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, 2022

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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2022, 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 $154,978,074.

As of March 9, 2023, 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 2023 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, 2022

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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 United States ("U.S.") and Canada and PreHevbri in Europe;
- 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 COVID-19 pandemic and the continuing effects of the 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 ability to regain and maintain compliance with The Nasdaq Capital Market's ("Nasdaq") listing standards; and
- our success at managing the risks involved in the foregoing items.
- 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

We are a commercial stage biopharmaceutical company driven by immunology in the pursuit of prevention and treatment of disease. Through our innovative approach to virus-like particles ("VLPs"), including a proprietary enveloped VLP ("eVLP") platform technology, we develop vaccine candidates that mimic the natural presentation of viruses, designed to elicit the innate power of the human immune system. We are 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"). We are headquartered in Cambridge, Massachusetts, with research operations in Ottawa, Canada, and a research and manufacturing site in Rehovot, Israel.

Product Pipeline

Our 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, 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. Our 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 ("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 as many as 2.2 million chronically infected people in the 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 no cure available for HBV infection and while public health initiatives highlight 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 30% of all adults aged 19 years and older.

In April 2022, the Centers for Disease Control and Prevention ("CDC") Advisory Committee on Immunization Practices ("ACIP") implemented a change to the adult HBV vaccine recommendations. As incorporated in the CDC's 2022 Adult Immunization Schedule and as published in the April 1, 2022, CDC Morbidity and Mortality Weekly Report, adults aged 19 to 59 years are now universally recommended to be vaccinated against HBV infection. Additionally, while adults aged 60 years and older with risk factors for HBV infection are still recommended to receive HBV vaccinations, adults aged 60 years and older without known risk factors for HBV may now also receive HBV vaccinations.

In addition to our approved vaccine, PreHevbrio [Hepatitis B Vaccine (Recombinant)], there are four other vaccines approved in the U.S. for the prevention of HBV infection in adults: Engerix-B® and Twinrix®, manufactured by GlaxoSmithKline Biologicals S.A. ("GSK"), Recombivax HB®, manufactured by Merck &. Co. ("Merck"), and Heplisav-B®, manufactured by Dynavax Technologies Corporation ("Dynavax").

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").

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") have included:

- 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 and subvariants – First identified in South Africa, VOC in November 2021

Glioblastoma ("GBM")

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. Median overall survival for recurrent GBM is even lower, at about 8 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 February 28, 2023:

Indication	Program	Technology	Current Status
Approved Vaccine	PreHevbrio[1,2,3]	VLP	Registration/Commercial
● Hepatitis B	*Hepatitis B Vaccine (Recombinant)*		
Prophylactic Candidates			
● Coronaviruses (Multivalent)	VBI-2901	eVLP	Ongoing Phase I
● COVID-19 (Beta variant)	VBI-2905	eVLP	Phase Ib
● COVID-19 (Ancestral)	VBI-2902	eVLP	Phase Ia
● Cytomegalovirus	VBI-1501	eVLP	Phase I Completed
● 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	Phase I/IIa
● Other CMV-Associated Cancers	Undisclosed	eVLP	Preclinical

[1]Approved for use in the U.S. and Canada, under the brand name PreHevbrio, for the prevention of infection caused by all known subtypes of HBV in adults 18 years of age and older.

[2] Approved for use in the European Union ("EU") / European Economic Area ("EEA") and the UK, under the brand name PreHevbri, for active immunization against infection caused by all known subtypes of the HBV in adults. It can be expected that hepatitis D will also be prevented by immunization with PreHevbri as hepatitis D (caused by the delta agent) does not occur in the absence of HBV infection.

[3]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 aged 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 was reflected in a CDC publication on April 1, 2022 and was a notable milestone as many insurance plans and institutions require an ACIP recommendation before a vaccine can be reimbursed or is made available to patients. Additionally, PreHevbrio was included in the 2023 annual update of the CDC Adult Immunization Schedule, as detailed in the CDC publication on February 10, 2023. VBI launched PreHevbrio in the U.S. at the end of the first quarter of 2022, and revenue generation began in the second quarter of 2022.

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

- *EU:* On May 2, 2022, we announced that the European Commission (the "EC") granted Marketing Authorization for PreHevbri [Hepatitis B Vaccine (Recombinant, Adsorbed)]. The European Commission's centralized marketing authorization is valid in all EU Member States as well as in the EEA countries (Iceland, Liechtenstein, and Norway). On September 8, 2022, we announced a partnership with Valneva SE ("Valneva") for the marketing and distribution of PreHevbri in select European markets, initially including the UK, Sweden, Norway, Denmark, Finland, Belgium, and the Netherlands. As part of this partnership, VBI expects PreHevbri will be available in certain European countries beginning in the first half of 2023.

- *UK:* On June 1, 2022, we announced that the MHRA granted marketing authorization for PreHevbri [Hepatitis B Vaccine (Recombinant, Adsorbed)]. This follows the EC centralized marketing authorization received in May 2022 and was conducted as part of the EC Decision Reliance Procedures ("ECDRP"). VBI expects to make PreHevbri available in the UK in the first half of 2023 as part of the partnership with Valneva.

- *Canada:* On December 8, 2022, we announced that Health Canada approved PreHevbrio [3-antigen Hepatitis B Vaccine (Recombinant)] for the prevention of infection caused by all known subtypes of HBV in adults aged 18 years and older. VBI expects to make PreHevbrio available in Canada in 2023.

- *Israel:* Approved and commercially available under the brand name Sci-B-Vac®.

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 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 aged 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. 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 Phase I study was initiated in September 2021 to assess VBI-2905, our eVLP vaccine candidate directed against the SARS-CoV-2 Beta variant. On April 5, 2022, we announced new data from the Phase Ib study (n=53). A single-dose booster of VBI-2905 increased the geometric mean titer ("GMT") of neutralizing antibodies directed against the Beta variant 3.8-fold, at day 28, in participants who had previously received two-doses of an mRNA vaccine (ancestral strain) – approximately 2-fold increases were also seen at day 28 in antibody GMTs against both the ancestral and delta variant. New preclinical data announced at the same time showed that against a panel of coronavirus variants in mice, reactivity was seen with VBI-2902 against all variants including the ancestral strain, Delta, Beta, Omicron, Lambda, and RaTG13 (a bat coronavirus that is distant to circulating human strains). In this same panel, VBI-2901 was able to elicit an even stronger response against all variants tested – as the strains became more divergent from the ancestral strain, VBI-2901 elicited a greater difference in GMT from VBI-2902, ranging from 2.5-fold higher against the ancestral strain to 9.0-fold higher against the bat coronavirus. Additionally, a validated pseudoparticle neutralization assay ("PNA") benchmarked against the WHO reference standard demonstrated that VBI-2902 elicited neutralizing antibody responses of 176 IU50/mL in its Phase Ia study – this international standard measure would predict a greater than 90% efficacy, with two internationally approved vaccines estimated to have 90% efficacy at 83 and 140 IU50/mL (Gilbert, PB, 2021).

The clinical and preclinical data for all three candidates continue to support the potential of the eVLP platform against coronaviruses. On September 29, 2022, we announced that we initiated the first clinical study of VBI's multivalent coronavirus candidate, VBI-2901, designed to increase breadth of protection against COVID-19 and related coronaviruses. Interim data from this study are expected mid-year 2023.

The VBI-2900 program is supported by a partnership with the Coalition for Epidemic Preparedness Innovations ("CEPI" and the partnership, 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. On December 6, 2022, we and CEPI announced that we expanded the scope of the CEPI Funding Agreement to advance the development of multivalent coronavirus vaccines that could be deployed against COVID-19 as well as a future "Coronavirus X".

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 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 with and without an immunomodulatory adjuvant, conducted at multiple study sites in New Zealand, Australia, Thailand, South Korea, Hong Kong Special Administrative Region of China, and China.

The data from the Phase Ib/IIa for 33 evaluable patients across all study arms suggested: (1) VBI-2601 was well tolerated at all dose levels with and without the adjuvant with no significant adverse events identified; (2) VBI-2601 induced both B cell (antibody) and T cell responses in chronically-infected HBV patients, (3) VBI-2601 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) 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 in combination with BRII-835 (VIR-2218), an investigational small interfering ribonucleic acid ("siRNA") targeting HBV, for the treatment of chronic HBV infection. 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. The study is being conducted at clinical sites in Australia, Taiwan, Hong Kong Special Administrative Region of China, South Korea, New Zealand, Singapore, and Thailand. VBI's partner, Brii Bio, is the study sponsor. A total of 50 adult, non-cirrhotic patients who received NRTI therapy for at least 12 months were randomized and dosed across three cohorts:

- Cohort A: BRII-835 Alone Regimen – Nine subcutaneous 100mg doses of BRII-835, dosed every four (4) weeks through Week 32
- Cohort B: BRII-835 Alone Regimen + nine 40μg intramuscular doses of VBI-2601 admixed with interferon-alpha (IFN-α) as co-adjuvant every four weeks from Week 8 through Week 40
- Cohort C: BRII-835 Alone Regimen + nine 40μg intramuscular doses of VBI-2601 without IFN-α every four weeks from Week 8 through Week 40

On February 15, 2023, we announced interim data from the Phase II combination study. The data, which was featured in an oral presentation at the 32nd Conference of the Asian Pacific Association for the Study of the Liver ("APASL") on February 18, 2023, demonstrated that the combination therapy was generally well-tolerated, restored strong anti-HBsAg antibody responses, and led to improved HBsAg-specific T-cell responses, when compared to BRII-835 alone. Notably:

- Mean changes in HBsAg reduction relative to baseline at week 40 were -1.68 log10 IU/mL in Cohort A, -1.75 log10 IU/mL in Cohort B, and -1.77 log10 IU/mL in Cohort C
- Potent HBV surface antibody levels (> 100 IU/L) were observed in more than 40% of participants in Cohorts B and C at week 40 – by comparison, no antibody responses were detected in Cohort A
- Out of 25 evaluable patients, a higher proportion of Cohort B and C patients demonstrated potent HBsAg-specific T-cell responses (70%; 14/20) relative to those in Cohort A (20%; 1/5) through week 44
- To date, two participants receiving combination regimens achieved either HBsAg below LLOQ (0.05 mIU/mL), to an undetectable level, or at LLOQ with maximum reductions of ≥ 4 log10 HBsAg – both participants mounted potent anti-HBs antibody and HBV-specific T-cell responses

Additional data from the study are expected to be announced later this year.

On January 5, 2022, we announced that the first patient was dosed in a second Phase IIa/IIb clinical study evaluating VBI-2601. This Phase II study assesses VBI-2601 as an add-on therapy to the standard-of-care in China nucleos(t)ide reverse transcriptase inhibitor ("NRTI") and pegylated interferon therapy (PEG-IFN-α,). Interim topline clinical data from part one of this Phase IIa/IIb clinical study is expected in the third quarter 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 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 two-arm study that enrolled 20 first-recurrent GBM patients to receive 10 µg of VBI-1901 in combination with either GM-CSF or GSK proprietary adjuvant system, AS01, as immunomodulatory adjuvants. AS01 is provided pursuant to a Clinical Collaboration and Support Study Agreement with GSK, which we entered into 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 arm was completed in October 2020.

Data from the Phase IIa portion of the study was announced throughout 2020, 2021, and 2022, with the latest data presented in November 2022 at the 2022 Society for Neuro-Oncology (SNO) Annual Meeting. 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 and 40% (n=4/10) in the VBI-1901 + AS01 study arm; (3) 2 patients with partial tumor responses, one of whom remained on protocol for over two years and had achieved a 93% tumor reduction relative to baseline at initiation of treatment at the start of the study, and 10 stable disease observations across all 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.

On June 22, 2022, we announced that the FDA granted Orphan Drug Designation for VBI-1901 for the treatment of GBM.

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 to support an accelerated approval application 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 the second quarter of 2023.

On October 12, 2022, we announced a collaboration with Agenus Inc. to evaluate VBI-1901 in combination with anti-PD-1 balstilimab in a Phase II study as part of the INSIGhT adaptive platform trial in patients with primary GBM. Subject to approval from regulatory bodies, we expect enrollment to initiate in the VBI-1901 study arm in INSIGhT mid-year 2023.

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. 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.

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 three ongoing clinical studies being conducted, by us or our partners, at clinical sites worldwide: 1) the Phase II study of VBI-2601 and BRII-835 (VIR-2218) at multiple study sites in Asia Pacific countries; 2) the Phase IIa/IIb study of VBI-2601 at multiple study sites in Asian Pacific countries; and 3) the Phase I clinical study of VBI-2901 in Canada. In addition to the active studies, we have planned clinical studies expected to begin in 2023, including two additional studies with VBI-1901. The enrollment of patients at some of the clinical sites in our studies has in the past been suspended due to the COVID-19 pandemic. Future COVID-19 outbreaks could suspend such studies again, and may suspend or delay the enrollment of patients at other clinical sites where we are conducting or planning to conduct clinical trials, or lead to the reallocation of resources or limit of access to clinical facilities. Additionally, if our trial participants are unable to travel to or visit our clinical study sites as a result of the reimposition of quarantines or other restrictions resulting from new outbreaks and a resurgence in COVID-19 cases, we could experience higher drop-out rates or delays in our clinical studies. Such quarantines and other 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, VBI-1901, and our coronavirus vaccine candidates may be negatively impacted.

During the years 2020 through 2022, in order to reduce exposure risk to COVID-19, we had 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. Further, restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business limited our ability to support our operations.

The COVID-19 pandemic has materially negatively affected the global economy, and the ongoing effects of the COVID-19 pandemic, including but not limited to, supply chain issues, global shortages of supplies, materials and products, volatile market conditions and rising global inflation, continue to do so. As a result of the COVID-19 pandemic, our business and results of operations were adversely affected and, as the ongoing effects of the COVID-19 pandemic continue to impact the global economy, these effects may continue to adversely affect our business and results of operations. The extent to which these effects 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 effects of 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 continue to disrupt the marketplace which could have an adverse effect on our operations.

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 Nasdaq. Our common shares commenced trading on Nasdaq 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 began working together on the launch strategy in 2019 and expanded the relationship in 2020 to build the leadership team and field teams dedicated to VBI, incorporating full-service commercialization solutions. As part of this partnership, we have fully-dedicated field team members across medical affairs, market access, and sales.

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 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 China, Hong Kong, Taiwan and Macau (collectively, the "Licensed Territory"), and to conduct a Phase Ib/IIa collaboration clinical trial for the purpose of comparing VBI-2601, 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 "Brii 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, 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 Brii 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 Brii 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 Brii 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 GSK

On September 10, 2019, we entered into the Collaboration Agreement with GSK (the "GSK Collaboration Agreement") pursuant to which we agreed to investigate the use of GSK's proprietary AS01 adjuvant in our Phase I/IIa study of VBI-1901. As a result of the GSK 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 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.

On April 28, 2022, we signed a sixth amendment to the collaboration agreement with the NRC to further broaden the scope to include generation and testing of stable pools of cells expressing SARS-CoV-2 spike protein.

On February 28, 2023, we signed a seventh amendment to the collaboration agreement with the NRC to extend the expiration date of the collaboration agreement to December 31, 2023.

Collaboration Agreement with the Agenus Inc. ("Agenus")

On October 12, 2022, the Company entered into a Clinical Collaboration Agreement with Agenus Inc. pursuant to which the Company will evaluate VBI-1901 in combination anti-PD-1 balstilimab in a Phase II study as part of the INSIGhT adaptive platform trial in patients first diagnosed with GBM. Subject to approval from regulatory bodies, we expect enrollment to initiate in the VBI-1901 study arm in INSIGhT mid-year 2023, as described in "Part I - Item I - Business - eVLP Platform - VBI-1901: Cancer Vaccine Immunotherapeutic Candidate".

Partnership with the CEPI

On March 9, 2021, we announced a partnership with CEPI 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.

On December 6, 2022, we and CEPI entered into an amendment to the CEPI Funding Agreement (the "CEPI Amendment") to expand the scope of the CEPI Funding Agreement. The CEPI Amendment, among others, (i) expands the definition of "Project Vaccine" to include additional multivalent vaccine constructs within the VBI-2900 program, (ii) removes certain pricing restrictions previously allocated to high-income countries in the CEPI Funding Agreement, (iii) updates the proposed volume commitment percentage contributions by us to CEPI for a Project Vaccine, and (iv) adds certain commercial benefits and related adjustments for CEPI following the pandemic period, including royalties paid to CEPI, in the event that CEPI provides funding for Phase III clinical studies of the Project Vaccine.

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 September 16, 2020, we signed the Contribution Agreement (as amended, the "Contribution Agreement") with Her Majesty the Queen in Right of Canada, as represented by the Minister of Industry (the "Minister"), whereby the Minister agreed to 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 $56 million from the SIF to support the development of our coronavirus vaccine program, VBI-2900, though Phase II clinical studies (the "Project"). We initially 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"). On March 28, 2022, we and the Minister signed an amendment to the Contribution Agreement, the main purpose of which was to extend the collaboration and move the Project Completion Date from March 31, 2022 to December 31, 2023. 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 ("K2HV") pursuant to the Loan and Guaranty Agreement (the "Loan Agreement"), dated May 22, 2020, as amended on May 7, 2021 (the "First Amendment") and on September 14, 2022 (the "Second Amendment"). 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

HBsAg products, including our 3-antigen HBV vaccines, are subject of a license agreement between Savient Pharmaceuticals Inc. and SciGen Ltd dated June 2004, (the "original Ferring License Agreement"). as subsequently amended and restated on October 18, 2022 (the "Amended and Restated Ferring License Agreement"). This Amended and Restated Ferring License Agreement amends and restates certain of the terms relating to the manufacture and marketing of HBsAg products, which includes, among others, updates to the definition of net sales, and a reduction in the fixed royalty rate on net sales of HBsAg products ("Product") from seven percent (7%) to three and a half percent (3.5%) in consideration for the grant of the license to utilize genetically engineered CHO cells encoding the hepatitis B antigen and certain information related to the manufacture of hepatitis B vaccines. In connection with the Amended and Restated Ferring License Agreement, the Company has also agreed to act as the guarantor for SciVac's obligations under the Amended and Restated Ferring License Agreement, or if the Amended and Restated Ferring License Agreement is assigned to a third party, guarantor for SciVac's obligations that have accrued up until the date of such assignment.

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 original Ferring License Agreement) of Product. Under the original 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 original 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 Amended and Restated Ferring License Agreement and SciGen Assignment Agreement will continue to be payable for the duration of the extended license periods.

Royalty payments under the Amended and Restated Ferring License Agreement or the original Ferring License Agreement of $33 and $18 were recorded in cost of revenues for the year ended December 31, 2022 and 2021, respectively.

Royalty payments under the SciGen Assignment Agreement of $47 and $13 were recorded in cost of revenues for the year ended December 31, 2022 and 2021, 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 Amended and Restated Ferring License Agreement), provided that the payment of 30% shall not apply to a grant of rights in or relating to: (i) the Original Territory (as defined in the original Ferring License Agreement); or (ii) the Berna Territory (as defined in the Amended and Restated 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 U.S. or (ii) first approval by the European Medicines Agency 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 U.S., 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 U.S.; 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, 2021, the milestone was met 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 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. No payments were made during the year ended December 31, 2022.

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. The facility was built in December 2006 and most recently received GMP certification renewal by the Ministry of Health of the State of Israel ("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 U.S.

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. ("Moderna"), 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 and Transgene SA.

Within the COVID vaccine space, over the last three years, more than one hundred vaccine candidates against SARS-CoV-2 were under development; four groups have obtained FDA approval or authorization for emergency use: (i) Pfizer, Inc/BioNTech SE; (ii) Moderna; (iii) J&J/Janssen; and (iv) Novavax. Approvals for additional vaccines targeting COVID-19 and its variants are anticipated. Other key companies in the space with vaccines recognized by the WHO and/or approved for use by other regulatory agencies include AstraZeneca AB, Bharat Biotech International Limited, CanSino Biologics Inc., Serum Institute of India Pvt. Ltd, Sinopharm/Beijing Institute of Biological Products Co., Ltd., and Sinovac Life Sciences Co., 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 contract development and manufacturing organizations ("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 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 27 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 27 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 2023 in the U.S., 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 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 27 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.

Employees

As of December 31, 2022, we had a total of 190 full-time and 6 part-time employees. The manufacturing site in Israel had 124 full-time employees and 4 part-time employees and the Ottawa research site employed 48 full-time and 2 part-time employees, as of December 31, 2022. Our headquarters in Cambridge, MA employed 18 full-time employees. None of our employees are represented by unions. Our management considers its relationship with our employees to be good.

We are committed to maintaining a diverse and inclusive work environment that promotes fairness and values each team members' unique experience and contribution to the workplace. By bringing together individuals with varying backgrounds, expertise, and perspectives into an inclusive and collaborative work environment, we believe we can better achieve our corporate objectives and deliver long-term, sustained value for key stakeholders – patients, healthcare providers, and shareholders. We review our internal diversity statistics on an annual basis, and while we believe we have created a team that is inclusive, we continually strive to better our diversity profile, including by: (i) improving the rate of self-identification with our internal workforce; and (ii) increasing access to groups where we don't have representation by working with certain academic centers and recruiters, and by leveraging diverse job boards and employment centers.

We also strongly believe that all employees should be treated with respect, and we strictly enforce our Non-Discrimination, Anti-Harassment, and Anti-Retaliation Policies to protect and maintain a safe, respected, and supportive workplace environment for all employees.

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 $1,865 during the fiscal year ended December 31, 2022.

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 $15.5 million and $19.6 million for the years ended December 31, 2022 and 2021, 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 (VBI-1901), our prophylactic coronavirus vaccine candidates (VBI-2900), our CMV candidate (VBI-1501), and the related eVLP platform. We 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 196 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 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 continuously monitor 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 has a patent whose term extends to 2023 in the U.S. 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. These trademarks are registered in 12 countries. There are two pending marks in the U.S. and one pending mark in Norway. There is one registered European Community mark. 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.

U.S., Europe, and Canada Regulatory Agencies

Before any of our products can be marketed and sold in the U.S., 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 U.S., which must be reviewed by the FDA before human clinical trials may begin; submission of a Scientific Advice application to EMA and/or MHRA 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 and /or MHRA, 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 and/or MHRA approval of a MAA, or Health Canada approval of a NDS.

Pre-clinical Testing

In the U.S., 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 U.S., 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 U.S., 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 U.S. 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 U.S., 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 U.S. 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 U.S., 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 U.S. 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. and Canada, and PreHevbri in Europe;

- 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 coronavirus pandemic and its ongoing effects have 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. The government-imposed precautionary measures have been relaxed in certain countries or states as COVID-19 cases have lessened, but there is no assurance that more strict measures will not be put in place again due to a future COVID-19 outbreaks.

We have three ongoing clinical studies being conducted, by us or our partners, at clinical sites worldwide: 1) the Phase II study of VBI-2601 and BRII-835 (VIR-2218) at multiple study sites in Asia Pacific countries; 2) the Phase IIa/IIb study of VBI-2601 at multiple study sites in Asian Pacific countries; and 3) the Phase I clinical study of VBI-2901 in Canada. In addition to the active studies, we have several planned clinical studies expected to begin in 2023, including two additional studies with VBI-1901. 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, VBI-1901, our coronavirus vaccine candidates (VBI-2900), and possibly our regulatory timelines for our 3-antigen HBV vaccine, in regions other than U.S., Europe and Canada may be negatively impacted.

In addition, during the years 2020 through 2022, measures taken to reduce exposure to COVID-19 and restrictions on our ability to travel, stay-at-home orders and other similar restrictions on our business limited the number of employees on sight at our manufacturing facility and our research and development laboratories and our ability to support our operations.

The COVID-19 pandemic has materially negatively affected the global economy, and the ongoing effects of the COVID-19 pandemic, including but not limited to, supply chain issues, global shortages of supplies, materials and products, volatile market conditions and rising global inflation, continue to do so. As a result of the COVID-19 pandemic, the Company's business and results of operations were adversely affected and, as the ongoing effects of the COVID-19 pandemic continue to impact the global economy, may continue to adversely affect our business and results of operations. The extent to which the effects of 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 effects of 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 continue to disrupt the marketplace which could have an adverse effect on our operations.

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 commercially launched the vaccine at the end of the first quarter of 2022. Successful commercialization of PreHevbrio in the U.S. will require significant resources, time, expertise, and experience. Despite the establishment of sales, marketing, market access, and medical capabilities as part of the partnership with Syneos, because this is VBI's first marketed product in the U.S., 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;
- 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.

Successful commercialization of our 3-antigen HBV vaccine and our pipeline candidates face significant obstacles, including establishing complex commercial capabilities or partnerships and obtaining regulatory approvals. We may not be able to achieve and sustain commercial success and/or we may fail to obtain regulatory approval in foreign jurisdictions which will prevent us from marketing or selling our products in such jurisdictions.

Our 3-antigen HBV vaccine is approved for sale in the U.S. and Canada (brand name PreHevbrio), in the EU/EEA and UK (brand name PreHevbri), and in Israel (brand name Sci-B-Vac). In countries where we have obtained the required regulatory approvals, we will require significant resources, partnerships, time, expertise, and experience to be commercially successful. For the UK and certain EU countries, initially including Sweden, Norway, Denmark, Finland, Belgium, the Netherlands, we are partnering with Valneva SE for the marketing and distribution of PreHevbri. Although we selected Valneva based on their local knowledge, experience, and relationships in each of the aforementioned European countries, because this is the first vaccine to be marketed and distributed as part of this partnership, there is no assurance that our partnership will be successful, and we and Valneva may not be able to successfully commercialize PreHevbri in such countries.

In international countries outside of the Valneva partnership, successful commercialization of our 3-antigen HBV vaccine and our pipeline candidates will require us to identify and establish additional partnerships or the required resources, experience, and expertise. There is no guarantee that we will be able to do so.

In countries where we do not currently have the required approvals, 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, for our pipeline programs, 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 the Licensed Territory, 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.

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, or our product(s) may be obsolete by the time they are approved for marketing, if ever.

In response to the COVID-19 pandemic, and in collaboration with the NRC, the Minister, 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 are in the early clinical stage and our development of our multivalent coronavirus vaccines VBI-2901 is also in the clinical stage; 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.

There continue to be ongoing efforts by public and private entities to develop vaccines against COVID-19, including from large, multinational pharmaceutical companies such as AstraZeneca, GSK, Johnson & Johnson, Moderna, Pfizer, Janssen, Novavax, and Sanofi, some of which have vaccines that are currently approved, authorized for emergency use, or have candidates that are at more advanced stage of development than our coronavirus vaccine candidates. It is possible that additional vaccines developed by such large, multinational pharmaceutical companies may receive further approvals and authorizations in the near term. These entities may develop COVID-19 vaccines that are more effective than any COVID-19 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 to competing vaccines and therapeutics that could reduce the commercial opportunity for our coronavirus vaccine candidates, once approved (if ever), the end of the public health emergency declared in connection with COVID-19 in the U.S. (and similar statuses of analogous foreign declarations) could ultimately render our product candidates obsolete to some degree, which 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 the Minister whereby the Minister agreed to contribute up to CAD $56 million from the SIF to support the development of our coronavirus vaccine program, VBI-2900, though the Project. In an amendment to the Contribution Agreement signed on March 28, 2022, we agreed to complete the Project, to be conducted exclusively in Canada except as permitted otherwise under certain circumstances, in or before December 31, 2023. 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 from K2HV, 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 $500,000 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. On December 6, 2022, we and CEPI entered into the CEPI Amendment, which, among other things, expanded the scope of the CEPI Funding Agreement to advance the development of multivalent coronavirus shots that could be deployed against COVID-19 as well as a future "Coronavirus X". 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, as amended by the CEPI Amendment. 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 or the CEPI Amendment, 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.

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 U.S. 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 U.S. government, we may have a widely used vaccine in circulation in Canada, the U.S. 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 commercially successful;
- 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 may 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 timely and cost-effective manner;
- the products, if safe and effective, may 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 may prevent us or our collaborators from exploiting technologies, and manufacturing or marketing products; and
- third-party competitors may gain greater market share due to superior products or marketing capabilities.

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 U.S., 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, collaborators, 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 and collaborators to conduct our clinical trials. CROs, collaborators, 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 or collaborators 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 and collaborators to ensure that accurate records are maintained to support the results of the clinical trials. While we or our CROs or collaborators 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 third-party investigators, such as universities and medical institutions and their faculty or staff, to conduct our clinical trials. These sites and third-party investigators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If these third-party 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 CROs and 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 results of our previous, current or future clinical trials may not support regulatory approval of our pipeline candidates or may result in the discovery of unexpected adverse side effects associated with the use thereof, or they may be deemed insufficient to substantiate certain promotional claims about our current and/or future products on the market, as applicable, any of which could have a material adverse effect on our business.

Even if our clinical trials are completed as planned, we cannot be certain that the FDA or other foreign regulatory authorities will agree with our conclusions regarding them, which may prevent us from receiving regulatory approvals, may restrict what data is included in the prescribing information and indication if approved, and may prevent us from developing differentiated and meaningful promotional claims as part of the marketing and commercialization of approved products. 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 U.S. 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.

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 U.S. and Canada under the brand name PreHevbrio, in the EU/EEA and the UK under the brand name PreHevbri, 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 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 ($534.1 million). The second claim is a civil action brought by two minors and their parents against SciVac and the 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, September 30, 2021, June 9, 2022, and January 12, 2023. The next preliminary hearing is scheduled to be held on July 13, 2023.

On December 5, 2022, another civil claim was filed in the District Court of the central district in Israel naming our subsidiary, SciVac, as a defendant. The claim was filed by a minor and his parents against SciVac, the IMoH, and Prof. Arieh Raziel, requesting compensation due to bodily injury of the minor, who was diagnosed as suffering from an Autism Spectrum Disorder (ASD). The plaintiffs allege that the minor's disabilities and the syndrome from which he suffers were caused due to a combination of several factors, including negligent pregnancy monitoring, negligent labor and delivery procedure, and administration of the alleged defective vaccine (Sci-B-Vac vaccine). According to applicable law in Israel, the Statement of Claim does not specify the claim amount, as it is a personal injury claim. Preliminary hearings will begin on July 3, 2023.

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 U.S., 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 U.S. or other regions (if any), the FDA and 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. 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 U.S. 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 our wholly owned manufacturing facility, our current or future contract manufacturers, or contract testing organizations to obtain or maintain FDA or other regulatory agencies' approval for manufacturing or testing facilities could have a material adverse impact on our business, results of operations, financial condition, and prospects.

Our wholly owned manufacturing facility and any of our current and future manufacturers, whether the facilities are ours or third-party manufacturer facilities, are subject to pre-approval and periodic, often unannounced, post-market regulatory inspections by the FDA and applicable foreign equivalents to evaluate regulatory compliance and product quality and safety. This continual regulatory monitoring and periodic inspections of the manufacturing facilities where our current and future products, as applicable, are produced can result in substantial costs, time, and efforts in connection with any perceived deficiencies, as well as the inherently costly and often burdensome quality-assurance and compliance efforts that are required year-round and in anticipation of a regulatory inspection or audit. Similar rules apply in the EU, the UK and Israel. 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 U.S. and ex-U.S. regulators for the manufacture of our finished products and pipeline candidates, which comes with additional risks, as we are ultimately responsible for any violations observed at any such third-party facilities but do not have the same level of day-to-day control or oversight as one would have at its own facility.

If we or our third-party manufacturers or contract testing organizations cannot successfully produce material that conforms to our specifications and cGMP requirements of any applicable regulatory agency, we may not be able to secure or maintain approval for our manufacturing or testing facilities. If the FDA or another regulatory agency does not approve these facilities for commercial production, or if they do not maintain a satisfactory regulatory standing, 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 or tested, a regulatory agency may impose restrictions on that product, the manufacturing or testing 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 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. 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 may 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, to the extent that they continue, 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. 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 current and/or future products and how much or under what circumstances healthcare providers will prescribe or administer our products, as applicable.

In both the U.S. and other countries, our product sales depend, or will depend, as applicable and 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 U.S. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the U.S. 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 U.S. has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

Governments outside the U.S. 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 U.S. and Europe with other approved HBV vaccines marketed by GSK, Dynavax, and Merck and will compete outside the U.S. 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 any pipeline candidates for which we obtain regulatory approval, if any, may never achieve market acceptance, even if we obtain regulatory approvals.

Regulatory approval to market a given medical product in a given country does not guarantee that the product will be accepted by the medical community or successful in generating revenue in the applicable market. Accordingly, the commercial success of our current and future products, as applicable, depends and 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 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 currently market or may commercialize in the future depends 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 vaccines or 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 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 or maintain 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, we may not be able to supply pipeline candidates or products for clinical or commercial purposes, and we may be required to 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 products.

The near and long-term commercial viability of our current and future (as applicable) products 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, our current commercialization efforts may be unsuccessful, and we may not be able to commercialize our pipeline candidates that are approved for marketing in the future, if any, or generate sufficient revenue to fund further research and development efforts.

There can be no assurances that any new or existing collaborations, including our collaborations with Syneos, Valneva, and Brii Bio, and/or government funding will ever result in the successful development or commercialization of any products for several reasons, including 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 products and pipeline candidates, in a timely manner or at all;
- such partners may not devote sufficient resources to the commercialization or clinical development of our products or 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 or hinder our commercial success.

Our marketing, promotional, and business practices 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 been among the highest enforcement priorities 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 U.S. 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 Phase I/IIa clinical study where it was administered in combination with an adjuvant 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 $113.3 million and $69.8 million in 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $489.6 million and cash of $62.6 million. Cash outflows from operating activities were $73.7 million for the year ended December 31, 2022. Our income generating activities have been from sales of PreHevbio in the U.S. and 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 continued commercialization activities of our 3-antigen HBV vaccine, 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 13, 2023, 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 our 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, 2022, we had $62.6 million of cash. In order to have sufficient cash and cash equivalents 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, immunotherapies, or therapies could 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 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 are subject to federal, provincial and state healthcare laws, regulations, and policies in connection with our healthcare-related activities and arrangements both in the U.S. and abroad, 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 and indirectly, through our relationships with third parties, such as, 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 U.S. 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 activities and business arrangements with third parties comply with applicable healthcare laws and regulations generally comes with substantial costs, as does, possibly to an even greater degree, any actual or alleged failure to comply with such laws. 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 an increase in federal and state regulation of payments made to physicians and teaching hospitals for marketing, medical directorships, and other purposes. These laws and any other similar initiatives, including, among many others, legislation requiring publication of drug costs, could materially and adversely impact our business, financial condition and results of operations.

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 and products are also subject to equivalent healthcare-related laws and regulations of applicable foreign countries, provinces, and/or any 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 U.S. fraud and abuse laws. In addition to the spectrum of potentially serious consequences that could result from our noncompliance with any such applicable laws or regulations, our global compliance efforts currently, and will continue to, require a significant commitment of our time, efforts, and money.

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

In the U.S., there have been a number of legislative and regulatory initiatives focused on containing the cost of healthcare. The federal Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA"), for example, substantially changed the way healthcare is financed by both governmental and private insurers. The ACA contains a number of provisions that could impact our business and operations, in both foreseeable and unforeseeable ways. 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.

Since its enactment, there have been numerous executive, judicial, and legislative challenges to the ACA, including several efforts to repeal or replace certain elements thereof, such as, for example, the lawsuit brought by the State of Texas (and others) challenging the constitutionality of the ACA after the so-called "Individual Mandate" was repealed by Congress, which was ultimately unsuccessful, as the Supreme Court ordered its dismissal in June 2021. While it appears that the ACA will remain intact, in its current form, for now, we cannot predict whether, or to what extent, it will undergo additional challenges and/or amendments in the future or the impact any such efforts will have on our business and financial results.

Various additional federal reform measures have been introduced in recent years, focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, in July 2021, the Biden administration released an executive order entitled, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response, on September 9, 2021, HHS released a "Comprehensive Plan for Addressing High Drug Prices" that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles.

Additionally, in August 2022, the Inflation Reduction Act ("IRA") was signed into law, which will, among other things, allow U.S. Department of Health and Human Services ("HHS") to negotiate the selling price of certain drugs and biologics that the Centers for Medicare & Medicaid Services ("CMS") reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years, or 11 years for biologics, can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2023, the IRA will also penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025.

In foreign healthcare markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict how our business will ultimately be affected by existing healthcare reform measures or what new statutory, regulatory, and/or administrative initiatives may be adopted in the future. However, we expect there to be continued, or increased, downward pressure on drug pricing in most, if not all, jurisdictions in which we currently, or may in the future, market one or more biological products. Any and all current and future reform measures at any level and in any country could result in, among other things, reduced demand for or market acceptance of our current and future (if any) products. If we or any third parties we may engage are slow or unable to adapt to changes in the applicable regulatory landscape or the adoption of new requirements and/or policies, or if we or such third parties are not able to maintain regulatory compliance, the success of our products and development pipeline will likely suffer, and we may have greater difficulty achieving or sustaining profitability.

Our internal computer systems, and/or those of our third-party vendors, collaborators, and/or other contractors may be subject to various federal and state confidentiality and data privacy laws in the U.S. 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 U.S. and research institutions in the U.S. 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 U.S., 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 U.S., 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 and the ongoing effects from such conditions 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, May 2021, and as recently as August 2022 – 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, United States Dollars and the Euro. As a result, we are exposed to the risks that the United States Dollar may devalue relative to the Canadian Dollar, the Euro or NIS, or, if the United States Dollar appreciates relative to the Canadian Dollar, the Euro or NIS, that the inflation rate in the U.S. may exceed such rate of devaluation of the United States Dollar, or that the timing of such devaluation may lag behind inflation in the U.S. The average exchange rate for the year ended December 31, 2022, was US$1.00 = NIS 3.3579, US$1.00 = CAD $1.3005 and US$ 1.00 = €0.9694. We cannot predict any future trends in the rate of inflation in the U.S.or the rate of devaluation, if any, of the United States Dollar against the Canadian Dollar, Euro 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 200 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 submit prior art, or initiate opposition, derivation, reexamination, supplemental, examination, interference proceedings, 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 these proceedings, these procedures are time consuming and expensive and may have a negative impact on our results. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, or reduce our ability to manufacture or commercialize products. Furthermore, if the scope or strength of protection provided by our patents and patent applications is threatened, it could discourage companies from collaborating with us to license, develop or commercialize current or future products. The ownership of our proprietary rights could also be challenged.

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. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. We cannot be certain that we or our licensors were the first to invent, or the first to file, patent applications covering our products and candidates. We also may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents. 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 trade secrets, know-how, other non-patent intellectual property, and 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 U.S. under the BPCIA or equivalent regulatory data exclusivity protection in other jurisdictions for our products*." Non-patent protection, however, can be weaker than the protection afforded by patents. For example, trade secret protection is effective only against wrongful acquisition, use or disclosure of confidential information, and only while the trade secret remains confidential and meets the legal standards to qualify as a trade secret. A competitor can avoid a claim of trade secret misappropriation by showing, for example, loss of confidentiality or independent development without use of a trade secret owner's information, however, this typically requires some time, effort, and financial resources to develop independently. In the event that our competition can develop a substantially equivalent product to our 3-antigen HBV vaccine independently, this competition could have a materially adverse effect on our business, financial condition, and operating results.

Our 3-antigen HBV vaccine is the only product we currently market in the U.S. and Israel or are planning to commercialize in Europe and Canada. Failure to obtain and retain marketing exclusivity or expiration of the market exclusivity could 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 U.S. 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.

Furthermore, the issuance of a patent, while presumed valid and enforceable, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees.

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 Amended and Restated Ferring License Agreement between us, Ferring International Center S.A. ("Ferring"), a company incorporated pursuant to the laws of Switzerland and SciVac, and the license from UMPC. Under the Amended and Restated Ferring License Agreement, we are committed to pay Ferring royalties equal to 3.5% of net sales (as defined therein) of HbsAg "Product" (as defined therein). Under the 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 original Ferring License Agreement) of Product. Under the original 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 original 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 Amended and Restated 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 U.S. in 2023 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 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 we are 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 U.S. and other important markets outside the U.S., 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 U.S. 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.

Patent rights are territorial, and patent protection extends only to those countries where we have issued patents. Filing, prosecuting, and defending patents on our products and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. could be less extensive than those in the U.S. Competitors may successfully challenge or avoid our patents, or manufacture products in countries where we have not applied for patent protection. Changes in the patent laws in the U.S. or other countries may diminish the value of our patent rights. As a result of these and other factors, the scope, validity, enforceability, and commercial value of our patent rights are uncertain and unpredictable.

The laws of foreign countries may not protect intellectual property rights to the same extent as the laws of the U.S. 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 U.S., 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 U.S. 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 U.S. and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

We rely on trade secrets to protect our proprietary technologies to maintain our competitive position, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, contract manufacturers, vendors and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets or similar knowledge relevant to our business could otherwise become known or be independently discovered by our competitors.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Our employees may have been previously employed at other companies in the industry, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product(s), which would materially adversely affect our commercial development efforts.

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 $58.3 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, availability of resources, 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. The fair value of our CMV asset was in excess of its carrying value by greater than 25% as of August 31, 2022. In the event we continue to experience challenging market conditions, insufficient internal resources due to competing programs, and changes in the competitive and technological landscape for CMV vaccines, this may give rise to a triggering event that may require the Company to record impairment charges on our IPR&D assets and/or goodwill in the future.

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 U.S. 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 U.S. 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.

K2HV, pursuant to the Loan Agreement, as amended by the First Amendment and the Second 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, 2022, was $55 million ($55.7 million including the exit fees).

In the event of a default, K2HV 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 K2HV, 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, as amended by the First Amendment and the Second 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 as amended by the First Amendment and the Second Amendment, 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, as amended by the First Amendment and the Second Amendment also contains other customary covenants, including minimum net revenue 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 K2HV 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 as amended by the First Amendment and the Second Amendment, K2HV made a term loan to us in aggregate amount of $50.0 million. During the year ended December 31, 2022, we made average monthly payments of interest in the amount of approximately $293. We are required to pay interest only until maturity on September 14, 2026.

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 the Wall Street Journal, Money Rates prime rate; 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 K2HV 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. 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 March 10, 2023, our common shares traded as high as $1.86 per share and as low as $0.334 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 and its ongoing effects has resulted in significant financial market volatility and uncertainty. 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.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common shares.

On July 1, 2022, we received a letter from the Listings Qualifications Department of Nasdaq indicating that, based upon the closing bid price of our common shares for the 30 consecutive business day period between May 18, 2022, through June 30, 2022, we did not meet the minimum bid price of $1.00 per share required for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). On December 29, 2022, we were granted an additional 180-day period, or until June 26, 2023, to regain compliance with the Minimum Bid Price Requirement.

In order to regain compliance with the Minimum Bid Price Requirement, our common shares must maintain a minimum closing bid price of $1.00 for at least ten consecutive business days during the additional 180-day grace period, which will end on June 26, 2023. As of the date of this filing, we have not regained compliance with the Minimum Bid Price Rule, and there can be no assurance that the market price of our common shares will remain at least $1.00 for a minimum of ten consecutive business days in order for us to regain compliance with the Minimum Bid Price Rule prior to June 26, 2023.

In the event that we do not regain compliance by June 26, 2023, Nasdaq will notify us that our common shares are subject to delisting. We would then be permitted to appeal any delisting determination to a Nasdaq Hearings Panel. Our common shares would remain listed on Nasdaq pending the panel's decision after the hearing. If we do not appeal the delisting determination, or do not succeed in such an appeal, we may list our common shares on an over-the-counter exchange. Any such delisting determination could seriously decrease or eliminate the value of an investment in our common shares.

To resolve the noncompliance, we may consider available options including a reverse share split, which may not result in a permanent increase in the market price of our shares, which is dependent on many factors, including general economic, market and industry conditions and other factors detailed from time to time in the reports we file with the Securities and Exchange Commission (the "SEC"). It is not uncommon for the market price of a company's shares to decline in the period following a reverse share split.

Although we expect to take actions intended to restore our compliance with the listing requirements, we can provide no assurance that any action taken by us would be successful, or that any such action would stabilize the market price or improve the liquidity of our shares. Should a delisting occur, an investor would likely find it significantly more difficult to dispose of, or to obtain accurate quotations as to the value of our shares, and our ability to raise future capital through the sale of our shares could be severely limited.

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, as amended by the First Amendment and the Second Amendment, with K2HV prohibits us from declaring or paying cash 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 cash 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 258,257,494 common shares outstanding as of December 31, 2022, approximately 74.1% 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, 2022, we had outstanding options, awards, convertible debt, and warrants for the purchase of 32,571,391 common shares. Of this amount, options, awards, convertible debt, and warrants for the purchase of 16,248,435 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.

Although we expect that we will not be classified as a passive foreign investment company ("PFIC") in 2023, there can be no assurance that we will not be classified as a PFIC in 2023 or any subsequent year, which would result in adverse U.S. federal income tax consequences to U.S. holders of our common shares.

A non-U.S. corporation, such as us, would be classified as a PFIC for U.S. federal income tax purposes for any taxable year if either (i) 75% or more of its gross income is passive income, or (ii) 50% or more of the value of its assets (based on an average of the values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. We do not expect to be a PFIC for the 2023 taxable year. However, the fair market value of our assets may be determined in large part by the market price of our common shares, which is likely to fluctuate, and the composition of our income and assets will be affected by how, and how quickly, we spend any cash that is raised in any financing transaction. No assurance can be provided that we will not be classified as a PFIC for the 2023 taxable year or any future taxable year. If we are a PFIC in any year, U.S. holders will be subject to certain adverse U.S. federal income tax consequences. Prospective U.S. holders should consult their tax advisors regarding our PFIC status.

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 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.

U.S. 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 U.S. As a result, it may be difficult for investors to effect service of process within the U.S. upon us or to enforce judgments obtained against us in U.S. courts, in any action, including actions predicated upon the civil liability provisions of U.S. federal securities laws or any other laws of the U.S. Additionally, rights predicated solely upon civil liability provisions of U.S. federal securities laws or any other laws of the U.S. may not be enforceable in original actions, or actions to enforce judgments obtained in U.S. courts, brought in Canadian or Israeli courts. In addition, two of our officers reside outside of the U.S., and all or a substantial portion of their assets may be located outside the U.S., which may make effecting service of process within the U.S. or enforcing judgments obtained against such persons in U.S. 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, U.S.

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 U.S. 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 ("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 will likely limit the ability of other shareholders to influence corporate matters.

As of December 31, 2022, approximately 25.9% of our outstanding common shares were 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. Increased turnover rates within our employee base 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, there may be 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.

For additional discussion of the impact of the COVID-19 pandemic on our business, please see the risk factor titled *"The coronavirus pandemic and its ongoing effects have 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 Exchange Act, 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 Exchange Act applicable to a publicly traded U.S. domestic issuer. The obligations of being a public reporting company require significant expenditures, including costs resulting from public company reporting obligations under the Exchange Act 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 Nasdaq. 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 U.S. 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 with no option to extend. 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. On September 5, 2019, the sub-sublease was assigned by Iogen Corporation to 310 Hunt Club GP Inc. ("the Assignee"). In 2022, we extended the lease for the laboratory and office space with a term ending on April 30, 2026. The base and additional rent for the premises is approximately $30 per month through December 31, 2023. 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 $24.00 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 $1,865 in 2022.

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 ($534.1 million). The second claim is a civil action brought by two minors and their parents against SciVac and the IMoH 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.

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, September 30, 2021, June 9, 2022, and January 12, 2023. The next preliminary hearing is scheduled to be held on July 13, 2023.

On December 5, 2022, another tort claim was filed in the District Court of the central district in Israel naming our subsidiary, SciVac, as a defendant. The claim was filed by a minor and his parents against SciVac, the IMoH, and Prof. Arieh Raziel, requesting compensation due to bodily injury of the minor, who was diagnosed as suffering from an Autism Spectrum Disorder (ASD). The plaintiffs allege that the minor's disabilities and the syndrome from which he suffers were caused due to a combination of several factors, including negligent pregnancy monitoring, negligent labor and delivery procedure, and administration of the alleged defective vaccine (Sci-B-Vac vaccine). Preliminary hearings will begin on July 3, 2023.

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

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 Nasdaq on May 9, 2016, under the symbol "VBIV."

Holders

As of March 8, 2023, we had approximately 814 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 with K2HV 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, 2022, 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

We are a commercial stage biopharmaceutical company driven by immunology in the pursuit of prevention and treatment of disease. Through our innovative approach to virus-like particles ("VLPs"), including a proprietary enveloped VLP ("eVLP") platform technology, we develop vaccine candidates that mimic the natural presentation of viruses, designed to elicit the innate power of the human immune system. We are 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"). We are headquartered in Cambridge, Massachusetts, with research operations in Ottawa, Canada, and a research and manufacturing site in Rehovot, Israel.

Product Pipeline

Our 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, 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. Our 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 ("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 as many as 2.2 million chronically infected people in the 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 no cure available for HBV infection and while public health initiatives highlight 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 30% of all adults aged 19 years and older.

In April 2022, the Centers for Disease Control and Prevention ("CDC") Advisory Committee on Immunization Practices ("ACIP") implemented a change to the adult HBV vaccine recommendations. As incorporated in the CDC's 2022 Adult Immunization Schedule and as published in the April 1, 2022, CDC Morbidity and Mortality Weekly Report, adults aged 19 to 59 years are now universally recommended to be vaccinated against HBV infection. Additionally, while adults aged 60 years and older with risk factors for HBV infection are still recommended to receive HBV vaccinations, adults aged 60 years and older without known risk factors for HBV may now also receive HBV vaccinations.

In addition to our approved vaccine, PreHevbrio [Hepatitis B Vaccine (Recombinant)], there are four other vaccines approved in the U.S. for the prevention of HBV infection in adults: Engerix-B® and Twinrix®, manufactured by GlaxoSmithKline Biologicals S.A. ("GSK"), Recombivax HB®, manufactured by Merck &. Co. ("Merck"), and Heplisav-B®, manufactured by Dynavax Technologies Corporation ("Dynavax").

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").

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") have included:

- 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 and subvariants – First identified in South Africa, VOC in November 2021

Glioblastoma ("GBM")

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. Median overall survival for recurrent GBM is even lower, at about 8 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 February 28, 2023:

Indication	Program	Technology	Current Status
Approved Vaccine			
● Hepatitis B	PreHevbrio[1,2,3] *Hepatitis B Vaccine (Recombinant)*	VLP	Registration/Commercial
Prophylactic Candidates			
● Coronaviruses (Multivalent)	VBI-2901	eVLP	Ongoing Phase I
● COVID-19 (Beta variant)	VBI-2905	eVLP	Phase Ib
● COVID-19 (Ancestral)	VBI-2902	eVLP	Phase Ia
● Cytomegalovirus	VBI-1501	eVLP	Phase I Completed
● 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	Phase I/IIa
● Other CMV-Associated Cancers	Undisclosed	eVLP	Preclinical

[1]Approved for use in the U.S. and Canada, under the brand name PreHevbrio, for the prevention of infection caused by all known subtypes of HBV in adults 18 years of age and older.

[2] Approved for use in the European Union ("EU") / European Economic Area ("EEA") and the UK, under the brand name PreHevbri, for active immunization against infection caused by all known subtypes of the HBV in adults. It can be expected that hepatitis D will also be prevented by immunization with PreHevbri as hepatitis D (caused by the delta agent) does not occur in the absence of HBV infection.

[3]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 aged 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 was reflected in a CDC publication on April 1, 2022 and was a notable milestone as many insurance plans and institutions require an ACIP recommendation before a vaccine can be reimbursed or is made available to patients. Additionally, PreHevbrio was included in the 2023 annual update of the CDC Adult Immunization Schedule, as detailed in the CDC publication on February 10, 2023. VBI launched PreHevbrio in the U.S. at the end of the first quarter of 2022, and revenue generation began in the second quarter of 2022.

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

- *EU:* On May 2, 2022, we announced that the European Commission (the "EC") granted Marketing Authorization for PreHevbri [Hepatitis B Vaccine (Recombinant, Adsorbed)]. The European Commission's centralized marketing authorization is valid in all EU Member States as well as in the EEA countries (Iceland, Liechtenstein, and Norway). On September 8, 2022, we announced a partnership with Valneva SE ("Valneva") for the marketing and distribution of PreHevbri in select European markets, initially including the UK, Sweden, Norway, Denmark, Finland, Belgium, and the Netherlands. As part of this partnership, VBI expects PreHevbri will be available in certain European countries beginning in the first half of 2023.

- *UK:* On June 1, 2022, we announced that the MHRA granted marketing authorization for PreHevbri [Hepatitis B Vaccine (Recombinant, Adsorbed)]. This follows the EC centralized marketing authorization received in May 2022 and was conducted as part of the EC Decision Reliance Procedures ("ECDRP"). VBI expects to make PreHevbri available in the UK in the first half of 2023 as part of the partnership with Valneva.

- *Canada:* On December 8, 2022, we announced that Health Canada approved PreHevbrio [3-antigen Hepatitis B Vaccine (Recombinant)] for the prevention of infection caused by all known subtypes of HBV in adults aged 18 years and older. VBI expects to make PreHevbrio available in Canada in 2023.

- *Israel:* Approved and commercially available under the brand name Sci-B-Vac®.

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 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 aged 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. 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 Phase I study was initiated in September 2021 to assess VBI-2905, our eVLP vaccine candidate directed against the SARS-CoV-2 Beta variant. On April 5, 2022, we announced new data from the Phase Ib study (n=53). A single-dose booster of VBI-2905 increased the geometric mean titer ("GMT") of neutralizing antibodies directed against the Beta variant 3.8-fold, at day 28, in participants who had previously received two-doses of an mRNA vaccine (ancestral strain) – approximately 2-fold increases were also seen at day 28 in antibody GMTs against both the ancestral and delta variant. New preclinical data announced at the same time showed that against a panel of coronavirus variants in mice, reactivity was seen with VBI-2902 against all variants including the ancestral strain, Delta, Beta, Omicron, Lambda, and RaTG13 (a bat coronavirus that is distant to circulating human strains). In this same panel, VBI-2901 was able to elicit an even stronger response against all variants tested – as the strains became more divergent from the ancestral strain, VBI-2901 elicited a greater difference in GMT from VBI-2902, ranging from 2.5-fold higher against the ancestral strain to 9.0-fold higher against the bat coronavirus. Additionally, a validated pseudoparticle neutralization assay ("PNA") benchmarked against the WHO reference standard demonstrated that VBI-2902 elicited neutralizing antibody responses of 176 IU50/mL in its Phase Ia study – this international standard measure would predict a greater than 90% efficacy, with two internationally approved vaccines estimated to have 90% efficacy at 83 and 140 IU50/mL (Gilbert, PB, 2021).

The clinical and preclinical data for all three candidates continue to support the potential of the eVLP platform against coronaviruses. On September 29, 2022, we announced that we initiated the first clinical study of VBI's multivalent coronavirus candidate, VBI-2901, designed to increase breadth of protection against COVID-19 and related coronaviruses. Interim data from this study are expected mid-year 2023.

The VBI-2900 program is supported by a partnership with the Coalition for Epidemic Preparedness Innovations ("CEPI" and the partnership, 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. On December 6, 2022, we and CEPI announced that we expanded the scope of the CEPI Funding Agreement to advance the development of multivalent coronavirus vaccines that could be deployed against COVID-19 as well as a future "Coronavirus X".

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 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 with and without an immunomodulatory adjuvant, conducted at multiple study sites in New Zealand, Australia, Thailand, South Korea, Hong Kong Special Administrative Region of China, and China.

The data from the Phase Ib/IIa for 33 evaluable patients across all study arms suggested: (1) VBI-2601 was well tolerated at all dose levels with and without the adjuvant with no significant adverse events identified; (2) VBI-2601 induced both B cell (antibody) and T cell responses in chronically-infected HBV patients, (3) VBI-2601 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) 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 in combination with BRII-835 (VIR-2218), an investigational small interfering ribonucleic acid ("siRNA") targeting HBV, for the treatment of chronic HBV infection. 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. The study is being conducted at clinical sites in Australia, Taiwan, Hong Kong Special Administrative Region of China, South Korea, New Zealand, Singapore, and Thailand. VBI's partner, Brii Bio, is the study sponsor. A total of 50 adult, non-cirrhotic patients who received NRTI therapy for at least 12 months were randomized and dosed across three cohorts:

- Cohort A: BRII-835 Alone Regimen – Nine subcutaneous 100mg doses of BRII-835, dosed every four (4) weeks through Week 32
- Cohort B: BRII-835 Alone Regimen + nine 40μg intramuscular doses of VBI-2601 admixed with interferon-alpha (IFN-α) as co-adjuvant every four weeks from Week 8 through Week 40
- Cohort C: BRII-835 Alone Regimen + nine 40μg intramuscular doses of VBI-2601 without IFN-α every four weeks from Week 8 through Week 40

On February 15, 2023, we announced interim data from the Phase II combination study. The data, which was featured in an oral presentation at the 32nd Conference of the Asian Pacific Association for the Study of the Liver ("APASL") on February 18, 2023, demonstrated that the combination therapy was generally well-tolerated, restored strong anti-HBsAg antibody responses, and led to improved HBsAg-specific T-cell responses, when compared to BRII-835 alone. Notably:

- Mean changes in HBsAg reduction relative to baseline at week 40 were -1.68 log10 IU/mL in Cohort A, -1.75 log10 IU/mL in Cohort B, and -1.77 log10 IU/mL in Cohort C
- Potent HBV surface antibody levels (> 100 IU/L) were observed in more than 40% of participants in Cohorts B and C at week 40 – by comparison, no antibody responses were detected in Cohort A
- Out of 25 evaluable patients, a higher proportion of Cohort B and C patients demonstrated potent HBsAg-specific T-cell responses (70%; 14/20) relative to those in Cohort A (20%; 1/5) through week 44
- To date, two participants receiving combination regimens achieved either HBsAg below LLOQ (0.05 mIU/mL), to an undetectable level, or at LLOQ with maximum reductions of ≥ 4 log10 HBsAg – both participants mounted potent anti-HBs antibody and HBV-specific T-cell responses

Additional data from the study are expected to be announced later this year.

On January 5, 2022, we announced that the first patient was dosed in a second Phase IIa/IIb clinical study evaluating VBI-2601. This Phase II study assesses VBI-2601 as an add-on therapy to the standard-of-care in China nucleos(t)ide reverse transcriptase inhibitor ("NRTI") and pegylated interferon therapy (PEG-IFN-α,). Interim topline clinical data from part one of this Phase IIa/IIb clinical study is expected in the third quarter 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 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 two-arm study that enrolled 20 first-recurrent GBM patients to receive 10 µg of VBI-1901 in combination with either GM-CSF or GSK proprietary adjuvant system, AS01, as immunomodulatory adjuvants. AS01 is provided pursuant to a Clinical Collaboration and Support Study Agreement with GSK, which we entered into 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 arm was completed in October 2020.

Data from the Phase IIa portion of the study was announced throughout 2020, 2021, and 2022, with the latest data presented in November 2022 at the 2022 Society for Neuro-Oncology (SNO) Annual Meeting. 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 and 40% (n=4/10) in the VBI-1901 + AS01 study arm; (3) 2 patients with partial tumor responses, one of whom remained on protocol for over two years and had achieved a 93% tumor reduction relative to baseline at initiation of treatment at the start of the study, and 10 stable disease observations across all 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.

On June 22, 2022, we announced that the FDA granted Orphan Drug Designation for VBI-1901 for the treatment of GBM.

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 to support an accelerated approval application 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 the second quarter of 2023.

On October 12, 2022, we announced a collaboration with Agenus Inc. to evaluate VBI-1901 in combination with anti-PD-1 balstilimab in a Phase II study as part of the INSIGhT adaptive platform trial in patients with primary GBM. Subject to approval from regulatory bodies, we expect enrollment to initiate in the VBI-1901 study arm in INSIGhT mid-year 2023.

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 "original 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.

On October 18, 2022, the Company amended and restated the original Ferring License Agreement (the "Amended and Restated Ferring License Agreement"), which amends and restates certain of the terms relating to the manufacture and marketing of HBsAg products, which includes, among others, updates to the definition of net sales, and a reduction in the fixed royalty rate on net sales of HBsAg products ("Product") from seven percent (7%) to three and a half percent (3.5%) in consideration for the grant of the license to utilize genetically engineered CHO cells encoding the hepatitis B antigen and certain information related to the manufacture of hepatitis B vaccines. In connection with the Amended and Restated Ferring License Agreement, the Company has also agreed to act as the guarantor for SciVac's obligations under the Amended and Restated Ferring License Agreement, or if the Amended and Restated Ferring License Agreement is assigned to a third party, guarantor for SciVac's obligations that have accrued up until the date of such assignment. 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 original Ferring License Agreement) of Product. Under the original 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 original 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 Amended and Restated Ferring License Agreement and SciGen Assignment Agreement will continue to be payable for the duration of the extended license periods.

Under a license agreement with UPMC and other licensors relating to eVLP technology, we had an exclusive license to a family of patents that will expire in the U.S. in 2023 and expired in other countries in 2021. UPMC is also a co-owner of the patent family covering our VBI-1501 CMV vaccine and we are negotiating an agreement with UPMC to cover this patent family. During year ended December 31, 2022, we did not make any milestone payments.

Financial Operations Overview

At present, our operations are focused on:

- continuing the commercialization of PreHevbrio in the U.S.;
- preparing for commercialization of our 3-antigen HBV vaccine in Europe and Canada;
- manufacturing our 3-antigen HBV vaccine at commercial scale to meet demand in the U.S., Europe, Canada and Israel, where it is approved, and to prepare for supply in markets where we may obtain marketing authorization;
- conducting the Phase I/IIa clinical studies 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 multivalent coronavirus candidate, VBI-2901;
- completing the Phase I clinical study of our prophylactic COVID-19 vaccine candidates, VBI-2902 and VBI-2905 (Beta variant);
- 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;
- developing VBI-2601, 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, under the brand name PreHevbrio in the U.S., and in Israel under the name Sci-B-Vac. In addition, we have sold through named patient programs in countries where our 3-antigen HBV vaccine was not approved, though those markets have generated a limited number of sales. 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, 2022, VBI had an accumulated deficit of approximately $489.6 million, stockholders' equity of approximately $64.2 million and cash of $62.6 million. Cash outflows from operating activities were $73.7 million for the year ended December 31, 2022. 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 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 from this uncertainty.

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 $113.3 million for the year ended December 31, 2022, 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 and clinical studies, and as we continue the commercialization of PreHevbrio in the U.S. and Canada, and PreHevbri in Europe. 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 subject us to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the rules and regulations of Nasdaq, and the Canadian securities regulators. We have also incurred and will continue to incur regulatory compliance costs and general and administrative costs related to our clinical regulatory operations and commercialization of our marketed product and product candidates.

Overall Performance

We had net losses of $113,303 and $69,753 for the years ended December 31, 2022 and 2021, respectively. We had an accumulated deficit of $489,609, cash of $62,629 and, net working capital of $40,748 as of December 31, 2022. We had cash outflows from operating activities of $73,695 for the year ended December 31, 2022.

Revenues, net

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

In the U.S., beginning in the second quarter of 2022, PreHevbrio was sold to a limited number of wholesalers and specialty distributors (collectively, our "Customers"). We expect to continue to expand our market share over the coming year. Revenues from product sales are recognized when we have satisfied our performance obligations, which is the transfer of control of our product upon delivery to the Customer. Our standard credit terms are short-term, and we expect to receive payment in less than one year, there is no significant financing component on the related receivables. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues.

In Israel, Sci-B-Vac is sold through procurement requests from four health funds ("HMOs") (collectively, the "Sci-B-Vac Customers").

Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment.

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

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, 2022, 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 advancement of our lead programs, including: our 3-antigen HBV vaccine; VBI-1901, our GBM vaccine immunotherapeutic candidate; VBI-1501, our CMV vaccine candidate; VBI-2601, our hepatitis B immunotherapeutic candidate; and VBI-2900, our coronavirus vaccine program. These costs 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.

Sales, General and Administrative ("SG&A") Expenses

SG&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. SG&A expenses are expensed when incurred.

Over the coming quarters, we expect to redefine the deployment of our commercial resources and, as such, reduce our commercial expenses. As a result, we expect our SG&A expenses will decrease.

Interest Expense, Net of Interest Income

Interest expense, net of interest income, 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, 2022 Compared to the Year Ended December 31, 2021

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

	Year ended December 31			
	2022	2021	**Change $**	**Change %**
Revenues, net	**$ 1,082**	$ 631	**$ 451**	**71%**
Expenses:				
Cost of revenues	**11,276**	10,770	**506**	**5%**
Research and development	**15,506**	19,558	**(4,052)**	**(21)%**
Sales, general and administrative	**56,120**	38,335	**17,785**	**46%**
Total operating expenses	**82,902**	68,663	**14,239**	**21%**
Loss from operations	**(81,820)**	(68,032)	**(13,788)**	**20%**
Interest expense, net of interest income	**(4,007)**	(4,732)	**725**	**(15)%**
Foreign exchange (loss) gain	**(27,476)**	3,011	**(30,487)**	**(1,013)%**
Loss before income taxes	**(113,303)**	(69,753)	**(43,550)**	**62%**
Income tax expense	**-**	**-**	**-**	**-%**
NET LOSS	**$ (113,303)**	$ (69,753)	**$ (43,550)**	**62%**

Revenues, net

Revenues, net for the year ended December 31, 2022 were $1,082 as compared to $631 for the year ended December 31, 2021. Revenues for the year ended December 31, 2022 increased by $451 or 71% due to an increase in product revenue as a result of the launch of PreHevbrio in the U.S. in late Q1 2022 with revenue generation beginning in Q2 2022. Over the next year, VBI expects to expand its market share, continuing to broaden access to PreHevbrio in the U.S. and Canada, and PreHevbri in select EU markets and in the UK.

Revenue Composition

	2022	2021
Product revenue, net	**$ 931**	$ 262
R&D service revenue, net	**151**	369
Total revenues, net	**$ 1,082**	$ 631

Revenues, net by Geographic Region

	Years ended December 31			
	2022	2021	**$ Change**	**% Change**
Revenue, net in United States	**$ 695**	$ -	**$ 695**	**100%**
Revenue, net in Israel	**315**	321	**(6)**	**(2)%**
Revenue, net in China/Hong Kong	**66**	306	**(240)**	**(78)%**
Revenue, net in Europe	**6**	4	**2**	**50%**
Total Revenue, net	**$ 1,082**	$ 631	**$ 451**	**71%**

Cost of Revenues

Cost of revenues for the year ended December 31, 2022 was $11,276 as compared to $10,770 for the year ended December 31, 2021. The increase in the cost of revenues of $506 or 5% is due to increased outsourced testing costs, direct labor costs, and inventory related costs incurred in the year ended December 31, 2022 compared to the year ended December 31, 2021.

Research and Development Expenses

R&D expenses for the year ended December 31, 2022 were $15,506 as compared to $19,558 for the year ended December 31, 2021. R&D expenses were offset by $8,859 for the year ended December 31, 2022 and $14,856 for the year ended December 31, 2021 due to government grants and funding arrangements. The decrease in R&D expenses of $4,052 or 21%, is mainly a result of (i) the decrease in the costs related to our coronavirus vaccine program, that were not offset by government grants and funding arrangements - for the year ended December 31, 2021, both the VBI-2902 and VBI-2905 clinical trials were ongoing compared to the year ended December 31, 2022 where there was only the VBI-2901 clinical trial ongoing and (ii) receipt of a refund from the FDA of $2,876 originally expensed in 2021 related to the Prescription Drug User Fee Act program fee for PreHevbrio due to the FDA's determination that we qualified as a small business in 2022, thereby reducing our regulatory cost by the refunded amount; partially offset by an increase in R&D expenses related to continued development of our other vaccine candidates, specifically, our GBM our vaccine immunotherapeutic candidate, VBI-1901, as we prepare for the next phase of development.

Sales, General and Administrative Expenses

SG&A expenses, net of government grants and funding arrangements, for the year ended December 31, 2022 were $56,120 as compared to $38,335 for the year ended December 31, 2021. SG&A expenses were offset by $735 for the year ended December 31, 2022 and $859 for the year ended December 31, 2021 due to government grants and funding arrangements. The SG&A expense increase of $17,785 or 46%, is mainly a result of the increase in the U.S. sales, marketing and other commercial activities related to PreHevbrio, most notably the deployment of our commercial field teams and development of our distribution infrastructure, as FDA regulatory approval of PreHevbrio occurred in late 2021. Additional increase in costs include increased insurance costs, increased professional costs, and increased labor costs.

Loss from Operations

The loss from operations for the year ended December 31, 2022 was $81,820 as compared to $68,032 for the year ended December 31, 2021. The $13,788 increase in the loss from operations resulted from the items discussed above.

Interest Expense, Net of Interest Income

Interest expense, net of interest income for the year ended December 31, 2022 was $4,007 as compared to $4,732 for the year ended December 31, 2021. The decrease in interest expense, net of interest income of $725 or 15% is due to the conversion of $2,000 of the secured term loan to common shares in the year ended December31, 2021, which resulted in $1,161 of additional interest accretion being recognized in interest expense, net of interest income and an increased interest income earned on cash due to higher interest rates applied for the year ended December 31, 2022. This decrease is partially offset by an increase in long-term debt of $20,000 beginning mid-September 2022 and an increased interest payments on our long-term debt due to higher interest rates applied during the year ended December 31, 2022.

Foreign Exchange (Loss) Gain

Foreign exchange loss for the year ended December 31, 2022 was $27,476 as compared to a gain of $3,011 for the year ended December 31, 2021. Certain intercompany loans between us and our subsidiaries are denominated in a currency other than the functional currency of each entity. The primary driver of the increase in foreign exchange loss was the impact of the relative strengthening of the U.S. and Canadian Dollars against the New Israeli Shekel upon translation of these intercompany loans.

Net Loss

Net loss of $113,303 for the year ended December 31, 2022, compared to $69,753 for the year ended December 31, 2021, respectively, is a result of the items discussed above.

Liquidity and Capital Resources

	Year ended December 31			
	2022	2021	**$ Change**	**% Change**
Cash	**$ 62,629**	$ 121,694	**$ (59,065)**	**(49)%**
Current Assets	**77,690**	130,284	**(52,594)**	**(40)%**
Current Liabilities	**36,942**	32,586	**4,356**	**13%**
Working Capital	**40,748**	97,698	**(56,950)**	**(58)%**
Accumulated Deficit	**(489,609)**	(378,371)	**(111,238)**	**29%**

As of December 31, 2022, we had cash of $62,629 as compared to $121,694 as of December 31, 2021. As of December 31, 2022, we had working capital of $40,748 as compared to working capital of $97,698 at December 31, 2021. Working capital is calculated by subtracting current liabilities from current assets.

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation ("FDIC") was appointed as receiver. We have deposit accounts at SVB. The standard deposit insurance amount is up to $250 per depositor, per insured bank, for each account ownership category. As of March 10, 2023, we had approximately $1.2 million in deposit accounts at SVB. On March 12, 2023, the U.S. Treasury, Federal Reserve, and FDIC announced that SVB depositors will have access to all of their money starting March 13, 2023.

Net Cash Used in Operating Activities

We incurred net losses of $113,303 and $69,753 in the year ended December 31, 2022 and 2021, respectively. We used $73,695 and $39,908 in cash for operating activities during the year ended December 31, 2022 and 2021, respectively. The increase in cash outflows is largely a result of an increase in commercial expenses related to the launch of PreHevbrio in the U.S., increased usage of cash as we build inventory for continued commercialization, less funding received from CEPI, and changes in other operating working capital balances. Cash received from the CEPI Funding Agreement, as amended by the CEPI Amendment, was $18,363 during the year ended December 31, 2021, compared to cash received of $964 during the year ended December 31, 2022.

Net Cash Used in Investing Activities

Net cash flows used in investing activities was $4,344 for the year ended December 31, 2022 compared to cash provided by investing activities of $23,156 for the year ended December 31, 2021. The decrease in cash flows in investing activities is largely as a result of the redemption of short-term investments of $25,151 during the year ended December 31, 2021. Net cash flows used in investing activities for the year ended December 31, 2022, were due to capital expenditures in the U.S., Canada and Israel.

Net Cash Provided by Financing Activities

Net cash flows provided by financing activities was $19,449 for the year ended December 31, 2022 compared to net cash flows provided by financing activities of $44,293 during the year ended December 31, 2021. During the year ended December 31, 2022, we received proceeds from our refinanced long-term debt compared to the year ended December 31, 2021, whereby we issued common shares for cash and received proceeds from our long-term debt amendment.

Sources of Liquidity

Jefferies Open Market Sale Agreement

On August 26, 2022, we 1) filed a registration statement on Form S-3 (File No. 333-267109), which included a base prospectus which covers the offering, issuance and sale of up to $300,000 of common shares, warrants, units and/or subscription rights; and 2) entered into an Open Market Sale Agreement with Jefferies LLC ("Jefferies"), pursuant to which we may offer and sell our 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"). The ATM Program replaced the Open Market Sale Agreements previously entered into with Jefferies on July 31, 2020 and September 3, 2021, pursuant to each of which we could offer and sell our common shares having an aggregate price of up to $125,000 from time to time, through "at the market" equity offering programs. Prior to termination, $27,022 of our common shares remained available for sale pursuant to the first ATM program, and $125,000 of our common shares remained available for sale pursuant to the second ATM program. Neither ATM program was utilized in 2022. We did not make any sales under the ATM Program during the year ended December 31, 2022.

K2 HealthVentures LLC ("K2HV") Long Term Debt

On May 22, 2020, the Company, along with its subsidiary VBI Cda (collectively, the "Borrowers"), entered into the Loan and Guaranty Agreement (the "Loan Agreement") with K2HV and any other lender from time-to-time party thereto (the "Lenders"). On May 22, 2020, the Lenders advanced the first tranche of term loans of $20,000. 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 until the original 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 per share.

On May 17, 2021, the Company entered into the First Amendment to the Loan and Guaranty Agreement ("First Amendment") with the Lenders and received additional loan advances of $12,000.

On September 14, 2022, the Company entered into the Second Amendment to the Loan Agreement (the "Second Amendment") with the Lenders to: (i) increase the amount of the term loans available under the Loan Agreement to $100,000 from $50,000, which term loans are available in up to four tranches subject to the achievement of milestones and other customary conditions, (ii) add certain minimum net revenue covenants to the Second Amendment, (iii) extend the final maturity date for the term loans to September 14, 2026, which may be extended to September 14, 2027, under certain circumstances, and (iv) to the extent that the maturity date is extended, the term loans will begin amortizing on a monthly basis on September 14, 2026.

On September 15, 2022, the Lenders advanced to the Borrowers the Restatement First Tranche Term Loan (as defined in the Second Amendment) in an aggregate amount of $50,000 which included the refinancing of the $30,000 in term loans that were outstanding under the Loan Agreement as amended by the First Amendment. The second tranche of term loans of up to $15,000 will be available from April 1, 2023, through June 30, 2023, subject to the achievement of certain clinical milestones and compliance with a liquidity requirement which requires the Company to have sufficient cash on hand to funds its operations for at least nine months (the "Liquidity Requirement"). The third tranche of term loans of up to $10,000 will be available from April 1, 2024, through June 30, 2024, so long as certain of the milestones for the second tranche of term loans were achieved, no events of default under the Loan Agreement have occurred and are continuing, and the Liquidity Requirement is satisfied. The fourth tranche of term loans of up to $25,000 shall be available at any time from September 14, 2022, until September 14, 2026, subject to the Lender's review of the Company's clinical and financial plans and Lender's investment committee approval.

Pursuant to the Second Amendment, the Lenders have the ability to convert $7,000 into common shares, by which $2,000 of the term loans shall be convertible into 1,369,863 shares of common stock at a conversion price of $1.46 per share and $5,000 of the term loans shall be convertible into 4,792,026 shares of common stock at a conversion price of $1.0434 per share ("K2HV conversion feature").

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 K2HV Warrant") at an exercise price of $1.12 per share. On May 17, 2021, in connection with the First Amendment, the Company amended and restated the Original K2HV Warrant to purchase an additional 312,500 common shares for a total of 937,500 common shares (the "First Amendment Warrant") with the same exercise price of $1.12 per share. On September 14, 2022, in connection with the Second Amendment and the advance of the first tranche of term loans of $50,000 by the Lenders, the Company issued the Lenders a warrant to purchase an additional 2,180,413 common shares (the "Second Amendment Warrant") with a warrant exercise price of $0.8026. If the full remaining $50,000 available in the K2HV tranches is advanced pursuant to the Second Amendment, up to an additional 2,180,413 common shares will be issuable pursuant to the Second Amendment Warrant. The First Amendment Warrant and the Second Amendment Warrant may be exercised either for cash or on a cashless "net exercise" basis. The First Amendment Warrant expires on May 22, 2030 and the Second Amendment Warrant expires on September 14, 2032.

The Company is required to make a final payment equal to 6.95% of the aggregate term loan principal on the maturity date of the term loan, or upon earlier prepayment of the term loans in accordance with the Second Amendment (the "Second Amendment Final Payment"). The final payment related to the refinanced $30,000 in term loans that were outstanding under the Loan Agreement as amended by the First Amendment of $2,224 remains and is due the earlier of June 1, 2024 or the earlier prepayment of the term loans in accordance with the Second Amendment (the "Original Final Payment").

Upon receipt of additional funds, issuable pursuant to the second, third and fourth tranches, under the Second Amendment, additional common shares will be issuable pursuant to the Second Amendment Warrant as determined by the principal amount of the second tranche, third tranche and fourth tranche actually funded multiplied by 3.5% and divided by the warrant exercise price of $0.8026, and the Second Amendment Final Payment will increase by 6.95% of the funds advanced.

The total principal amount of the loan under the Loan Agreement as amended by the Second Amendment, outstanding at December 31, 2022, including the Original Final Payment of $2,224 and the Second Amendment Final Payment of $3,475 in connection with the Second Amendment, is $55,699. The principal amount of the loan made under the Loan Agreement as amended by the Second Amendment accrues interest at an annual rate equal to the greater of (a) 8.00% or (b) prime rate plus 4.00%. The interest rate as of December 31, 2022 was 11.50%. The Company is required to pay only interest until September 14, 2026.

CEPI Partnership

On March 9, 2021, we 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. On December 6, 2022, we and CEPI entered into the CEPI Amendment to expand the scope of the CEPI Funding Agreement. The CEPI Amendment, among others, (i) expands the definition of "Project Vaccine" to include additional multivalent vaccine constructs within the VBI-2900 program, (ii) removes certain pricing restrictions previously allocated to high-income countries in the CEPI Funding Agreement, (iii) updates the proposed volume commitment percentage contributions by us to CEPI for a Project Vaccine, and (iv) adds certain commercial benefits and related adjustments for CEPI following the pandemic period, including royalties paid to CEPI, in the event that CEPI provides funding for Phase III clinical studies of the Project Vaccine. Since inception of the CEPI Funding Agreement we received $19,327, of which there is a balance remaining of $6,966 in other current liabilities on the consolidated balance sheet.

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, 2022, 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, commercial, and manufacturing activities with respect to the advancement of our 3-antigen HBV vaccine and the advancement of our pipeline candidates. As of December 31, 2022, VBI had an accumulated deficit of $489,609, stockholders' equity of $64,163 and cash of $62,629. Cash outflows from operating activities were $73,695 for the year ended December 31, 2022.

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 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-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 from this uncertainty. 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, 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, as amended by the CEPI Amendment, we will receive up to $33,018 in funding to support the development of the Company's coronavirus vaccine program. 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, 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 COVID-19 pandemic, its ongoing effects, the continuing armed conflict between Russia and Ukraine, and inflation among others, have 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 are dependent upon obtaining sufficient capital to fund the research and development of its pipeline candidates, 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, 2022, 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 ("NOLs")

At December 31, 2022, the Company had NOLs aggregating approximately $409.4 million. The NOLs are available to reduce taxable income of future years and expire as follows:

	Netherlands	United States	Canada	Israel	Total
2025	$ -	$ -	$ 843	$ -	$ 843
2026	-	10	3,510	-	3,520
2027	-	446	4,067	-	4,513
2028	-	718	1,575	-	2,293
2029	-	672	2,949	-	3,621
2030	-	2,556	955	-	3,511
2031	-	3,617	1,181	-	4,798
2032	-	2,962	-	-	2,962
2033	-	3,126	1,380	-	4,506
2034	-	5,626	5,166	-	10,792
2035	-	4,661	1,553	-	6,214
2036	-	5,323	8,242	-	13,565
2037	-	6,017	9,263	-	15,280
2038	-	-	2,301	-	2,301
2039	-	-	7,322	-	7,322
2040	-	-	15,544	-	15,544
2041	-	-	11,423	-	11,423
2042	-	-	20,159	-	20,159
No expiration	250	19,641	-	256,305	276,196
Total losses	**$ 250**	**55,375**	**$ 97,433**	**$ 256,305**	**$ 409,363**

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, 2022, 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, 2022, 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 U.S. ("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

Product revenues, net

Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product upon delivery to the Customer. The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Because our standard credit terms are short-term and we expect to receive payment in less than one-year, there is no significant financing component on the related receivables. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues. Since our performance obligation is part of a contract that has an original expected duration of one year or less, we elect not to disclose the information about our remaining performance obligations.

Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment. If we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of revenue that we report in a particular period. We evaluate our estimates of variable considerations including, but not limited to, product returns, chargebacks, rebates, and other fees, periodically or when there is an event or change in circumstances that may indicate that our estimates may change.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration such as product returns, chargebacks, discounts, rebates, and other fees that are offered within contracts between us and our Customers, healthcare providers, pharmacies and others relating to our product sales. We estimate variable consideration using either the most likely amount method or the expected value method, depending on the type of variable consideration and what method better predicts the amount of consideration we expect to receive. We take into consideration relevant factors such as industry data, current contractual terms, available information about Customers' inventory, resale and chargeback data and forecasted customer buying and payment patterns, in estimating each variable consideration. The variable consideration is recorded at the time product sales is recognized, resulting in a reduction in product revenue and a reduction in accounts receivable (if the Customer offsets the amount against its accounts receivable) or as an accrued liability (if we pay the amount through our accounts payable process). Variable consideration requires significant estimates, judgment and information obtained from external sources.

Product Returns

Consistent with industry practice, we offer our Customers a limited right of return based on the product's expiration date for product that has been purchased from us. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We consider several factors in the estimation of potential product returns including expiration dates of the product shipped, the limited product return rights, available information about Customers' inventory and other relevant factors.

Chargebacks

Our Customers subsequently resell our product to healthcare providers, pharmacies and others. In addition to distribution agreements with Customers, we enter into arrangements with qualified healthcare providers that provide for chargebacks and discounts with respect to the purchase of our product. Chargebacks represent the estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are determined at the time of resale to the qualified healthcare providers by Customers, and we issue credits for such amounts generally within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consists of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to the qualified healthcare providers, and chargebacks for units that our Customers have sold to the qualified healthcare providers, but for which credits have not been issued.

Trade Discounts and Allowances

We provide our Customers with discounts which include early payment incentives that are explicitly stated in our contracts, and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Distribution Fees

Distribution fees include fees paid to certain Customers for sales order management, data, and distribution services. Distribution fees are recorded as a reduction of revenue in the period the related product revenue is recognized.

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, 2022. 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 12% 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, 2022. 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, 2022.

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"). Debt discount is 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 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 COVID-19 pandemic and its ongoing effects is currently indeterminable and continually 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 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, 2022 and 2021, is $0 and $29, respectively. The car loan lease was repaid during the year ending December 31, 2022.

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, 2022, and 2021, we had cash of $62.6 million and $121.7 million, respectively which has been deposited in high interest rate bank accounts. Our cash 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, 2022, and 2021 we had long-term debt outstanding of $55.7 million and $32.2 million, respectively. The principal amount of the loan made under the Loan Agreement, as amended by the Second Amendment accrues interest at an annual rate equal to the greater of (a) 8.00% or (b) prime rate plus 4.00%. The interest rate as of December 31, 2022 was 11.50%. 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, Europe, Canada, and the U.S. and therefore we incur expenses in NIS, the Euro, Canadian Dollars, and United States Dollars. We also contract with certain vendors 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, 2022, and December 31, 2021, 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, 2022, 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, 2022. 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, 2022, 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 2023 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, 2022 and 2021
- Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2022 and 2021
- Consolidated Statements of Stockholders' Equity - For the Years Ended December 31, 2022 and 2021
- Consolidated Statements of Cash Flows - For the Years Ended December 31, 2022 and 2021
- Notes to Consolidated Financial Statements

2. **Exhibits**

See Index to Exhibits

ITEM 16: FORM 10-K SUMMARY.

Not applicable.

VBI Vaccines Inc.

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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, 2022 and 2021, 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, 2022, and 2021, and the consolidated results of its operations and its 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 faces several 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 as of December 31, 2022 and cash outflows from operating activities for the year-ended December 31, 2022 and, as such, will require significant additional funds to conduct clinical and non-clinical trials, commercially launch its products, and achieve regulatory approvals that 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 a separate opinion on the critical audit matters or on the accounts or disclosures to which it they relate.

Valuation of In-Process Research and Development

As described in Notes 2 and 7 to the financial statements, the Company's consolidated In-Process Research & Development ("IPR&D") indefinite-lived intangible asset balance was approximately $58 million as of December 31, 2022, 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, 2022. 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 IPR&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 financial statements, at each balance sheet date the Company estimates its accrued research and development 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 $6.7 million is included in other current liabilities on the December 31, 2022 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 13, 2023

VBI Vaccines Inc. and Subsidiaries

Consolidated Balance Sheets
(in thousands, except share amounts)

	December 31, 2022	December 31, 2021
CURRENT ASSETS		
Cash	**$ 62,629**	$ 121,694
Accounts receivable, net	**94**	8
Inventory, net	**6,599**	2,576
Prepaid expenses	**2,309**	2,373
Other current assets	**6,059**	3,633
Total current assets	**77,690**	130,284
NON-CURRENT ASSETS		
Other long-term assets	**1,355**	1,259
Property and equipment, net	**12,253**	11,037
Right of use assets	**3,316**	3,344
Intangible assets, net	**58,345**	62,091
Goodwill	**2,127**	2,261
Total non-current assets	**77,396**	79,992
TOTAL ASSETS	**$ 155,086**	$ 210,276
CURRENT LIABILITIES		
Accounts payable	**$ 12,973**	$ 4,280
Other current liabilities	**22,588**	26,941
Current portion of deferred revenues	**409**	526
Current portion of lease liability	**972**	839
Total current liabilities	**36,942**	32,586
NON-CURRENT LIABILITIES		
Lease liability, net of current portion	**2,365**	2,516
Long-term debt, net of debt discount	**48,888**	28,441
Liabilities for severance pay	**524**	574
Deferred revenues, net of current portion	**2,204**	2,277
Total non-current liabilities	**53,981**	33,808
COMMITMENTS AND CONTINGENCIES (NOTE 17)		
STOCKHOLDERS' EQUITY		
Common shares (unlimited authorized; no par value) (2022 issued and outstanding –258,257,494; 2021 - issued and outstanding 258,250,273)	**442,312**	442,235
Additional paid-in capital	**90,020**	81,583
Accumulated other comprehensive (loss) income	**21,440**	(1,565)
Accumulated deficit	**(489,609)**	(378,371)
Total stockholders' equity	**64,163**	143,882
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 155,086**	$ 210,276

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	
	2022	2021
Revenues, net	**$ 1,082**	$ 631
Operating expenses:		
Cost of revenues	**11,276**	10,770
Research and development	**15,506**	19,558
Sales, general and administrative	**56,120**	38,335
Total operating expenses	**82,902**	68,663
Loss from operations	**(81,820)**	(68,032)
Interest expense, net of interest income	**(4,007)**	(4,732)
Foreign exchange (loss) gain	**(27,476)**	3,011
Loss before income taxes	**(113,303)**	(69,753)
Income tax expense	**-**	-
NET LOSS	**$ (113,303)**	$ (69,753)
Other comprehensive income (loss)	**23,005**	(2,830)
COMPREHENSIVE LOSS	**$ (90,298)**	$ (72,583)
Net loss per share of common shares, basic and diluted	**$ (0.44)**	$ (0.27)
Weighted-average number of common shares outstanding, basic and diluted	**258,257,296**	254,947,202

See accompanying Notes to Consolidated Financial Statements

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, 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**
Adjustments for prior periods from adoption of ASU 2020-06	**-**	**-**	**(2,746)**	**-**	**2,065**	**(681)**
Common shares issued upon exercise of options	**7,221**	**12**	**-**	**-**	**-**	**12**
Warrant issued in connection with debt amendment	**-**	**-**	**1,550**	**-**	**-**	**1,550**
Stock-based compensation	**-**	**65**	**9,633**	**-**	**-**	**9,698**
Net loss	**-**	**-**	**-**	**-**	**(113,303)**	**(113,303)**
Currency translation adjustments	**-**	**-**	**-**	**23,005**	**-**	**23,005**
BALANCE AS OF DECEMBER 31, 2022	**258,257,494**	**$ 442,312**	**$ 90,020**	**$ 21,440**	**$ (489,609)**	**$ 64,163**

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	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	**$ (113,303)**	$ (69,753)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	**2,061**	1,835
Stock-based compensation	**9,698**	9,628
Amortization of debt discount	**1,707**	2,999
Loss on extinguishment of long-term debt	**172**	-
Inventory reserve	**1,186**	174
Unrealized foreign exchange loss (gain)	**27,445**	(496)
Net change in operating working capital items:		
Change in accounts receivable	**(87)**	69
Change in inventory	**(5,690)**	(513)
Change in prepaid expenses	**18**	(787)
Change in other current assets	**(2,738)**	5,558
Change in other long-term assets	**(173)**	(584)
Change in operating right of use assets	**1,357**	1,071
Change in accounts payable	**8,893**	356
Change in deferred revenues	**16**	(328)
Change in other current liabilities	**(2,910)**	11,931
Payments made on operating lease liabilities	**(1,347)**	(1,068)
Net cash flows used in operating activities	**(73,695)**	(39,908)
INVESTING ACTIVITIES		
Redemption of short-term investments	**-**	25,151
Purchase of property and equipment	**(4,344)**	(1,995)
Net cash flows used in/ provided by investing activities	**(4,344)**	23,156
FINANCING ACTIVITIES		
Proceeds from issuance of common shares for in financing transactions	**-**	33,293
Share issuance costs	**-**	(1,067)
Proceeds from issuance of common shares upon exercise of warrants	**-**	85
Proceeds from issuance of common shares upon exercise of stock options	**12**	4
Proceeds from debt financing	**20,000**	12,000
Debt issuance costs	**(563)**	(22)
Net cash flows provided by financing activities	**19,449**	44,293
Effect of exchange rates on cash	**(475)**	328
CHANGE IN CASH FOR THE YEAR	**$ (59,065)**	$ 27,869
CASH, BEGINNING OF YEAR	**$ 121,694**	$ 93,825
CASH, END OF YEAR	**$ 62,629**	$ 121,694
Supplementary information:		
Interest paid	**$ 3,231**	$ 2,039
Non-cash investing and financing:		
Adjustments for prior periods from adoption of ASU 2020-06	**$ 681**	-
Warrant modification in connection with debt amendment	**-**	$ 867
Warrants issued in connection with financing transactions	**1,550**	-
Common shares issued in connection with cashless warrant exercise	**-**	4,298
Common shares issued upon conversion of long-term debt	**-**	2,000
Capital expenditures included in accounts payable and other current liabilities	**406**	185
Share issuance costs included in accounts payable and other current liabilities	**67**	50

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"); 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 COVID-19 pandemic has materially negatively affected the global economy, and the ongoing effects of the COVID-19 pandemic, including but not limited to, supply chain issues, global shortages of supplies, materials and products, volatile market conditions and rising global inflation, continue to do so. As a result of the COVID-19 pandemic, our business and results of operations were adversely affected and, as the ongoing effects of the COVID-19 pandemic continue to impact the global economy, these effects may continue to adversely affect our business and results of operations. The extent to which these effects 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 effects of 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 continue to disrupt the marketplace which could have an adverse effect on our operations.

Liquidity and Going Concern

The Company 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 $489,609 and cash of $62,629 as of December 31, 2022. Cash outflows from operating activities were $73,695 for the year-ended December 31, 2022.

The Company will require significant additional funds to conduct clinical and non-clinical trials, commercially launch our products, and achieve regulatory approvals. Additional financing may be obtained from the issuance of equity securities, the issuance of additional debt, government or non-governmental organization grants or subsidies, 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 from this uncertainty.

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 ("K2HV") 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 LLC ("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 first ATM Program. On July 31, 2020, the Company entered into an Open Market Sale Agreement with 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 "first 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.

On July 1, 2022, we received a letter from the Listings Qualifications Department of Nasdaq indicating that, based upon the closing bid price of our common shares for the 30 consecutive business day period between May 18, 2022, through June 30, 2022, we did not meet the minimum bid price of $1.00 per share required for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until December 28, 2022, to regain compliance. On December 29, 2022, we were granted an additional 180-day grace period to regain compliance with the Minimum Bid Price Requirement. To regain compliance and qualify for continued listing on Nasdaq, the closing bid price of our common shares must be at least $1.00 for a minimum of 10 consecutive business days during the additional 180-day grace period, which will end on June 26, 2023. Nasdaq's determination was based on our meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on Nasdaq, with the exception of the Minimum Bid Price Requirement, and our written notice of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. We have not regained compliance as of the date of this filing, and if we fail to regain compliance during this grace period, our common shares will be subject to delisting by Nasdaq, which could seriously decrease or eliminate the value of an investment in our common shares.

On August 26, 2022, the Company 1) filed a registration statement for a base prospectus which covers the offering, issuance and sale of up to $300,000 of common shares, warrants, units and/or subscription rights; and 2) entered into an Open Market Sale Agreement with 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"). The ATM Program replaces Open Market Sale Agreements previously entered into with Jefferies on July 31, 2020, and September 3, 2021, pursuant to each of which we could offer and sell our common shares having an aggregate price of up to $125,000 from time to time, through ATM equity offering programs. Both ATM programs were terminated, effective as of August 26, 2022. Prior to termination, $27,022 of our common shares remained available for sale pursuant to the first ATM program, and $125,000 of our common shares remained available for sale pursuant to the second ATM program. Neither ATM program was utilized in 2022.

In September 2022, the Company refinanced its existing term loan facility with K2HV to increase the amount of term loans available to $100,000 among other items. See Note 10 for more details. The refinanced long-term debt has a maturity date of September 14, 2026.

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.

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 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.

The Company has not experienced any losses in cash and accounts receivable for the years ended December 31, 2022 and 2021.

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation ("FDIC") was appointed as receiver. The Company has deposit accounts at SVB. The standard deposit insurance amount is up to $250 per depositor, per insured bank, for each account ownership category. As of March 10, 2023, the Company had approximately $1,200 in deposit accounts at SVB. On March 12, 2023, the U.S. Treasury, Federal Reserve, and FDIC announced that SVB depositors will have access to all of their money starting March 13, 2023.

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, 2022 or 2021.

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: (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 costs of rights to IPR&D projects acquired in an asset acquisition are expensed in the consolidated statements of operations unless the project has an alternative future use. These costs include initial payments incurred prior to regulatory approval in connection with research and development agreements that provide rights to develop, manufacture, market and/or sell pharmaceutical products.

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 as a result of the Company's annual testing on August 31, 2022. 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 including: 1) the amount and timing of costs to develop the IPR&D into viable products; 2) the amount and timing of future cash inflows; 3) the discount rate; and 4) the probability of technical and regulatory success. The discount rate used was 12% and the cumulative probability of technical and regulatory success to achieve approval to market the products ranged from approximately 10% to 17%.

The fair value of our CMV asset was in excess of its carrying value by greater than 25% as of August 31, 2022. In the event we continue to experience challenging market conditions, insufficient internal resources due to competing programs, and changes in the competitive and technological landscape for CMV vaccines, this may give rise to a triggering event that may require the Company to record impairment charges on our IPR&D assets in the future.

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, 2022. 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, 2022.

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"). Debt discount is 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, 2022, 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 $6,966. See more information on the CEPI Funding Agreement in Note 14.

Revenue Recognition

Product Sales, net

We sell our product to a limited number of wholesalers and specialty distributors in the U.S., to Valneva, as part of our marketing and distribution agreement covering the U.K. and certain EU markets and directly to health fund customers in Israel (collectively, our "Customers").

Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product upon delivery to the Customer. The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Because our standard credit terms are short-term and we expect to receive payment in less than one-year, there is no significant financing component on the related receivables. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues. Since our performance obligation is part of a contract that has an original expected duration of one year or less, we elect not to disclose the information about our remaining performance obligations.

Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment. If we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of revenue that we report in a particular period. We evaluate our estimates of variable considerations including, but not limited to, product returns, chargebacks, rebates, and other fees, periodically or when there is an event or change in circumstances that may indicate that our estimates may change.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration such as product returns, chargebacks, discounts, rebates, and other fees that are offered within contracts between us and our Customers, healthcare providers, pharmacies and others relating to our product sales. We estimate variable consideration using either the most likely amount method or the expected value method, depending on the type of variable consideration and what method better predicts the amount of consideration we expect to receive. We take into consideration relevant factors such as industry data, current contractual terms, available information about Customers' inventory, resale and chargeback data and forecasted customer buying and payment patterns, in estimating each variable consideration. The variable consideration is recorded at the time product sales is recognized, resulting in a reduction in product revenue and a reduction in accounts receivable (if the Customer offsets the amount against its accounts receivable) or as an accrued liability (if we pay the amount through our accounts payable process). Variable consideration requires significant estimates, judgment and information obtained from external sources.

Product Returns

Consistent with industry practice, we offer our Customers a limited right of return based on the product's expiration date for product that has been purchased from us. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We consider several factors in the estimation of potential product returns including expiration dates of the product shipped, the limited product return rights, available information about Customers' inventory and other relevant factors.

Chargebacks

Our Customers subsequently resell our product to healthcare providers, pharmacies and others. In addition to distribution agreements with Customers, we enter into arrangements with qualified healthcare providers that provide for chargebacks and discounts with respect to the purchase of our product. Chargebacks represent the estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are determined at the time of resale to the qualified healthcare providers by Customers, and we issue credits for such amounts generally within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consists of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to the qualified healthcare providers, and chargebacks for units that our Customers have sold to the qualified healthcare providers, but for which credits have not been issued.

Trade Discounts and Allowances

We provide our Customers with discounts which include early payment incentives that are explicitly stated in our contracts, and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Distribution Fees

Distribution fees include fees paid to certain Customers for sales order management, data, and distribution services. Distribution fees are recorded as a reduction of revenue in the period the related product revenue is recognized.

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, 2022 and 2021. 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, 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 $56,510 and $30,406 at December 31, 2022 and 2021, 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. 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. There was no dilutive effect on the earnings per share for the years ended December 31, 2022 and 2021.

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

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 simplifies 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 has removed the separation models required for convertible debt with cash conversion features and convertible instruments with beneficial conversion features. It has also removed certain settlement conditions that are currently required for equity contracts to qualify for the derivative scope exception and simplifies the diluted earnings per share calculation for convertible instruments.

On January 1, 2022, the Company adopted ASU 2020-06 using the modified retrospective method and recognized a cumulative effect of initially applying the ASU as an adjustment to the January 1, 2022 opening balance of accumulated deficit. 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. The Company eliminated the beneficial conversion feature from additional paid-in capital; eliminated the interest accretion on the beneficial conversion feature through December 31, 2021 from the opening balance of accumulated deficit; and eliminated the corresponding debt discount. The prior period consolidated financial statements have not been retrospectively adjusted and continue to be reported under the accounting standards in effect for those periods.

Accordingly, the cumulative effect of the changes made on our January 1, 2022 consolidated balance sheet for the adoption of the ASU was as follows:

	Balance as at December 31, 2021	Adjustments from adoption of ASU 2020-06	Balance as at January 1, 2022
Liabilities			
Long-term debt, net of debt discount	**$ 28,441**	**$ 681**	**$ 29,122**
Stockholders' equity			
Additional paid-in capital	**$ 81,583**	**$ (2,746)**	**$ 78,837**
Accumulated deficit	**$ (378,371)**	**$ 2,065**	**$ (376,306)**

Recently Issued Accounting Standards, not yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). The amendments in ASU 2016-13, among other things, require the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Financial institutions and other organizations will now use forward-looking information to better inform their credit loss estimates. Many of the loss estimation techniques applied today will still be permitted, although the inputs to those techniques will change to reflect the full amount of expected credit losses. ASU 2016-13 will be effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. This ASU will be implemented through a modified retrospective method of transition. While the Company is currently evaluating the adoption impact of ASU 2016-13 on its consolidated financial statements, the preliminary assessment is that the adoption of this standard is not expected to have a material effect on the Company's consolidated financial statements.

4. INVENTORY, NET

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

	2022	2021
Finished goods	**$ 893**	$ -
Work-in-process	**1,869**	645
Raw materials	**3,837**	1,931
Inventory, net	**$ 6,599**	$ 2,576

The Company recorded a provision of approximately $1,186 and $174 during the years ended December 31, 2022 and 2021, 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:

	2022	2021
Government receivables	$ 4,033	$ 1,438
Other current assets	2,026	2,195
Total other current assets	$ 6,059	$ 3,633

6. PROPERTY AND EQUIPMENT

	2022		
	Cost	Accumulated Depreciation	Net Book Value
Machinery and equipment	$ 7,836	$ (3,447)	$ 4,389
Furniture and office equipment	585	(152)	433
Computer equipment and software	1,084	(694)	390
Leasehold improvements	10,729	(3,688)	7,041
	20,234	$ (7,981)	$ 12,253

	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

Related depreciation expense for the years ended December 31, 2022, and 2021 was $2,009 and $1,768, respectively.

7. INTANGIBLE ASSETS AND GOODWILL

	2022				
	Gross Carrying Amount	Accumulated Amortization	Cumulative Impairment Charge	Cumulative Currency Translation	Net Book Value
License	$ 669	$ (669)	$ -	$ -	$ -
IPR&D assets	61,500	-	(300)	(2,855)	58,345
	$ 62,169	$ (669)	$ (300)	$ (2,855)	$ 58,345

	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

The license is held in Israel at SciVac. Amortization expenses for the years ended December 31, 2022 and 2021 amounted to $52 and $67, respectively. The license is fully amortized as of December 31, 2022. 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, 2021 relates to currency translation adjustments which decreased by $3,690 for the year ended December 31, 2022. The change in carrying value from December 31, 2020 to December 31, 2021 relates to currency translation adjustments which increased IPR&D assets by $2.

	2022			
	Gross Carrying Amount	**Cumulative Impairment Charge**	**Cumulative Currency Translation**	**Net Book Value**
Goodwill	**$ 8,714**	**$ (6,292)**	**$ (295)**	**$ 2,127**

	2021			
	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, 2021 relates to currency translation adjustments which decreased goodwill by $134 for the year ended December 31, 2022. The change in carrying value for goodwill from December 31, 2020 relates to currency translation adjustments which increased by $0 for the year ended December 31, 2021.

8. OTHER CURRENT LIABILITIES

Other current liabilities consisted of the following:

	2022	2021
Accrued research and development expenses (including clinical trial accrued expenses)	**$ 6,561**	$ 8,196
Accrued professional fees	**3,250**	2,294
Payroll and employee-related costs	**4,036**	4,805
Deferred funding	**6,966**	10,183
Other current liabilities	**1,775**	1,463
Total other current liabilities	**$ 22,588**	$ 26,941

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, 2022 and 2021 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	2022	2021
Warrants	**3,564,882**	1,384,469
Stock options and unvested stock awards	**22,844,620**	18,573,708
K2HV conversion feature	**6,161,889**	1,369,863
	32,571,391	21,328,040

10. LONG-TERM DEBT

	2022	2021
Long-term debt, net of debt discount of $6,811 ($3,783 at December 31, 2021)	**$ 48,888**	$ 28,441
Less: current portion, net of debt discount of $0 ($0 at December 31, 2021)	-	-
	$ 48,888	$ 28,441

On May 22, 2020, the Company (along with its subsidiary VBI Cda) entered into the Loan and Guaranty Agreement (the "Loan Agreement") with K2HV and any other lender from time-to-time party thereto (the "Lenders"). On May 22, 2020, the Lenders advanced the first tranche of term loans of $20,000. 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 until the original 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 per share.

On May 17, 2021, the Company entered into the First Amendment to the Loan and Guaranty Agreement ("First Amendment") with the Lenders and received additional loan advances of $12,000.

On September 14, 2022, the Company entered into the Second Amendment to the Loan Agreement (the "Second Amendment") with the Lenders to: (i) increase the amount of the term loans available under the Loan Agreement to $100,000 from $50,000, which term loans are available in up to four tranches subject to the achievement of milestones and other customary conditions, (ii) add certain minimum net revenue covenants to the Second Amendment, extend the final maturity date for the term loans to September 14, 2026, which may be extended to September 14, 2027, under certain circumstances, and (iv) to the extent that the maturity date is extended, the term loans will begin amortizing on a monthly basis on September 14, 2026.

On September 15, 2022, the Lenders advanced to the Borrowers the Restatement First Tranche Term Loan (as defined in the Second Amendment) in an aggregate amount of $50,000 which included the refinancing of the $30,000 in term loans that were outstanding under the Loan Agreement as amended by the First Amendment. The second tranche of term loans of up to $15,000 will be available from April 1, 2023, through June 30, 2023, subject to the achievement of certain clinical milestones and compliance with a liquidity requirement which requires the Company to have sufficient cash on hand to funds its operations for at least nine months (the "Liquidity Requirement"). The third tranche of term loans of up to $10,000 will be available from April 1, 2024, through June 30, 2024, so long as certain of the milestones for the second tranche of term loans were achieved, no events of default under the Loan Agreement have occurred and are continuing, and the Liquidity Requirement is satisfied. The fourth tranche of term loans of up to $25,000 shall be available at any time from September 14, 2022, until September 14, 2026, subject to the Lender's review of the Company's clinical and financial plans and Lender's investment committee approval.

Pursuant to the Second Amendment, the Lenders have the ability to convert $7,000 into common shares, by which $2,000 of the term loans shall be convertible into 1,369,863 shares of common stock at a conversion price of $1.46 per share and $5,000 of the term loans shall be convertible into 4,792,026 shares of common stock at a conversion price of $1.0434 per share ("K2HV conversion feature").

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 K2HV Warrant") at an exercise price of $1.12 per share. On May 17, 2021, in connection with the First Amendment, the Company amended and restated the Original K2HV Warrant to purchase an additional 312,500 common shares for a total of 937,500 common shares (the "First Amendment Warrant") with the same exercise price of $1.12 per share. On September 14, 2022, in connection with the Second Amendment and the advance of the first tranche of term loans of $50,000 by the Lenders, the Company issued the Lenders a warrant to purchase an additional 2,180,413 common shares (the "Second Amendment Warrant") with a warrant exercise price of $0.8026 per share. If the full remaining $50,000 available in the K2HV tranches is advanced pursuant to the Second Amendment, up to an additional 2,180,413 common shares will be issuable pursuant to the Second Amendment Warrant. The First Amendment Warrant and the Second Amendment Warrant may be exercised either for cash or on a cashless "net exercise" basis. The First Amendment Warrant expires on May 22, 2030 and the Second Amendment Warrant expires on September 14, 2032.

The Company is required to make a final payment equal to 6.95% of the aggregate term loan principal on the maturity date of the term loan, or upon earlier prepayment of the term loans in accordance with the Second Amendment (the "Second Amendment Final Payment"). The final payment related to the refinanced $30,000 in term loans that were outstanding under the Loan Agreement as amended by the First Amendment of $2,224 remains and is due the earlier of June 1, 2024 or the earlier prepayment of the term loans in accordance with the Second Amendment (the "Original Final Payment").

Upon receipt of additional funds, issuable pursuant to the second, third and fourth tranches, under the Second Amendment, additional common shares will be issuable pursuant to the Second Amendment Warrant as determined by the principal amount of the second tranche, third tranche and fourth tranche actually funded multiplied by 3.5% and divided by the warrant exercise price of $0.8026, and the Second Amendment Final Payment will increase by 6.95% of the funds advanced.

The Company accounted for the Second Amendment as a debt extinguishment and resulted in an extinguishment loss of $172, which is included in interest expense, net of interest income in the consolidated statement of operations and comprehensive loss. The term loans under the Loan Agreement as amended by the First Amendment were derecognized and the term loan under the Loan Agreement as amended by the Second Amendment was recorded at fair value of $48,340, which resulted in a total debt discount of $7,359. Fees paid to the Lender, including the fair value of the Second Amendment Warrant of $1,550 and the facility fee of $563, were included in the calculation of extinguishment loss. Fees paid to third parties were de minimums and expensed as incurred 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 Second Amendment, outstanding at December 31, 2022, including the Original Final Payment of $2,224 and the Second Amendment Final Payment of $3,475 in connection with the Second Amendment, is $55,699. The principal amount of the loan made under the Loan Agreement as amended by the Second Amendment accrues interest at an annual rate equal to the greater of (a) 8.00% or (b) prime rate plus 4.00%. The interest rate as of December 31, 2022 was 11.50%. The Company is required to pay only interest until September 14, 2026. The effective interest rate on the loan of $50,000, excluding the Original Final Payment and Second Amendment Final Payment, is 14.55%.

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 September 14, 2026, or if the milestone for the Restatement Third Tranche Term Loan (as defined in the Second Amendment) has been achieved, September 14, 2027, and the Loan Agreement as amended by the Second Amendment includes both financial and non-financial covenants. The Company was in compliance with these covenants as of December 31, 2022.

The obligations under the Loan Agreement as amended by the Second 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, 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.

The total initial debt discount related to the Second Amendment is $7,359, as of December 31, 2022 the unamortized debt discount was $6,811. The total initial debt discount related to First Amendment was $7,209 (subsequent to adjustments made as a result of the implementation of ASU-2020-06), as of December 31, 2021 the unamortized debt discount was $3,783.

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, 2022 and 2021 was as follows:

	2022	2021
Interest expense	**$ 3,515**	$ 2,105
Amortization of debt discount	**1,707**	2,999
Extinguishment loss	**172**	-
Interest income	**(1,387)**	(372)
Total interest expense, net of interest income	**$ 4,007**	$ 4,732

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
2023	$ -
2024	2,224
2025	-
2026	53,475
Total	$ 55,699

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, 2022 and 2021 was $170 and $110, 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, 2022 and 2021 was $442 and $352, 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.

Severance payments pursuant to the aforementioned statutory or contractual obligations, included in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2022 and 2021 was $5 and $16, respectively.

12. STOCKHOLDERS' EQUITY AND ADDITIONAL PAID-IN CAPITAL

Authorized

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

Common Shares Issuances

2022 common share issuances were as follows:

i. On January 10, 2022, the Company issued 7,221 common shares upon exercise of stock options at an average exercise price of $1.65 for gross proceeds of $12.

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 stock options $1.66 for gross proceeds of $4.

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, 2022, there were 842,803 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, 2022, 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, 2022, there were 21,477,925 options outstanding and 2,650 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 1,518,724 at December 31, 2022.

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, 2022 and 2021.

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 90^{th} 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 6^{th} 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, 2022 and 2021. All RSUs issued under the 2016 Plan at December 31, 2022 and 2021 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, 2022.

Stock-Based Compensation Expense

The table below provides information, as of December 31, 2022, 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	842,803	$ 4.19
2014 Plan	521,242	5.02
2016 Plan	21,480,575	2.24
Total	22,844,620	$ 2.38

Activity related to stock options is as follows:

	Number of Stock Options	Weighted Average Exercise Price
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
Granted	**5,140,000**	**1.51**
Exercised	**(7,221)**	**1.65**
Forfeited	**(825,188)**	**2.59**
Balance outstanding at December 31, 2022	**22,841,970**	**$ 2.38**
Exercisable at December 31, 2022	**15,563,719**	**$ 2.51**

	Outstanding			Exercisable	
Exercise Price	Number Of Options	Weighted Average Remaining Contractual Life (Years)	Number Of Options	Weighted Average Exercise Price
$ 0.00 – 1.49	3,615,000	7.20	3,320,826	$ 1.42
1.50 – 2.49	9,095,000	7.71	4,728,745	1.68
2.50 – 3.49	7,562,200	7.94	4,964,491	3.09
3.50 – 4.49	2,048,528	3.62	2,028,415	4.18
4.50 +	521,242	2.53	521,242	5.03
	22,841,970	7.22	15,563,719	$ 2.51

The weighted average remaining contractual life of exercisable options was years 6.54 and 6.50 years at December 31, 2022 and 2021, 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, 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
Vested	**(35,984)**	**1.48**
Forfeited	**(695)**	**1.46**
Unvested shares outstanding at December 31, 2022	**2,650**	**$ 1.46**

The intrinsic value of outstanding options at December 31, 2022 was $0 (the intrinsic value of vested options was $0 and the intrinsic value of those expected to vest was $0). The fair value of the vested RSU's was $53 for the year ended December 31, 2022. There were 7,221 options exercised for the year ended December 31, 2022 and the intrinsic value of exercised options was $2 for the year ended December 31, 2022. 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.

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:

	2022	2021
Volatility	**93.23%**	96.87%
Risk free interest rate	**1.75%**	0.59%
Expected term in years	**5.83**	5.85
Expected dividend yield	**0.00%**	0.00%
Weighted average fair value per option	**$ 1.13**	$ 2.40

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:

	2022	2021
Research and development	**$ 1,998**	$ 1,839
General and administration	**7,585**	7,697
Cost of revenue	**115**	92
Total stock-based compensation expense	**$ 9,698**	$ 9,628

There is $8,950 of unrecognized compensation from all equity awards as of December 31, 2022. This expense will be recognized over a weighted average period of 1.43 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 to purchase up to an aggregate of 625,000 common shares (the "Original K2HV Warrant"). The Original K2HV Warrant expires on May 22, 2030 and has an exercise price of $1.12 per share.

During the fourth quarter of the year ended December 31, 2021, 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 amended and restated the Original K2HV Warrant to purchase an additional 312,500 common shares for a total of 937,500 common shares (the "First Amendment Warrant") with the same Warrant Price of $1.12. The Frist Amendment Warrant expires on May 22, 2030.

On June 9, 2021, the Company issued 646,257 common shares upon exercise of 2,068,824 warrants on a cashless "net exercise" basis.

On September 14, 2022, in connection with the Second Amendment, as described in Note 10, the Company issued a warrant to purchase an additional 2,180,413 common shares (the "Second Amendment Warrant") with a warrant exercise price of $0.8026 per share. The Second Amendment Warrant expires on September 14, 2032.

The value attributed to the Second Amendment Warrant were based on the Black-Scholes option pricing model by applying the following assumptions:

	Second Amendment Warrant
Volatility	**95.00%**
Risk free interest rate	**3.35%**
Expected term in years	**10.0**
Expected dividend yield	**0.00%**
Fair value per warrant	**$ 0.71**

Activity related to the warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price
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
Issued	**2,180,413**	**0.80**
Balance outstanding at December 31, 2022	**3,564,882**	**$ 0.97**

13. REVENUE, NET AND DEFERRED REVENUE

Revenue, net comprises of the following:

	2022	2021
Product revenue, net	**$ 931**	$ 262
R&D Service revenue	**151**	369
	$ 1,082	$ 631

Cost of revenues for the year ended December 31, 2022 for product revenue and R&D services revenue is $11,235 and $41, respectively. Cost of revenues for the year ended December 31, 2021 for product revenue and R&D services revenue is $10,475 and $295, 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, 2022:

	Total	2023	2024 and thereafter
Product revenue, net	**$ 469**	**$ -**	**$ 469**
R&D Service revenue	**2,144**	**409**	**1,735**
Total	**$ 2,613**	**$ 409**	**$ 2,204**

The following table presents changes in the deferred revenue balance for the year ended December 31, 2022:

Balance at January 1, 2021	**$ 3,104**
Balance at December 31, 2021	**$ 2,803**
Recognition of deferred revenue	**(66)**
Currency translation	**(124)**
Balance at December 31, 2022	**$ 2,613**
Short Term	**$ 409**
Long Term	**$ 2,204**

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, 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;

- Brii Bio granted the Company 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, the Company and Brii Bio amended the License Agreement (the "Brii Second Amendment") whereby:

- the Company and Brii Bio agreed to conduct an additional Phase II combination clinical trial of VBI-2601, 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 Company 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 License Agreement.

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 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 license using the residual method.

There was no additional consideration contemplated in the Brii 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 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, 2022, R&D services related to Brii Bio that remain unsatisfied are $1,944, out of the $2,613 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 ("GSK Collaboration Agreement") pursuant to which we will investigate the use of GSK's proprietary $AS01_B$ adjuvant system in our study of VBI-1901. As a result of the Collaboration Agreement, a second study arm was added to Part B of the 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, 2022 and 2021 are $232 and $504, 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.

On April 28, 2022, we signed a sixth amendment to the collaboration agreement with the NRC to further broaden the scope to include generation and testing of stable pools of cells expressing SARS-CoV-2 spike protein.

On February 28, 2023, we signed a seventh amendment to the collaboration agreement with the NRC to extend the expiration date of the collaboration agreement to December 31, 2023.

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, 2022 and 2021 are $851 and $1,152, 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.

On December 6, 2022, we and CEPI entered into an amendment to the CEPI Funding Agreement (the "CEPI Amendment") to expand the scope of the CEPI Funding Agreement. The CEPI Amendment, among others, (i) expands the definition of "Project Vaccine" to include additional multivalent vaccine constructs within the VBI-2900 program, (ii) removes certain pricing restrictions previously allocated to high-income countries in the CEPI Funding Agreement, (iii) updates the proposed volume commitment percentage contributions by us to CEPI for a Project Vaccine, and (iv) adds certain commercial benefits and related adjustments for CEPI following the pandemic period, including royalties paid to CEPI, in the event that CEPI provides funding for Phase III clinical studies of the Project Vaccine.

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 CEPI Funding Agreement are expensed as incurred in Research and Development expenses and overhead charges are included in General and Administrative. For the year ended December 31, 2022 and 2021, the Company recognized $3,648 and $8,240, respectively, such expenses, for the year ended December 31, 2022 were reduced by the same amount. During the year ended December 31, 2022, the Company received $964 from CEPI and as of December 31, 2022, the Company had $6,966 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 Brii 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, 2022 and 2021 were $258 and de minimis, respectively.

Agenus Inc.

On October 12, 2022, the Company entered into a Clinical Collaboration Agreement ("Agenus Collaboration Agreement") pursuant to which the Company will evaluate VBI-1901 in combination anti-PD-1 balstilimab in a Phase II study as part of the INSIGhT adaptive platform trial in patients first diagnosed with GBM.

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 INSIGhT adaptive platform trial will be expensed as incurred in Research and Development expenses; costs for the year ended December 31, 2022 is $3,748.

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, 2022 and 2021, the Company recognized $0 and $273, respectively, as a reduction in expenses. As of December 31, 2022 and 2021, the Company had $41 and $44, respectively, recorded as deferred government grants, recorded in other current liabilities on the consolidated balance sheet.

Strategic Innovation Fund ("SIF")

On September 16, 2020, we signed the Contribution Agreement (as amended, the "Contribution Agreement") with Her Majesty the Queen in Right of Canada, as represented by the Minister of Industry (the "Minister"), whereby the Minister agreed to 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 $56 million from the SIF to support the development of our coronavirus vaccine program, VBI-2900, though Phase II clinical studies (the "Project"). We initially 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"). On March 28, 2022, we and the Minister signed an amendment to the Contribution Agreement, the main purpose of which was to extend the collaboration and move the Project Completion Date from March 31, 2022 to December 31, 2023. 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.

Costs associated with the Contribution Agreement are expensed as incurred in Research and Development expenses and overhead charges are included in General and Administrative. For the year ended December 31, 2022 and 2021, the Company recognized $6,038 and $7,248, respectively, as a reduction in expenses. As of December 31, 2022 and 2021, the Company had $790 and $947, 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:

	2022	2021
Netherlands	**$ (394)**	$ -
United States	**(3,909)**	(1,870)
Canada	**(46,364)**	(30,002)
Israel	**(62,636)**	(37,881)
Total	**$ (113,303)**	$ (69,753)

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:

	2022	2021
Loss before income taxes	**$ (113,303)**	$ (69,753)
Canadian statutory tax rate	**26.50%**	26.50%
Expected benefit of income tax	**(30,025)**	(18,485)
Research and development tax credits	**(386)**	-
Change in tax rate	**1,970**	-
Change in valuation allowance*	**12,562**	19,099
Difference between Canadian and foreign tax rates	**2,771**	1,313
Stock based compensation	**2,362**	2,387
Foreign exchange translation	**10,814**	(4,574)
Permanent statutory to GAAP difference	**(308)**	480
Other	**240**	(220)
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 2022 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 United States statutory income tax rate is approximately 24.04% based on current year apportionment.

The Deferred tax asset (liability) consisted of the following:

	2022	2021
Net operating losses	**$ 98,147**	$ 86,397
Research and development tax credits	**13,995**	14,102
Property and equipment	**1,072**	1,050
Reserves and other	**2,253**	1,996
Intangible assets	**(15,461)**	(16,454)
Allowable capital losses	**56**	56
Debt obligations	**(2,683)**	(1,757)
Deferred financing costs	**1,201**	1,779
Net deferred tax assets	**98,580**	87,169
Less: valuation allowance	**(98,580)**	(87,169)
Net deferred tax assets (liabilities)	**$ -**	$ -

As of December 31, 2022 and 2021, the Company had United States federal net operating loss carryovers ("NOLs") of approximately $55,375 and $53,968, 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, 2022. 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, 2022, the Company also had Canadian net operating loss carryovers of approximately $97,433 and $84,491, respectively, available to offset future taxable income which expire beginning in 2024.

As of December 31, 2022 and 2021, the Company had $6,242 and $5,868 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, 2022 and 2021, the Company had unclaimed research and development expenses in Canada of approximately $24,997 and $21,740, respectively, which are available to offset future taxable income indefinitely.

As of December 31, 2022 and 2021, the Company had $213 and $213, 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, 2022 and 2021, the Company also had Israel net operating loss carryovers of approximately $256,305 and $214,186, respectively, which can be carried forward indefinitely.

As of December 31, 2022, the Company had NOLs aggregating approximately $409,363. The NOLs are available to reduce taxable income of future years and expire as follows:

	Netherlands	United States	Canada	Israel	Total
2025	$ -	$ -	$ 843	$ -	$ 843
2026	-	10	3,510	-	3,520
2027	-	446	4,067	-	4,513
2028	-	718	1,575	-	2,293
2029	-	672	2,949	-	3,621
2030	-	2,556	955	-	3,511
2031	-	3,617	1,181	-	4,798
2032	-	2,962	-	-	2,962
2033	-	3,126	1,380	-	4,506
2034	-	5,626	5,166	-	10,792
2035	-	4,661	1,553	-	6,214
2036	-	5,323	8,242	-	13,565
2037	-	6,017	9,263	-	15,280
2038	-	-	2,301	-	2,301
2039	-	-	7,322	-	7,322
2040	-	-	15,544	-	15,544
2041	-	-	11,423	-	11,423
2042	-	-	20,159	-	20,159
No expiration	250	19,641	-	256,305	276,196
Total losses	**$ 250**	**55,375**	**$ 97,433**	**$ 256,305**	**$ 409,363**

17. COMMITMENTS AND CONTINGENCIES

Licensing

eVLP Technology Purchase Agreement

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. 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. No payments were made in 2022.

Ferring and SciGen License Agreements

On October 18, 2022, the Company amended and restated the original Ferring License Agreement (the "Amended and Restated Ferring License Agreement"), which amends and restates certain of the terms relating to the manufacture and marketing of HBsAg products, which includes, among others, updates to the definition of net sales, and a reduction in the fixed royalty rate on net sales of HBsAg products ("Product") from seven percent (7%) to three and a half percent (3.5%) in consideration for the grant of the license to utilize genetically engineered CHO cells encoding the hepatitis B antigen and certain information related to the manufacture of hepatitis B vaccines (collectively, the "Technology"). In connection with the Amended and Restated Ferring License Agreement, the Company has also agreed to act as the guarantor for SciVac's obligations under the Amended and Restated Ferring License Agreement, or if the Amended and Restated Ferring License Agreement is assigned to a third party, guarantor for SciVac's obligations that have accrued up until the date of such assignment. 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 original Ferring License Agreement) of Product. Under the original 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 original 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 Amended and Restated Ferring License Agreement and SciGen Assignment Agreement will continue to be payable for the duration of the extended license periods.

Royalty payments under the Amended and Restated Ferring License Agreement or the original Ferring License Agreement of $33 and $18 were recorded in cost of revenues for the year ended December 31, 2022 and 2021, respectively.

Royalty payments under the SciGen Assignment Agreement of $47 and $13 were recorded in cost of revenues for the year ended December 31, 2022 and 2021, 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 Amended and Restated Ferring License Agreement), provided that the payment of 30% shall not apply to a grant of rights in or relating to: (i) the Original Territory (as defined in the original Ferring License Agreement); or (ii) the Berna Territory (as defined therein).

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 ($534,101). 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.

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, June 9, 2022, and January 12, 2023. The next preliminary hearing is scheduled to be held on July 13, 2023.

On December 5, 2022, another tort claim was filed in the District Court of the central district in Israel naming our subsidiary, SciVac, as a defendant. The claim was filed by a minor and his parents against SciVac, the Ministry of Health of the State of Israel, and Prof. Arieh Raziel, requesting compensation due to bodily injury of the minor, who was diagnosed as suffering from an Autism Spectrum Disorder ("ASD"). The plaintiffs allege that the minor's disabilities and the syndrome from which he suffers were caused due to a combination of several factors, including negligent pregnancy monitoring, negligent labor and delivery procedure, and administration of the alleged defective vaccine (Sci-B-Vac vaccine). Preliminary hearings will begin on July 3, 2023.

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

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.

The Company has entered into various non-cancelable lease agreements for its office, lab, and manufacturing facilities, which are classified as operating leases. The office facility lease agreement in the United States ("U.S.") expires on October 31, 2024 with no option to extend. Our manufacturing facility lease agreement in Israel has been extended for 5 years with a term now ending January 31, 2027. A lease for additional office space in Israel has a term ending November 30, 2025 with an option to extend for two additional years and June 30, 2027 with an option to extend the term for five additional years. In September 2022, the Company extended the term of our lease for our research facility in Canada, which comprises office and laboratory space, for three additional years, which now has a term ending on December 31, 2025.

During the year ended December 31, 2022, the Company entered into new lease agreements and recognized a ROU asset of $1,207.

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:		
2022 operating lease costs:	**$**	**1,865**
2021 operating lease costs:		1,463
Other information:		
Weighted average remaining lease term		2.96
Weighted average discount rate		13%

Operating lease costs are included in cost of revenues, research and development, and general and administrative expenses in the statement of operation and comprehensive loss.

The following table summarizes future undiscounted cash payments reconciled to the lease liabilities:

Year ending December 31	
2023	**$ 1,327**
2024	**1,228**
2025	**719**
2026	**619**
2027	**168**
Total	**4,061**
Effect of discounting	**(724)**
Total lease liability	**3,337**
Less: current portion	**972**
Long term lease liability	**$ 2,365**

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, net from external customers are attributed to geographic areas based on location of the contracting customers.

	2022	2021
United States	**$ 695**	$ -
Israel	**315**	321
China/Hong Kong	**66**	306
Europe	**6**	4
Total	**$ 1,082**	$ 631

There was no revenue attributed to our country of domicile, Canada, for years ended December 31, 2022 and 2021.

For the year ended December 31, 2022, the Company had 4 customers that individually accounted for 18%, 15%, 14% and 10% of revenues.

For the year ended December 31, 2021, the Company had 3 customers that individually accounted for 12%, 26% and 49% of revenues.

Tangible long-lived assets (Property and equipment and right of use assets) attributed to geographic areas are as follows:

	2022	2021
Israel	**$ 13,892**	$ 12,567
United States	**985**	1,273
Canada (country of domicile)	**692**	541
Total	**$ 15,569**	$ 14,381

20. RELATED PARTY TRANSACTIONS

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, 2022 and 2021, is $0 and $29, respectively. The car loan was repaid in full during the year ended December 31, 2022.

21. SUBSEQUENT EVENTS

On January 26, 2023, the Company approved the grant of 1,322,500 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 26, 2033.

EXHIBIT INDEX

Exhibit No.	Description
1.1	Open Market Sale Agreement[SM], dated August 26, 2022, by and between VBI Vaccines, Inc. and Jefferies LLC (incorporated by reference to Exhibit 1.1 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on November 10, 2022).
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	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 (incorporated by reference to Exhibit 10.1B to the Annual Report on Form 10K (SEC File No. 001-37769), filed with the SEC on March 7, 2022).
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+	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).
10.3+	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).
10.4	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).
10.5	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).
10.6+	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).

10.7+	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).
10.8	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).
10.9+	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)
10.10(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).
10.11	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).
10.12	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).
10.13(3)	Collaborative Research Agreement, dated March 30, 2020, between National Research Council of Canada and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.21 to the Annual Report on Form 10-K (SEC File No. 001-37769) filed with the SEC on March 7, 2022).
10.14(3)	First Amendment to the Collaborative Research Agreement, dated December 21, 2020, between National Research Council of Canada and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.22 to the Annual Report on Form 10-K (SEC File No. 001-37769) filed with the SEC on March 7, 2022).
10.15(3)	Second Amendment to the Collaborative Research Agreement, dated July 8, 2021, between National Research Council of Canada and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.23 to the Annual Report on Form 10-K (SEC File No. 001-37769) filed with the SEC on March 7, 2022).
10.16(3)	Third Amendment to the Collaborative Research Agreement, dated August 27, 2021, between National Research Council of Canada and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.24 to the Annual Report on Form 10-K (SEC File No. 001-37769) filed with the SEC on March 7, 2022).
10.17(2)(3)	Fourth Amendment to the Collaborative Research Agreement, signed November 15, 2021, between National Research Council of Canada and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.25 to the Annual Report on Form 10-K (SEC File No. 001-37769) filed with the SEC on March 7, 2022).
10.18(2)(3)	Fifth Amendment to the Collaborative Research Agreement, signed February 8, 2022, between National Research Council of Canada and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.26 to the Annual Report on Form 10-K (SEC File No. 001-37769) filed with the SEC on March 7, 2022).
10.19(2)(3)	Sixth Amendment to the Collaborative Research Agreement, signed April 28, 2022, between National Research Council of Canada and Variation Biotechnologies Inc. (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 May 9, 2022).
10.20+	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).
10.21	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).
10.22(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).
10.23	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).
10.24	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).
10.25+	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).
10.26	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).
10.27	Assignment Agreement, dated October 16, 2012, by and among FDS Pharma LLP, SciGen Ltd., and SciGen (I.L.) 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).
10.28	Amendment to the Assignment Agreement, dated February 14, 2013, by and among SciGen Ltd., SciGen (I.L.) 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).
10.29[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).
10.30[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 (incorporated by reference to Exhibit 10.38 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 7, 2022).
10.31	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).
10.32+	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).

10.33	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).
10.34	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).
10.35	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).
10.36	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).
10.37	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).
10.38	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).
10.39	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).
10.40	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).
10.41	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).
10.42	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).
10.43(2)(3)	Second Amendment to the Collaboration and License Agreement with Brii Bioscience, dated December 20, 2021 (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 7, 2022).
10.44+	Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective January 1, 2022 (incorporated by reference to Exhibit 10.52 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 7, 2022).
10.45+	Amended to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective December 16, 2021 (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 9, 2022).
10.46(2)(3)	Amendment to the Contribution Agreement, signed March 28, 2022, 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 10.5 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on May 9, 2022).
10.47	Second Amendment to Loan and Guaranty Agreement, dated as of September 14, 2022, 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 Company's Current Report on Form 8-K (SEC File No. 00137769), filed with the SEC on September 15, 2022).

10.48	Warrant, dated September 14, 2022 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (SEC File No. 001-37769), filed with the SEC on September 15, 2022).
10.49*(2)(3)	Amendment to 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 December 6, 2022.
10.50*+	Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective January 1, 2023
10.51*(2)(3)	Amended and Restated License Agreement, dated October 18, 2022, by and among Ferring International Center S.A., SciVac Ltd. and VBI Vaccines Inc.
10.52*(2)(3)	Seventh Amendment to the Collaborative Research Agreement, signed February 28, 2023, between National Research Council of Canada and Variation Biotechnologies Inc.
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 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, 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 13th day of March, 2023.

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 13, 2023 */s/ Jeffrey Baxter*
Jeffrey Baxter, President, Chief Executive Officer and Director (Principal Executive Officer)

Date: March 13, 2023 */s/ Christopher McNulty*
Christopher McNulty, Chief Financial Officer and Head of Business Development and Director (Principal Financial and Accounting Officer)

Date: March 13, 2023 */s/ Steven Gillis*
Steven Gillis,
Director

Date: March 13, 2023 */s/ Michel De Wilde*
Michel De Wilde
Director

Date: March 13, 2023 */s/ Blaine McKee*
Blaine McKee
Director

Date: March 13, 2023 */s/ Joanne Cordeiro*
Joanne Cordeiro
Director

Date: March 13, 2023 */s/ Damian Braga*
Damian Braga
Director

[***] 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.

CEPI

Amendment Agreement # 1
(CEPI Identification #: [●])

Agreement Summary

COUNTERPARTY INFORMATION

Name:	Variation Biotechnologies Inc. (“Awardee “)
Mailing Address:	160 Second Street, 3rd Floor , Cambridge, MA 02142
Nominated Contact (optional):	Adam Buckley

CEPI INFORMATION

Name:	Coalition for Epidemic Preparedness Innovations (“**CEPI**”)
Mailing Address:	PO Box 1030 Hoff, 0218 Oslo, Norway
Visiting Address:	Skøyen Atrium, Askekroken 11, 0277 Oslo

AMENDMENT AGREEMENT INFORMATION

Project Name:	Development of SA-Variant Monovalent & Multivalent SARS-CoV2 Vaccine Candidates
Effective Date:	Date of last signature below
Original Agreement:	On 9 March 2021 the parties entered into a COVID-19 Outbreak Response Agreement regarding the development of a safe and effective vaccine against SARS-CoV-2, (“**Original Agreement”)**
Subsequent amendments to Original Agreement (if any):	n/a
Reasons for Amendment Agreement (optional)	Re-scope of Project from a SARS2-Beta to a pan-betacoronavirus vaccine candidate and agreed arrangements for Volume Commitment Percentage Contribution and Commercial Benefits.
This amendment agreement includes and incorporates by reference:	The amendment agreement (referred to as the “**Amendment Agreement**”) means this Agreement Summary together with the following, which in the event of conflict shall have priority in the order set out below: - Agreed Amendments *(Annex A)* - Terms and Conditions of Amendment *(Annex B)* - the Original Agreement (as amended by any subsequent amendments mutually agreed by the parties whether listed above or not)

THIS AMENDMENT AGREEMENT is between CEPI and the counterparty listed above and shall enter into full force and effect on the Effective Date (as defined above) and remain in effect for the duration of the Original Agreement (unless otherwise agreed in this Amendment Agreement. Each party to this Amendment Agreement may be referred to individually as a "**Party**" and together as the "**Parties**."

In consideration of each Party remaining bound by the duties and obligations set out in the Original Agreement and keeping the benefit of the rights set out in the Original Agreement (in each case as such duties, obligations and rights may be amended pursuant to this Amendment Agreement), the Parties have agreed to enter into this Amendment Agreement in order to take into account and/or document certain changes to their respective circumstances and/or other aspects relevant to the subject matter of the Original Agreement and the Parties' ongoing relationship.

Signed for and on behalf of **COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS** by:

Signature: */s/ Richard Hatchett*

Name: Richard Hatchett

Title: Chief Executive Officer

Date: December 6, 2022

Signed for and on behalf of **Variation Biotechnologies Inc** by:

Signature: */s/ Jeff Baxter*

Name: Jeff Baxter

Title: CEO

Date: December 5, 2022

Annex A

Agreed Amendments

The Parties agree to amend the Original Agreement as follows:

1.1 **Agreement Summary.**

1.1.1 **CEPI Information.** The individual nominated as Project Lead under the CEPI Information section of the Agreement Summary shall be deleted and replaced with the following: [TBC]

1.1.2 **Annexes.** The list of annexes incorporated by reference in the Agreement Information section of the Agreement Summary shall be amended to include the following: Volume Commitment Percentage Contribution (Annex H); and Commercial benefits (Annex I).

1.2 **Modified Definitions for Existing Terms.** The Definitions for the following terms shall be deleted and replaced with the following in Clause 1 of the Annex A: Terms and Conditions:

1.2.1 "**Additional COVID-19 Candidate**" means any of Awardee's vaccine candidates against SARS-CoV-2 containing antigens from only SARS-CoV-2 or other coronaviruses and not from any other viruses, other than the Project Vaccine or *** (as defined herein), and excluding *** (as defined herein), in any form or dosage of pharmaceutical composition or preparation. For clarity, *** may be selected by CEPI for clinical development as a Project Vaccine as described in Clauses 1.40.

1.2.2 "**Project Vaccine**" means one or more of Awardee's vaccine candidates VBI-2904, VBI-2905, VBI-2906 and VBI-2907 (as described in the iPDP) and any other of the Awardee's vaccine candidates expressly identified in the iPDP, or arising directly from the performance of the iPDP, in any form or dosage of pharmaceutical composition or preparation (including any variant, bivalent, multivalent or combination candidate vaccines of any of the foregoing which are included in the iPDP and Budget from time to time), but excluding [***] unless and until [***] is selected by CEPI for clinical development and the iPDP is updated accordingly.

1.2.3 "**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 indicated in Annex H.

1.3 **New Terms and Definitions**: The following terms and definitions shall be added to the Definitions in Clause 1 of the Annex A: Terms and Conditions:

1.3.1 "**Net Sales**" means the gross amount invoiced by Awardee and Awardee's Affiliates to third parties for the sale of any Project Vaccine to third parties including distributors (which may include marketing authorization holders) or wholesalers (for the avoidance of doubt including any royalties received by Awardee and Awardee's Affiliates with respect to such sales of Project Vaccines), less the following items, in each case to the extent related specifically to the Project not otherwise recovered by or reimbursed to Awardee or Awardee's Affiliates:

(i) all trade, promotional, quantity, and cash discounts, wholesaler fees and refunds actually allowed;

(ii) all credits and allowances actually granted due to spoiled, damaged, or outdated goods, rejections, defects, expired dating, returns (including wholesaler and retailers returns), recalls, rebates, charge backs, volume discounts, billing errors, retroactive price reductions (including those granted to managed health care organizations, wholesalers, purchasing groups, retailers or federal, state or provincial governments) in each case which effectively reduce the selling price or gross sales of the Project Vaccines;

(iii) tariffs, duties and similar governmental charges

(iv) excise, sale and use taxes, or value added taxes, and equivalent taxes to the extent added to the sale price and set forth separately as such in the total amount invoiced; and

(v) freight, transport, packing, handling, and insurance charges associated with transportation, but only if separately stated on the same invoice as for the sale, lease or other disposition of the Project Vaccine.

Net Sales does not include any financial or non-financial consideration (which may include royalties) related to sales, leases, dispositions or other transfers of Project Vaccines (A) among or between Awardee, Awardee's Affiliates, and Sublicensees for the purpose of subsequent resale to a third party; (B) to end-users in, or customers purchasing on behalf of, an LMIC; and (C) where for no consideration, that are for use in nonclinical/clinical trials or registration; or as samples or for charitable purposes.

1.3.2 "**Phase 3 Funding**" has the meaning described in Annex I.

1.3.3 "**Sublicensee**" means a third party to which Awardee or an Affiliate of Awardee grants a sublicense under any Intellectual Property in the Project Vaccine excluding any wholesaler, distributor (which may include local marketing authorization holders), or other Subawardee and Sublicensing shall have a corresponding meaning.

1.3.4 "**VBI-2901**" means Awardee's clinical stage trivalent vaccine against the L-strain of SARS-CoV2, MERS and SARS-CoV1.

1.4 **Pricing Objectives**. Clause 15.9(b) of the Annex A: Terms and Conditions shall be deleted and replaced with the following (to remove the reference to "and (iii) [***]% for allocation to HICs"):

1.4.1 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; and (ii) [***]% for allocation to UMICs; 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;

1.5 **Waiver of Commercial benefits**. Clause 16.2 of the Annex A: Terms and Conditions shall be amended to retain only the first sentence, and so shall read as follows:

1.5.1 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.

1.6 **Commercial Benefits Following Pandemic Period**. Clause 16.3 of the Annex A: Terms and Conditions shall be inserted as follows (such that it reflects the second and third sentence of the previous Clause 16.2, with modifications):

1.6.1 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, including in respect of any sales of a Project Vaccine for which CEPI provides funding beyond the completion of 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 work in good faith to effect the sharing of such Commercial Benefits in the Field according to terms in Annex I for a Project Vaccine for which CEPI has provided funding.

1.7 **Annex H: Volume Commitment Percentage Contribution**. A new annex, "Annex H. Volume Commitment Percentage Contribution", shall be added as follows:

Proposed Volume Commitments by VBI to CEPI for a Project Vaccine (based on a hypothetical scenario)

Funding For:	CEPI Percent Funding	Stage Percent	CEPI Stage Percent	CEPI Cumulative Percent
Preclinical	[***]%	[***]%	[***]%	[***]%
Phase 1	[***]%	[***]%	[***]%	[***]%
Phase 2	[***]%	[***]%	[***]%	[***]%
Phase 3	[***]%	[***]%	[***]%	[***]%
Manufacturing/Approval	[***]%	[***]%	[***]%	[***]%

Funding for Manufacturing/Approval means funding for (i) approval and registration as set out in the iPDP; (ii) WHO pre-qualification or emergency use listing; and (iii) reasonably sufficient commercial manufacturing capabilities as required to meet Awardee's obligations hereunder.

In the event that CEPI declines to fund future development under clause 4.1, or the CEPI Percent Funding for a future stage of work is decreased (including without limitation due to co-funding by VBI or a third party organization), VBI's Volume Commitment would be adjusted based on CEPI's Percent Funding of each Stage Percent above (for example, if CEPI did not contribute to Manufacturing & Approval costs, the CEPI Cumulative Percent in the hypothetical scenario above would be reduced by [***]%). The numbers used in the "CEPI Percent Funding" above that are parenthetically noted to be TBD are examples for illustration purposes only. In no event will the Volume Commitment Percentage be any lower than the CEPI Cumulative Percent already due to CEPI based on its contributions to the funding stages already completed by the Project Vaccine.

1.8 **Annex I. Commercial Benefits**. A new annex, "Annex I. Commercial benefits", shall be added as follows:

Subject to Clause 16.3 of this Agreement the following terms would apply to the sharing of Commercial Benefits in respect of any sales or other exploitation of a Project Vaccine for which CEPI provides at least **% of funding for phase 3 clinical studies including all costs approved by CEPI associated with the phase 3 study and any associated manufacturing and process development costs during phase 3 that are required to generate data for inclusion in a Biological License Application (BLA) to the U.S Food and Drug Administration (FDA) or equivalent ("Phase 3 Funding"):

- Royalties: [***]% of Net Sales on amounts above $[***]/annum, excluding the sales of Project Vaccine allocated under VBI's Volume Commitments to CEPI specified in Annex H.

- Anti-Stacking Provision: In the event that VBI requires a royalty-bearing license to third party intellectual property, the royalties owed to CEPI will be reduced by [***]% of the royalties payable to a third party, provided that the maximum permitted reduction in CEPI's royalty shall be [***]%.

- Sublicensing: In the event of Sublicensing, CEPI would receive [***]% of any and all compensation paid by a Sublicensee to Awardee of Affiliate, including but not limited to: i) upfront payments, ii) development milestones, iii) earn-outs, iv) royalties paid to VBI or its Affiliate, v) the value of any premium paid above fair market value for any Sublicensing arrangement that includes the purchase or option to purchase shares in VBI or Affiliate. CEPI is not be entitled to royalties on Net Sales of Project Vaccine sold by a Sublicensee.

If CEPI provides less than [***]% of Phase 3 Funding the sharing of Commercial Benefits in respect of any sales or other exploitation of a Project Vaccine, the royalties and sublicensing payments above which are applicable to at least [***]% of Phase 3 Funding shall be adjusted as per the tiers indicated below. For the avoidance of doubt the anti-stacking reduction shall continue to apply without adjustment:

- equal to or less than [***]% of Phase 3 Funding: no royalties or sublicensing payments shall apply;

- greater than [***]% and less than [***]% of Phase 3 Funding: a royalty of [***]% of Net Sales and/or a [***]% share of any Sublicensing shall apply;

- equal to [***]% of Phase 3 Funding: a [***]% royalty of Net Sales and/or a [***]% share of any Sublicensing shall apply; and

- greater than [***]% and less than [***]% of Phase 3 Funding: the rates applicable to at least [***]% of Phase 3 Funding, multiplied by a discounted factor determined according to the following formula: [***]% + [***]% for every [***]% increase in Phase 3 funding above [***]%.

As an example for the above tier applicable to Phase 3 Funding greater than [***]% and less than [***]%, if CEPI were to provide [***]% of Phase 3 Funding, the following would apply:

- a royalty payment of [***]% (i.e., [***]% multiplied by a discount factor of [***], calculated as follows: [***]; and /or

- a Sublicensing payment of [***]% (i.e., [***]% multiplied by a discount factor of [***], calculated as follows: [***].

Annex B

Terms and Conditions of Amendment

1. The Original Agreement will be amended on the terms and in the manner set out in Annex A. In the event of conflict between this Amendment Agreement and the Original Agreement, the terms of this Amendment Agreement shall prevail.

2. Unless otherwise stated in Annex A, all agreed amendments shall come into force as of the Effective Date.

3. This Amendment Agreement shall be supplemental to and shall form an integral part of the Original Agreement.

4. Save as set out in Annex A, nothing in this Amendment Agreement shall be deemed to be an amendment to the terms of the Original Agreement or a waiver or consent by CEPI to any breach or potential breach (present or future) of any provision of the Original Agreement or any waiver of any default which arises on or after the date of this Amendment Agreement. Nothing in this Amendment Agreement shall be construed as constituting a release or discharge of the Parties from their obligations and liabilities under the Original Agreement.

5. Save as set out in Annex A, the Original Agreement shall continue in full force and effect and where necessary shall be read and construed as if the terms of this Amendment Agreement were inserted thereon by way of addition or substitution (as the case may be).

6. All terms used in this Amendment Agreement shall have the same meaning as terms used in the Original Agreement. Unless the context otherwise requires, references in the Original Agreement to "this agreement" shall be to the Original Agreement as amended by this Amendment Agreement.

7. All provisions of the Original Agreement regarding third party rights, signing by counterparts, amendments/variations, governing law and jurisdiction and/or dispute resolution shall apply to this Agreement, as if set out in full and so that references in those provisions to "this agreement" shall be construed as references to this Amendment Agreement and reference to "party" or "parties" shall be construed as references to the Parties.

Exhibit 10.49

AMENDMENT TO CONSULTING AGREEMENT

This Amendment to Consulting Agreement (the "**Amendment**"), effective as of **January 1st, 2023** (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, January 1, 2018, January 1, 2019, January 1, 2020, January 1, 2021, and further amended as of January 1, 2022 (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, 2023 (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 **$51,500.00 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.

4. 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.

5. Binding Effect. This Amendment shall be binding on and inure to the benefit of the Parties and their respective successors and assigns.

6. 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

1. Bonus payable as of February 15th, 2023 – CAD **$108,000**

2. The Company shall cause VBI Vaccines Inc., a British Columbia corporation (the "**Parent**") to grant to Francisco Diaz-Mitoma, as designee of Consultant, **75,000** stock options (the "**Options**"), each Option exercisable for one common share of Parent, to be granted effective as of **January 26, 2023**, 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.

[***] 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.

LICENSE AGREEMENT

This License Agreement (the "Agreement") is made as of September 1, 2021 (the "Effective Date"), by and among Ferring International Center S.A., a company incorporated pursuant to the laws of Switzerland, having its principal place of business at Ch. De la Vergognausaz 50, 1162 Saint-Prex, Switzerland ("Ferring") ("**Licensor**"), and SciVac Ltd, a company incorporated under the laws of Israel, having a place of business at 13 Gad Feinstein Rd Rehovot, 7610303 Israel ("**Licensee**") and VBI Vaccines Inc. a company incorporated under the laws of British Columbia, Canada, having a place of business at 160 Second Street, Cambridge, MA 02142 ("**Guarantor**").

PREMISES

1st. Guarantor is the parent company of Licensee, which manufactures and sells a prophylactic Hepatitis B vaccine in association with the trademark Sci-B-Vac;

2nd. Licensee is party to that certain License Agreement which was signed in June 2004 by Savient Pharmaceuticals ("**Savient**") and and SciGen Ltd. ("**SciGen**") and subsequently amended by four separate amendments (the "Original License"), pursuant to which a license was granted to certain rights related to the manufacture and marketing of Sci-B-Vac and which Original License completely replaced two Prior Agreements (as defined herein) between the Parties;

3rd. Through a series of transactions, the Licensor assumed the rights and obligations of Savient and Licensee assumed the obligations of SciGen;

4th. The Parties hereto have decided, based upon the approval of Sci-B-Vac (using the brand name PreHevbrio™) by the FDA in the United States (the "**Approved Product**") and in order to advance the development and commercialization of Sci-B-Vac and to resolve their dispute regarding the payment of royalties under the Original License, to modify and clarify their respective rights and obligations; and

5th. The Parties wish to replace the Original License and the terms and conditions thereunder with the terms and conditions of this Agreement.

IN CONSIDERATION of the mutual undertakings and covenants set forth herein, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. **Definitions** For the purposes of this Agreement, the following terms shall have the meaning set forth below:

   1.1. **"Affiliate"** of either one of the Parties hereto shall mean any individual, sole proprietorship, firm, partnership, corporation, trust, joint venture or other entity, whether *de jure* or *de facto,* which, directly or indirectly, controls, is controlled by or is under common control with such person or entity. As used in this definition, "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the policies and management of a person or entity, whether by the ownership of stock, by contract or otherwise.

1.2. **"BTGIL"** means Bio-Technology General (Israel) Ltd., an Affiliate of Licensor, existing under the laws of Israel and having a place of business in Be'er Tuvia, Israel.

1.3. "**CHO**" means Chinese Hamster Ovary.

1.4. **"Clone"** means genetically engineered CHO cells encoding the Hepatitis B Antigen.

1.5. "**CMO**" means a third party contract manufacturer selected by Licensee for the manufacture of Product, which can include a joint venture entity involving Licensee.

1.6. "**Combination Vaccine**" means (i) a vaccine containing portions of two or more separate vaccines, in all cases including the Product; or (ii) any product containing both (x) the Product and (y) one or more other active agents, toxins, radioisotopes, adjuvants or other active ingredients, which do not by themselves constitute Products, and which are components of the Combination Vaccine whether packaged separately but sold together or packaged and sold together. For the avoidance of doubt, while a "Combination Vaccine" contains the Product, a "Combination Vaccine" shall not itself be deemed a "Product" for purposes of this Agreement; it being understood that the Approved Product is a Product and not a "Combination Product" under this Agreement.

1.7. **"Confidential Information**" means the Technology, the Process and all information and data of any kind, which by its nature is confidential or proprietary, whether such information is disclosed orally, by observation during visits to or inspections of the disclosing Party's facilities, or in writing or in any other form. For the avoidance of doubt, Confidential Information shall be deemed to include information and data exchanged between the Parties prior to the Signature Date and under the Original License.

1.8. **"Distributor"** means a third party to which Licensee may grant the right to Market Product in any country or countries in the Territory, pursuant to Section 6 below.

1.9. **"Effective Date"** shall have the meaning given thereto in the preamble.

1.10. "**Formulated**" means sterilized bulk Product with added buffer followed by adsorption onto alhydrogel.

1.11. "**HBsAg**" means Hepatitis B Antigen produced using the Clone.

1.12. "**Hepatitis B Antigen**" means S, Pre-S1 and Pre-S2 epitopes of the hepatitis B virus.

1.13. "**Hepatitis B Competitor**" means any recombinant product comprising [***] or a [***], or the active ingredients for such a product, other than the Product and a Combination Vaccine

1.14. "**IIA**" means the Israel Innovation Authority, formerly known as the Office of the Chief Scientist of the Ministry of Trade, Industry and Labor of Israel.

1.15. **"License Period"** shall have the meaning ascribed to it in Section 14.1.

1.16. **"Licensed Indications"** means all pharmaceutical uses for which Regulatory Approval is obtained for the Product.

1.17. **"Market"** or **"Marketing"** means promotion and/or marketing and/or distribution and/or sale of the Product.

1.18. **"Net Sales"** means the ex-works selling price for Product (in bulk or in its final presentation) or Combination Vaccine (calculated as set forth below) invoiced by Licensee, or an Affiliate or designee of Licensee or a Sub-Licensee, for the first sale of such Product or Combination Vaccine to a third party, as established in a bona fide arms length transaction between Licensee or an Affiliate or designee of Licensee or Sub-Licensee and such third party less the following deductions actually incurred, allowed, paid, accrued or specifically allocated in its financial statements for:

(a) customary and reasonable trade, quantity, and cash discounts, wholesaler allowances and inventory management fees;

(b) customary and reasonable credits, rebates and chargebacks (including those to managed-care entities, purchasing entities and government agencies), and allowances or credits to customers on account of rejections or returns (including wholesaler and retailer returns) or on account of retroactive price reductions affecting such Product;

(c) freight and transportation charges relating to such Product, including handling and insurance thereof; and

(d) sales (such as VAT or its equivalent) and excise taxes, other consumption taxes, and customs duties (excluding any taxes paid on the income from such sales) to the extent not otherwise reimbursed by a credit or a refund for such taxes, duties or payments made.

Net Sales shall also include the fair market value of Product transferred by Licensee to related parties for onward sale or use or on consignment. Net Sales shall specifically exclude: (i) the fair market value of amounts of Product actually used in clinical trials to develop and obtain regulatory approval for Products or Combination Vaccine; and (ii) the fair market value of amounts of Product or Combination Vaccine actually used by Licensee, its Affiliates or its contractors for product testing or retention which is specifically required by a regulatory authority in the Territory and/or used by Licensee or its Affiliates as product samples for which no consideration is paid, provided the quantity of Product or Combination Vaccine actually utilized for purposes of such clinical trials, retention and product testing and/or product samples shall not exceed in the aggregate for all of these purposes ten percent (10%) of annual Product sales during any given Royalty Year during this Agreement. With respect to Net Sales of Combination Vaccine, for which no royalty has previously been paid to Licensor on Product used in the manufacture of such Combination Vaccine, and for which the Product and each of the other active agents or active ingredients not constituting Products have established market prices when sold separately (market prices as to Product being defined as the ex works price charged by Licensee, its Affiliates or Sub-Licensees as manufacturers, or in the case of other active agents or active ingredients being defined as the ex works price charged by the manufacturer, in a direct arms length sale to a third party), Net Sales shall be determined by multiplying the sales price for each Combination Vaccine by a fraction, the numerator of which shall be the established market price for the Product contained in the Combination Vaccine and the denominator of which shall be the sum of the established market prices for the Product plus the other active agents or active ingredients contained in the Combination Vaccine. To the extent that this formula is inapplicable at any particular time, the Parties shall discuss and agree in good faith upon a fair and equitable method of calculating Net Sales for the Combination Vaccine in question."

If the Product is sold as a Bundled Product (as hereafter defined) in a country in the Territory, then the Net Sales for the Product attributable to such Bundled Product shall be the average price of Product sold in such country in the Territory during the applicable period, provided that in any event any discount applied to such Bundled Product shall in any event be applied at the same discount across all products sold by Guarantor and its Affiliates with the Bundled Product (i.e., no disproportionate discount shall apply to the Licensed Product). "***Bundled Product***" means products in which a non-Product is sold or discounted together with a Product for purchase by or for resale to a customer. In any event, Licensee and its respective Sublicensees and Affiliates shall conduct pricing and discounting activities in a good faith, consistent manner without disadvantaging the Product relative to the other products priced or sold as Bundled Product.

1.19. "**Original License**" has the meaning given thereto in the recitals;

1.20. **"Party"** or **"Parties"** means Licensor, Licensee, or Guarantor, or all of them, depending on the context.

1.21. **"Prior Agreements"** means the Scigen-Distribution Agreement and the Production Rights Agreement.

1.22. **"Process"** means Licensor's proprietary process for the production of the Product, as was used at the Rehovot Facility for the production of an HbsAg vaccine as of the effective date of the Original License

1.23. **"Product"** means HBsAg, either in bulk or Formulated, meeting the Specifications, to be manufactured by Licensee or CMO or a Sub-licensee and for sale by Licensee, an Affiliate of Licensee or Sub-licensee as a Hepatitis B virus vaccine. "Product" shall include, but not limited to, HBsAg for sale as a Therapeutic or as part of a Combination Vaccine it being understood that the Approved Product is a Product and not a "Combination Product" under this Agreement.

1.24. **"Production Rights Agreement**" means the License Agreement entered into as of December 23, 1997 by and between Licensor and Scitech Genetics Pte. Ltd, a predecessor in interest to Licensee, as amended by Amendment No. 1 of January 18, 1998, an additional amendment effective June 1, 1999 and Amendment No. 3 effective February 1, 2001.

1.25. **"Rehovot Facility"** means BTGIL's former facility in Rehovot, Israel.

1.26. **"Regulatory Approval"** means all governmental approvals required for the commercial production of the Product in any country in the Territory, or required to Market Product in any country of the Territory.

1.27. "**Royalty**" shall have the meaning ascribed to such term in Section 8.1 below.

1.28. "**Royalty Year**" means, as to each individual country in the Territory, consecutive twelve (12) month periods commencing upon the date of Regulatory Approval being obtained therein.

1.29. **"Scigen-Distribution Agreement"** means the License Agreement entered into as of November 22, 1988 by and between Licensor and Scitech Medical Products Pte. Ltd, a predecessor in interest to Licensee, with respect to the marketing and distribution of the Product, as amended by Amendment No. 1 of October 1, 1995, Amendment No. 2 of December 22, 1996 and Amendment No. 3 effective December 1997.

1.30. **"Sci-B-Vac"** has the meaning given thereto in the Recitals.

1.31. **"Signature Date**" means the first date upon which the signatures of both Parties shall have been affixed to this Agreement.

1.32. **"Specifications"** means characteristics which, subject to the relevant Regulatory Approvals, are the same or may be substantially similar to those set forth in **Exhibit A** which is attached hereto and made a part hereof, or such other mutually agreed upon specifications.

1.33. "**Sub-Licensee**" means any party, other than an Affiliate, including, without limitation, collaborators, development or commercialization partners**,** or similar party to whom Licensee has sublicensed any of its rights to the Technology hereunder to manufacture Product.

1.34. "**Sub-License Agreement**" has the meaning given thereto in Section 8.10.

1.35. **"Technology"** means the Clone, and any know-how and information provided by Licensor (or its predecessors) to Licensee which relates to the manufacture of the Product which shall include all trade secrets generally disclosed in the Original License, including, without limitation, manufacturing procedures, the Specifications, standard operating procedures or protocols for the Process and the analytical tests and quality control and testing procedures and validation protocols and expertise applied to the manufacture of the Product, provided, however that it shall not include (i) procurement or compliance with local standards and requirements; (ii) validation and related standard operating procedures for the manufacturing facility; (iii) any scale changes at the manufacturing facility or work flowing from such changes; (iv) the transfer of the Product into any receptacle other than bottles and into vials from bottles; (v) any modifications made to the manufacturing process or procedures by Licensee without the assistance of Licensor or its predecessors or (vi) standard operating procedures generated by Licensee which are not based on standard operating procedures obtained from Licensor or its predecessors.

1.36. **"Term"** shall have the meaning ascribed to it in Section 14.1.

1.37. **"Territory"** means all of the countries in the world.

1.38. **"Therapeutic"** means Product or Combination Vaccine for use against infections caused by the Hepatitis B virus.

2. Restatement

2.1. The Parties agree that, except for the representations and warranties of Savient in 11.2 of the Original License, which shall survive, this Agreement shall restate and replace the Original License in its entirety and shall, from and after the Effective Date, govern the relationship of the Parties with respect to the subject matter hereof.

Without derogating from the generality of the foregoing, the Parties hereby release and discharge each other and their respective Affiliates, successors and assigns from any claims, demands, and rights of action arising out of and/or based upon any act or omission committed by either of them or an Affiliate under the Original License, prior to the Effective Date, including, without limitation, any demand for payment or reimbursement of any payment.

3. License Grant

3.1. Licensor hereby grants to Licensee the following rights, and only for the Licensed Indications:

3.1.1. the exclusive right and license (a) to utilize the Technology and other Confidential Information disclosed by Licensor for the purpose of manufacturing, or having manufactured, Product; (ii) to sublicense any of the rights granted to Licensee hereunder to Sub-Licensees, subject to the applicable terms and conditions of this Agreement.

3.2. The Parties agree and acknowledge that the Process and any Technology, Confidential Information and related information, data and materials provided to Licensee under the Original Agreement are specific to the Product and its manufacture, marketing, sale and distribution and do not relate to, and consequently no restrictions, subject to Section 21.13 below, shall apply hereunder with respect to other products (including products using the Product, such as Combination Vaccine) and the manufacture thereof.

3.3. Nothing contained in this Agreement, or in the definition of the terms “manufacture,” “produce or production” as used in this Agreement, shall be deemed to in any way restrict Licensee or a third party, subject to Section 21.13 below, engaged by Licensee on Licensee’s behalf from formulating Formulated Product and filling and packaging commercial containers for Product from bulk Product, or using Product in the manufacture of Combination Vaccine, anywhere in the world, without restriction.

4. Regulatory Approvals

4.1. Licensee shall be fully responsible for preparing, duly filing and actively prosecuting applications for Regulatory Approval of the Product in the US, Europe and Canada and in such other countries in the Territory which it so chooses, in its own name or the name of an Affiliate, or only if it is not possible to file for Regulatory Approval of the Product except in the name of a Distributor, then in the name of the Distributor. Licensee shall keep Licensor currently informed about the progress made towards obtaining Regulatory Approval of the Product in each country in the Territory where such approval has been sought and shall provide Licensor with written reports in reasonable detail on an annual basis. Licensee shall also promptly notify Licensor, in writing, of the receipt of Regulatory Approval of the Product in any country in the Territory, as soon as such Regulatory Approval is obtained.

4.2. Licensee has obtained Regulatory Approval for Sci-B-Vac in the United States and Europe. The obligation in this section 4.2 is not time specific and Licensee shall have complete discretion as to the process of obtaining Regulatory Approval of Sci-B-Vac so long as Licensee is complying with the terms and conditions of this Agreement (including the obligation to use its commercially reasonable efforts).

5. Non-Competition

5.1. During the Term of this Agreement, neither Licensee nor its Affiliates shall, directly or indirectly, manufacture, distribute, sell or otherwise transfer any Hepatitis B Competitor; it being understood and agreed that any acquiror of all the capital stock of either Guarantor or Licensee shall not be deemed to be subject to the restrictions of this Section 5.1.

6. Distributors

6.1. Licensee, or its Affiliates as applicable, shall be entitled, in its sole discretion and at its sole responsibility, to Market Product through Distributors pursuant to arrangements with such Distributors consistent and complying with the following:

6.1.1. Distributor shall keep confidential, shall not disclose Confidential Information regarding this Agreement disclosed to it by Licensee or its Affiliates or the CMO and shall return to Licensee or its Affiliates or to the CMO or destroy all documents containing such Confidential Information promptly, upon the termination of the distributorship; and

6.1.2. that if it is not possible to file for Regulatory Approval of the Product except in the name of the Distributor, then upon termination of the Distributorship, Distributor shall, at Licensee request, and without cost, promptly assign to Licensee or Licensee nominee, any application for Regulatory Approval of the Product theretofore made in the Distributor's jurisdiction, or any such Regulatory Approval to the extent permitted by applicable law.

6.2. For the avoidance of doubt, Licensee shall refrain from disclosing any Confidential Information that constitutes any aspect of the Technology which constitutes a trade secret of Licensor to any Distributor.

6.3. Licensee shall promptly notify Licensor, in writing, of the appointment of each Distributor and its name and address.

7. **Milestone Payments; Consideration For Rights and Licenses**

7.1. The following non-refundable, milestone payments to Licensor were paid by Licensee pursuant to the Original License as full and complete consideration for the rights and licenses granted thereby, which rights and licenses replaced and superceded the rights granted under the Prior Agreements:

7.1.1. [***] which were remitted by Licensee to Licensor in December of 2003, receipt of which Licensor hereby acknowledges; and

7.1.2. [***] which was paid by Licensee to Licensor on or before December 1, 2004.

8. **Royalties and Reporting**

8.1. In consideration for the grant of the Technology and other Confidential Information licensed or otherwise disclosed under this Agreement, Licensee shall pay or cause to be paid to Licensor during the Term a royalty at a fixed rate of three and a half percent (3.5%) of Net Sales (the "**Royalties**").

8.2. Licensee shall report to Licensor in writing, within thirty (30) days of the end of each calendar quarter, Net Sales during such quarter along with a calculation of the Royalties owed to Licensor, broken down by types of Product (vaccines, Combination Vaccines and Therapeutics), the country of manufacture, and the country of sale. Each such report shall be signed by Guarantor's Chief Financial Officer and accompanied by payment of the amount due.

8.3. Following the date of first sale of a Product, by January 31st of each year during the Term, Licensee shall furnish Licensor with a written statement certified by Guarantor's Chief Financial Officer, containing Net Sales during the just ended calendar year. Licensor shall have the right to request certification of such statement, by an independent auditor of the books and records of Guarantor and Licensee and their respective Affiliates. Licensor shall be solely responsible for the cost of such auditor, unless such auditor finds any inaccuracy in the statement, in which case Licensee shall forthwith pay to Licensor the full cost of the independent auditor (if but only if there is a five percent (5%) inaccuracy) and any additional payment due under such auditor's certification.

8.4. All payments to be made to Licensor pursuant to this Agreement shall be made in United States Dollars to such bank account as Licensor may direct from time to time during the Term.

8.5. Licensee shall keep and shall cause its Affiliates engaged in sales of Product to keep true and complete records in accordance with generally accepted accounting principles on Net Sales in relation to the Product. Such records shall contain sufficient detail to enable the determination of any Royalty or other payment due to Licensor hereunder.

8.6. Upon reasonable written notice to Licensee, Licensor, through its designated accountants ("CPA"), shall have access during normal business hours and at Licensor's expense to all such records of Licensee and its Affiliates at the end of every calendar year and within the period of three (3) years thereafter.

8.7. Licensor's CPA shall report to Licensor on such records only to the extent reasonably necessary to enable Licensor to assess whether the obligation of Licensee and its Affiliates with respect to the maintenance of such records has been fulfilled and/or to determine the amount of any Royalty or other payment due to Licensor hereunder. The CPA shall be obligated to maintain the confidentiality of such records.

8.8. Licensee shall withhold and pay to the appropriate authorities in respect of any amount due to Licensor as Royalties, any and all withholding taxes imposed by any taxing authority. In such event, Licensee shall provide Licensor with evidence of such withholding and payment. All payments due herein shall otherwise be made without any set-offs or deductions of any nature.

8.9. Foreign currency shall be converted into United States Dollars using an exchange rate equal to the exchange rate for the purchase of United States Dollars, as reported by *The Wall Street Journal*, on the last day of the calendar quarter for which the payment is due.

8.10. Licensee will pay, within five (5) business days of its receipt, to Licensor thirty percent (30%) of any and all Consideration (as defined below) Licensee and Guarantor and their respective Affiliates and assigns received for a sublicense or other grant of rights to any Sub-Licensee, (a "Sub-License Agreement"). Licensee shall supply to Licensor a complete unredacted copy of each such Sub-License Agreement, together with such payment, provided that Licensor shall not disclose such Sub-License Agreement in whole or in part to any third party. "Consideration" shall mean any and all non-royalty consideration, in any form, received by Licensee or Guarantor and/or their respective Affiliates from such Sub-Licensee (other than consideration based on Net Sales for which a royalty is due under this Agreement). Licensee covenants and agrees that it will not intentionally structure the financial terms of such Sub-License Agreements in a manner intended to avoid, reduce or diminish the amount of Consideration that would otherwise be subject to the terms of this Section 8.10 or its obligations to pay the specified portion thereof to Licensor.

8.11. The thirty percent (30%) payment described in Section 8.10 shall not apply to a grant of rights in or relating to the countries in the Original Territory (which is the Territory as defined in the Original Agreement, prior to any amendment) or the Berna Territory countries, each as described in Exhibit B. With respect to the countries described in Exhibit B, Licensee covenants and agrees that it will not intentionally structure the financial terms of any Sub-License Agreement in or relating to such countries in a manner intended to avoid, reduce or diminish the amount of Royalties that would otherwise be due to Licensor pursuant to Section 8.1.

8.12. The provisions of Section 8 shall apply, *mutatis mutandis*, to payments and reports that shall be due to Licensor in respect of any Consideration, and all references to Affiliates thereunder shall be construed as including Sub-Licensees. For the avoidance of doubt, Licensee guarantees the compliance by any Sub-Licensee with any commercial provision of a Sub-License Agreement, unless, but only to the extent, that such Sub-Licensee enters into an agreement with Licensor which covenants and agrees to full performance of Sub-Licensee's obligations under this Agreement.

9. Representations and Warranties by Licensor

9.1. Subject to Section 10, as of June 3, 2004 (the original date of the Original License Agreement), Licensor represented and warranted to Licensee as follows:

9.1.1. Licensor had all right, title and interest in and to the Vaccine (defined for purposes of this section only as "Hepatitis B virus vaccine containing HBsAg that was manufactured for Licensor at the Rehovot Facility, but is not the Product"), the patent rights in patents directed to the manufacture of HBsAG, the Process and the Technology, which were free and clear of any liens, charges, encumbrances or other security interests in the Original Territory (as described in Exhibit B);

9.1.2. The Process had enabled Licensor to produce HBsAG meeting the Specifications as specifically listed in Exhibit A, at the Rehovot Facility, when [***] with [***]; and

9.1.3. The Clone was to be provided to Licensee in viable condition and was to be unchanged from that used in the Rehovot Facility.

9.2 **EXCEPT AS SPECIFICALLY SET FORTH IN SECTION 9.1 LICENSOR DISCLAIMS ALL OTHER EXPRESS AND IMPLIED WARRANTIES ON THE PRODUCT, PROCESS AND THE TECHNOLOGY (AS SUCH TERMS ARE DEFINED IN SECTION 1 ABOVE). For the avoidance of doubt, Licensor does not warrant that the Process and the Technology shall enable Licensee to produce HBsAG meeting the Specifications.**

10. Representations. Warranties and General Undertakings by Licensee

10.1. Effective as of the original date of the Original License Agreement, Licensee accepted the Process and the Technology "as is";

10.2. Effective as to the original date of the Original License Agreement, Licensee undertakes to Licensor as follows:

10.2.1. Licensee shall comply, and shall ensure that the CMO complies, with the relevant terms of this Agreement and applicable laws; and

10.2.2. In carrying out Licensee's undertakings and responsibilities pursuant to this Agreement, Licensee shall comply, and shall ensure that the CMO and/or Sub-Licensee comply, in all material respects, with all laws and regulations, licenses, permits, approvals and procedures applicable in any country of the Territory where Product is manufactured.

10.3. Licensee, at its own expense, shall be responsible for obtaining and causing to remain in effect such licenses, permits, approvals, and consents as may be required for its performance and responsibilities under this Agreement, and also those of any Distributor. Such licenses, permits, approvals and consents shall, wherever possible, be in Licensee's own name.

10.4. Licensee shall immediately report to Licensor on:

10.4.1. any material development coming to its attention which may, in any way, materially and adversely affect its performance under this Agreement; and

10.4.2. any breach by the CMO of the terms and conditions of this Agreement; and

10.4.3. any serious adverse event alleged or known to be a result of the use of Product.

11. Indemnification

11.1. Licensee shall assume responsibility for, and shall defend, indemnify and hold Licensor and its Affiliates harmless against and from any and all losses, expenses (including reasonable attorneys' fees and expenses at trial and appellate levels), recoveries and damages, including costs and expenses of a total or partial Product recall, arising out of, based on or caused by, any claim, suit or proceeding brought by a third party relating to or resulting from any breach by Licensee (or any employee, agent, contractor or Affiliate of one or more of Licensee or the CMO or a Sub-Licensee) of any of its obligations hereunder including the representations, warranties and undertakings of Section 10, or from the manufacture and/or supply of Product by the CMO for Licensee, or from the supply of Product by Licensee to any other party who purchases Product from Licensee, or from the negligence or other wrongdoing of Licensee or any of the above, provided that Licensee shall incur no obligation to defend, indemnify or hold Licensor and its Affiliates harmless against and from any liabilities resulting from a breach by Licensor (or any employee, agent or contractor of Licensor, or its Affiliates) of any of their obligations hereunder or from Licensor's gross negligence or other wrongdoing of Licensor or its Affiliates (or any employee, agent or contractor thereof).

11.2. In no event shall Licensor (or its Affiliates) be liable for any representation or warranty, express or implied, with respect to the Product or the Technology which may have been made or given by Licensee or the CMO; or any Sub-Licensee; or any employee, agent, or contractor of Licensee or of the CMO or of any Sub-Licensee, and which representation or warranty was not specifically authorized by Licensor in writing, and Licensee shall indemnify Licensor and hold it harmless against and from any liability, loss or expense arising from any third party claims resulting from any such representation or warranty.

11.3. Licensor shall promptly notify Licensee in writing of its receipt of notice of any claim or any actual or threatened legal action initiated against Licensor as to which this Section 11 applies. Licensor shall cooperate with Licensee in the defense of the claim or action and Licensee shall keep Licensor informed of developments in such action.

11.4. In the case of an action against Licensor, or its Affiliates to which this Section 11 applies, Licensee shall consult Licensor with respect to the choice of attorneys for the defense of the action, and furthermore, in addition to the attorneys selected by Licensee to defend the action, Licensor shall also be entitled to engage at its own expense its own attorneys to assist in such defense.

12. **Infringement**

12.1. Licensee shall be responsible for ensuring that it is free to operate in those countries of the Territory where it makes, uses and sells Products and Licensee shall refrain from committing any act, and shall ensure that the CMO and any Sub-Licensee do not commit any act, which Licensee has reason to believe, infringes upon an issued patent in the country in which such act takes place. It is understood and agreed that Licensor does not hereby and will not warrant to Licensee or the CMO or any Sub-Licensee that the Technology, the Process, the Product or, without limitation, manufacture, use or Marketing of the Product does not and will not infringe any patent owned by a third party, and Licensor shall have no responsibility whatsoever to defend against any claim, suit and/or proceeding asserted or filed against Licensor and/or Licensee and/or the CMO and/or a Sub-Licensee or their Affiliates (or any employee, agent or contractor thereof) alleging such infringement. Licensee shall assume full responsibility for, and shall defend, indemnify and hold Licensor harmless against and from any and all such patent infringement suits filed by a third party directly or indirectly in relation to the Licensee's use of the Product, the Process and the Technology.

13. Relationship of Parties

13.1. The relationship between Licensee and Licensor under this Agreement is that of licensor and licensee, and nothing contained in this Agreement shall constitute either Party as the agent or representative of the other Party for any purpose whatsoever.

13.2. In particular, but without derogating from the generality of the foregoing, neither Party shall have any right to assume or create any obligation, contract or commitment, expressed or implied, or make any representation, on behalf, or in the name, of the other Party, and each Party shall indemnify and hold harmless the other Party against and from any liability arising from any such act by such Party.

14. Term and Termination

14.1. Unless earlier terminated pursuant to any provision of this Agreement, this Agreement shall remain in force on a country-by-country basis in the Territory (the **"Term"**) until the date which is seventeen (17) years after the date of commencement of the first Royalty Year in respect of such country (each, a **"License Period"**). The Parties confirm that, pursuant to the Original License, upon expiry of the full term of the first License Period having commenced, Licensee exercised its option to extend the Original License in respect of all the countries of the Territory to a full license term of seventeen (17) years by payment to Licensor of a one-time lump sum payment of (U.S. Dollars One Hundred Thousand (US$100,000) in April of 2019.

14.2. Provided that the license has been in effect for, and elapsed after, a seventeen (17) year License Period with respect to a country in the Territory, Licensee shall thereafter have a royalty-free license to the Technology in such country.

14.3. Upon termination of this Agreement, Licensee and the CMO and any manufacturing Sub-Licensee shall immediately cease the manufacture, marketing, sale and distribution of Product in those countries of the Territory where Royalties have not been paid for the full seventeen year Term and shall return to Licensor all Technology and other Confidential Information in their possession, including the Clone and all clones derived therefrom in use in such countries. Upon the termination of this Agreement, Licensee shall, at Licensor's request, promptly assign to Licensor or Licensor's nominee, any application for Regulatory Approval or any Regulatory Approval obtained in those countries of the Territory where Royalties have not been paid for the full seventeen year Term. If any application cannot be so transferred or assigned, Licensee shall, at Licensor's request, actively continue to process such application and shall assign such Regulatory Approval when received, and Licensor shall reimburse Licensee for its reasonable out-of-pocket expenses. Once transferred, Licensee will not retain any residual rights to any such application or Regulatory Approval.

14.4. Licensor shall have the right to terminate this Agreement by written notice to Licensee if Licensee should:

14.4.1. be declared bankrupt or insolvent, or request or suffer the appointment of a receiver for its assets, or make a composition with its creditors or take or suffer any similar action in consequence of debt;

14.4.2. fail to make any payment due Licensor under this Agreement for a period of forty-five (45) days following notice from Licensor that such payment is due;

14.4.3. fail to prevent the Technology from being transferred without Licensor's and the IIA's prior written consent;

or

14.4.4. otherwise breach any material provision of this Agreement and fail to cure such breach within sixty (60) days after Licensor gives notice of such breach to Licensee.

14.5. Licensee shall have the right to terminate this Agreement by written notice to Licensor if Licensor should:

14.5.1. be declared bankrupt or insolvent, or request or suffer the appointment of a receiver for its assets, or make a composition with its creditors or take or suffer any similar action in consequence of debt; or

14.5.2. breach any material provision of this Agreement and fail to cure such breach within sixty (60) days after Licensee gives notice of such breach to Licensor.

14.6. No Party shall be entitled to any compensation upon, or by reason of, the termination of this Agreement for any reason, other than for the material breach of this Agreement by the other Party, except that each Party shall be entitled to collect any debt then owed to it by the other Party and shall have any rights that this Agreement provides upon termination.

15. Force Majeure

15.1. Each Party shall be relieved of its obligations under this Agreement to the extent that fulfillment of such obligations shall be prevented by strikes, embargoes, riots, fires, floods, war, hurricanes, windstorms, acts or defaults of common carriers, governmental laws, acts or regulations, contamination, shortages of materials or any other occurrence, whether or not similar to the foregoing, beyond the reasonable control of the Party whose performance is affected thereby.

15.2. If any Party is prevented from fulfilling its obligations under this Agreement by reason of a circumstance covered by this Section 15, the Party unable to fulfill its obligations shall, upon the occurrence of any such circumstance, promptly notify the other Parties of such circumstance and of the likely duration thereof, use its reasonable commercial efforts to alleviate each circumstance and promptly continue performance hereunder upon the cessation of such circumstance.

16. Confidentiality

16.1. Commencing on the Signature Date, during the Term and at all times thereafter, each of Licensor and Licensee shall retain in strict confidence all Confidential Information obtained from the other pursuant to, or in connection with, this Agreement. Neither Party shall disclose any Confidential Information of the other to any person, firm or corporation, or any other third party. Neither Party shall use any such Confidential Information for any purpose not contemplated by this Agreement.

16.2. Notwithstanding the foregoing, each of the Parties may disclose Confidential Information of the other:

16.2.1. to its (or its Affiliates) directors, officers, employees, Sub-Licensees, commercial and research and development collaborators, and consultants, to the extent, if any, required for the performance of their duties in connection with this Agreement, provided each such person is individually and personally obligated in writing to comply with confidentiality undertakings no less stringent than the provisions of this Section 16;

16.2.2. to the extent necessary to obtain Regulatory Approvals; or

16.2.3. to the extent required by law, regulation or judicial order, or the rules and regulations of any stock exchange, provided that prior to disclosure pursuant to this clause the disclosing Party gives to the other Party prompt notice of such required disclosure and fully cooperates with such Party's efforts to obtain a protective order or other appropriate remedy; and provided further that any such disclosure shall be in writing, shall, to the extent possible, be designated confidential at the time of disclosure, and shall be held by the recipient in accordance with the provisions of this Section 16.

16.3. The obligations of nondisclosure and nonuse pursuant to this Section 16 shall not apply to any Party with respect to any Confidential Information of the other Party that such Party can establish by written record:

16.3.1. was known to such Party prior to the disclosure thereof by the other Party; or

16.3.2. was in the public domain prior to the disclosure thereof to such Party or subsequently entered the public domain by some means other than as a result of a breach of this Agreement by such Party; or

16.3.3. was subsequently disclosed to such Party by a third party having a lawful right to make the disclosure.

17. Limitation on Remedies

Except as specifically set forth herein, neither Party shall be liable to the other Party under any circumstances for any special, indirect, incidental or consequential damages, lost profits, business interruption losses, or loss of business relationships.

18. Governing Law; Litigation

18.1. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New Jersey, United States of America, without regard to the conflicts of laws provisions therein.

18.2. Licensee hereby irrevocably submits to the jurisdiction of the federal courts and the state courts of the State of New Jersey with respect to any legal proceedings in connection with this Agreement, confirms that the service of process out of such courts and delivered by certified mail or courier, fees prepaid, shall be deemed to be service upon Licensee for purposes of such legal proceedings; waives any objection it may have that such legal proceedings have been brought in an inconvenient forum; and agrees to produce witnesses in New Jersey which are reasonably identified by Licensor for depositions or as witnesses at trial. All such proceedings shall be conducted in the English language.

18.3. Nothing contained herein shall bar Licensor from applying to any court for injunctive relief to prevent the breach or threatened breach of the provisions hereof. Without derogating from the generality of the foregoing, each Party hereby consents to the jurisdiction of such country or countries in which other Party elects to seek an injunction in favor of Licensor preventing breach of this Agreement.

18.4. Licensee shall maintain and keep in force for the Term of this Agreement comprehensive general liability insurance and product liability insurance, each of which shall have a limit which is at least [***] per occurrence and in the aggregate. Such insurance shall be placed with a first class insurance carrier with at least a BBB rating by Standard & Poors. Promptly after execution and delivery of this Agreement, Licensee shall furnish a certificate of insurance evidencing the foregoing coverage and limit.

19. **Insurance**

19.1. Employers' liability insurance shall cover any employee of any kind.

20. Notices

20.1. All notices and other communications required or desired to be given or sent by one Party to the other Party shall be in writing and shall be deemed to have been given: (a) on the date of delivery, if delivered to the persons identified below, (b) five (5) business days after mailing if mailed, with proper postage, by certified or registered mail, postage prepaid, return receipt requested, addressed as set forth below, (c) on the date of receipt if sent by email, or (d) three (3) business days after delivery to a nationally recognized overnight courier service marked for overnight delivery, as follows:

If to Licensee:

SciVac Ltd.
13 Gad Feinstein Rd
Rehovot, 7610303 Israel
Attn: Chief Financial Officer
cmnulty@vbivaccines.com

with a copy to: Legal Counsel
mbradley@vbivaccines.com

If to Licensor:

Ferring International Center SA
Ch. De la Vergognausaz 50,
1162 Saint-Prex, Switzerland
Attn: Chief Legal Officer
Ferring-General-Counsel@ferring.com

or to such other address as may be designated by notice; provided that any notice of change of address shall be effective only upon receipt.

21. Miscellaneous

21.1. Any payment not received when due shall bear interest from the due date at the rate of [***] per month (or such other percentage, if lower, as shall not exceed the maximum rate permitted by law).

21.2. This Agreement, together with the exhibits attached hereto, constitutes the entire agreement between the Parties with respect to Licensor's HBsAg-based Technology and Products in any form, and supersedes all prior understandings, agreements and discussions between them and/or their Affiliates, oral or written, with respect to such subject matter.

21.3. This Agreement shall not be modified or amended except by a written instrument referencing this Agreement signed by the Parties hereto.

Neither Party shall assign its rights or obligations under this Agreement, or any intellectual property rights or Technology licensed under this Agreement, either in whole or in part, without the prior written consent of the other Party except to a party acquiring all of the assigning party's business to which this Agreement relates. Any assignment in violation of this Section 21.3 shall be null and void. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

21.4. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

21.5. No waiver or failure to act, with respect to any breach or default under this Agreement, whether or not the other Party has notice thereof, shall be deemed to be a waiver with respect to any subsequent breach or default, whether of a similar or different nature.

21.6. Those provisions of this Agreement which are intended to survive the termination, expiration or nullification of this Agreement, including, without limitation, the provisions of Sections 2, 8.5, 8.6, 14.2, 16, 17, 18, 19, 20, 21.1, 21.4, 21.6, 21.7, 21.10, 21.11, 21.12, and 21.13 shall so survive and shall be enforceable according to the terms set forth herein.

21.7. The provisions of this Agreement are severable. The invalidity, in whole or in part, of any provision of this Agreement shall not affect the validity or enforceability of any other of its provisions. If one or more provisions hereof shall be declared invalid or unenforceable, the remaining provisions shall remain in full force and effect and shall be construed in the broadest possible manner to give effect to the purposes hereof. The Parties further agree to replace such void or unenforceable provisions of this Agreement with valid and enforceable provisions which will achieve, to the extent possible, the economic, business and other purposes of the void or unenforceable provisions.

21.8. The Parties will execute and deliver such other instruments and take such other steps as may be necessary to fully effect this Agreement.

21.9. The Parties agree that press releases and other public communications of any sort relating to this Agreement or the matters contemplated hereby are subject to the approval of both Parties hereto, such approval not to be unreasonably withheld; provided, however, that Licensee may make such public communications as may be required of it as a publicly traded corporation on the NASDAQ stock exchange in the United States of America.

21.10. Nothing in this Agreement, express or implied, is intended to confer on any person other than the Parties hereto, or their respective permitted successors and assigns, any benefits, rights or remedies. All titles and article headings contained in this Agreement are inserted only as a matter of convenience and reference. They do not define, limit, extend or describe the scope of this Agreement or the intent of any of its provisions.

21.11. Neither Licensee nor Licensor shall settle or compromise any claim or action in a manner that imposes any material restrictions or obligations on the other Party without such other Party's prior written consent, which consent shall not be unreasonably withheld.

21.12. This Agreement may be executed electronically and in counterparts and signature pages may delivered by electronic transmission, each of which will be deemed an original, and both of which together will constitute one and the same instrument.

21.13. Notwithstanding anything hereinabove to the contrary, where approval is required by the IIA in order to engage in any act contemplated under this Agreement, such approval shall be deemed a condition precedent for such act.

21.14. Guarantee. Guarantor hereby agrees to be bound by the terms and conditions of Exhibit C until such time as this Agreement is assigned to a third party, in which event the guarantee in Exhibit C shall only apply to obligations of Licensee which have accrued up until the date of the assignment.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, Licensor and Licensee are duly authorized for themselves and their Affiliates and have caused this Agreement to be executed by their duly authorized representatives as of the dates written below.

SCIVAC LTD.

By: */s/ Jeffrey Baxter*
Jeffrey Baxter
Title: Chief Executive Officer
Date: October 18, 2022

VBI VACCINES INC.

By: */s/ Jeffrey Baxter*
Jeffrey Baxter
Title: Chief Executive Officer
Date: October 18, 2022

FERRING INTERNATIONAL CENTER S.A.

By: */s/ Curt McDaniel*
Curt McDaniel
Title: Senior Vice President and Chief Legal Officer
Date: October 18, 2022

By: */s/ Dominic Moorhead*
Dominic Moorhead
Title: Executive VP and Chief Financial Officer
Date: October 18, 2022

List of Exhibits

A	Specifications
B	Countries
C	Guarantee

EXHIBIT A
Specifications

[***]

EXHIBIT B
Countries

[***]

EXHIBIT C
Guarantee

1. **Guarantee**. The Guarantor hereby guarantees to Licensor as a primary obligor and not merely as a surety, the due and punctual payment of all of the obligations of Licensee and for the due and punctual performance of its obligations under this Agreement (the "**Guaranteed Obligations**"). The Guarantor agrees that its guarantee hereunder constitutes a guarantee of payment when due and not of collection, and waives any right to require as a condition to its obligations hereunder that any resort be had by Licensor. The Guarantor waives demand of payment from to the Licensor of any of the Guaranteed Obligations, filing of claims with a court in the event of insolvency or bankruptcy of the Licensee, any right to require a proceeding first against the Licensee.

2. **No Limitations, Etc.** The Guarantor agrees that (to the fullest extent permitted by law) its obligations hereunder are unconditional and shall not be subject to any defense or setoff, counterclaim, recoupment or termination whatsoever by reason of the invalidity, illegality or unenforceability of the Guaranteed Obligations (other than the defense of payment or performance) or the absence of any action to enforce the same or waiver or consent with respect to any provisions hereof or thereof. Without limiting the generality of the foregoing, to the fullest extent permitted by applicable law, the guarantees of Guarantor shall not be discharged or impaired or otherwise affected by, and Guarantor hereby waives any defense to the enforcement hereof by reason of, any circumstance (other than the defense of payment or performance) (including without limitation, any statute of limitations) that might otherwise constitute a legal or equitable discharge of, Licensee.

3. **Reinstatement**. The Guarantor agrees that its guarantee hereunder shall continue to be effective, or be reinstated, as the case may be, if at any time, payment, or any part thereof, of any of the Guaranteed Obligations is rescinded or must otherwise be restored or returned by any court of competent jurisdiction upon the insolvency, bankruptcy, dissolution, liquidation or reorganization of Licensee, or upon or as a result of the appointment of a receiver, intervenor or conservator of, or trustee or similar officer for, Licensee or any substantial part of its property, or otherwise, all as though such payments had not been made. In the event that any payment, or any part thereof, of any of the Guaranteed Obligations is rescinded, reduced, restored or returned upon the insolvency, bankruptcy, dissolution, liquidation or reorganization of Licensee, or upon or as a result of the appointment of a receiver, intervenor or conservator of, or trustee or similar officer for, Licensee or any substantial part of its property, or otherwise, the Guaranteed Obligation shall, to the fullest extent permitted by law, be reinstated and deemed reduced only by such amount paid or performed and not so rescinded, reduced, restored or returned.

4. **Further Agreements**. The Guarantor also hereby agrees to pay any and all reasonable out-of-pocket expenses (including reasonable counsel fees and expenses) incurred by Licensor in enforcing any rights hereunder.

5. **Amendments with respect to the Guaranteed Obligations**. The Guarantor shall remain obligated hereunder notwithstanding that, without any reservation of rights against the Guarantor and without notice to or further assent by the Guarantor, any demand for payment of any of the Guaranteed Obligations made by Licensor may be rescinded by Licensor and any of the Guaranteed Obligations continued, and the Guaranteed Obligations, or the liability of any other person or entity for any part thereof, or right of offset with respect thereto, may, from time to time, in whole or in part, be renewed, extended, amended, modified, , compromised, waived, surrendered or released by Licensor, and this Agreement and any other documents executed and delivered in connection therewith may be amended, modified, supplemented or terminated, in whole or in part, as Licensor and Licensee may deem advisable from time to time.

National Research Council Canada | Conseil national de recherches Canada

Amendment 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 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 corporation incorporated under the laws of Canada
whose registered office address is located at:
310 Hunt Club Road East, Suite 201
Ottawa, Ontario K1H 7A6 (called the **"Collaborator" or "VBI"**)

(Individually called a **"Party"** and collectively called the **"Parties"**)

WHEREAS the Parties entered into an Agreement signed by the NRC on 30 March 2020, for a Project described as "COVID-19 vaccine evaluation" (hereinafter called the "Original Agreement")

WHEREAS the Parties amended the Original Agreement, first on 21 December 2020 to add additional scope of work (called "Amendment One"), a second amendment on July 8, 2021 (called "Amendment Two"), a third amendment on 28 August 2021 ("Amendment Three"), a fourth amendment was executed on 15 November 2021 ("Amendment Four"), a fifth amendment on 08 February 2022 ("Amendment Five") and a sixth amendment on April, 28, 2022 ("Amendment Six"). The Original Agreement, Amendment One, Amendment Two, Amendment Three, Amendment Four, Amendment Five and Amendment Six collectively called "The Agreements".

WHEREAS the Parties wish to execute a seventh amendment to make changes to the Statement of Work due to insufficient results collected to date, as well as to add new tasks

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 unmodified terms, the Parties confirm the Original Agreement.

2. The attached Statement of Work and Deliverables amends the Statements of Work and Deliverables listed in The Agreements and adds additional scope of work for clone #20. For clarity, the changes are more fully described in the Background section of the attached Statement of Work.

3. The total value of the work defined in the attached Statement of Work and Deliverables is estimated to be ***.

4. VBI is a Canadian Small and Medium Enterprise (SME) and benefits from a Fee Reduction of *** for the work associated with this Amendment. 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.

5. The amount that VBI will pay to the NRC for the additional work detailed in this Amendment Seven is ***.

6. The Invoicing Schedule for Task 1.21 listed in The Agreements is hereby revised as follows:

Delete:
"Upon completion of Task 1.21 Amount Due: ***"

and replace with:
"Upon completion of Task 1.21.1 Amount Due: ***" and
"Upon completion of Task 1.21.2 Amount Due: ***".

7. The following new invoicing schedule is added:

Invoicing Schedule	Amount Due*
Upon signature of Amendment 7, for the additional plating for Task 2.9.2	CAD ***

*plus applicable taxes

8. The expiry date, last amended in Amendment Six to be December 31, 2022 is hereby extended to a new expiry date of December 31, 2023. The Parties agree that Project work performed between December 31, 2022 and this Amendment is subject to the terms and conditions of The Agreements and this Amendment Seven. This Amendment will be effective on the date of the last Party's signature.

9. This Amendment 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 facsimile copy or 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 Amendment Seven.

SIGNED by VBI at Ottawa, Ontario

VARIATION BIOTECHNOLOGIES INC.

Date: February 28, 2023

Per: */s/ Jeffrey Baxter*
Name: Jeffrey Baxter
Title: CEO

SIGNED by the NRC at *Ottawa, Ontario*, Canada

NATIONAL RESEARCH COUNCIL OF CANADA

Date: February 28, 2023

Per: /s/ *Lakshmi Krishnan*
Lakshmi Krishnan
Vice President, Life Sciences Division

STATEMENT OF WORK AND DELIVERABLES

***

PROJECT CONTACTS

Role	Name	Phone	e-mail
Client Technical Contact	Dr. Catalina Soare	***	***
Client Business Contact	Dr. Leigh O'Hara	***	***
NRC Project Leader (Technical Contact)	Dr. Alaka Mullick	***	***
NRC Project Managers	Dao Ly Krista Melville	***	***
NRC Business Contact	Dr. Paul Payette	***	***

-end-

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. 333-267109) and Form S-8 (Nos. 333-267114, 333-259282, 333-240268, 333-226261 and 333-212160) of our report dated March 13, 2023, on our audits of the consolidated financial statements as of December 31, 2022 and 2021 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 13, 2023. 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 13, 2023

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, 2022 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 13, 2023

/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, 2022 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 13, 2023

/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, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Jeffrey 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 13, 2023

/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, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Christopher 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 13, 2023

/s/ Christopher McNulty

Christopher McNulty
Chief Financial Officer and Head of Business Development (Principal Financial and Accounting Officer)