute relates to disclosure of Confidential Information or to public safety.

22 Miscellaneous:

22.1 **Relationship of the Parties**. Neither Party shall by reason of this Agreement be empowered to act as agent for the other Party or to pledge the credit of the other Party. Neither Party shall be held liable for or incur liability in respect of the acts or defaults of the other Party.

22.2 **Announcements and Use of Names**. Neither Party shall issue any press release, public statement or public announcement with respect to this Agreement without the prior written consent of the other Party except to the extent required by applicable law or the rules of any public stock exchange. Neither Party shall use the name or trademarks of the other Party or its Affiliates in any press release, public statement or publication without the named Party's prior express written consent except to the extent required by applicable law or the rules of any public stock exchange. After the initial announcement, or as required by law, either Party may disclose a description of the Project, the names of each Party and its Project Lead, and the amount of the CEPI funding without the prior consent of the other Party.

22.3 **Assignment.** Neither Party shall, without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, assign its rights or obligations under this Agreement to any third party, except that CEPI may do so to an organisation of equivalent charitable mission and Awardee may do so to an Affiliate or as part of a sale of the entire business consistent with the satisfaction of Awardee's obligations under this Agreement, provided that in each instance, such permitted assignee assumes all rights and obligations under this Agreement. This Agreement will be binding upon, inure solely to the benefit of and be enforceable by each Party and their respective permitted successors and assigns.

22.4 **Notice**. Any notice to be given pursuant to this Agreement shall be in writing in the English language and shall be delivered by overnight courier, by registered, recorded delivery or certified mail (postage prepaid) to the address of the recipient Party provided in the Agreement Summary or such other address as a Party may from time to time designate by notice in writing. Any notice given pursuant to this Clause shall be deemed to have been received on the day of receipt, provided receipt occurs on a Business Day of the recipient Party or otherwise on the next following Business Day of the recipient.

22.5 **Entire Agreement**. This Agreement, including the Agreement Summary and Annexes, constitutes the entire agreement and understanding between the Parties relating to its subject matter and together they supersede and replace all prior arrangements, whether written or oral, between the Parties relating to the subject matter of this Agreement.

22.6 **Amendments to this Agreement**. No variation, amendment, modification or supplement to this Agreement, including its Annexes, shall be valid unless and until it is made in writing and signed by a duly authorised representative of each Party provided that minor amendments to administrative provisions of this Agreement may be made by exchange of emails between the Parties.

22.7 **Order of Precedence**. If there is any conflict between the provisions of this Agreement, the Third Party Code and any Work Package, then the provisions of this Agreement shall prevail, followed by the provisions of the Third Party Code, and finally by the provisions of the Work Package.

22.8 **Force Majeure**. Neither Party shall be deemed to have defaulted under or to be in breach of this Agreement for failure or delay in fulfilling material obligations when such failure or delay is directly caused by an event outside of their reasonable control which was not reasonably foreseeable on the Effective Date, including but not limited to acts of war, insurrections, acts of terrorism, acts of God or acts, omissions or delays in acting or failure to act by any of CEPI's funders (collectively a "**Force Majeure Event**"). Each Party shall inform the other promptly and in writing of any Force Majeure Event and the Parties shall seek to agree on the appropriate course of action under the circumstances. In the case of an Outbreak, the Parties shall be expected to continue to carry out their obligations pursuant to applicable Work Packages with all due health and safety precautions.

22.9 **No Rights for Third Parties**. A person who is not a Party to this Agreement has no right under the Contracts (Rights of Third Parties) Act of 1999 or otherwise to enforce or to enjoy the benefit of any term of this Agreement except that Gavi shall have the right to enforce its rights under Clause 15 and Clause 19.

22.10 **No Waiver**. Neither Party shall be deemed to have waived any of its rights or remedies under this Agreement unless the waiver is expressly made in writing and signed by a duly authorised representative of that Party.

22.11 **Headings**. The captions to the clauses, subclauses and paragraphs are not a part of this Agreement but are merely for convenience to assist in locating and reading this Agreement.

22.12 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

22.13 **Business Day Requirements**. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.

22.14 **Further Assurances**. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

22.15 **Counterparts and Electronic Signing**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Additionally, this Agreement may be signed electronically by exchanging signed PDF versions or by using an electronic signature platform which meets the European Union requirements for valid electronic signatures (such as DocuSign®).

22.16 **Choice of Law**. This Agreement shall be governed by and construed in accordance with the laws of England and Wales without giving effect to any choice of law or conflict of law provisions or rules that would cause the application of the laws of any other jurisdiction.

22.17 **Interpretation**. In this Agreement:

(a) any headings in this Agreement shall not affect the interpretation of this Agreement;

(b) unless the context otherwise requires, reference to the singular includes the plural and vice versa, any reference to a person includes a body corporate and words importing one gender include both genders;

(c) a reference to a statute or statutory provision is (unless otherwise stated) a reference to the applicable UK or other country's statute as it is in force for the time being, taking account of any amendment, extension, or re-enactment and includes any subordinate legislation for the time being in force made under it, and reference to a policy, procedure or protocol of CEPI is a reference to the version of the policy, procedure or protocol from time to time in force and duly communicated to the Awardee, *provided that* CEPI has not received any objection to any updated policy, procedure or protocol within ten (10) Business Days of receipt of notice by Awardee. In the event that CEPI receives any objection to any updated policy, procedure or protocol within thirty (30) days of receipt of notice by Awardee, the Parties shall discuss in good faith the reasons for such objection and determine the applicability of any such updates; and

(d) where the words "include(s)" or "including" are used in this Agreement, they are deemed to have the words "without limitation" following them, and are illustrative and shall not limit the sense of the words preceding them.

Annex B: Team Charter

**

Annex C: Integrated Product Development Plan

**

Annex D: Budget

**

Annex E: List of AMC Countries, UMICs and HICs as at the Effective Date

1. AMC Countries

The 92 Gavi COVAX AMC-eligible countries and economies (based on 2018 and 2019 World Bank GNI data) which as at the Effective Date are:

- Low income: Afghanistan, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Congo, Dem. Rep., Eritrea, Ethiopia, Gambia, The Guinea, Guinea-Bissau, Haiti, Korea, Dem. People's Rep., Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Togo, Uganda, Yemen, Rep.,

- Lower-middle income: Angola, Algeria, Bangladesh, Bhutan, Bolivia, Cabo Verde, Cambodia, Cameroon, Comoros, Congo, Rep. Côte d'Ivoire, Djibouti, Egypt, Arab Rep., El Salvador, Eswatini, Ghana, Honduras, India, Indonesia, Kenya, Kiribati, Kyrgyz Republic Lao PDR, Lesotho, Mauritania, Micronesia, Fed. Sts., Moldova, Mongolia, Morocco, Myanmar, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, São Tomé and Principe, Senegal, Solomon Islands, Sri Lanka, Sudan, Timor-Leste, Tunisia, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Zambia, Zimbabwe

- Additional IDA eligible: Dominica, Fiji, Grenada, Guyana, Kosovo, Maldives, Marshall Islands, Samoa, St. Lucia, St. Vincent and the Grenadines, Tonga, Tuvalu.

2. Upper Middle Income Countries

Those countries identified by the OECD as having upper middle income economies, as may be updated from time-to-time by the OECD. As at the Effective Date the list is set out at under the column 'Upper Middle Income Countries'.

http://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/DAC-List-of-ODA-Recipients-for-reporting-2020-flows.pdf

3. High Income Countries

Those countries identified by the Organisation for Economic Co-operation and Development (or "**OECD**") as having high income economies, as may be updated from time-to-time by the OECD. As at the Effective Date the list is set out at:

http://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/DAC-List-of-ODA-Recipients-for-reporting-2020-flows.pdf

Annex F: Sub-Contractors

[To to be updated during the term of the Agreement]

Annex G: Pre-existing Agreements

The Canada Agreement

The NRC Agreement

Exhibit 10.51

CONFIDENTIAL EXECUSION VERSION

[***] Certain information has been excluded pursuant to Regulation S-K, Item 601(b)(10)(iv) from this Document because it is both not material and is the type that the registrant treats as private or confidential.

AMENDMENT 2 TO COLLABORATION AND LICENSE AGREEMENT

This Amendment #2 (hereinafter "**Amendment 2**") is signed as of the signature date(s) below and made effective December 20 2021, below ("**Amendment 2 Effective Date**") and entered into by and between VBI Vaccines, Inc. a company organized under the laws of the Province of British Columbia, Canada ("**VBI**") and having a principal place of business at 310 Hunt Club Road, Suite 201, Ottawa ON K1V 1C1, and Brii Biosciences Limited, an exempted company organized under the laws of the Cayman Islands ("**Brii Bio**") having its registered office at Vistra (Cayman) Limited, PO Box 3119, Grand Pavilion Hibiscus Way, 802 West Bay Road Grand Cayman KYI-1205. VBI and Brii Bio are referred to individually as a "**Party**" and are collectively referred to as the "**Parties**".

WHEREAS, this Amendment 2 amends the Collaboration and License Agreement with an effective date of December 4, 2018 between VBI and Brii Bio (the "**Agreement**") and as amended by the Amending Agreement with an effective date of April 8, 2021 ("**Amendment 1**"); and

WHEREAS, VBI and Brii Bio find it in their respective interests to amend the Agreement.

NOW THEREFORE, in consideration of the promises and covenants herein contained, the Parties hereto agree as follows:

1. **Amendment to Article 1- Definitions.** As of the Amendment 2 Effective Date, Article 1 of the Agreement shall be amended as follows:

    a. Section 1.18 shall be revised as follows:

        i. **"Collaboration Clinical Trial(s)" or "Collaboration Clinical Study(ies)"** shall mean the Phase II Clinical Trial, ***and the BRII-179 + PEG-IFN Phase II combination clinical study,*** to be conducted in accordance with the Development Plan in the Licensed Territory for the purpose of comparing VBI-2601 and a Novel Composition across multiple cohorts and dosing regimens.

    b. Section 1.98 shall be added to the Agreement and shall read as follows:

        i. "Combo Clinical Trial" shall mean the BRII-179/BRII-835 combination Phase II clinical study.

c. Section 1.99 shall be added to the Agreement and shall read as follows:

> "Combo Animal Study" shall mean the toxicology study in rats using the Licensed Product and (ii) a further study of the Licensed Product alone and with BRII-835 siRNA in a chronic HBV-AAV mouse model in support of the Combo Clinical Trial..

2. Amendment to Section 6.4-Rights of Reference. As of the Amendment 2 Effective Date the following changes to Section 6.4 will apply:

a. Each Party shall have the right to cross reference, file or incorporate by reference any regulatory submission, in connection with the Collaboration Clinical Trial, for any Licensed Product, or any component thereof (including all Approvals), in order to support regulatory submissions that such Party may make for a Licensed Product in its respective territory.

b. With respect to any data arising out of the Combo Clinical Trial, Brii Bio shall be the sole owner of any such data. Brii Bio agrees to publish the topline data ("Topline Data") from the Combo Clinical Trial as soon as reasonable after the interim & final data readouts in compliance with Applicable Laws and Brii Bio's publication procedures. Brii Bio will make reasonable efforts to include individual baseline clinical status and biomarker data from the Combo Clinical Trial in the publication to the extent practical and permitted by Applicable Laws.

c. VBI shall have the right to cross reference, file or incorporate by reference such Topline Data to the extent necessary to support its regulatory submissions for Licensed Products outside of the Licensed Territory. To the extent VBI requires additional clinical data from the Combo Clinical Trial necessary to support VBI's regulatory submissions for Licensed Products outside of the Licensed Territory, the Parties shall discuss in good faith a resolution to such written request from the Regulatory Authority.

d. All other uses of such data by VBI are limited solely to those permitted by this Agreement, and VBI may not use such data for any other purpose without the prior consent of Brii Bio during and after the Term. For the avoidance of doubt, no Party shall be obligated as a result of this Section 6.4 to develop or prepare additional information or materials beyond those that it has otherwise developed or prepared for its own purposes. For the avoidance of doubt, in the event that the Parties decide not to jointly develop and implement a Global Development Plan pursuant to Section 5.5, then neither Party shall have the right to reference any data obtained by the other Party pursuant to independent Clinical Trials conducted by such other Party, except that the Parties shall provide to each other any information or data generated in any Clinical Trials regarding the safety of the Licensed Products.

3. **Amendment to Section 12 to add 12.9** – As of the Amendment 2 Effective Date Section 12.9 shall be added to the Agreement and shall read as follows:

12.9 Brii Bio hereby grants VBI a non-exclusive, royalty free license under the Brii Bio Technology arising from the data generated in these Combo Animal Study and Combo Clinical Trial solely for VBI's use in the development, manufacture or commercialization of the Licensed Product in combination with an siRNA in the Field in the VBI Territory, and only to the extent that such license of Brii Bio Technology [***]. VBI acknowledges and agrees that Vir-2218 (i.e., BRII 835) is [***] subject to the terms and conditions of a separate collaboration agreement between Vir and Brii Bio.

Brii represents and agrees that, to Brii's knowledge, any interest in or rights to [***] by virtue of its collaboration therewith, [***] pursuant to the Agreement or this Amendment #2 and [***].

4. **Amendment to Section 6.1(c)(i)-Licensed Territory.** As of the Amendment 2 Effective Date the following changes to 6.1(c)(i) will apply:

Brii Bio, or its designated Affiliate, shall have the sole right to prepare and submit***, and shall be the sole and exclusive owner of,*** all Regulatory Documentation in the Licensed Territory, including applications for Marketing Approval and all Marketing Approvals in the Licensed Territory, provided that VBI shall have the right to cross reference such Regulatory Documentation and Marketing Approvals in the VBI Territory subject to the limitations in Section 6.4.

5. **Amendment to Section 17.7-Notices.** As of the Amendment 2 Effective Date Section 17.7 is amended to reflect the following:

a. **To VBI:**

i. VBI Vaccines Inc.
160 Second Street. 3rd Floor
Cambridge, MA 02142

6. **Amendment to Schedule 7.1(a).** As of the Amendment 2 Effective Date, Schedule 7.1(a) shall be deleted and replaced with the following:

Schedule 7.1(a)

Clinical Supply Key Terms

***

7. Except as specifically amended hereby, all terms of the Agreement remain in full force and effect. In the event of any conflict between the Agreement and this Amendment 2, the provisions of this Amendment 2 shall prevail. All terms not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

8. This Amendment 2 to the Agreement may be executed in two or more counterparts, each of which shall be an original and such counterparts together shall constitute the entire Amendment 2 to the Agreement. Electronically executed and electronically transmitted signatures shall have the full force and effect of an original signature.

IN WITNESS WHEREOF, each of the Parties has caused this Amendment 2 to be duly executed by its authorized representative on the date set forth below.

BRII BIOSCIENCES LIMITED

/s/ Zhi Hong
Name: Zhi Hong
Title: Chief Executive Officer
Date: December 20, 2021

VBI VACCINES INC.

/s/ Jeff Baxter
Name: Jeff Baxter
Title: Chief Executive Officer
Date: December 20, 2021

Exhibit 10.52

AMENDMENT TO CONSULTING AGREEMENT

This Amendment to Consulting Agreement (the "**Amendment**"), effective as of **January 1st, 2022** (the "**Effective Date**"), is by and between Variation Biotechnologies Inc., a corporation incorporated pursuant to the laws of Canada (the "**Company**") having an address of 310 Hunt Club Road East, Ottawa, Ontario K1V 1C1 and F. Diaz-Mitoma Professional Corporation (Ontario corporation number 002356634) having an address of 210 Barrow Crescent, Kanata, Ontario K2L 2C7 ("**Consultant**"). The Consultant and Company are sometimes referred to as a "**Party"** and are collectively referred to as the "**Parties"**.

WHEREAS, the Company and Consultant are parties to a certain Consulting Agreement dated July 1, 2016, amended as of January 1, 2017, amended January 1, 2018, amended January 1, 2019, January 1, 2020, and further amended as of January 1, 2021 (the "**Consulting Agreement**");

AND WHEREAS, the Consultant and the Company wish to amend the Consulting Agreement on the terms and conditions set out in this Amendment;

NOW THEREFORE, in consideration of the mutual covenants contained herein, the Parties agree as follows:

1. Amendment to Section 1(a). As of the Effective Date, Section 1(a) of the Consulting Agreement shall be deleted in its entirety and replaced with the following:

> **(a) Term**. This Agreement shall be in effect beginning on the Effective Date and, unless terminated earlier pursuant to the provisions of this Section 1, shall continue until December 31, 2022 (the "**Term**"). This Agreement may be renewed any number of times, with or without a short interruption in continuity of Services (as defined below), by written notice from the Company which is accepted by signature of the Consultant.

2. Amendment to Section 5(a). As of the Effective Date, Section 5(a) of the Consulting Agreement shall be deleted in its entirety and replaced with the following:

> **5. Payment for Consulting Services**.
>
> **(a) Consideration.** As consideration for the Services, the Company shall pay Consultant a fee of **$50,000.00 CAD** per month (plus any HST or GST payable).

3. **Replacement of Appendix C.** As of the Effective Date, Appendix C of the Consulting Agreement shall be deleted in its entirety and replaced with the version of Appendix C attached as Schedule A to this Amendment.

4. Consulting Agreement to Remain in Full Effect. Except as amended by this Amendment, the Consulting Agreement shall continue to be in full force and effect, without amendment, and is hereby ratified and confirmed. The Consulting Agreement shall henceforth be read and construed in conjunction with this Amendment.

5. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the Province of Ontario and the federal laws of Canada applicable therein.

6. Further Assurances. Each Party shall do such further acts and execute such further documents as may be required to give effect to this Amendment and carry out the intent thereof.

7. Binding Effect. This Amendment shall be binding on and inure to the benefit of the Parites and their respective successors and assigns.

8. Execution and Counterparts. This Amendment may be executed in counterparts, including counterpart signature pages or counterpart facsimile or scanned signature pages (each of which shall be deemed an original), all of which together shall constitute one and the same instrument.

(*Signature page follows.*)

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed by their respective authorized officers as of the Effective Date.

VARIATION BIOTECHNOLOGIES INC.

/s/ Jeff Baxter

Name: Jeff Baxter
Title: Chief Executive Officer

F. DIAZ-MITOMA PROFESSIONAL CORPORATION

/s/ Dr. Francisco Diaz-Mitoma

Name: Dr. Francisco Diaz-Mitoma
Title: President

Schedule A

Appendix C – Performance Incentives

Bonus payable as of February 15th, 2022 – CAD **$223,560**

1. The Company shall cause VBI Vaccines Inc., a British Columbia corporation (the "**Parent**") to grant to Francisco Diaz-Mitoma, as designee of Consultant, **400,000** stock options (the "**Options**"), each Option exercisable for one common share of Parent, to be granted effective as of **January 27, 2022**, which was the date on which the board of directors of Parent approved such grant, and to be subject to the provisions of the Plan. Conditions regarding the Options and their exercise, including the exercise price, the term of the Options and the timing of vesting shall be set out in an Option Agreement between the Parent and Francisco Diaz-Mitoma. The common shares issuable upon exercise of the Options shall bear the appropriate legend to indicate such shares are "control securities" as defined in General Instruction C.1(a) of Form S-8.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of VBI Vaccines, Inc. and Subsidiaries (the "Company") on Form S-3 (No. 333-240266) and Form S-8 (Nos. 333-259282, 333-240268, 333-226261 and 333-212160) of our report dated March 7, 2022, on our audits of the consolidated financial statements as of December 31, 2021 and 2020 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 7, 2022. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
March 7, 2022

Exhibit 31.1

CERTIFICATION

I, Jeffrey Baxter, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2021 of VBI Vaccines Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2022

/s/ Jeffrey Baxter
Jeffrey Baxter
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Christopher McNulty, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2021 of VBI Vaccines Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2022

/s/ Christopher McNulty

Christopher McNulty
Chief Financial Officer and Head of Business Development (Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

In connection with the annual report of VBI Vaccines Inc. (the "Company") on Form 10-K for the year ended December 31, 2021 as filed with the Securities and Exchange Commission (the "Report"), I, Jeff Baxter, Chief Executive Officer (Principal Executive Officer) of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: March 7, 2022

/s/ Jeffrey Baxter
Jeffrey Baxter
Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

CERTIFICATION

In connection with the annual report of VBI Vaccines Inc. (the "Company") on Form 10-K for the year ended December 31, 2021 as filed with the Securities and Exchange Commission (the "Report"), I, Chris McNulty, Chief Financial Officer and Head of Business Development (Principal Financial and Accounting Officer) of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: March 7, 2022

/s/ Christopher McNulty

Christopher McNulty
Chief Financial Officer and Head of Business Development (Principal Financial and Accounting Officer)