

VBI Vaccines Inc.

**2023 Annual Report to
Shareholders**

**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, 2023**

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

(State or other jurisdiction
of incorporation or organization)

N/A

(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, 2023, 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 \$21,950,347.

As of April 16, 2024, the registrant had 28,432,275 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 2024 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, 2023

TABLE OF CONTENTS

<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND OTHER INFORMATION CONTAINED IN THIS REPORT</u>	ii
<u>PART I.</u>	
<u>ITEM 1: BUSINESS</u>	1
<u>ITEM 1A: RISK FACTORS</u>	27
<u>ITEM 1B: UNRESOLVED STAFF COMMENTS</u>	68
<u>ITEM 1C: CYBERSECURITY</u>	68
<u>ITEM 2: PROPERTIES</u>	69
<u>ITEM 3: LEGAL PROCEEDINGS</u>	70
<u>ITEM 4: MINE SAFETY DISCLOSURES</u>	70
<u>PART II.</u>	
<u>ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	71
<u>ITEM 6: [RESERVED]</u>	71
<u>ITEM 7: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	71
<u>ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	98
<u>ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	98
<u>ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	98
<u>ITEM 9A: CONTROLS AND PROCEDURES</u>	98
<u>ITEM 9B: OTHER INFORMATION</u>	99
<u>ITEM 9C: DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.</u>	99
<u>PART III.</u>	
<u>ITEM 10: DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE</u>	100
<u>ITEM 11: EXECUTIVE COMPENSATION</u>	100
<u>ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	100
<u>ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	100
<u>ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	100
<u>PART IV.</u>	
<u>ITEM 15: EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	101
<u>ITEM 16: FORM 10-K SUMMARY</u>	101
<u>SIGNATURES</u>	109

VBI Vaccines, Sci-B-Vac, PreHevbrio, PreHevbri, our logo, and other trademarks or service marks appearing in this report are the property of VBI Vaccines Inc. or its subsidiaries. Trade names, trademarks, and service marks of other companies appearing in this report are the property of their respective owners. Solely for convenience, the trademarks, service marks, and trade names included in this report are without the ®, ™, or other applicable symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the rights of the applicable licensors to these trademarks, service marks, and trade names.

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 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 endemic and its effects 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;
- our ability to comply with the covenants and meet the obligations of our credit facility;
- 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, if, 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;
- our success at managing the risks involved in the foregoing items; and
- other factors discussed in this Form 10-K.

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

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

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

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

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

PART I

ITEM 1. BUSINESS

Overview

We are 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 and a proprietary mRNA-launched eVLP (“MLE”) 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.

2023 Organizational Changes

On April 4, 2023, we announced that we planned to reduce our internal workforce and other expenses by 30-35%, activity which began in April 2023 and was completed by the end of September 2023. As a result of this, our operating expenses from normal business were approximately 30-35% lower in the second half of 2023 as compared with the second half of 2022.

2023 Reverse Stock Split

On April 12, 2023, we effected a 1-for-30 reverse stock split (the “Reverse Stock Split”) of our issued and outstanding common shares effective as of April 12, 2023, pursuant to which every 30 of our issued and outstanding common shares were automatically converted into one common share without any change in the par value per share. Per the requirements of the *Business Corporations Act* (British Columbia), under which we are regulated, if fractional shares held by registered shareholders were to be converted into whole shares, each fractional share remaining after the completion of the Reverse Stock Split that was less than half of a share was cancelled and each fractional share that was at least half of a share was rounded up to one whole share. No shareholders received cash in lieu of fractional shares.

Recent Developments

April 2024 Offering

On April 9, 2024, we entered into a securities purchase agreement with certain institutional investors named therein pursuant to which we issued and sold 2,272,728 common shares and accompanying warrants to purchase up to 2,272,728 common shares (the “April 2024 Warrants”) at a combined offering price of \$0.88 per common share and accompanying April 2024 Warrant in a registered direct offering (the “April 2024 Offering”). The April 2024 Offering closed on April 11, 2024. The April 2024 Warrants have an exercise price of \$0.76 per share, are immediately exercisable on the date of issuance, and expire five years following the date of issuance. Net proceeds to us from the April 2024 Offering, after deducting placement agent fees and estimated offering expenses payable by us, were approximately \$1,700.

In connection with the April 2024 Offering, we also issued to H.C. Wainwright & Co., LLC or its designees, placement agent warrants to purchase up to 136,364 common shares (the “April 2024 Placement Agent Warrants”) as compensation in connection with the April 2024 Offering. The April 2024 Placement Agent Warrants have substantially the same terms and conditions as the April 2024 Warrants, except that the April 2024 Placement Agent Warrants have an exercise price of \$1.10 per share, which represents 125% of the offering price per common share and accompanying April 2024 Warrant and expire five years following the commencement of sales pursuant to the April 2024 Offering.

February 2024 Agreements with Brii Bio

On February 13, 2024, we entered into a series of agreements with Brii Biosciences Limited (“Brii Bio”), pursuant to which, subject to achievement of certain activities, we would receive up to \$33,000 in consideration from Brii Bio, consideration which will be used to correspondingly reduce our obligations due under the Loan Agreement. See “Item 1—Business—Partnership with Brii Bio” below.

As part of that series of agreements, we and SciVac Ltd. (“SciVac”) entered into a purchase agreement (the “Rehovot Purchase Agreement”) with a wholly-owned subsidiary of Brii Bio, to be formed in Israel (“Brii Israel”) prior to the closing, and joined as a party to the agreement prior to the closing as the purchaser, and Brii Biosciences, Inc, a Delaware corporation, pursuant to which, upon achievement of certain activities and closing of the transactions contemplated by the Rehovot Purchase Agreement, subject to the terms and conditions therein, SciVac will sell to Brii Israel certain assets, including SciVac and its affiliates’ interest and rights in certain leases with respect to the vaccine manufacturing facility in Israel, for an aggregate purchase price of \$10,000, which is then required to be paid to K2HV pursuant to the terms of the Fourth Amendment (each as defined below).

The Rehovot Purchase Agreement contains representations and warranties of SciVac and Brii Israel that are typical for transactions of this type. The Rehovot Purchase Agreement also contains covenants on the part of the Company that are typical for transactions of this type.

The closing of the transactions pursuant to the Rehovot Purchase Agreement are subject to the terms and conditions therein, including closing conditions that are typical for transactions of this type and our completing the Essential Activities (as defined below). Closing will not occur prior to June 30, 2024.

As previously disclosed, we and our subsidiary VBI Cda (as defined herein), as borrowers, entered into a Loan and Guaranty Agreement dated as of May 22, 2020, as amended by the first amendment, dated as of May 17, 2021 (the “First Amendment”), that second amendment, dated as of September 14, 2022 (the “Second Amendment”), and that third amendment, dated as of July 5, 2023 (the “Third Amendment”), and as such agreement may be amended from time to time in the future (collectively, the “Loan Agreement”) with K2 HealthVentures LLC (“K2HV”) and any other lenders party thereto from time to time (collectively, the “Loan Parties”) with the obligations under the Loan Agreement secured on a senior basis by a lien on substantially all of our assets (including our subsidiaries).

On February 13, 2024, the Loan Parties entered into an amendment (the “Fourth Amendment”) to the Loan Agreement, effective upon entry into certain transactions with Brii Bio, pursuant to which the parties have agreed to, among other things, (i) remove a financial covenant requiring us to maintain minimum net revenue of 75% of projections, (ii) the forbearance by K2HV and the other lenders party thereto, prior to the earlier of (A) December 31, 2024, (B) the date the Side Letter ceases to be in full force and effect prior to the completion of the Essential Activities and (C) the date the Essential Activities are complete (the “Forbearance Expiration Date”) from exercising their remedies with respect to the occurrence of Events of Default (as defined in the Loan Agreement) subject to certain exceptions, and (iii) following the Forbearance Expiration Date, add a financial covenant requiring us to maintain a minimum cash amount equal to our obligations under the Loan Agreement at all times.

The effectiveness of the Fourth Amendment was conditioned upon entry into the Brii Purchase Agreement, the Rehovot Purchase Agreement, and the Side Letter, each of which were entered into by us and the respective parties thereto on February 13, 2024, as described above. See “Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments—Liquidity and Capital Resources—K2 HealthVentures LLC (“K2HV”) Long Term Debt”.

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. We have also developed a technology that leverages the strengths of both eVLP and mRNA technologies to create a proprietary mRNA-launched eVLP platform technology. This novel approach to particulate vaccines adds a genetic code for particle-forming structural protein – the same protein at the core of our eVLPs – to a mRNA vaccine, fundamentally changing the cellular interaction with the vaccine. The addition of this structural protein instructs cells to not only create target antigens but also to create eVLPs in vivo. These particles are released from the cells that generate them to circulate in the body, provoking the immune system to drive B-cell and T-cell responses.

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 candidates is preliminary and investigative. The investigational programs have not been approved by the United States Food and Drug Administration (“FDA”), European Medicines Agency, United Kingdom Medicines and Healthcare products Regulatory Agency, 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 United States (“U.S.”) alone. Worldwide, this number is estimated to be as high as 350 million, with approximately 800,000 deaths resulting from the consequences of HBV infection each year.

Despite the highly infectious nature of HBV, due to its often-asymptomatic nature, it is estimated that as many as 67% of chronically infected adults in the U.S. are unaware of their infection status. There is 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”). While the declaration of a public health emergency associated with COVID-19 expired in the U.S. in May 2023, new strains of the coronavirus continue to evolve and boosters for currently approved vaccines addressing new strains are expected in the foreseeable future.

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 15 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.

Pipeline Programs

The table below is an overview of our commercial vaccine and our investigational programs as of March 31, 2024:

Indication	Program	Technology	Current Status
Approved Vaccine			
● Hepatitis B	PreHevbrio ^{1,2,3} <i>Hepatitis B Vaccine (Recombinant)</i>	VLP	Registration/Commercial
Prophylactic Candidates			
● Coronaviruses (Multivalent)	VBI-2901	eVLP	Ongoing Phase I
● COVID-19 (Beta variant)	VBI-2905	eVLP	Phase Ib Completed
● COVID-19 (Ancestral)	VBI-2902	eVLP	Phase Ia Completed
● Cytomegalovirus	VBI-1501	eVLP	Phase I Completed
● Coronaviruses (Multivalent)	Undisclosed	eVLP	Pre-Clinical
● Undisclosed	Undisclosed	MLE	Pre-Clinical
Therapeutic Candidates			
● Glioblastoma	VBI-1901	eVLP	Ongoing Phase IIb
● Hepatitis B	VBI-2601 (BR11-179) ⁴	VLP	Ongoing Phase II
● Undisclosed	Undisclosed	MLE	Pre-clinical

¹Approved 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.

²Approved 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.

³Approved for use in Israel, under the brand name Sci-B-Vac, for active immunization against hepatitis B virus (HBV infection).

⁴On February 13, 2024, the Company and VBI Cda entered into the Brii Purchase Agreement (as defined herein) with Brii Bio, pursuant to which, upon achievement of certain activities, the Company and VBI Cda will sell, transfer, convey and assign to Brii Bio, substantially all of the intellectual property related to VBI-2601 owned by the Company and VBI Cda. See “Item 1–Business–Partnership with Brii Bio” below.

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. In June 2023, PreHevbrio was also awarded part of the CDC 2023 Adult Vaccine contract, for up to \$25,350. The CDC vaccine contracts are established for the purchase of vaccines by immunization programs that receive CDC immunization cooperative agreement funds (i.e., state health departments, certain large city immunization projects, and certain current and former U.S. territories).

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. On July 19, 2023, we announced that PreHevbri is now available in the Netherlands and Belgium for active immunization against infection caused by all known subtypes of HBV in adults. PreHevbri became available in Sweden at the end of 2023, and VBI expects that PreHevbri will be made available in certain additional European Union countries in 2024 through its partnership with Valneva.
- UK: On June 1, 2022, we announced that the UK Medicines and Healthcare Products Regulatory Agency 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. The UK is included in the Valneva marketing and distribution agreement for PreHevbri. On June 15, 2023, VBI announced the launch and availability of PreHevbri in the UK as part of the Valneva partnership.
- 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.
- Israel: Approved and commercially available under the brand name Sci-B-Vac[®] since 2000.
- APAC: On July 5, 2023, we announced a license and collaboration agreement with Bii Bio for the development and commercialization of PreHevbri in the Asia Pacific region ("APAC"), excluding Japan.

On February 13, 2024, we entered into a series of agreements with Bii Bio, including as related to PreHevbri. See "Item 1 – Business – Partnership with Bii Bio" below.

Prophylactic Investigational Candidates

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

In response to the SARS-CoV-2 (COVID-19) pandemic, VBI initiated development of a prophylactic coronavirus vaccine program in 2020. Coronaviruses are enveloped viruses by nature which make them a prime target for VBI's flexible eVLP platform technology. At that time, 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 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 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 was announced on September 27, 2023, demonstrating that VBI-2901 induced broad and durable protective titers against variants of concern. Notably:

- All participants saw boosting and/or high neutralizing responses against a panel of COVID-19 variants, including Wuhan, Delta, Beta, Omicron BA.5, as well as multiple animal coronaviruses including bat and pangolin variants
- Participants with low baseline neutralization titers (geometric mean titer (“GMT”): 148 IU50/mL), who are at the highest risk of infection, saw the greatest vaccine-induced boosting effects across all variants tested at Day 28, after one dose, with increases of: 8.5x against Wuhan, 9.1x against Delta, 14.2x against Beta, and 5.8x against Omicron BA.5
- All participants who received one dose had enhanced persistence of neutralizing responses, with only about 25% reduction in GMT against Wuhan after 5 months vs. peak responses
- Similar enhanced durability trends were observed against all tested variants
- By comparison, a published study [Gilboa et al., 2022] evaluating immune responses after a third dose of a licensed mRNA vaccine in nearly 4,000 healthcare workers in Israel demonstrated an approximate 77% decline in GMT against Wuhan after 5 months vs. peak responses
 - In the same study [Gilboa et al., 2022], durability trends against other variants, including Omicron, were seen to wane even more aggressively, with 4-fold to 10-fold lower neutralization titers within 4 months of the third dose

Durability and breadth of the antibody response to COVID-19 variants were maintained at month 12 after the first dose of VBI-2901 were administered in this Phase I study. Additional data are expected from the Phase I study in 2024.

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 \$33,018; a partnership with the Strategic Innovation Fund, established by the Government of Canada, with an award of up to CAD \$55,976; contribution of up to CAD \$1,000 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 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-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, was a two-arm study that enrolled 20 first-recurrent GBM patients who received 10 µg of VBI-1901 in combination with either GM-CSF or GSK proprietary adjuvant system, AS01, as immunomodulatory adjuvants. AS01 was 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; (4) 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 (5) 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.

On October 12, 2022, we announced a collaboration with Agenus Inc. to evaluate VBI-1901 in combination with anti-PD-1 balstilimab in a second Phase II study as part of the INSIGHT adaptive platform trial in patients with primary GBM.

On September 7, 2023, we announced that the dosing of the first patient in a Phase IIb study of VBI-1901 in recurrent GBM patients with first tumor recurrence. This study expands the existing study to include a Part C, which is a multi-center, randomized, controlled, open-label study. On April 3, 2024, we announced early tumor response data from the ongoing Phase IIb study during a presentation at World Vaccine Congress 2024. Early data from patients eligible for evaluation at week 12 show two observations of stable disease, indicating no tumor progression, in the VBI-1901 treatment arm (n=2/5, 40% disease control rate [DCR]). By comparison, no tumor responses have been observed in the control arm to-date (n=0/6, 0% DCR), with all patients seeing a 2-8x increase in tumor size by week 6. As of March 22, 2024, 17 patients have been randomized 1:1 to either the active, VBI-1901 treatment arm, or to the control, standard-of-care treatment arm (SoC). 14 leading neuro-oncology centers are actively recruiting patients across the US, with 2 new clinical sites activated in March 2024, and a third expected to be active in April 2024. Additional interim data analyses are expected mid-year 2024 and year-end 2024, subject to speed of enrollment.

On February 13, 2024, we entered into a series of agreements with Brii Bio. Upon completion of the Essential Activities pursuant to the Side Letter (each as defined below), VBI Cda and Brii Bio will enter into a license agreement (the “Brii VBI-1901 License Agreement”) pursuant to which Brii Bio shall issue a secured promissory note in the amount of \$5,000 as consideration for a perpetual, royalty-free, milestone-free, sublicensable, fully-paid, and exclusive license to VBI-1901 for development and commercialization in the APAC region (excluding Japan), which such note is then required to be assigned to K2HV pursuant to the terms of the Fourth Amendment See “Item 1–Business–Partnership with Brii Bio” below.

VBI-2601 is a 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 July 5, 2023, we announced the A&R Collaboration Agreement (as defined below) with Bii Bio, expanding Bii Bio's rights to the development and commercialization of VBI-2601 from Greater China rights to global rights.

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 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. Bii 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 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

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).

On September 6, 2023, we announced that Bii Bio announced topline interim cohort-level unblinded week 36 data from the Phase II add-on therapy study. Per the topline interim results announced by Bii Bio, the cohort level unblinded data from the study demonstrated that in the intent to treat analysis at week 24 (end of treatment or “EoT”), 26.3% (15 patients) treated with VBI-2601/PEG-IFNα achieved HBsAg loss compared to 19.3% (11 patients) with placebo/PEG-IFNα; at week 36 (12 weeks follow-up), 24.6% (14 patients) treated with VBI-2601/PEG-IFNα had HBsAg loss, compared with 14.0% (8 patients) with placebo/PEG-IFNα. In the per protocol analysis at week 24, 32.6% (15 patients) treated with VBI-2601/PEG-IFNα achieved HBsAg loss compared to 21.6% (11 patients) with placebo/PEG-IFNα; at week 36, 31.8% (14 patients) and 14.9% (7 patients) had HBsAg loss, respectively. In addition, 9 out of 15 patients in the cohort treated with VBI-2601/PEG-IFNα achieved HBsAg seroconversion at EoT (week 24), versus 1 out of 11 in the cohort treated with PEG-IFNα alone. The cohort level unblinded 24 weeks safety data showed VBI-2601/PEG-IFNα treatment was generally safe and tolerated, with adverse events similar to those associated with PEG-IFNα treatment or VBI-2601 as previously reported.

In November 2023, in two late-breaking poster presentations at AASLD The Liver Meeting® 2023, Bii Bio announced new data from the Phase II study of VBI-2601 (BR11-179) highlighting progress towards achieving HBV functional cure:

- Direct evidence that BR11-179 induced functional antibody responses can contribute to increased and sustained HBsAg loss rate
- New insight utilizing BR11-179 to enrich patients with intrinsic humoral immune responses for higher HBsAg loss or HBV functional cure rates.

On February 13, 2024, we entered into a series of agreements with Bii Bio, including as related to VBI-2601. See “Item 1–Business–Partnership with Bii Bio” below.

Corporate History

We were incorporated under the laws of British Columbia by Memorandum of Association on April 9, 1965 under the name “Alice Arm Molybdenum 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, 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 Senicav 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 PreHevbrio 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.

Partnership with Bii Bio

Amended and Restated Collaboration Agreement with Bii Bio

On December 4, 2018, we entered into a license and collaboration (the “Bii Collaboration and License Agreement”) with Bii Bio, as amended on April 8, 2021, pursuant to which:

- (i) we and Bii 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 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 Bii Bio (either being the “Licensed Product”);

- (ii) we granted Bii 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) Bii Bio granted us an exclusive royalty-free license under Bii Bio's technology and Bii 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 Bii Bio further amended the Bii Collaboration and License Agreement (the "Bii Second Amendment Collaboration and License Agreement") whereby:

- (i) we and Bii 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) Bii Bio granted us a non-exclusive royalty free license under the Bii 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 Bii Collaboration and License Agreement, as amended by the Bii Second Amendment Collaboration and License Agreement, the Company was responsible for the R&D Services and Bii Bio was responsible for costs relating to the clinical trials for the Licensed Territory.

The initial consideration of the Bii Collaboration and License Agreement consisted of an \$11,000 non-refundable upfront payment. As part of the Bii Collaboration and License Agreement, the Company and Bii Bio entered into a stock purchase agreement. Under the terms of the stock purchase agreement, the Company issued to Bii Bio 76,502 common shares valued at \$3,626 (based on the Company's common share price on December 4, 2018).

On July 5, 2023, the Company and Bii Bio entered into the Amended and Restated Collaboration and License Agreement (the "A&R Collaboration Agreement"), which amended and restated the Bii Collaboration and License Agreement to, among other things, and subject to the terms and conditions set forth in the A&R Collaboration Agreement, expand the Licensed Territory to the entire world (the "New Licensed Territory") for Bii Bio's exclusive rights and licenses to make, have made, use, sell, offer for sale, and import VBI-2601 ("VBI-2601 Licensed Product"). Pursuant to the A&R Collaboration Agreement, the Company granted Bii Bio an exclusive royalty-bearing license, with the right to grant sublicenses through multiple tiers, to (i) perform studies, regulatory and other activities, as may be required to obtain and maintain marketing approval of the VBI-2601 Licensed Products in the New Licensed Territory; and (ii) research, develop, make, have made, distribute, use, sell, offer for sale, have sold, import, export or otherwise commercialize the VBI-2601 Licensed Products for the field of the diagnosis and treatment of hepatitis B in the New Licensed Territory. Except for the rights and licenses expressly granted in the A&R Collaboration Agreement and prior to the Bii Purchase Agreement, the Company and Bii Bio retained all rights under their respective intellectual property. Prior to the February 2024 transactions with Bii Bio and the Bii Purchase Agreement, the A&R Collaboration Agreement constituted the entire agreement between the VBI and Bii Bio relating to VBI-2601 and superseded all previous agreements, including the Bii Collaboration and License Agreement and the Bii Second Amendment Collaboration and License Agreement.

The A&R Collaboration Agreement will be in effect on a region-by-region basis until the last-to-expire of the latest of the following terms in each region of the New Licensed Territory: (i) expiration, invalidation or lapse of the last Company patent claiming such VBI-2601 Licensed Product, (ii) 10 years from the date of first commercial sale of such VBI-2601 Licensed Product in the applicable region, or (iii) termination or expiration of the Company's obligation to pay third party royalties with respect to sales of such VBI-2601 Licensed Product in such region. Upon expiration (but not an earlier termination) of the A&R Collaboration Agreement in each region of the New Licensed Territory, the Company will grant Bii Bio a perpetual, non-exclusive, fully paid-up, royalty free license, which such licenses, pursuant to the Bii Purchase Agreement (as defined below), shall also be irrevocable under the Company's technology related to the VBI-2601 Licensed Products in such region to make and sell VBI-2601 Licensed Products for the field of the diagnosis and treatment of hepatitis B in such region.

Pursuant to the Brie Purchase Agreement, on February 13, 2024, we and Brie Bio agreed to amend the A&R Collaboration Agreement to, among other things, subject to achievement of certain activities and subject to the terms and conditions set forth in the A&R Collaboration Agreement, (i) amend the terms of the royalty bearing license granted by us to Brie Bio for research studies and development of VBI-2601 to be “perpetual and irrevocable”, (ii) omit the requirement for Brie Bio to obtain marketing approval and commercialize VBI-2601 in the U.S. and China, (iii) revise the indemnity requirements such that Brie Bio indemnifies us with respect to certain transferred intellectual property after the effective date of the Brie Purchase Agreement and we indemnify Brie Bio prior to such date, (iv) omit the requirement for Brie Bio to make royalty and milestone payments to us, and (v) omit certain of our rights to terminate the A&R Collaboration Agreement and certain other effects of termination of the A&R Collaboration Agreement.

Collaboration Agreement with Brie Bio (PreHevbri)

On July 5, 2023, the Company and Brie Bio also entered into a Collaboration and License Agreement (the “Collaboration Agreement” and together with the A&R Collaboration Agreement, the “Brie Collaboration Agreements”), to, among other things, and subject to the terms and conditions set forth in the Collaboration Agreement, acquired an exclusive license for PreHevbri in APAC, excluding Japan (“PreHevbri Licensed Territory”), for Brie Bio’s exclusive rights and licenses to make, have made, use, sell, offer for sale, and import PreHevbri (“PreHevbri Licensed Product”). Pursuant to the Collaboration Agreement, the Company granted Brie Bio an exclusive royalty-bearing license, with the right to grant sublicenses through multiple tiers, to (i) perform studies, regulatory and other activities, as may be required to obtain and maintain marketing approval of the PreHevbri Licensed Products in the PreHevbri Licensed Territory; and (ii) research, develop, make, have made, distribute, use, sell, offer for sale, have sold, import, export or otherwise commercialize the PreHevbri Licensed Products for the field of the diagnosis and treatment of hepatitis B in the PreHevbri Licensed Territory. Except for the rights and licenses expressly granted in the Collaboration Agreement and prior to the Brie Purchase Agreement, the Company and Brie Bio retained all rights under their respective intellectual property.

The Collaboration Agreement will be in effect on a region-by-region basis until the last-to-expire of the latest of the following terms in each region of the New Licensed Territory: (i) 10 years from the date of first commercial sale of such PreHevbri Licensed Product in the applicable region, or (ii) termination or expiration of the Company’s obligation to pay third party royalties with respect to sales of such PreHevbri Licensed Product in such region. Upon expiration (but not an earlier termination) of the Collaboration Agreement in each region of the PreHevbri Licensed Territory, the Company will grant Brie Bio a perpetual, non-exclusive, fully paid-up, royalty free license, which such license, pursuant to the Brie Purchase Agreement, shall also be irrevocable, under the Company’s technology related to the PreHevbri Licensed Products in such region to make and sell PreHevbri Licensed Products for the field of the diagnosis and treatment of hepatitis B in such region.

Pursuant to the Brie Purchase Agreement, on February 13, 2024, we and Brie Bio agreed to amend the Collaboration Agreement to, among other things, subject to achievement of certain activities and subject to the terms and conditions set forth in the Collaboration Agreement, (i) amend the terms of the royalty bearing license granted by us to Brie Bio for the global development activities of PreHevbri to be “perpetual and irrevocable”, (ii) omit the requirement for Brie Bio to obtain marketing approval for PreHevbri in certain territories and (iii) omit the requirement for Brie Bio to make royalty and milestone payments to us.

Brie Purchase Agreement

On February 13, 2024, we and VBI Cda entered into a Purchase Agreement with Brie Bio (the “Brie Purchase Agreement”), pursuant to which, subject to achievement of certain activities, we and VBI Cda will sell, transfer, convey and assign to Brie Bio, substantially all of the intellectual property related to VBI-2601 owned by us and VBI Cda, for a secured promissory note in the principal amount up to \$10,000 (the “Note”) to be issued by Brie Bio, which is then required to be assigned to K2HV pursuant to the terms of the Fourth Amendment (as defined herein), in exchange for a reduction in our obligations under the Loan Agreement equal to the initial principal amount of the Note. The Note was issued by Brie Bio on February 13, 2024. The initial principal amount of the Note is \$2,500, which shall be increased by an aggregate amount equal to \$7,500 upon our obtaining applicable consents under the Amended and Restated Ferring License Agreement (as defined herein). In the event of certain breaches by us of the Brie Purchase Agreement and any such breach is not cured with 30 days, the aggregate principal amount of the Note shall be reduced by an aggregate amount equal to \$2,500.

Rehovot Purchase Agreement

On February 13, 2024, the Company and SciVac entered into the Rehovot Purchase Agreement with Brie Israel and Brie Biosciences, Inc., a Delaware corporation, pursuant to which, upon closing of the transactions contemplated by the Rehovot Purchase Agreement, SciVac will sell to Brie Israel certain assets including SciVac and its affiliates’ interest and rights in and to certain assets and leases with respect to a vaccine manufacturing facility in Israel, for an aggregate purchase price of \$10,000, which is then required to be paid to K2HV pursuant to the terms of the Fourth Amendment.

The Rehovot Purchase Agreement contains representations and warranties of SciVac and Brie Israel that are typical for transactions of this type. The Rehovot Purchase Agreement also contains covenants on the part of the Company that are typical for transactions of this type.

The closing of the transactions pursuant to the Rehovot Purchase Agreement are subject to the terms and conditions therein, including closing conditions that are typical for transactions of this type and our completing the Essential Activities. Closing will not occur prior to June 30, 2024.

2023 Supply Agreement

On July 5, 2023, in connection with the Brie Collaboration Agreements, the Company and Brie Bio entered into a supply agreement (the “Supply Agreement”) related to the clinical and commercial manufacture and supply of VBI-2601 and PreHevbri and any related manufacturing expenditures, as negotiated. Pursuant to the Supply Agreement. The Company achieved a qualified underwritten public offering of \$5,000 of its common shares within 90 days of the effective date of the Supply Agreement, and as such, the Company received an advance payment of \$5,000 from Brie Bio.

2023 Letter Agreement

Pursuant to the letter agreement, dated July 5, 2023, by and among the Company, SciVac, and Brie Bio, the Company also granted to Brie Bio a security interest, subject to a Subordination Agreement between Brie Bio and K2HV, in all of its respective right, title, and interest in and to all intellectual property, know-how, and licenses to the extent related to PreHevbri and VBI-2601, and all proceeds of the foregoing, in order to secure performance of all of the Company’s obligations under the Brie Collaboration Agreements, the Supply Agreement, and the Loan Agreement.

Brie Purchase Agreement

On February 13, 2024, we and VBI Cda entered into a Purchase Agreement with Brie Bio (the “Brie Purchase Agreement”), pursuant to which, we and VBI Cda will sell, transfer, convey and assign to Brie Bio, substantially all of the intellectual property related to VBI-2601 owned by us and VBI Cda, for a secured promissory note in the principal amount up to \$10,000 (the “Note”) to be issued by Brie Bio, which is then required to be assigned to K2HV pursuant to the terms of

the Fourth Amendment (as defined herein), in exchange for a reduction in our obligations under the Loan Agreement equal to the initial principal amount of the Note. The Note was issued to Brii Bio on February 13, 2024. The initial principal amount of the Note is \$2,500, which shall be increased by an aggregate amount equal to \$7,500 upon our obtaining applicable consents under the Amended and Restated Ferring License Agreement (as defined herein). In the event of certain breaches by us of the Brii Purchase Agreement and any such breach is not cured with 30 days, the aggregate principal amount of the Note shall be reduced by an aggregate amount equal to \$2,500.

Brii Side Letter

On February 13, 2024, we and Brii Bio entered into a side letter (the “Side Letter”) setting forth certain essential and additional priority activities to transfer manufacturing responsibility for clinical supply and commercial supply of VBI-2601 and PreHevbri for the Brii Territories set forth in the Side Letter (the “Essential Activities”) we are required to complete as a condition to the entry into the License Agreement and consummation of the transactions pursuant to the Rehovot Purchase Agreement. The principal amount of the Note shall increase up to \$18,000 upon completion of the Essential Activities and our obligations under the Loan Agreement shall be reduced by a corresponding amount.

Brii License Agreement

On February 13, 2024, we entered into a series of agreements and amendments to existing agreements with Brii Bio. Upon completion of the Essential Activities pursuant to the Side Letter, VBI Cda and Brii Bio will enter into a license agreement (the “Brii License Agreement”) pursuant to which Brii Bio shall issue a secured promissory note in the amount of \$5,000 as consideration for a perpetual, royalty-free, milestone-free, sublicensable, fully-paid, and exclusive license to the GBM program (VBI-1901) for development and commercialization in the APAC region (excluding Japan), which such note is then required to be assigned to K2HV pursuant to the terms of the Fourth Amendment. The entry by VBI Cda and Brii Bio into the Brii License Agreement is subject to our completing the Essential Activities.

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.

On April 17, 2023, the Company signed an eighth amendment to the collaboration agreement with the NRC to further broaden the scope to include the development of stable cell lines for our multivalent vaccine candidate against coronaviruses.

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.

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 \$1,000 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 \$55,976 from the Strategic Innovation Fund (“SIF”) to support the development of our coronavirus vaccine program, VBI-2900, through 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, 2024, 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 December 31, 2023 to March 31, 2027. 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 Minister, 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 K2HV pursuant to the Loan Agreement as amended by the First Amendment, the Second Amendment, the Third Amendment and the Fourth 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 and VBI-2601, 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.

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).

Royalty payments under the Amended and Restated Ferring License Agreement or the original Ferring License Agreement of \$250 and \$33 were recorded in cost of revenues for the years ended December 31, 2023 and 2022, respectively.

Royalty payments under the SciGen Assignment Agreement of \$155 and \$47 were recorded in cost of revenues for the years ended December 31, 2023 and 2022, respectively.

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. Given the Acquired Patents have expired, VBI Cda is not required to make any future contingent payments to the Sellers.

Included in the eVLP Acquired Patents were patents (the “UPMC Patents”) co-owned by L’Université 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, which expired in 2023, including any supplementary protection certificates. UPMC is also a co-owner of the patent family covering our VBI-1501 CMV vaccine and we are negotiating extension of the existing license to cover this patent family. During the years ended December 31, 2023 and 2022, we did not make any milestone payments.

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.

Under the ePixis License Agreement and the ePixis Amendment, no payments were made during the years ended December 31, 2023 and 2022. The patents expired in 2023 in the U.S. and in other countries in 2021, and we are accordingly no longer obligated to compensate UPMC for development of vaccines based on the eVLP vaccine platform intellectual property.

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 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. In 2023, our facility passed a subsequent surveillance inspection by the FDA. On March 21, 2024, our facility passed a routine regulatory inspection by the IMoH. On February 13, 2024, we entered into the Rehovot Purchase Agreement to sell our manufacturing capabilities and certain assets, including our and our affiliates’ interest and rights in and to certain assets and leases with respect to the Rehovot facility to Bria Bio, subject to customary closing conditions typical for such transactions, including our completion of the Essential Activities pursuant to the Side Letter, and which such closing will not occur prior to June 30, 2024. See “Item I–Business–Recent Developments–February 2024 Transactions with Bria Bio” for more information. Following the completion of the sale of the Rehovot facility, if the sale is completed subject to the terms and conditions in the Rehovot Purchase Agreement, we will also be dependent on Bria Israel to manufacture our supply of our 3-antigen HBV vaccine.

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, Pfizer, Inc. (“Pfizer”) and Moderna, Inc (“Moderna”); and mid-size pharmaceutical companies and emerging biotechnology companies including Dynavax, Novavax Inc., BioNTech SE, among others; 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.

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”), Immatix 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 immunotherapeutics are in development by Vigeo Therapeutics Inc, Medicenna Inc and Polaris Pharmaceuticals Inc.

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) Novavax and J&J Janssen (which on May 22, 2023, requested the voluntary withdrawal of the emergency use authorization due to lack of demand and which was revoked by the FDA on June 1, 2023). 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 GSK’s 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. Following the completion of the sale of the Rehovot facility, if the sale is completed subject to the terms and conditions in the Rehovot Purchase Agreement, we will also be dependent on Bria Israel to manufacture our supply of our 3-antigen HBV vaccine.

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 CROs to conduct our clinical programs including the GBM clinical program and our prophylactic coronavirus vaccine program. Our reliance on these CROs 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. Following the completion of the sale of the Rehovot facility, if the sale is completed subject to the terms and conditions in the Rehovot Purchase Agreement, we will be dependent on Bii Israel to manufacture our 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 were 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 expired in 2023 and we are accordingly no longer obligated to compensate UPMC for development of vaccines based on the eVLP vaccine platform intellectual property. 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. During the years ended December 31, 2023 and 2022, we did not make any milestone payments.
- 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, 2023, we had a total of 131 full-time and 7 part-time employees. The manufacturing site in Israel had 88 full-time employees and 5 part-time employees and the Ottawa research site employed 31 full-time and 2 part-time employees, as of December 31, 2023. Our headquarters in Cambridge, MA employed 12 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 \$1,866 during the fiscal year ended December 31, 2023.

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.

Upon closing of the transactions contemplated by the Rehovot Purchase Agreement, SciVac will sell to Brii Israel, certain assets, interest and rights in certain assets and leases, which will not occur prior to June 30, 2024. See "Item I–Business–Recent Developments" for more information.

Research and Development

We invest heavily in R&D. R&D expenses were \$9,343 and \$15,506 for the years ended December 31, 2023 and 2022, 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 9 active patent families consisting of 114 fully owned or co-owned or exclusively licensed patents and patent applications. The highlights of our patent portfolio include:

- GBM vaccine immunotherapeutic candidate related intellectual property: we own or co-own two 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.

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 has now expired. Our most recently filed patent family will have a patent term that extends to 2041. See “Item 1–Business–Partnership with Brii Bio”.

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 15 countries. There is one pending mark in Canada. 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 Lipid Particle Vaccine (“LPV”) mark in Canada in connection with our LPV technology platform.

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, the EMA, the 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 with requirements that became effective 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 Exchange Act, 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 Exchange Act, 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;
- We may not be able to adhere to our credit facility which includes customary and financial covenants;
- 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;
- Our ability to regain and maintain compliance with Nasdaq listing standards.

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

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 continue to 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 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, 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 Brio Bio for development of a HBV recombinant protein-based immunotherapeutic globally, 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, however, 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, Moderna, Pfizer, and Novavax, 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. in May 2023 (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 \$55,976 from the SIF to support the development of our coronavirus vaccine program, VBI-2900, through the Project. In an amendment to the Contribution Agreement signed on March 28, 2024, we agreed to complete the Project, to be conducted exclusively in Canada except as permitted otherwise under certain circumstances, in or before March 31, 2027. 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 Minister, 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 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 CEPI whereby CEPI agreed to contribute up to \$33,018 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.

COVID-19 has been classified as an endemic 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 Minister 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 Bii Bio may be unable to successfully carry out the development and commercialization plans under the Bii Collaboration Agreements, 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 1,879,500 (\$518,197). 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, January 12, 2023 and July 13, 2023. The next preliminary hearing is scheduled to be held on June 20, 2024.

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. Arie Razi, requesting compensation due to bodily injury of the minor, who was diagnosed as suffering from an Autism Spectrum Disorder. 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 have not yet been scheduled.

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 (BRIL-179), which are currently manufactured by us at our manufacturing site in Rehovot, Israel, and which such facility and certain related assets are being sold to Bii Israel, subject to satisfaction of customary closing conditions and certain other conditions, 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. Furthermore, following the completion of the sale of the Rehovot facility, if the sale is completed subject to the terms and conditions in the Rehovot Purchase Agreement, we will also be dependent on Bii Israel to manufacture our supply of our 3-antigen HBV vaccine.

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 of our 3-antigen HBV vaccine and VBI-2601. Our current manufacturing facility in Rehovot, Israel, which pursuant to the Rehovot Purchase Agreement will be sold by SciVac to Bii Israel, subject to the completion of certain activities and to the terms and conditions therein, 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. Furthermore, following the completion of the sale of the Rehovot facility, subject to the terms and conditions in the Rehovot Purchase Agreement, we will be dependent on Bii Israel to manufacture our supply of our 3-antigen HBV vaccine. If the 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 the 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 the 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 of 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. Following the completion of the sale of the Rehovot facility, if the sale is completed subject to the terms and conditions in the Rehovot Purchase Agreement, we will be dependent on Bii Israel to manufacture our supply of our 3-antigen HBV vaccine.

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 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. Following the completion of the sale of the Rehovot facility, if the sale is completed subject to the terms and conditions in the Rehovot Purchase Agreement, we will be dependent on Bii Israel to manufacture our supply of our 3-antigen HBV vaccine.

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 in the past due to the COVID-19 pandemic, and may experience in the future due to a resurgence of coronavirus, armed conflict, including in the Middle East and its impact on the Red Sea shipping routes, and other global events, 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, 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. Additionally, following the completion of the sale of the Rehovot facility, if the sale is completed subject to the terms and conditions in the Rehovot Purchase Agreement, we will be dependent on Bii Israel to manufacture our supply of our 3-antigen HBV vaccine, which such production and manufacture may be impacted by the ongoing conflict in the Middle East and the Red Sea shipping disruptions and could impact 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 or purchase 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 or purchase 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. Following the completion of the sale of the Rehovot facility, if the sale is completed subject to the terms and conditions in the Rehovot Purchase Agreement, we will be dependent on Bria Israel to manufacture our supply of our 3-antigen HBV vaccine.

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 Bria 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 an ongoing Phase IIb 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. Moreover, the purchase agreement for the April 2024 Offering prohibits us from issuing common shares or common share equivalents for 30 days, subject to certain exceptions. 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 \$92,836 and \$113,303 for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of \$582,445 and cash of \$23,685. Cash outflows from operating activities were \$60,883 for the year ended December 31, 2023. Our income generating activities have been from sales of PreHevbrio in the U.S., PreHevbri in Europe, and Sci-B-Vac in Israel, which 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 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 Bria Collaboration Agreements, 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 April 16, 2024, 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, 2023, we had \$23,685 of cash. Based on our available cash at December 31, 2023, together with the net proceeds from the April 2024 Offering, in order to continue to fund our operations, we must raise additional equity or debt capital in the near term and cannot provide any assurance that we will be successful in doing so. If we are unable to obtain additional financing in the near future, we may be required to pursue a reorganization proceeding, including under applicable bankruptcy or insolvency laws. Holders of our common shares will likely not receive any value or payments in a restructuring or similar scenario. In the event we pursue bankruptcy protection, we will be subject to the risks and uncertainties associated with such proceedings. There can be no guarantees that if we seek bankruptcy protection, we will emerge from bankruptcy protection as a going concern or that holders of our common shares will receive any recovery from any bankruptcy proceedings.

Risks Related to Our Business

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. Pursuant to the Rehovot Purchase Agreement, subject to achievement of certain activities, SciVac will sell to Bria Israel certain assets including SciVac and its affiliates' interest and rights in and to certain assets and leases with respect to a vaccine manufacturing facility in Israel, for an aggregate purchase price of \$10,000, which is then required to be paid to K2HV pursuant to the terms of the Fourth Amendment. The closing of the transactions pursuant to the Rehovot Purchase Agreement, subject to the terms and conditions therein, may affect, delay or hinder completion of the Essential Activities, a condition to closing, and affect the closing of the transaction which will not occur prior to June 30, 2024.

Any armed conflicts, war, terrorist activities, or political instability in the region and the consequences thereof, such as shipping disruptions in the Red Sea, which have caused shipping delays and other supply chain issues, and additional added costs for imported goods, 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.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organization commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts, war, 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.

It is currently not possible to predict the duration or severity of the ongoing war or its effects on our business, operations, and financial conditions. The ongoing war is rapidly evolving and developing, and could disrupt our business and operations, interrupt our sources and availability of supply and hamper our ability to raise additional funds or sell our securities, among others. As a result of reduced transport in and out of Israel due to the ongoing war, we have experienced delays in shipping supplies and materials in and out of Israel, and while there have been temporary delays to date, there may be additional disruption in transport in the future. We currently do not have any active study sites in Israel. The ongoing war has not, however, materially affected our customers, manufacturing, research and development, supply chain, and manufacturing commercialization activities. However, there can be no assurances that further unforeseen events will not have a material adverse effect on us or our operations in the future.

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. As of the date of this Form 10-K, we currently have about 93 employees who are located in and/or reside in Israel, including one member of our senior management. Shelter-in-place and work-from-home measures, government-imposed restrictions on movement and travel and other precautions taken to address the ongoing war have and may again temporarily disrupt our management and employees' ability to effectively perform their daily tasks. Additionally, three employees located in Israel are responsible for global operations, including manufacturing, regulatory, and quality control. 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. As many Israeli citizens are subject to military service should the Israel Defense Force deem it necessary, it is possible there will be further military reserve duty call-ups in the future, which may cause disruptions and delays in our operations.

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.

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.

The reduction in our internal workforce, our intention to sell the manufacturing facility in Rehovot, Israel, and other cost reductions we are undertaking to reduce our operating expenses could disrupt our business.

On April 4, 2023, we announced organizational changes including our plan to reduce our internal workforce and other expenses by 30-35%, activity which began in April 2023 and was completed by the end of September 2023. The headcount reduction and other actions to reduce our operating costs may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees seeking alternative employment, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. Our workforce reductions could also harm our ability to attract and retain qualified management and personnel who are critical to our business. In addition, our former employees may initiate lawsuits related to their termination. The reduction in internal workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives.

Any of the foregoing may be disruptive to our operations. If we are unable to realize the anticipated benefits from the reduction in internal workforce, or if we experience significant unintended adverse consequences from the reduction in internal workforce, our business, financial condition, and results of operations may be materially adversely affected.

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 endemic 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 endemics 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. As a result of the ongoing war between Russia and Ukraine and between Israel and Hamas, related sanctions could be announced by the U.S. and other countries, and may 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. The U.S. and other countries could impose wider sanctions and take other actions should conflict further escalate. It is not possible to predict the broader consequences of 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.

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.

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, 2023, was US\$1.00 = NIS 3.6893, US\$1.00 = CAD \$1.3496 and US\$ 1.00 = €0.9241. 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 114 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., Europe, and Israel. 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 UPMC. 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 expired 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 extension of our existing license to cover this patent family. During the years ended December 31, 2023 and 2022, we did not make any milestone payments.

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 Bii 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 \$36,499 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. 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.

For the year ended December 31, 2023, we recognized a non-cash, pre-tax IPR&D impairment charge of \$22,600, specifically attributable to the congenital CMV asset. 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 our IPR&D assets, this may give rise to additional triggering events that may require the Company to record further impairment charges on our IPR&D assets and/or goodwill in the future.

Impairment in the value of IPR&D has, and any impairment of goodwill, other intangible assets, and long-lived assets in the future could, negatively impact our results of operations.

Under generally accepted accounting principles, we review our intangible assets and long-lived assets for impairment when events or changes in circumstances indicate the carrying value may not be recoverable. Goodwill is required to be tested for impairment at least annually. Factors that may be considered when determining if the carrying value of our goodwill, other intangible assets and long-lived assets may not be recoverable include a sustained, significant decline in our stock price and market capitalization or a significant decline in our expected future cash flows. If our stock price decreases to the point where the fair value of our assets (as partially indicated by our market capitalization) is less than our book value, this could indicate a potential impairment and we may be required to record an impairment charge. Our valuation methodology for assessing impairment requires management to make judgments and assumptions based on projections of future operating performance. We operate in highly competitive environments and projections of future operating results and cash flows may vary significantly from actual results. As a result, we may incur substantial impairment charges to earnings in our financial statements should an impairment of our goodwill, other intangible assets and long-lived assets be determined resulting in an adverse impact on our results of operations.

The drop in market conditions experienced in April 2023 was considered a triggering event for an interim impairment test for property and equipment, IPR&D, and goodwill. As a result of our evaluation, we recognized a non-cash, pre-tax impairment charge of \$24,600 during the year ended December 31, 2023, which consists of non-cash impairment charge of \$22,600 related to the IPR&D intangible asset, specifically attributable to the congenital CMV asset, \$1,000 related to the property and equipment assets and \$1,000 related to goodwill. These charges in the year ended December 31, 2023, and any future charges related to intangible assets have, and may in the future have, a material adverse effect on our results of operations or financial condition. A significant impairment charge could have a material negative impact on our financial condition and results of operations. We will continue to evaluate our intangible assets for potential impairment in accordance with our accounting policies.

Events giving rise to impairment are difficult to predict and are an inherent risk in the pharmaceutical industry. Some of the potential risks that could result in impairment of our IPR&D include negative clinical trial results, adverse regulatory developments, delay or failure to obtain regulatory approval, additional development costs, changes in the manner of our use or development of our product candidate, competition, earlier than expected loss of exclusivity, pricing pressures, higher operating costs, changes in tax laws, prices that third parties are willing to pay for our IPR&D or similar assets in an arm's-length transaction being less than the carrying value of our IPR&D, and other market and economic environment changes or trends, such as the continuing impacts of the COVID-19 endemic. We operate in highly competitive environments and projections of future operating results and cash flows may vary significantly from actual results. Events or changes in circumstances may lead to significant impairment charges on our IPR&D in the future. As a result, we may incur substantial impairment charges to earnings in our financial statements should an impairment of our goodwill, other intangible assets and long-lived assets be determined resulting in an adverse impact on our results of operations.

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 credit facility contains certain customary covenants as well as financial and non-financial covenants, and instances of non-compliance may lead to the declaration of an event of default, which could accelerate our repayment obligations, increase the interest rate under the credit facility, and lead to the foreclosure on substantially all of our assets, among others.

The Loan Agreement, as amended by the First Amendment, the Second Amendment, the Third Amendment, and the Fourth Amendment, contains customary covenants as well as financial and non-financial covenants.

Pursuant to the Fourth Amendment, K2HV has agreed to the forbearance of the Loan Agreement to the earlier of (i) December 31, 2024, (ii) the date the Side Letter ceases to be in full force and effect prior to the completion of the Essential Activities, and (iii) the Forbearance Expiration Date from exercising their remedies with respect to the occurrence of Events of Default subject to certain exceptions. We have also agreed, to remove the minimum net revenue covenant and, following the Forbearance Expiration Date, to add to a financial covenant requiring us to maintain a minimum cash amount equal to our obligations under the Loan Agreement at all times.

We have in the past not been in compliance with certain covenants in the Loan Agreement and had sought forbearance, and there is no assurance that we will be able to comply with covenants in the Loan Agreement in the future, or obtain from K2HV any extensions or waivers of instances of non-compliance or forbearance on our repayment obligations. Failure to comply with such covenants, or to obtain extensions, waivers, or forbearance for any instances of non-compliance or ability to make repayments, may constitute event of defaults under the Loan Agreement. Upon the occurrence and during the continuance of an event of default, subject to certain exceptions, K2HV is entitled to declare all obligations under the Loan Agreement immediately due and payable and to stop advancing money or extending credit to us under the Loan Agreement. Additionally, upon the occurrence and during the continuance of an event of default, the applicable interest rate under the Loan Agreement will be increased by 5.00% per annum. The principal amount of the term loan as of December 31, 2023, was \$50,000 (\$55,699 including the exit fees). As of December 31, 2023, we were required under applicable accounting rules to reclassify the outstanding principal amount of the Loan Agreement, as amended, as a current liability rather than a long-term liability due to the failure to meet the minimum Net Revenue covenant for the measurement periods ended September 30, 2023, and December 31, 2023. The reclassification of the indebtedness as a current liability has resulted in negative net working capital as of December 31, 2023. 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 may result in K2HV foreclosing on all or a portion of our assets and force us to curtail or cease our operations.

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 such 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, the Second Amendment, the Third Amendment, and the Fourth Amendment, or any of the other loan documents, a breach of certain covenants under the Loan Agreement, our insolvency, a material adverse effect occurring, subject to certain exceptions.

Additionally, 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. Pursuant to the Third Amendment, K2HV also has a security interest in all of our respective right, title and interest in substantially all of our intellectual property. Pursuant to the Fourth Amendment, effective at all times after the Forbearance Expiration Date, we have agreed to maintain at all times unrestricted cash and cash equivalents in collateral accounts subject to a perfected security interest in favor of the applicable Secured Party (as defined in the Loan Agreement), in an amount not less than the aggregate amount of outstanding obligations. As a result, if we default under our obligations or do not have adequate unrestricted cash and cash equivalents after the Forbearance Expiration Date to hold in such collateral accounts, K2HV 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 pledge of these assets and intellectual property and other restrictions may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged under the credit facility, 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 close the transactions contemplated by various agreements entered into with Brii Bio in February 2024, our obligations due under the Loan Agreement may not be reduced, which will adversely affect our liquidity position, financial condition and business operations.

Pursuant to the Brii Purchase Agreement, subject to achievement of certain activities, in consideration for the sale, transfer, conveyance and assignment to Brii Bio of substantially all of the intellectual property related to VBI-2601 owned by us and VBI Cda, we received the Note with an initial principal amount of \$2,500, which shall be increased by \$7,500, up to total principal amount of \$10,000, upon our obtaining the applicable consents under the Amended and Restated Ferring License Agreement. Additionally, pursuant to the Side Letter, upon completion of the Essential Activities, the principal amount of the Note may be further increased to up to \$18,000 in principal amount. The entry by VBI Cda and Brii Bio into the Brii License Agreement, pursuant to which VBI Cda will grant Brii Bio an exclusive license to the GBM program (VBI-1901) for development and commercialization in the APAC region (excluding Japan), for a secured promissory note in the principal amount of \$5,000, and the closing of the transactions pursuant to the Rehovot Purchase Agreement, for consideration of \$10,000, are subject to the terms and conditions therein and our completion of the Essential Activities. There can be no assurances that we will be able to obtain the applicable consents under the Brii License Agreement or that we complete any or all of the Essential Activities pursuant to the Side Letter. If we are unable to obtain the applicable consents under the Brii License Agreement or complete the Essential Activities, the amount of consideration we may receive from the completion of the transactions contemplated by various agreements with Brii Biosciences may be reduced, and as such our obligations due under the Loan Agreement would only be reduced by the corresponding amount, which in turn will affect our liquidity position, financial condition, business and results of operation

After the Forbearance Expiration Date, we will additionally be obligated to maintain a minimum cash amount in collateral accounts for the benefit of the Secured Parties equal to our obligations due under the Loan Amendment at all times. If the Loan Agreement is not reduced by the full potential aggregate consideration we may receive from completion of the transactions contemplated by various agreements entered into with Brii Bio in February 2024, we will be required to maintain a greater amount of cash in such collateral accounts, which may in turn reduce our capital available to fund our business, operations, and research and development of our products, among others, and have an adverse effect on our liquidity position. There can be no assurance that additional financing we will need to maintain the minimum cash amount will be available to us in the future, or if it is, that it will be available at terms acceptable to us, or that the issuance of any equity securities or securities convertible into equity securities in such financing would not cause the percentage ownership of our shareholders to be diluted, among others.

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, the Second Amendment, and the Third Amendment, K2HV made a term loan to us in aggregate amount of \$50,000. During the year ended December 31, 2023, we made average monthly payments of interest in the amount of approximately \$515. 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 April 12, 2024, our common shares traded as high as \$4.45 per share and as low as \$0.45 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. 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 November 1, 2023, we received a letter from the Listing Qualifications Department of Nasdaq indicating that, based upon the closing bid price of our common shares for the 30 consecutive business day period between September 19, 2023 through October 31, 2023, 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 letter also indicated that we will be provided with the Compliance Period, in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

In order to regain compliance with Nasdaq's minimum bid price requirement, our common shares must maintain a minimum closing bid price of \$1.00 for a minimum of ten consecutive business days during the Compliance Period. In the event that we do not regain compliance by the end of the Compliance Period, we may be eligible for additional time to regain compliance. To qualify, we will be required to meet the continued listing requirement for the market value of our publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split if necessary. If we meet these requirements, we may be granted an additional 180 calendar days to regain compliance. However, if it appears to Nasdaq that we will be unable to cure the deficiency, or if we are not otherwise eligible for the additional cure period, Nasdaq will provide notice that our common shares will be subject to delisting. We have not regained compliance as of the date of this Form 10-K.

If we fail to regain compliance during the Compliance Period or any subsequent grace period granted by Nasdaq, our common shares will be subject to delisting by Nasdaq. 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 delisting could seriously decrease or eliminate the value of an investment in our common shares and result in significantly increased uncertainty as to the Company's ability to raise additional capital.

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. For example, we did not meet the minimum bid price for the period between May 18, 2022 to June 30, 2022, and we effected the Reverse Stock Split in April 2023 with the primary intent of increasing the price of our common shares immediately following the Reverse Stock Split to regain compliance with the minimum bid price requirement, and regained compliance in April 2023. It cannot be assured that any future reverse stock split will result in any sustained proportionate increase in the market price of our common shares, which is dependent upon many factors, including the business and financial performance of the company, general market conditions, and prospects for future success, which are unrelated to the number of shares of our common shares outstanding. It is not uncommon for the market price of a company's common shares to decline in the period following a reverse stock 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, that we would successfully maintain compliance with the minimum bid price requirement or any of Nasdaq's other listing requirements 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.

Certain of our warrants contain reset provisions, which may dilute the interests of our shareholders, depress the price of our common shares, and make it difficult for us to raise additional capital.

Certain of our warrants (the “July 2023 warrants”) issued in the underwritten public offering and concurrent registered direct offering consummated in July 2023 contain reset provisions applicable to the exercise price. Pursuant to such reset provisions of the July 2023 warrants, as the consideration paid per common share under the ATM Program (as defined below) was less than the exercise price of the July 2023 warrants in effect immediately prior to such issuance, the exercise price of the July 2023 warrants was reduced, and the exercise price in effect as of the filing date of this Form 10-K is \$0.6057 per share. If in the future, while any of the July 2023 warrants are outstanding, we issue securities at an effective purchase price per common share that is less than the applicable exercise price of the July 2023 warrants as then in effect, we will be required, subject to certain limitations and adjustments as provided in the July 2023 warrants, to further reduce the relevant exercise price of the July 2023 warrants. Such adjustments can dilute the book value per common share and reduce any proceeds we may receive from the exercise of the July 2023 warrants. In addition, the perceived risk of dilution may cause our shareholders to be more inclined to sell their common shares, which may in turn depress the price of common shares regardless of our business performance. We may also find it more difficult to raise additional equity capital while any of the July 2023 warrants are outstanding.

If we sell additional equity or debt securities to fund our operations, it may impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, which may impose restrictive covenants that adversely impact our business. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to expand our operations or otherwise capitalize on our business opportunities due to such restrictions, our business, financial condition and results of operations could be materially adversely affected.

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, the Second Amendment, and the Third 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 23,918,983 common shares outstanding as of December 31, 2023, approximately 95.41% 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, 2023, we had outstanding options, awards, convertible debt, and warrants for the purchase of 16,323,250 common shares. Of this amount, options, awards, convertible debt, and warrants for the purchase of 14,642,758 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 2024, there can be no assurance that we will not be classified as a PFIC in 2024 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 2024 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 2024 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 \$250,000 as measured on the last business day of our second fiscal quarter, or (2) our annual revenues are less than \$100,000 during the most recently completed fiscal year and the value of our common shares held by non-affiliates is less than \$700,000 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.

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 endemics and epidemics, and similar events. A resurgence in COVID-19 cases, reinstatement of efforts to mitigate the coronavirus, such as shelter-in-place and social distancing measures, and the effects of COVID-19, such as adverse effects on the global economy, supply chain issues, global shortages of supplies, material and products, volatile market conditions and rising global inflation, for example, may lead to disruptions and interruptions in our business and clinical trials. 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.

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 1C: CYBERSECURITY

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations. These risks include intellectual property theft, fraud, extortion, harm to employees or customers, violation of privacy laws, litigation and legal risk, and reputational risk. Recognizing the critical importance of cybersecurity, we have implemented robust measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data.

Our cybersecurity management program includes governance, policies, procedures, and technology to identify and mitigate risks from cybersecurity threats. Both management and the Board of Directors are actively involved in assessing cybersecurity threats and implementing preventive measures.

Day-to-day assessment and management of cybersecurity risks are overseen by the Head of IT and Information Security Expert. These individuals possess relevant expertise and backgrounds in cybersecurity work, and are responsible for prevention, mitigation, detection, and remediation of cybersecurity incidents. Reports and updates are provided to the management and Board of Directors to ensure effective oversight. The Board of Directors receives an annual report from the Head of IT with respect to management of risks from cybersecurity threats. Such report covers the Company's information technology security program, including its current status, capabilities and plans.

We undertake activities to prevent, detect, and minimize the effects of cybersecurity incidents, including annual risk reviews, policy reviews, and penetration tests. Business continuity, incident response, and recovery plans are in place to respond to and remedy any cybersecurity incidents.

Third-party assessors, consultants, and auditors assist us in assessing and managing cybersecurity risks by providing expert advice on cybersecurity strategy, technologies, testing, and cybersecurity event monitoring.

Policies and procedures are established to oversee risks associated with third-party service providers, and contractual mechanisms are in place to mitigate these risks. Third-party provider contracts are negotiated to ensure the vendor warrants maintaining industry best practices in IT security, including disaster recovery, peripheral IT security, access control, among others.

To date, no cybersecurity incident has materially affected our results of operations or financial condition. However, we acknowledge that an actual or perceived breach of our security could damage our reputation, cause our existing customers to suspend or terminate our relationships, interfere with our ability to acquire new customers, interfere with progress of our clinical trials, jeopardize existing regulatory approvals or interfere with our ability to pursue regulatory approvals for our product candidates, and impact our ability to execute on our overall business strategy. We maintain a cyber liability insurance policy to pre-emptively mitigate financial risks associated with cybersecurity incidents. However, our cyber liability insurance may be inadequate or may not be available in the future on acceptable terms, or at all. In addition, our cyber liability insurance policy may not cover all claims made against us, and defending a suit, regardless of its merit, could be costly and divert management's attention from our business and operations.

For further information on specific cybersecurity risk factors, please refer to "Item 1A – Risk Factors – *'Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security'*".

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, located in Rehovot, Israel, is currently comprised of approximately 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.

Upon closing of the transactions contemplated by the Rehovot Purchase Agreement, subject to the terms and conditions therein, SciVac will sell to Brii Israel certain assets, including SciVac and its affiliates' interest and rights in certain assets and leases with respect to the Rehovot facility, which such closing will not occur prior to June 30, 2024. See "Item I-Business-Recent Developments-February 2024 Transactions with Brii Bio" for more information.

- 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 originally ending on December 31, 2023. On September 5, 2019, the sub-sublease was assigned by Iogen Corporation to 310 Hunt Club GP Inc. ("the Assignee"). In 2023, 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 \$25 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 required 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 \$1,866 in 2023.

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 1,879,500 (\$518,197). 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, January 12, 2023, and July 13, 2023. The next preliminary hearing is scheduled to be held on June 20, 2024.

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. Arie Razi, requesting compensation due to bodily injury of the minor, who was diagnosed as suffering from an Autism Spectrum Disorder. 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 have not yet been scheduled.

SciVac 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 April 12, 2024, we had approximately 247 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, 2023, 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 Annual Report on Form 10-K (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 its innovative approach to virus-like particles ("VLPs"), including a proprietary enveloped VLP ("eVLP") platform technology and a proprietary mRNA-launched eVLP ("MLE") platform technology, VBI develops vaccine candidates that mimic the natural presentation of viruses, designed to elicit the innate power of the human immune system. VBI is committed to targeting and overcoming significant infectious diseases, including hepatitis B ("HBV"), COVID-19 and coronaviruses, and cytomegalovirus ("CMV"), as well as aggressive cancers including glioblastoma ("GBM"). VBI is headquartered in Cambridge, Massachusetts, with research operations in Ottawa, Canada, and a research and manufacturing site in Rehovot, Israel.

Product Pipeline

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. We have also developed a technology that leverages the strengths of both eVLP and mRNA technologies to create a proprietary mRNA-launched eVLP platform technology. This novel approach to particulate vaccines adds a genetic code for particle-forming structural protein – the same protein at the core of our eVLPs – to a mRNA vaccine, fundamentally changing the cellular interaction with the vaccine. The addition of this structural protein instructs cells to not only create target antigens but also to create eVLPs in vivo. These particles are released from the cells that generate them to circulate in the body, provoking the immune system to drive B-cell and T-cell responses.

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 candidates 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 United States (“U.S.”) alone. Worldwide, this number is estimated to be as high as 350 million, with approximately 800,000 deaths resulting from the consequences of HBV infection each year.

Despite the highly infectious nature of HBV, due to its often-asymptomatic nature, it is estimated that as many as 67% of chronically infected adults in the U.S. are unaware of their infection status. There is 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., and Heplisav-B®, manufactured by Dynavax Technologies Corporation.

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”). While the declaration of a public health emergency associated with COVID-19 expired in the U.S. in May 2023, new strains of the coronavirus continue to evolve and boosters for currently approved vaccines addressing new strains are expected in the foreseeable future.

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 15 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.

Pipeline Programs

The table below is an overview of our commercial vaccine and our investigational programs as of March 31, 2024:

Indication	Program	Technology	Current Status
Approved Vaccine	PreHevbrio ^{1,2,3} <i>Hepatitis B Vaccine (Recombinant)</i>	VLP	Registration/Commercial
• Hepatitis B			
Prophylactic Candidates			
• Coronaviruses (Multivalent)	VBI-2901	eVLP	Ongoing Phase I
• COVID-19 (Beta variant)	VBI-2905	eVLP	Phase Ib Completed
• COVID-19 (Ancestral)	VBI-2902	eVLP	Phase Ia Completed
• Cytomegalovirus	VBI-1501	eVLP	Phase I Completed
• Coronaviruses (Multivalent)	Undisclosed	eVLP	Pre-Clinical
• Undisclosed	Undisclosed	MLE	Pre-Clinical
Therapeutic Candidates			
• Glioblastoma	VBI-1901	eVLP	Ongoing Phase IIb
• Hepatitis B	VBI-2601 (BR11-179) ⁴	VLP	Ongoing Phase II
• Undisclosed	Undisclosed	MLE	Pre-clinical

¹Approved 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.

²Approved 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.

³Approved for use in Israel, under the brand name Sci-B-Vac, for active immunization against hepatitis B virus (HBV infection).

⁴On February 13, 2024, the Company and Variation Biotechnologies Inc., a Canadian federal corporation (“VBI Cda”) entered into the Brie Purchase Agreement with Brie Bio, pursuant to which, upon achievement of certain activities, the Company and VBI Cda will sell, transfer, convey and assign to Brie Bio, substantially all of the intellectual property related to VBI-2601 owned by the Company and VBI Cda. See “Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments—February 2024 Transactions With Brie Bio” below.

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. In June 2023, PreHevbrio was also awarded part of the CDC 2023 Adult Vaccine contract, for up to \$25,350. The CDC vaccine contracts are established for the purchase of vaccines by immunization programs that receive CDC immunization cooperative agreement funds (i.e., state health departments, certain large city immunization projects, and certain current and former U.S. territories).

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. On July 19, 2023, we announced that PreHevbri is now available in the Netherlands and Belgium for active immunization against infection caused by all known subtypes of HBV in adults. PreHevbri became available in Sweden at the end of 2023, and VBI expects that PreHevbri will be made available in certain additional European Union countries in 2024 through its partnership with Valneva.

- UK: On June 1, 2022, we announced that the UK Medicines and Healthcare Products Regulatory Agency 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. The UK is included in the Valneva marketing and distribution agreement for PreHevbri. On June 15, 2023, VBI announced the launch and availability of PreHevbri in the UK as part of the Valneva partnership.

- 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.

- Israel: Approved and commercially available under the brand name Sci-B-Vac® since 2000.

- APAC: On July 5, 2023, we announced a license and collaboration agreement with Bii Bio for the development and commercialization of PreHevbri in the Asia Pacific region (“APAC”), excluding Japan.

On February 13, 2024, we entered into a series of agreements with Bii Bio. See “Item 7–Management’s Discussion and Analysis of Financial Condition and Results of Operations–Recent Developments–February 2024 Transactions with Bii Bio” and “Item 7–Management’s Discussion and Analysis of Financial Condition and Results of Operations–Expanded Hepatitis B Partnership With Bii Bio” below.

Prophylactic Investigational Candidates

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

In response to the SARS-CoV-2 (COVID-19) pandemic, VBI initiated development of a prophylactic coronavirus vaccine program in 2020. Coronaviruses are enveloped viruses by nature which make them a prime target for VBI’s flexible eVLP platform technology. At that time, 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 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 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 was announced on September 27, 2023, demonstrating that VBI-2901 induced broad and durable protective titers against variants of concern. Notably:

- All participants saw boosting and/or high neutralizing responses against a panel of COVID-19 variants, including Wuhan, Delta, Beta, Omicron BA.5, as well as multiple animal coronaviruses including bat and pangolin variants

- Participants with low baseline neutralization titers (geometric mean titer (“GMT”): 148 IU50/mL), who are at the highest risk of infection, saw the greatest vaccine-induced boosting effects across all variants tested at Day 28, after one dose, with increases of: 8.5x against Wuhan, 9.1x against Delta, 14.2x against Beta, and 5.8x against Omicron BA.5
- All participants who received one dose had enhanced persistence of neutralizing responses, with only about 25% reduction in GMT against Wuhan after 5 months vs. peak responses
- Similar enhanced durability trends were observed against all tested variants
- By comparison, a published study [Gilboa et al., 2022] evaluating immune responses after a third dose of a licensed mRNA vaccine in nearly 4,000 healthcare workers in Israel demonstrated an approximate 77% decline in GMT against Wuhan after 5 months vs. peak responses
 - In the same study [Gilboa et al., 2022], durability trends against other variants, including Omicron, were seen to wane even more aggressively, with 4-fold to 10-fold lower neutralization titers within 4 months of the third dose

Durability and breadth of the antibody response to COVID-19 variants were maintained at month 12 after the first dose of VBI-2901 were administered in this Phase I study. Additional data are expected from the Phase I study in 2024.

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 \$33,018; a partnership with the Strategic Innovation Fund, established by the Government of Canada, with an award of up to CAD \$55,976; contribution of up to CAD \$1,000 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 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-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, was a two-arm study that enrolled 20 first-recurrent GBM patients who received 10 µg of VBI-1901 in combination with either GM-CSF or GSK proprietary adjuvant system, AS01, as immunomodulatory adjuvants. AS01 was 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; (4) 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 (5) 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.

On October 12, 2022, we announced a collaboration with Agenus Inc. to evaluate VBI-1901 in combination with anti-PD-1 balstilimab in a second Phase II study as part of the INSIGHT adaptive platform trial in patients with primary GBM.

On September 7, 2023, we announced that the dosing of the first patient in a Phase IIb study of VBI-1901 in recurrent GBM patients with first tumor recurrence. This study expands the existing study to include a Part C, which is a multi-center, randomized, controlled, open-label study. On April 3, 2024, we announced early tumor response data from the ongoing Phase IIb study during a presentation at World Vaccine Congress 2024. Early data from patients eligible for evaluation at week 12 show two observations of stable disease, indicating no tumor progression, in the VBI-1901 treatment arm (n=2/5, 40% disease control rate [DCR]). By comparison, no tumor responses have been observed in the control arm to-date (n=0/6, 0% DCR), with all patients seeing a 2-8x increase in tumor size by week 6. As of March 22, 2024, 17 patients have been randomized 1:1 to either the active, VBI-1901 treatment arm, or to the control, standard-of-care treatment arm (SoC). 14 leading neuro-oncology centers are actively recruiting patients across the US, with 2 new clinical sites activated in March 2024, and a third expected to be active in April 2024. Additional interim data analyses are expected mid-year 2024 and year-end 2024, subject to speed of enrollment.

On February 13, 2024, we entered into a series of agreements with Bii Bio. Upon completion of the Essential Activities pursuant to the Side Letter (each as defined below), VBI Cda and Bii Bio will enter into a license agreement (the “Bii VBI-1901 License Agreement”) pursuant to which Bii Bio shall issue a secured promissory note in the amount of \$5,000 as consideration for a perpetual, royalty-free, milestone-free, sublicensable, fully-paid, and exclusive license to VBI-1901 for development and commercialization in the APAC region (excluding Japan), which such note is then required to be assigned to K2HV pursuant to the terms of the Fourth Amendment. See “Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments – February 2024 Agreements with Bii Bio” below.

VBI-2601: HBV Immunotherapeutic Candidate

VBI-2601 is a 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 July 5, 2023, we announced the A&R Collaboration Agreement (as defined below) with Bii Bio, expanding Bii Bio’s rights to the development and commercialization of VBI-2601 from Greater China rights to global rights.

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 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. Bii 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 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

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).

On September 6, 2023, we announced that Bii Bio announced topline interim cohort-level unblinded week 36 data from the Phase II add-on therapy study. Per the topline interim results announced by Bii Bio, the cohort level unblinded data from the study demonstrated that in the intent to treat analysis at week 24 (end of treatment or “EoT”), 26.3% (15 patients) treated with VBI-2601/PEG-IFN α achieved HBsAg loss compared to 19.3% (11 patients) with placebo/PEG-IFN α ; at week 36 (12 weeks follow-up), 24.6% (14 patients) treated with VBI-2601/PEG-IFN α had HBsAg loss, compared with 14.0% (8 patients) with placebo/PEG-IFN α . In the per protocol analysis at week 24, 32.6% (15 patients) treated with VBI-2601/PEG-IFN α achieved HBsAg loss compared to 21.6% (11 patients) with placebo/PEG-IFN α ; at week 36, 31.8% (14 patients) and 14.9% (7 patients) had HBsAg loss, respectively. In addition, 9 out of 15 patients in the cohort treated with VBI-2601/PEG-IFN α achieved HBsAg seroconversion at EoT (week 24), versus 1 out of 11 in the cohort treated with PEG-IFN α alone. The cohort level unblinded 24 weeks safety data showed VBI-2601/PEG-IFN α treatment was generally safe and tolerated, with adverse events similar to those associated with PEG-IFN α treatment or VBI-2601 as previously reported.

In November 2023, in two late-breaking poster presentations at AASLD The Liver Meeting® 2023, Bii Bio announced new data from the Phase II study of VBI-2601 (BRII-179) highlighting progress towards achieving HBV functional cure:

- Direct evidence that BRII-179 induced functional antibody responses can contribute to increased and sustained HBsAg loss rate
- New insight utilizing BRII-179 to enrich patients with intrinsic humoral immune responses for higher HBsAg loss or HBV functional cure rates.

On February 13, 2024, we entered into a series of agreements with Bii Bio, including as related to VBI-2601 (BRII-179). See “Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments—February 2024 Transactions with Bii Bio” below.

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’Université 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 Ltd.’s, an Israeli company (“SciVac”) 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.

Under a license agreement with UPMC and other licensors relating to eVLP technology, we have an exclusive license to a family of patents that expired 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, 2023, we did not make any milestone payments.

Expanded Hepatitis B Partnership with Bii Bio

On July 5, 2023, we announced the expansion of our hepatitis B partnership with Bii Bio. Through (i) a Collaboration and License Agreement (the “Collaboration Agreement”), dated July 5, 2023, by and between us and Bii Bio, and (ii) the Amended and Restated Collaboration and License Agreement, which amended and restated that certain collaboration and license agreement (the “Bii Collaboration and License Agreement”) between us and Bii Bio, dated December 4, 2018, as amended on April 8, 2021 and December 20, 2021 (the “A&R Collaboration Agreement, and together with the Collaboration Agreement, the “Bii Collaboration Agreements”), dated July 5, 2023, by and between us and Bii Bio, Bii Bio expanded its exclusive license to VBI-2601 to global rights and acquired an exclusive license for PreHevbri in APAC, excluding Japan. As part of this collaboration, Bii Bio paid us an upfront payment of \$15,000, consisting of a \$3,000 equity investment in a concurrent registered direct offering (as discussed herein), \$5,000 as an advance payment for the clinical and commercial manufacture and supply of the VBI-2601 licensed product and PreHevbri and any related manufacturing expenditures, pursuant to a supply agreement (the “Supply Agreement”) dated July 5, 2023 by and between us and Bii Bio, and \$7,000 as a non-refundable upfront payment pursuant to the Bii Collaboration Agreements. In addition, pursuant to the Letter Agreement, dated July 5, 2023, by and among us, SciVac and Bii Bio, we also granted to Bii Bio a security interest, subject to a Subordination Agreement between Bii Bio and K2HV, in all of our respective right, title and interest in and to all intellectual property, know-how, and licenses to the extent related to PreHevbri and VBI-2601, and all proceeds of the foregoing, in order to secure performance of all of our obligations under the Bii Collaboration Agreements, the Supply Agreement, and the Loan Agreement (as defined herein).

2023 Organizational Changes

On April 4, 2023, we announced that we planned to reduce our internal workforce and other expenses by 30-35%, activity which began in April 2023 and was completed by the end of September 2023. As a result of this, our operating expenses from normal business were approximately 30-35% lower in the second half of 2023 as compared with the second half of 2022.

2023 Reverse Stock Split

On April 12, 2023, we effected a 1-for-30 reverse stock split (the “Reverse Stock Split”) of our issued and outstanding common shares effective as of April 12, 2023, pursuant to which every 30 of our issued and outstanding common shares were automatically converted into one common share without any change in the par value per share. Per the requirements of the *Business Corporations Act* (British Columbia), under which we are regulated, if fractional shares held by registered shareholders were to be converted into whole shares, each fractional share remaining after the completion of the Reverse Stock Split that was less than half of a share was cancelled and each fractional share that was at least half of a share was rounded up to one whole share. No shareholders received cash in lieu of fractional shares.

Nasdaq Minimum Bid Price Requirement

On November 1, 2023, we received a letter from the Listing Qualifications Department of the Nasdaq Capital Market’s (“Nasdaq”) indicating that, based upon the closing bid price of our common shares for the 30 consecutive business day period between September 19, 2023 through October 31, 2023, 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 letter also indicated that we will be provided with a compliance period of 180 calendar days, or until April 29, 2024 (the “Compliance Period”), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

In order to regain compliance with Nasdaq’s minimum bid price requirement, our common shares must maintain a minimum closing bid price of \$1.00 for a minimum of ten consecutive business days during the Compliance Period. In the event that we do not regain compliance by the end of the Compliance Period, we may be eligible for additional time to regain compliance. To qualify, we will be required to meet the continued listing requirement for the market value of our publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split if necessary. If we meet these requirements, we may be granted an additional 180 calendar days to regain compliance. We have not regained compliance as of the date of this Form 10-K, and if we fail to regain compliance during the Compliance Period or any subsequent grace period granted by Nasdaq, 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 and result in significantly increased uncertainty as to the Company’s ability to raise additional capital.

Recent Developments

February 2024 Agreements with Bii Bio

On February 13, 2024, we entered into a series of agreements with Bii Bio, pursuant to which, subject to the achievement of certain activities, we would receive up to \$33,000 in consideration from Bii Bio, consideration which will be used to correspondingly reduce our obligations due under the Loan Agreement (as defined herein).

Bii Purchase Agreement

On February 13, 2024, the Company and VBI Cda entered into a purchase agreement (the “Brii Purchase Agreement”) with Brii Bio, pursuant to which, subject to the achievement of certain activities, the Company and VBI Cda will sell, transfer, convey and assign to Brii Bio, substantially all of the intellectual property related to VBI-2601 owned by the Company and VBI Cda, for a secured promissory note in the principal amount up to \$10,000 (the “Note”) to be issued by Brii Bio, which is then required to be assigned to K2HV pursuant to the terms of the Fourth Amendment, in exchange for a reduction in the Company’s obligations under the Loan Agreement equal to the initial principal amount of the Note. The initial principal amount of the Note will be \$2,500, which shall be increased by an aggregate amount equal to \$7,500 upon the Company obtaining applicable consents under the Amended and Restated Ferring License Agreement. In the event of certain breaches by VBI of the Brii Purchase Agreement and any such breach is not cured with 30 days, the aggregate principal amount of the Note shall be reduced by an aggregate amount equal to \$2,500.

In addition to the foregoing, the Brie Purchase Agreement contains certain amendments to the Brie Collaboration Agreements, which such amendments are further described below.

Amendments to the Brie Collaboration Agreements

As previously disclosed and described above, on December 4, 2018, we and Brie Bio entered into the Brie Collaboration and License Agreement, pursuant to which we and Brie Bio agreed to collaborate on the development of a Hepatitis B recombinant protein-based immunotherapeutic in the licensed territory, which consists of China, Hong Kong, Taiwan, and Macau (collectively, the “VBI-2601 Licensed Territory”). Further, as previously disclosed and as described above, on July 5, 2023, we and Brie Bio entered into the Brie Collaboration Agreements.

Pursuant to the Brie Purchase Agreement, on February 13, 2024, the Company and Brie Bio agreed to amend the Collaboration Agreement to, among other things, subject to the terms and conditions set forth in the Collaboration Agreement, (i) amend the terms of the royalty bearing license granted by the Company to Brie Bio for the global development activities of PreHevbri to be “perpetual and irrevocable”, (ii) omit the requirement for Brie Bio to obtain marketing approval for PreHevbri in certain territories and (iii) omit the requirement for Brie Bio to make royalty and milestone payments to the Company.

Additionally, pursuant to the Brie Purchase Agreement, on February 13, 2024, we and Brie Bio also agreed, subject to achievement of certain activities, to amend the A&R Collaboration Agreement to, among other things, subject to the terms and conditions set forth in the A&R Collaboration Agreement, (i) amend the terms the royalty bearing license granted by the Company to Brie Bio for research studies and development of VBI-2601 to be “perpetual and irrevocable”, (ii) omit the requirement for Brie Bio to obtain marketing approval and commercialize VBI-2601 in the U.S. and China, (iii) revise the indemnity requirements such that Brie Bio indemnifies us with respect to certain transferred intellectual property after the effective date of the Brie Purchase Agreement and we indemnify Brie Bio prior to such date, (iv) omit the requirement for Brie Bio to make royalty and milestone payments to us, and (v) omit certain of our rights to terminate the A&R Collaboration Agreement and certain other effects of termination of the A&R Collaboration Agreement.

Side Letter

On February 13, 2024, the Company and Brie Bio entered into the Side Letter setting forth certain essential and additional priority activities to transfer manufacturing responsibility for clinical supply and commercial supply of VBI-2601 and PreHevbri for the Brie Territories set forth in the Side Letter (the “Essential Activities”) the Company is required to complete as a condition to the entry into the Brie License Agreement and consummation of the transactions pursuant to the Rehovot Purchase Agreement. The principal amount of the Note shall increase up to \$18,000 upon completion of the Essential Activities and the Company’s obligations under the Loan Agreement shall be reduced by a corresponding amount.

Brie License Agreement

On February 13, 2024, we entered into a series of agreements and amendments to existing agreements with Brie Bio. Upon completion of the Essential Activities pursuant to the Side Letter, VBI Cda and Brie Bio will enter into the Brie License Agreement pursuant to which Brie Bio shall issue a secured promissory note in the amount of \$5,000 as consideration for a perpetual, royalty-free, milestone-free, sublicensable, fully-paid, and exclusive license to the GBM program (VBI-1901) for development and commercialization in the APAC region (excluding Japan), which such note is then required to be assigned to K2HV pursuant to the terms of the Fourth Amendment.

The entry by VBI Cda and Brie Bio into the Brie License Agreement is subject to the Company completing the Essential Activities.

Rehovot Purchase Agreement

On February 13, 2024, the Company and SciVac (the “Seller”) entered into the Rehovot Purchase Agreement with a wholly-owned subsidiary of Brii Bio, to be formed in Israel prior to the closing, and joined as a party to the agreement prior to the closing as the purchaser (the “Brii Israel”), and Brii Biosciences, Inc., a Delaware corporation, pursuant to which, upon achievement of certain activities and closing of the transactions contemplated by the Rehovot Purchase Agreement, subject to the terms and conditions therein, SciVac will sell to Brii Israel certain assets, including Seller and its affiliates’ interest and rights in and to certain assets and leases with respect to the vaccine manufacturing facility in Rehovot, Israel, for an aggregate purchase price of \$10,000, which is then required to be paid to K2HV pursuant to the terms of the Fourth Amendment.

The Rehovot Purchase Agreement contains representations and warranties of the Seller and Brii Israel that are typical for transactions of this type. The Rehovot Purchase Agreement also contains covenants on the part of the Company that are typical for transactions of this type.

The closing of the transactions pursuant to the Rehovot Purchase Agreement are subject to the terms and conditions therein, including closing conditions that are typical for transactions of this type and the Company’s completion of the Essential Activities. Closing will not occur prior to June 30, 2024.

Amendment to Loan Agreement with K2 HealthVentures

As previously disclosed, we and our subsidiary VBI Cda, a Canadian federal corporation (“VBI Cda”), as borrowers, entered into a Loan Agreement (as defined herein) dated as of May 22, 2020, as amended by the First Amendment, the Second Amendment, the Third Amendment, and the Fourth Amendment (each as defined herein), and as such agreement may be amended from time to time in the future with K2HV (as defined herein) and any other lenders party thereto from time to time (collectively, the “Loan Parties”) with the obligations under the Loan Agreement secured on a senior basis by a lien on substantially all of our assets (including our subsidiaries).

On February 13, 2024, the Loan Parties entered into an amendment (the “Fourth Amendment”) to the Loan Agreement, effective upon entry into certain transactions with Brii Bio, pursuant to which the parties have agreed to, among other things, (i) remove a financial covenant requiring us to maintain minimum net revenue of 75% of projections, (ii) the forbearance by K2HV and the other lenders party thereto, prior to the earlier of (A) December 31, 2024, (B) the date the Side Letter (as defined below) ceases to be in full force and effect prior to the completion of the Essential Activities (as defined below) and (C) the date the Essential Activities (as defined below) are complete (the “Forbearance Expiration Date”) from exercising their remedies with respect to the occurrence of Events of Default (as defined in the Loan Agreement) subject to certain exceptions, and (iii) following the Forbearance Expiration Date, add a financial covenant requiring us to maintain a minimum cash amount equal to its obligations under the Loan Agreement at all times.

The effectiveness of the Fourth Amendment was conditioned upon entry into the Brii Purchase Agreement, the Rehovot Purchase Agreement, and the Side Letter (each as defined below), each of which were entered into by us and the respective parties thereto on February 13, 2024, as described above. See “K2 HealthVentures LLC (“K2HV”) Long Term Debt”.

April 2024 Offering

On April 9, 2024, we entered into a securities purchase agreement with certain institutional investors named therein pursuant to which we issued and sold 2,272,728 common shares and accompanying warrants to purchase up to 2,272,728 common shares (the “April 2024 Warrants”) at a combined offering price of \$0.88 per common share and accompanying April 2024 Warrant in a registered direct offering (the “April 2024 Offering”). The April 2024 Offering closed on April 11, 2024. The April 2024 Warrants have an exercise price of \$0.76 per share, are immediately exercisable on the date of issuance, and expire five years following the date of issuance. Net proceeds to us from the April 2024 Offering, after deducting placement agent fees and estimated offering expenses payable by us, were approximately \$1,700.

In connection with the April 2024 Offering, we also issued to H.C. Wainwright & Co., LLC or its designees, warrants to purchase up to 136,364 common shares (the “April 2024 Placement Agent Warrants”) as compensation in connection with the April 2024 Offering. The April 2024 Placement Agent Warrants have substantially the same terms and conditions as the April 2024 Warrants, except that the April 2024 Placement Agent Warrants have an exercise price of \$1.10 per share, which represents 125% of the offering price per common share and accompanying April 2024 Warrant and expire five years following the commencement of sales pursuant to the April 2024 Offering.

Financial Operations Overview

At present, our operations are focused on:

- continuing the commercialization of PreHevbrio in the U.S. and commercialization of PreHevbri in Europe;
- completing certain activities as part of the partnership with Bria Bio and preparation to transfer the Rehovot, Israel manufacturing facility to Bria Bio pursuant to the Rehovot Purchase Agreement;
- manufacturing our 3-antigen HBV vaccine at commercial scale to meet demand in the U.S., Europe, and Israel, where it is approved, and to prepare for supply in markets where we or our partner Bria Bio may obtain marketing authorization;
- manufacturing VBI-2601, our protein-based immunotherapeutic candidate for treatment of chronic HBV, in collaboration with Bria Bio;
- continuing the Phase IIb clinical study of our GBM vaccine immunotherapeutic candidate, VBI-1901, in the recurrent GBM setting;
- preparing for a clinical study of VBI-1901 in the primary GBM setting;

- continuing the Phase I clinical study of our multivalent coronavirus candidate, VBI-2901;
- continuing our development and scaling-up production processes for our prophylactic coronavirus vaccine candidates using a Contract Development and Manufacturing Organization (“CDMO”) located in Canada;
- 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., PreHevbri in the UK and certain countries in Europe, and Sci-B-Vac in Israel. 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 securities, 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, 2023, VBI had an accumulated deficit of approximately \$582,445, stockholders’ equity of approximately \$7,527 and cash of \$23,685. Cash outflows from operating activities were \$60,883 for the year ended December 31, 2023. 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 \$92,836 for the year ended December 31, 2023, which includes a \$24,600 non-cash impairment realized in the year ended December 31, 2023, 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 \$92,836 and \$113,303 for the years ended December 31, 2023 and 2022, respectively, which includes a \$24,600 and \$0 non-cash impairment realized in the years ended December 31, 2023 and 2022, respectively. We had an accumulated deficit of \$582,445 at December 31, 2023. We had \$23,685 of cash and net negative working capital of \$39,505 as of December 31, 2023. As described elsewhere, in early July 2023, we received \$15,000 as an upfront payment from Bii Bio, pursuant to the Bii Collaboration Agreements and the concurrent registered direct offering, and aggregate gross proceeds of \$20,500 from the underwritten public offering.

Revenues, net

Revenues, net consist of product sales of PreHevbrio in the U.S., PreHevbri in the UK and certain countries in the EU as part of our partnership with Valneva, and sales of Sci-B-Vac in Israel, license revenue from the Bii Collaboration Agreements, as well as R&D services revenue recognized as part of the Bii Collaboration Agreements 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 and beginning in 2023, PreHevbri was sold to our partner Valneva in the UK and certain countries in the EU (collectively, our “Customers”). We expect to continue to expand our market share in 2024 and beyond. 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.

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 sales, 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 past quarters, we redefined the deployment of our commercial resources and, as such, reduced our commercial expenses. As a result, we expect our SG&A expenses will decrease in future quarters.

Interest Expense, Net of Interest Income

Interest expense, net of interest income, is associated with our long-term debt as discussed in Note 11 of the Notes to the Consolidated Financial Statements.

Results of Operations

Year Ended December 31, 2023 Compared to the Year Ended December 31, 2022

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

	Year ended December 31			
	2023	2022	Change \$	Change %
Revenues, net	\$ 8,682	\$ 1,082	\$ 7,600	702%
Expenses:				
Cost of revenues	12,507	11,276	1,231	11%
Research and development	9,343	15,506	(6,163)	(40)%
Sales, general and administrative	42,143	56,120	(13,977)	(25)%
Impairment charges	24,600	-	24,600	100%
Total operating expenses	88,593	82,902	5,691	7%
Loss from operations	(79,911)	(81,820)	1,909	(2)%
Interest expense, net of interest income	(6,401)	(4,007)	(2,394)	60%
Foreign exchange loss	(6,524)	(27,476)	20,952	(76)%
Loss before income taxes	(92,836)	(113,303)	20,467	(18)%
Income tax expense	-	-	-	-%
NET LOSS	\$ (92,836)	\$ (113,303)	\$ 20,467	(18)%

Revenues, net

Revenues, net for the year ended December 31, 2023, were \$8,682 as compared to \$1,082 for the year ended December 31, 2022. Revenues for the year ended December 31, 2023, increased by \$7,600 or 702% due to an increase in product revenue, as well as license revenue and R&D services revenue associated with the Bii Collaboration Agreements. Product revenue increased due to revenue growth since the launch of PreHevbrio in the U.S. in the first quarter of 2022 and the sale of PreHevbrio to our European partner Valneva as a result of our launch in the UK, the Netherlands, and Belgium in the second quarter of 2023, offset by lower sales in the Israeli market. License revenue increased due to the Bii Collaboration Agreements, which provided exclusive global rights to VBI-2601 and an exclusive license to PreHevbrio in APAC, excluding Japan, to Bii Bio, during the year ended December 31, 2023. R&D service revenue increased due to the recognition of performance obligations relating to the Bii Collaboration and License Agreement prior to the amendment and restatement, during the year ended December 31, 2023.

Revenue Composition

	2023	2022
Product revenue, net	\$ 3,107	\$ 931
License revenue	3,596	-
R&D service revenue	1,979	151
	<u>\$ 8,682</u>	<u>\$ 1,082</u>

Revenues, net by Geographic Region

	Years ended December 31			
	2023	2022	\$ Change	% Change
Revenue, net in United States	\$ 1,845	\$ 695	\$ 1,150	165%
Revenue, net in Israel	167	315	(148)	(47)%
Revenue, net in China/Hong Kong	5,585	66	5,519	8,362%
Revenue, net in Europe	1,085	6	1,079	17,983%
	<u>\$ 8,682</u>	<u>\$ 1,082</u>	<u>\$ 7,600</u>	<u>702%</u>

Cost of Revenues

Cost of revenues for the year ended December 31, 2023, was \$12,507 as compared to \$11,276 for the year ended December 31, 2022. The increase in the cost of revenues of \$1,231 or 11% was due to increased sales and increased outsourced testing costs during the year ended December 31, 2023, compared to the year ended December 31, 2022.

Research and Development Expenses

R&D expenses for the year ended December 31, 2023, were \$9,343 as compared to \$15,506 for the year ended December 31, 2022. R&D expenses were offset by \$8,313 for the year ended December 31, 2023, and \$8,859 for the year ended December 31, 2022, due to government grants and funding arrangements. The decrease in R&D expenses of \$6,163 or 40%, is mainly a result of a decrease in R&D expenses related to the development of our vaccine candidates VBI-2901 and VBI-1901. During the majority of the year ended December 31, 2022, preparations were underway to begin clinical trials for both VBI-2901 and VBI-1901, which increased R&D expenses. Although VBI-2901 and VBI-1901 were both in clinical trials during the year ended December 31, 2023, the clinical trial for VBI-2901 is nearing completion and VBI-1901 began later in the second half of 2023, both of which decreased R&D expenses in comparison to the year ended December 31, 2022.

Sales, General and Administrative Expenses

SG&A expenses, net of government grants and funding arrangements, for the year ended December 31, 2023, were \$42,143 as compared to \$56,120 for the year ended December 31, 2022. SG&A expenses were offset by \$750 for the year ended December 31, 2023, and \$735 for the year ended December 31, 2022, due to government grants and funding arrangements. The SG&A expense decrease of \$13,977 or 25%, was mainly a result of the recent organizational changes beginning in April 2023 and concluding in September 2023, which reduced our internal headcount, commercial field teams, and our activity-based commercial expenses related to PreHevbrio in the U.S.

Impairment charges

Non-cash pre-tax impairment charges for year ended December 31, 2023, were \$24,600, which consisted of a non-cash pre-tax impairment charge of \$22,600 related to IPR&D, specifically attributable to the congenital CMV asset, \$1,000 related to property and equipment assets, and \$1,000 related to goodwill. There were no impairment charges for the year ended December 31, 2022. See Note 6 in the consolidated financial statements.

Loss from Operations

The loss from operations for the year ended December 31, 2023, was \$79,911 as compared to \$81,820 for the year ended December 31, 2022. The \$1,909 decrease in the loss from operations was due to a reduction in headcount and other spend as discussed above, offset by an increase of \$24,600 from the non-cash impairment charge.

Interest Expense, Net of Interest Income

Interest expense, net of interest income for the year ended December 31, 2023, was \$6,401 as compared to \$4,007 for the year ended December 31, 2022. The increase in interest expense, net is due to an increase in long-term debt of \$20,000 beginning mid-September 2022 and increased interest payments on our long-term debt due to higher interest rates applied during the year ended December 31, 2023.

Foreign Exchange Loss

Foreign exchange loss for the year ended December 31, 2023, was \$6,524 as compared to a loss of \$27,476 for the year ended December 31, 2022. The decrease in the foreign exchange loss was a result of the changes in the foreign currency exchange rates (NIS and CAD) in which the foreign currency transactions were denominated for each of those periods, including the foreign exchange impact of intercompany loans that are translated at period end.

Net Loss

Net loss of \$92,836 for the year ended December 31, 2023, compared to \$113,303 for the year ended December 31, 2022, is a result of the items discussed above.

Liquidity and Capital Resources

	Year ended December 31		\$ Change	% Change
	2023	2022		
Cash	\$ 23,685	\$ 62,629	\$ (38,944)	(62)%
Current Assets	36,231	77,690	(41,459)	(53)%
Current Liabilities	75,736	36,942	38,794	105%
Working Capital	(39,505)	40,748	(80,253)	(197)%
Accumulated Deficit	(582,445)	(489,609)	(92,836)	19%

As of December 31, 2023, we had cash of \$23,685 as compared to \$62,629 as of December 31, 2022. As of December 31, 2023, we had negative working capital of \$39,505 as compared to working capital of \$40,748 at December 31, 2022. Working capital is calculated by subtracting current liabilities from current assets.

On August 26, 2022, we filed a registration statement on Form S-3 (File No. 333-267109) with the SEC, as further described herein. As of the filing date of this Form 10-K, we became subject to the limitations of General Instruction I.B.6 of Form S-3, which limits the amount of funds we can raise through primary public offerings of securities in any twelve-calendar month period using a registration statement on Form S-3 to one-third of the aggregate market value of our common shares held by non-affiliates. Therefore, we will be limited in the amount of proceeds we are able to raise by selling our common shares using Form S-3, until such time as our public float held by non-affiliates exceeds \$75,000.

Net Cash Used in Operating Activities

We incurred net losses of \$92,836 and \$113,303 in the years ended December 31, 2023 and 2022, respectively. We used \$60,883 and \$73,695 in cash for operating activities during the years ended December 31, 2023 and 2022, respectively. The decrease in cash outflows is largely a result of non-cash reconciling items, mainly impairment charges incurred in the year ended December 31, 2023, and unrealized foreign exchange loss and the change in operating working capital, most notably in inventory, other current assets, accounts payable, deferred revenues, and other current liabilities.

Net Cash Used in Investing Activities

Net cash flows used in investing activities was \$867 for the year ended December 31, 2023, compared to cash provided by investing activities of \$4,344 for the year ended December 31, 2022. The cash outflow in both periods is a result of routine property and equipment purchases.

Net Cash Provided by Financing Activities

Net cash flows provided by financing activities was \$22,698 for the year ended December 31, 2023, compared to net cash flows provided by financing activities of \$19,449 during the year ended December 31, 2022. The cash flow provided for the year ended December 31, 2023, related to proceeds from the issuance of our securities in the July 2023 underwritten public offering and the concurrent registered direct offering described below, and sales of our common shares under our ATM Program (as defined below), whereas the cash flow provided for the year ended December 31, 2022, related to proceeds from debt financing.

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”). During the year ended December 31, 2023, the Company issued 1,046,808 common shares under the ATM Program, for total gross proceeds of \$738 at a weighted average price of \$0.7048 per share. The Company incurred \$107 in sales agent commissions and share issuance costs related to the common shares issued during the year ended December 31, 2023, resulting in net proceeds of \$631. As of December 31, 2023, approximately \$124,262 of common shares remained available for issuance under the ATM Program. Upon filing of this Form 10-K, we will become subject to General Instruction I.B.6 of Form S-3, pursuant to which in no event will we sell our common shares in a registered primary offering using Form S-3 with a value exceeding more than one-third of our public float in any 12 calendar month period so long as our public float remains below \$75,000. Therefore, the amount we may be able to raise using the ATM Program will be significantly less than \$125,000, until such time as our public float held by non-affiliates exceeds \$75,000. The aggregate market value of our outstanding common shares held by non-affiliates as of filing of this Form 10-K, or the public float, is approximately \$25,174, which was calculated based on 27,334,007 common shares outstanding held by non-affiliates and at a price of \$0.9210 per share, the closing price of our common shares on April 8, 2024. As of the date hereof, we have not offered or sold any securities pursuant to General Instruction I.B.6 of Form S-3 during the prior 12 calendar month period that ends on and includes the date hereof.

July 2023 Underwritten Public Offering and Registered Direct Offering

In July 2023, the Company closed (i) an underwritten public offering of 12,445,454 common shares and accompanying common warrants to purchase up to 12,545,454 common shares (which included 1,536,363 common shares and common warrants to purchase up to 1,636,363 common shares issued pursuant to the underwriters’ partial exercise of their option to purchase additional common shares and common warrants), at a combined public offering price of \$1.65 per share and accompanying common warrant, and (ii) a concurrent registered direct offering, pursuant to the expanded hepatitis B partnership with Bii Bio, of 1,818,182 common shares and accompanying common warrants to purchase 1,818,182 common shares, at a combined purchase price of \$1.65 per share and accompanying common warrant. The accompanying common warrants issued and sold in each of the underwritten public offering and concurrent registered direct offering have an initial exercise price of \$1.65 per share, which, pursuant to certain anti-dilution provisions of the warrants, has been reduced to \$0.6057 per share, as of December 31, 2023, and expire five years from the date of issuance. The aggregate gross proceeds from the underwritten public offering, including aggregate gross proceeds from the underwriters’ exercise of their option to purchase additional securities, were \$20,500. The aggregate gross proceeds from the concurrent registered direct offering were \$3,000. As of March 31, 2023, the current exercise price of the warrants is \$0.6057 per share.

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 \$43.80 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 45,662 common shares at a conversion price of \$43.80 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 additional tranches subject to the achievement of milestones and other customary conditions, (ii) add certain minimum net revenue covenants, (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 next tranche of term loans of up to \$10,000 will be available from April 1, 2024, through June 30, 2024, so long as certain milestones are achieved, no events of default under the Loan Agreement have occurred and are continuing, and the Liquidity Requirement is satisfied. The final 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 45,662 common shares at a conversion price of \$43.80 per share and \$5,000 of the term loans shall be convertible into 159,734 common shares at a conversion price of \$31.302 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 20,833 common shares (the “Original K2HV Warrant”) at an exercise price of \$33.60 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 10,417 common shares for a total of 31,250 common shares (the “First Amendment Warrant”) with the same exercise price of \$33.60 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 72,680 common shares (the “Second Amendment Warrant”) with a warrant exercise price of \$24.08. If and/or when additional tranches are advanced pursuant to the Second Amendment, the Company will issue additional warrants to purchase up to 72,680 common shares pursuant to the Second Amendment Warrant. If the full remaining \$50,000 available in the K2HV tranches is advanced pursuant to the Second Amendment, up to an additional 72,680 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 various 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 applicable tranche actually funded multiplied by 3.5% and divided by the warrant exercise price of \$24.08, 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, 2023, 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, 2023 was 12.50%. 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 16.13%.

On July 5, 2023, the Borrowers and K2HV entered into (i) an amendment (the “Third Amendment”) to the Loan Agreement, and (ii) an amendment to the Pledge and Security Agreement, dated May 22, 2020, by and among the Company, VBI DE, VBI Cda, K2HV, and Ankura Trust Company, LLC, as collateral trustee for the lenders, pursuant to which the parties have agreed to permit the Brii Collaboration Agreements, the Supply Agreement (the “Supply Agreement”), dated July 5, 2023 by and between the Company and Brii Bio, and the Letter Agreement (the “Letter Agreement”), dated July 5, 2023, by and among the Company, SciVac and Brii Bio. The Company granted to K2HV a security interest in, all of its respective right, title, and interest in and to substantially all of the Company’s intellectual property. In addition, among others, any breach, default or other triggering event by the Company occurring under the Brii Collaboration Agreements resulting in Brii Bio exercising a right to terminate the Brii Collaboration Agreements, will cross default the Third Amendment.

The secured term loan maturity date is September 14, 2026, until which we are required to pay only interest, or if the milestone for the next tranche of the term loans has been achieved, September 14, 2027. The Loan Agreement, as amended by the Second Amendment, includes both financial and non-financial covenants, including quarterly minimum Net Revenue targets. We were not in compliance with the minimum Net Revenue covenant for the measurement periods ended September 30, 2023 and December 31, 2023, and did not qualify for an exception for this covenant, which constituted an Event of Default. In anticipation of K2HV declaring an Event of Default as a result of such failure to comply with the Net Revenue covenant, we began discussions with K2HV with respect to possible forbearance and other remedies. On October 27, 2023, the Borrowers and K2HV entered into the Extension Agreement, pursuant to which the due date for us to deliver the compliance certificate for the period ending September 30, 2023, pursuant to the Loan Agreement, was extended from October 30, 2023, to November 6, 2023, which date was extended again from November 6, 2023, to November 13, 2023, pursuant to a subsequent letter agreement dated November 3, 2023. Pursuant to the Extension Agreement, as amended, K2HV agreed to refrain from declaring an Event of Default under the Loan Agreement and/or the Loan Documents (as defined in the Loan Agreement) prior to November 13, 2023.

On November 13, 2023, the Borrowers entered into a forbearance agreement with the Lenders (the “Forbearance Agreement”), pursuant to which the Lenders agreed to forbear from exercising the Secured Parties’ (as defined in the Loan Agreement) rights with respect to the failure to meet the minimum Net Revenue covenant for the measurement period ended September 30, 2023, from November 13, 2023, through and including November 28, 2023 (the “Forbearance Period”), subject to compliance by the Borrowers with certain terms and conditions as set forth in the Forbearance Agreement. Such conditions included delivery of cash flow budget and adherence reports, and adherence with such budget and cash flow forecast. On each of November 28, 2023, December 12, 2023, December 26, 2023, January 9, 2024, January 23, 2024, and February 6, 2024, the Loan Parties entered into extensions to the Forbearance Agreement pursuant to which the Lenders agreed to extend the Forbearance Period through and including December 12, 2023, December 26, 2023, January 9, 2024, January 23, 2024, February 6, 2024, and February 20, 2024, respectively, subject to compliance by the Borrowers with the same terms and conditions as set forth in the Forbearance Agreement.

On February 13, 2024, the Loan Parties entered into an amendment (the “Fourth Amendment”) to the Loan Agreement, effective upon entry into certain transactions with Brii Bio, pursuant to which the Loan Parties agreed to, among other things, (i) remove a financial covenant requiring us to maintain minimum net revenue of 75% of projections, (ii) the forbearance by K2HV and the other lenders party thereto, prior to the earlier of (A) December 31, 2024, (B) the date the Side Letter ceases to be in full force and effect prior to the completion of the Essential Activities (as defined below) and (C) the date the Essential Activities are complete (the “Forbearance Expiration Date”) from exercising their remedies with respect to the occurrence of Events of Default subject to certain exceptions, and (iii) following the Forbearance Expiration Date, add a financial covenant requiring the Company to maintain a minimum cash amount equal to our obligations under the Loan Agreement at all times.

The obligations under the Loan Agreement as amended by the Third Amendment (as defined below) are secured on a senior basis by a lien on substantially all of the assets of the Company and its subsidiaries. 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 effectiveness of the Fourth Amendment was conditioned upon entry into the Brii Purchase Agreement, the Rehovot Purchase Agreement, and the Side Letter, each of which were entered into by us and the respective parties thereto on February 13, 2024, as described above. In connection with the Note issued to us by Brii Bio and assigned to K2HV pursuant to the Fourth Amendment and the sale of the Rehovot, Israel facility, our obligations due under the Loan Agreement may be correspondingly reduced by up to an aggregate of \$33,000 upon obtaining certain consents, the completion of certain activities and the closing of the sale of the Rehovot facility, subject to the terms and conditions therein.

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 \$3,601 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, 2023, 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, 2023, VBI had an accumulated deficit of \$582,445, stockholders’ equity of \$7,527 and cash of \$23,685. Cash outflows from operating activities were \$60,883 for the year ended December 31, 2023.

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. Based on available cash at December 31, 2023, together with the net proceeds from the April 2024 Offering, in order to continue to fund our operations, we must raise additional equity or debt capital in the near term and cannot provide any assurance that we will be successful in doing so. If we are unable to obtain additional financing in the near future or complete the Brie Transactions on a timely basis, we may be required to pursue a reorganization proceeding, including under applicable bankruptcy or insolvency laws. The above conditions raise substantial doubt about our ability to 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. 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 and maintain regulatory approvals, and, subject to such approvals, commercially launch and sell 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, 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 or we are unable to complete the Brie Transactions on a timely basis, 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.

The common warrants sold in July 2023 in the underwritten public offering and the registered direct offering contain reset provisions applicable to the exercise price to be triggered upon issuance of equity or equity-linked securities at an effective common share purchase price of less than the exercise price in effect. Such obligations may make any additional financing difficult to obtain or unavailable to the Company.

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 continuing war between Russia and Ukraine and between Israel and Hamas, 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, 2023, 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.

Nasdaq Minimum Bid Price Requirement

On November 1, 2023, we received a letter from the Listing Qualifications Department of Nasdaq indicating that, based upon the closing bid price of our common shares for the 30 consecutive business day period between September 19, 2023 through October 31, 2023, 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 letter also indicated that we will be provided with the Compliance Period, in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

In order to regain compliance with Nasdaq's minimum bid price requirement, our common shares must maintain a minimum closing bid price of \$1.00 for a minimum of ten consecutive business days during the Compliance Period. In the event that we do not regain compliance by the end of the Compliance Period, we may be eligible for additional time to regain compliance. To qualify, we will be required to meet the continued listing requirement for the market value of our publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split if necessary. If we meet these requirements, we may be granted an additional 180 calendar days to regain compliance. We have not regained compliance as of the date of this Form 10-K, and if we fail to regain compliance during the Compliance Period or any subsequent grace period granted by Nasdaq, 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 and result in significantly increased uncertainty as to the Company's ability to raise additional capital.

April 2024 Offering

On April 9, 2024, we entered into a securities purchase agreement with certain institutional investors named therein pursuant to which we issued and sold 2,272,728 common shares and accompanying April 2024 Warrants at a combined offering price of \$0.88 per common share and accompanying April 2024 Warrants in the April 2024 Offering. The April 2024 Offering closed on April 11, 2024. The April 2024 Warrants have an exercise price of \$0.76 per share, are immediately exercisable on the date of issuance, and expire five years following the date of issuance. Net proceeds to us from the April 2024 Offering, after deducting placement agent fees and estimated offering expenses payable by us were approximately \$1,700.

In connection with the April 2024 Offering, we also issued to H.C. Wainwright & Co., LLC or its designees the April 2024 Placement Agent Warrants as compensation in connection with the April 2024 Offering. The April 2024 Placement Agent Warrants have substantially the same terms and conditions as the April 2024 Warrants, except that the April 2024 Placement Agent Warrants have an exercise price of \$1.10 per share, which represents 125% of the offering price per common share and accompanying April 2024 Warrant and expire five years following the commencement of sales pursuant to the April 2024 Offering.

Net Operating Loss Carryforwards (“NOLs”)

At December 31, 2023, the Company had NOLs aggregating approximately \$454,508. The NOLs are available to reduce taxable income of future years and expire as follows:

	<u>Netherlands</u>	<u>United States</u>	<u>Canada</u>	<u>Israel</u>	<u>Total</u>
2025	-	-	862	-	862
2026	-	10	3,590	-	3,600
2027	-	446	4,159	-	4,605
2028	-	718	1,610	-	2,328
2029	-	672	3,016	-	3,688
2030	-	2,556	977	-	3,533
2031	-	3,617	1,207	-	4,824
2032	-	2,962	-	-	2,962
2033	-	3,126	1,411	-	4,537
2034	-	5,626	5,284	-	10,910
2035	-	4,661	1,589	-	6,250
2036	-	5,323	6,995	-	12,318
2037	-	6,017	9,473	-	15,490
2038	-	-	2,353	-	2,353
2039	-	-	7,488	-	7,488
2040	-	-	15,896	-	15,896
2041	-	-	11,682	-	11,682
2042	-	-	13,434	-	13,434
2043	-	-	11,449	-	11,449
No expiration	798	23,790	-	291,711	316,299
	<u>\$ 798</u>	<u>59,524</u>	<u>\$ 102,475</u>	<u>\$ 291,711</u>	<u>\$ 454,508</u>

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, 2023, 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, 2023, 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 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.

Due to the drop in market conditions experienced in April 2023, the Company performed an interim impairment test. The IPR&D assets, consisting of the CMV and GBM programs acquired in a business combination (the 2016 merger between VBI and SciVac), are 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 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: 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 15% and the cumulative probability of technical and regulatory success to achieve approval to market the products ranged from approximately 10% to 17%. During the second quarter of 2023, the Company recorded an impairment of IPR&D of \$19,000, as a partial impairment to the congenital CMV asset, as a result of its interim impairment test performed as of April 30, 2023. The Company performed its annual test as of August 31, 2023, and determined there was no additional IPR&D impairment. The methodology and significant estimates and assumptions used in determining the fair value of the IPR&D assets as of August 31, 2023, were the same as the interim impairment test performed as of April 30, 2023. As discussed above, the Company considered the further decline in market conditions in September 2023 to be an additional triggering event for the second interim impairment test to be performed. During the third quarter of 2023, the Company recorded an impairment of IPR&D of \$3,600, as a partial impairment to the congenital CMV asset, as a result of its interim impairment test performed as of September 30, 2023. The methodology and significant estimates and assumptions used in determining the fair value of the IPR&D assets as of September 30, 2023, were the same as the annual impairment test, other than the discount rate. This discount rate used was 25%. In October 2023, the Company considered a further decline in market conditions to be a triggering event for a third interim impairment test to be performed. There was no additional impairment as a result of the impairment test performed as of October 31, 2023. The methodology and significant estimates and assumptions used in determining the fair value of the IPR&D assets as of October 31, 2023, were the same as the interim impairment test performed as of September 30, 2023.

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 performed 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 interim impairment test performed as of April 30, 2023, its annual impairment test performed as of August 31, 2023, and the second interim impairment test performed as of September 30, 2023. As discussed above, the Company considered the further decline in market conditions in October 2023 to be an additional triggering event for the third interim impairment test to be performed. During the fourth quarter of 2023, the Company recorded an impairment of goodwill of \$1,000 as a result of its interim impairment test performed as of October 31, 2023. The Company consists of a single reporting unit and uses its market capitalization to determine the fair value of the reporting unit. In order to determine the market capitalization, the Company used the trailing 20-day volume weighted average price of its shares as of October 31, 2023.

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 in the process of developing and commercializing novel pharmaceutical and biologic 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 emergence and effects of public health crises, such as endemics and epidemics and the consequences of the ongoing war between Russia and Ukraine and between Israel and Hamas, including related sanctions and countermeasures, are difficult to predict, and could adversely impact geopolitical and macroeconomic conditions, the global economy, and contribute to increased market volatility, which may in turn adversely affect our business and operations. 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.

In addition, we began the reduction of our internal workforce by 30-35% in April 2023, which was completed by the end of September 2023. As a result of this and other reductions in spend, although our operating expenses from normal business were 30-35% lower in the second half of 2023 as compared with the second half of 2022, there is no assurance that the reductions in spend will result in a continued or sustained overall reduction of our operating expenses.

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

Not applicable.

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, 2023, and 2022, we had cash of \$23,685 and \$62,629, 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, 2023, and 2022 we had long-term debt outstanding of \$55,699 and \$55,699, 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, 2023 was 12.50%. 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, 2023, and December 31, 2022, 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 Corporate 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 Corporate Development concluded that, as of December 31, 2023, 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 Corporate Development assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. 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 Corporate Development determined that, as of December 31, 2023, 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 2024 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this 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, 2023 and 2022](#)
- [Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2023 and 2022](#)
- [Consolidated Statements of Stockholders' Equity - For the Years Ended December 31, 2023 and 2022](#)
- [Consolidated Statements of Cash Flows - For the Years Ended December 31, 2023 and 2022](#)
- [Notes to Consolidated Financial Statements](#)

2. Exhibits

See Index to Exhibits

ITEM 16: FORM 10-K SUMMARY.

Not applicable.



VBI Vaccines Inc.

Table of Contents

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets – December 31, 2023 and 2022	F-4
Consolidated Statements of Operations and Comprehensive Loss - For the Years Ended December 31, 2023 and 2022	F-5
Consolidated Statements of Stockholders' Equity - For the Years Ended December 31, 2023 and 2022	F-6
Consolidated Statements of Cash Flows - For the Years Ended December 31, 2023 and 2022	F-7
Notes to Consolidated Financial Statements	F-8

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, 2023 and 2022, 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, 2023, and 2022, 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, 2023 and cash outflows from operating activities for the year-ended December 31, 2023 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 8 to the financial statements, the Company's consolidated In-Process Research & Development ("IPR&D") indefinite-lived intangible asset balance was approximately \$36.5 million as of December 31, 2023, 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. During the year ended December 31, 2023, the Company identified triggering events that required interim impairment tests to be performed in addition to the annual test. As a result of these impairment tests the Company recorded impairment of \$22.6 million on its IPR&D assets. 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 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 \$2.0 million is included in other current liabilities on the December 31, 2023 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
April 16, 2024

VBI Vaccines Inc. and Subsidiaries

Consolidated Balance Sheets
(in thousands, except share amounts)

	December 31, 2023	December 31, 2022
CURRENT ASSETS		
Cash	\$ 23,685	\$ 62,629
Accounts receivable, net	-	94
Inventory, net	8,499	6,599
Prepaid expenses	2,284	2,309
Other current assets	1,763	6,059
Total current assets	36,231	77,690
NON-CURRENT ASSETS		
Other long-term assets	1,178	1,355
Property and equipment, net	9,665	12,253
Right of use assets	2,248	3,316
Intangible assets, net	36,499	58,345
Goodwill	1,130	2,127
Total non-current assets	50,720	77,396
TOTAL ASSETS	\$ 86,951	\$ 155,086
CURRENT LIABILITIES		
Accounts payable	\$ 6,431	\$ 12,973
Other current liabilities	10,284	22,588
Current portion of deferred revenues	7,276	409
Current portion of lease liability	976	972
Current portion of long-term debt, net of debt discount	50,769	-
Total current liabilities	75,736	36,942
NON-CURRENT LIABILITIES		
Deferred revenues, net of current portion	1,832	2,204
Lease liability, net of current portion	1,295	2,365
Long-term debt, net of debt discount	-	48,888
Liabilities for severance pay	561	524
Total non-current liabilities	3,688	53,981
COMMITMENTS AND CONTINGENCIES (NOTE 17)		
STOCKHOLDERS' EQUITY		
Common shares (unlimited authorized; no par value) (2023 issued and outstanding – 23,918,983; 2022 issued and outstanding – 8,608,539)	454,214	442,312
Additional paid-in capital	107,431	90,020
Accumulated other comprehensive income	28,327	21,440
Accumulated deficit	(582,445)	(489,609)
Total stockholders' equity	7,527	64,163
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 86,951	\$ 155,086

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	
	2023	2022
Revenues, net	\$ 8,682	\$ 1,082
Operating expenses:		
Cost of revenues	12,507	11,276
Research and development	9,343	15,506
Sales, general and administrative	42,143	56,120
Impairment charges	24,600	-
Total operating expenses	88,593	82,902
Loss from operations	(79,911)	(81,820)
Interest expense, net of interest income	(6,401)	(4,007)
Foreign exchange loss	(6,524)	(27,476)
Loss before income taxes	(92,836)	(113,303)
Income tax expense	-	-
NET LOSS	(92,836)	\$ (113,303)
Deemed dividend on certain warrants	(1,005)	-
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS	\$ (93,841)	(113,303)
Other comprehensive income	6,887	23,005
COMPREHENSIVE LOSS	\$ (85,949)	\$ (90,298)
Net loss per share of common shares, basic and diluted	\$ (6.03)	\$ (13.16)
Weighted-average number of common shares outstanding, basic and diluted	15,572,494	8,608,530

See accompanying Notes to Consolidated Financial Statements

VBI Vaccines Inc. and Subsidiaries

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

	<u>Number of Common Shares</u>	<u>Share Capital</u>	<u>Additional Paid-in Capital</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
BALANCE AS OF DECEMBER 31, 2021	8,608,298	\$ 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	241	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	<u>8,608,539</u>	<u>\$ 442,312</u>	<u>\$ 90,020</u>	<u>\$ 21,440</u>	<u>\$ (489,609)</u>	<u>\$ 64,163</u>
Common shares issued in financing transactions, net of issuance costs	15,310,444	22,652	-	-	-	22,652
Warrants issued in connection with financing transactions	-	(10,760)	10,760	-	-	-
Stock-based compensation	-	10	6,651	-	-	6,661
Net loss	-	-	-	-	(92,836)	(92,836)
Currency translation adjustments	-	-	-	6,887	-	6,887
BALANCE AS OF DECEMBER 31, 2023	<u>23,918,983</u>	<u>\$ 454,214</u>	<u>\$ 107,431</u>	<u>\$ 28,327</u>	<u>\$ (582,445)</u>	<u>\$ 7,527</u>

See accompanying Notes to Consolidated Financial Statements

VBI Vaccines Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(in thousands)

	For the Years Ended December 31	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (92,836)	\$ (113,303)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,990	2,061
Stock-based compensation	6,661	9,698
Amortization of debt discount	1,881	1,707
Loss on extinguishment of long-term debt	-	172
Impairment charges	24,600	-
Inventory reserve	1,668	1,186
Change in operating right of use assets	1,408	1,357
Unrealized foreign exchange loss	6,609	27,445
Net change in operating working capital items:		
Change in accounts receivable	99	(87)
Change in inventory	(3,718)	(5,690)
Change in prepaid expenses	17	18
Change in other current assets	4,281	(2,738)
Change in other long-term assets	102	(173)
Change in accounts payable	(6,652)	8,893
Change in deferred revenues	6,356	16
Change in other current liabilities	(11,943)	(2,910)
Payments made on operating lease liabilities	(1,406)	(1,347)
Net cash flows used in operating activities	<u>(60,883)</u>	<u>(73,695)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(867)	(4,344)
Net cash flows used in investing activities	<u>(867)</u>	<u>(4,344)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common shares for cash	24,273	-
Share issuance costs	(1,575)	-
Proceeds from issuance of common shares for cash, upon exercise of stock options	-	12
Proceeds from debt financing	-	20,000
Debt issuance costs	-	(563)
Net cash flows provided by financing activities	<u>22,698</u>	<u>19,449</u>
Effect of exchange rates on cash	<u>108</u>	<u>(475)</u>
CHANGE IN CASH FOR THE YEAR	<u>\$ (38,944)</u>	<u>\$ (59,065)</u>
CASH, BEGINNING OF YEAR	<u>\$ 62,629</u>	<u>\$ 121,694</u>
CASH, END OF YEAR	<u>\$ 23,685</u>	<u>\$ 62,629</u>
Supplementary information:		
Interest paid	\$ 6,130	\$ 3,231
Non-cash investing and financing:		
Adjustments for prior periods from adoption of ASU 2020-06	\$ -	681
Warrants issued in connection with financing transactions	10,760	-
Warrants issued in connection with debt amendment	-	1,550
Capital expenditures included in accounts payable and other current liabilities	142	406
Share issuance costs included in other current liabilities	112	67

See accompanying Notes to Consolidated Financial Statements

VBI Vaccines Inc. and Subsidiaries

Notes to Consolidated Financial Statements
(in thousands except share and per share amounts)

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 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 and a proprietary mRNA-launched eVLP (“MLE”) 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.

2023 Organizational Changes

As announced on April 4, 2023, the Company reduced its internal workforce by 30-35%, which began in April and was completed by the end of September 2023. As a result of this and other reductions in spend, VBI operating expenses, excluding impairment charges, were 30-35% lower in the second half of 2023 as compared with the second half of 2022.

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 \$582,445 and cash of \$23,685 as of December 31, 2023. Cash outflows from operating activities were \$60,883 for the year-ended December 31, 2023.

The Company will require significant additional funds to conduct clinical and non-clinical trials, achieve and maintain regulatory approvals, and commercially launch and sell our approved products. 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. Based on available cash at December 31, 2023, together with the net proceeds from the April 2024 Offering, in order to continue to fund our operations, we must raise additional equity or debt capital in the near term and cannot provide any assurance that we will be successful in doing so. If we are unable to obtain additional financing in the near future, we may be required to pursue a reorganization proceeding, including under applicable bankruptcy or insolvency laws. 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 15.

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"). During the year ended December 31, 2023, the Company issued 1,046,808 common shares under the ATM Program, for total gross proceeds of \$738 at a weighted average price of \$0.7048 per share. The Company incurred \$107 in sales agent commissions and share issuance costs related to the common shares issued during the year ended December 31, 2023, resulting in net proceeds of \$631. As of December 31, 2023, approximately \$124,262 of common shares remained available for issuance under the ATM Program.

Upon filing of this Form 10-K, we will become subject to General Instruction I.B.6 of Form S-3, pursuant to which in no event will we sell our common shares in a registered primary offering using Form S-3 with a value exceeding more than one-third of our public float in any 12 calendar month period so long as our public float remains below \$75,000. Therefore, the amount we may be able to raise using the ATM Program will be significantly less than \$125,000, until such time as our public float held by non-affiliates exceeds \$75,000. The aggregate market value of our outstanding common shares held by non-affiliates as of filing of this Form 10-K, or the public float, is approximately \$25,174, which was calculated based on 27,334,007 common shares outstanding held by non-affiliates and at a price of \$0.9210 per share, the closing price of our common shares on April 8, 2024. As of the date hereof, we have not offered or sold any securities pursuant to General Instruction I.B.6 of Form S-3 during the prior 12 calendar month period that ends on and includes the date hereof.

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 11 for more details. The refinanced long-term debt has a maturity date of September 14, 2026.

On July 5, 2023, the Company announced the expansion of its hepatitis B partnership with Bii Bio. Through (i) a Collaboration and License Agreement (the "Collaboration Agreement"), dated July 5, 2023, by and between the Company and Bii Bio, and (ii) the Amended and Restated Collaboration and License Agreement (the "A&R Collaboration Agreement, which amended and restated the Bii Collaboration and License Agreement, and together with the Collaboration Agreement, the "Bii Collaboration Agreements"), dated July 5, 2023, by and between the Company and Bii Bio, Bii Bio expanded its exclusive license to VBI-2601 to global rights and acquired an exclusive license for PreHevbri in Asia Pacific ("APAC"), excluding Japan. As part of this collaboration, Bii Bio paid the Company an upfront payment of \$15,000 consisting of a \$3,000 equity investment in a concurrent registered direct offering (discussed below), \$5,000 as an advance payment for the clinical and commercial manufacture and supply of VBI-2601 and PreHevbri and any related manufacturing expenditures pursuant to a supply agreement (the "Supply Agreement") dated July 5, 2023, by and between the Company and Bii Bio, and \$7,000 as a non-refundable upfront payment pursuant to the Bii Collaboration Agreements. In addition, pursuant to the Letter Agreement (the "Letter Agreement"), dated July 5, 2023, by and among the Company, SciVac, and Bii Bio, the Company also granted to Bii Bio a security interest, subject to a Subordination Agreement between Bii Bio and K2 HealthVentures LLC ("K2HV"), in all of its respective right, title, and interest in and to all intellectual property, know-how, and licenses to the extent related to PreHevbri and VBI-2601, and all proceeds of the foregoing, in order to secure performance of all of the Company's obligations under the Bii Collaboration Agreements, the Supply Agreement, and the Loan Agreement (as defined herein).

In July 2023, the Company closed (i) an underwritten public offering of 12,445,454 common shares and accompanying common warrants to purchase up to 12,545,454 common shares (which included 1,536,363 common shares and common warrants to purchase up to 1,636,363 common shares issued pursuant to the underwriters' partial exercise of their option to purchase additional common shares and common warrants) at a combined public offering price of \$1.65 per common share and accompanying common warrant, and (ii) a concurrent registered direct offering, pursuant to the expanded hepatitis B partnership with Brii Bio, of 1,818,182 common shares and accompanying common warrants to purchase up to 1,818,182 common shares, at a combined purchase price of \$1.65 per share and accompanying common warrant. The accompanying common warrants issued and sold in each of the underwritten public offering and the registered direct offering have an initial exercise price of \$1.65 per share, which, pursuant to certain anti-dilution provisions of the warrants, was reduced to \$0.6057 per share, as of December 31, 2023, and expire five years from the date of issuance. The aggregate gross proceeds from the underwritten public offering, including aggregate gross proceeds from the underwriters' exercise of their option to purchase additional securities, were \$20,500. The aggregate gross proceeds from the concurrent registered direct offering were \$3,000.

As of December 31, 2023, the Company had outstanding warrants to purchase up to an aggregate of 14,363,636 common shares, issued in July 2023. Pursuant to certain anti-dilution provisions of the warrants, as the consideration paid per common share under the ATM Program was less than the exercise price of such warrants in effect immediately prior to such issuance ("New Issuance Price"), the exercise price of the warrants (the "Exercise Price") was reduced to the New Issuance Price. As of December 31, 2023, the Exercise Price in effect was \$0.6057 per share, which resulted in a deemed dividend of \$1,005 as the fair value of the warrants was greater subsequent to the reduction in Exercise Price than it was immediately prior to such reduction in Exercise Price. The fair values were determined using the Black-Scholes option pricing model.

On November 1, 2023, the Company received a letter from the Listing Qualifications Department of the Nasdaq Capital Market's ("Nasdaq") indicating that, based upon the closing bid price of the Company's common shares for the 30 consecutive business day period between September 19, 2023 through October 31, 2023, it 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 letter also indicated that the Company will be provided with a compliance period of 180 calendar days, or until April 29, 2024 (the "Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

In order to regain compliance with Nasdaq's minimum bid price requirement, the common shares must maintain a minimum closing bid price of \$1.00 for a minimum of ten consecutive business days during the Compliance Period. In the event that the Company does not regain compliance by the end of the Compliance Period, it may be eligible for additional time to regain compliance. To qualify, the Company will be required to meet the continued listing requirement for the market value of our publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split if necessary. If we meet these requirements, the Company may be granted an additional 180 calendar days to regain compliance. The Company has not regained compliance as of the date of this Form 10-K, and if it fails to regain compliance during the Compliance Period or any subsequent grace period granted by Nasdaq, its common shares will be subject to delisting by Nasdaq, which could seriously decrease or eliminate the value of an investment in the common shares and result in significantly increased uncertainty as to the Company's ability to raise additional capital.

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.

Reverse Stock Split

On April 12, 2023, VBI effected a 1-for-30 reverse stock split (the “Reverse Stock Split”) of its issued and outstanding common shares, pursuant to which every 30 of VBI’s issued and outstanding common shares were automatically converted into one common share without any change in the par value per share. All share and per share amounts, including common shares underlying stock options, restricted stock units, and warrants, and applicable exercise prices, have been retroactively adjusted for all periods presented herein to give effect to the Reverse Stock Split as required in accordance with United States of America generally accepted accounting principles (“U.S. GAAP”). Per the requirements of the Business Corporations Act (British Columbia), under which the Company is regulated, if fractional shares held by registered shareholders were to be converted into whole shares, each fractional share remaining after the completion of the Reverse Stock Split that was less than half of a share was cancelled and each fractional share that was at least half of a share was rounded up to one whole share. No shareholders received cash in lieu of fractional shares.

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 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, 2023 and 2022.

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 the fair value of the asset. If the carrying amount of the asset exceeds the fair value of the asset, then an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

See Notes 6 and 7 for more details on impairment testing on property and equipment for the year ended December 31, 2023.

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. See Note 6 and 8 for more details on impairment testing for the year ended December 31, 2023.

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. See Note 6 and 8 for more details on impairment testing for the year ended December 31, 2023.

Restructuring charges

Restructuring costs include charges associated with exit or disposal activities that meet the definition of restructuring under FASB ASC Topic 420, Exit or Disposal Cost Obligations ("ASC 420"). The Company's restructuring plans are typically completed within a one-year period or less. Restructuring costs incurred under these plans may include (i) one-time termination benefits related to employee separations, (ii) contract termination costs, and (iii) other related costs associated with exit or disposal activities including, but not limited to, costs for consolidating or closing facilities.

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, 2023, 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 \$3,601. See more information on the CEPI Funding Agreement in Note 15.

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 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, 2023 and 2022. 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 \$48,077 and \$56,510 at December 31, 2023 and 2022, 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, 2023 and 2022.

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

Credit Losses

In June 2016, the FASB issued Accounting Standards Update ("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. Our adoption of this ASU, effective January 1, 2023, did not have a material impact on our consolidated financial statements and the related footnote disclosures.

Debt with Conversions and Other Options

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.

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

Income Taxes

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (“ASU 2023-09”) which enhances the transparency and decision usefulness of income tax disclosures. The amendments under ASU 2023-09 require public business entities to annually (1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income or loss by the applicable statutory income tax rate). ASU 2023-09 will be effective for fiscal years beginning after December 15, 2024. Public business entities are permitted to early adopt the standard for annual financial statements that have not yet been issued or made available for issuance. The Company will apply this ASU for year ended December 31, 2025 and we do not anticipate that this new guidance will have a material impact on the note disclosures going forward.

4. INVENTORY, NET

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

	2023	2022
Finished goods	\$ 1,661	\$ 893
Work-in-process	2,734	1,869
Raw materials	4,104	3,837
	<u>\$ 8,499</u>	<u>\$ 6,599</u>

The Company recorded a provision of approximately \$1,668 and \$1,186 during the years ended December 31, 2023 and 2022, 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:

	2023	2022
Government receivables	\$ 1,268	\$ 4,033
Other current assets	495	2,026
	<u>\$ 1,763</u>	<u>\$ 6,059</u>

6. IMPAIRMENT CHARGES

The drop in market conditions experienced in April 2023, September 2023, and October 2023 were considered triggering events for interim impairment tests for property and equipment, In-Process Research and Development ("IPR&D") and goodwill. The impairment test compares the carrying amount of the assets to their respective fair values. If the carrying amount exceeds the fair value of the assets, such excess is recorded as an impairment charge.

Impairment charges consist of the following:

	2023	2022
Property and equipment (Note 7)	\$ 1,000	\$ -
IPR&D (Note 8)	22,600	-
Goodwill (Note 8)	1,000	-
	<u>\$ 24,600</u>	<u>\$ -</u>

7. PROPERTY AND EQUIPMENT

	2023		
	Cost	Accumulated Depreciation	Net Book Value
Machinery and equipment	\$ 7,328	\$ (4,399)	\$ 2,929
Furniture and office equipment	596	(216)	380
Computer equipment and software	1,206	(885)	321
Leasehold improvements	10,922	(4,887)	6,035
	<u>20,052</u>	<u>\$ (10,387)</u>	<u>\$ 9,665</u>

	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
	<u>\$ 20,234</u>	<u>\$ (7,981)</u>	<u>\$ 12,253</u>

Related depreciation expense for the years ended December 31, 2023 and 2022 was \$1,990 and \$2,009, respectively.

As discussed above, in April 2023, the Company performed an interim impairment test. The fair value of the property and equipment's assets included in the impairment test was determined using a combination of the market approach and the cost approach 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 the property and equipment include: 1) current market prices; 2) cost to replace the assets; and 3) factors to account for obsolescence. The Company recorded an impairment of property and equipment of \$1,000 as a result of its interim impairment test performed as of April 30, 2023. The Company considered the further decline in market conditions in September 2023 and October 2023 to be an additional triggering events for additional interim impairment tests to be performed, which such tests resulted in no further impairment as of September 30, 2023 and October 31, 2023.

8. INTANGIBLE ASSETS AND GOODWILL

	Gross Carrying Amount	Accumulated Amortization	2023		
			Cumulative Impairment Charge	Cumulative Currency Translation	Net Book Value
IPR&D assets	\$ 61,500	\$ -	\$ (22,900)	\$ (2,101)	\$ 36,499

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

The Company's intangible assets determined to have indefinite useful lives, IPR&D and goodwill, are tested for impairment annually, or more frequently if events or circumstances indicate that the assets might be impaired. As discussed above, in April 2023, the Company performed an interim impairment test. The IPR&D assets, consisting of the CMV and GBM programs acquired in a business combination (the 2016 merger between VBI and SciVac), are 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 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: 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 15% and the cumulative probability of technical and regulatory success to achieve approval to market the products ranged from approximately 10% to 17%. During the second quarter of 2023, the Company recorded an impairment of IPR&D of \$19,000, as a partial impairment to the congenital CMV asset, as a result of its interim impairment test performed as of April 30, 2023. The Company performed its annual test as of August 31, 2023 and determined there was no additional IPR&D impairment. The methodology and significant estimates and assumptions used in determining the fair value of the IPR&D assets as of August 31, 2023 were the same as the interim impairment test performed as of April 30, 2023. As discussed above, the Company considered the further decline in market conditions in September 2023 to be an additional triggering event for the second interim impairment test to be performed. During the third quarter of 2023, the Company recorded an impairment of IPR&D of \$3,600, as a partial impairment to the congenital CMV asset, as a result of its interim impairment test performed as of September 30, 2023. The methodology and significant estimates and assumptions used in determining the fair value of the IPR&D assets as of September 30, 2023 were the same as the annual impairment test, other than the discount rate. This discount rate used was 25%. In October 2023, the Company considered a further decline in market conditions to be a triggering event for a third interim impairment test to be performed. There was no additional impairment as a result of the impairment test performed as of October 31, 2023. The methodology and significant estimates and assumptions used in determining the fair value of the IPR&D assets as of October 31, 2023 were the same as the interim impairment test performed as of September 30, 2023.

During the year ended December 31, 2023, the Company recorded an impairment of IPR&D of \$22,600, as a partial impairment to the congenital CMV asset, as a result of its impairment tests performed.

The IPR&D assets are in VBI Cda and the change in carrying value for IPR&D assets from December 31, 2022, relates to currency translation adjustments which increased by \$754 for the year ended December 31, 2023, excluding the effect of the impairment charge of \$22,600. The change in carrying value from December 31, 2021 to December 31, 2022 relates to currency translation adjustments which decreased IPR&D assets by \$3,690.

	Gross Carrying Amount	2023		
		Cumulative Impairment Charge	Cumulative Currency Translation	Net Book Value
Goodwill	\$ 8,714	\$ (7,292)	\$ (292)	\$ 1,130

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

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 performed 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 interim impairment test performed as of April 30, 2023, its annual impairment test performed as of August 31, 2023, and the second interim impairment test performed as of September 30, 2023. As discussed above, the Company considered the further decline in market conditions in October 2023 to be an additional triggering event for the third interim impairment test to be performed. During the fourth quarter of 2023, the Company recorded an impairment of goodwill of \$1,000 as a result of its interim impairment test performed as of October 31, 2023. The Company consists of a single reporting unit and uses its market capitalization to determine the fair value of the reporting unit. In order to determine the market capitalization, the Company used the trailing 20-day volume weighted average price of its shares as of October 31, 2023.

The goodwill is in VBI Cda and the change in carrying value from December 31, 2022 relates to currency translation adjustments which increased goodwill by \$3 for the year ended December 31, 2023, excluding the effect of the impairment charge of \$1,000. The change in carrying value for goodwill from December 31, 2021 relates to currency translation adjustments which decreased by \$134 for the year ended December 31, 2022.

9. OTHER CURRENT LIABILITIES

Other current liabilities consisted of the following:

	2023	2022
Accrued research and development expenses (including clinical trial accrued expenses)	\$ 2,018	\$ 6,561
Accrued professional fees	1,674	3,250
Payroll and employee-related costs	1,934	4,036
Deferred funding	3,601	6,966
Other current liabilities	1,057	1,775
	<u>\$ 10,284</u>	<u>\$ 22,588</u>

Included in payroll and employee-related costs are one time termination benefits as a result of our organizational changes which took place mostly in the second quarter of 2023, as discussed in Note 1. The Company did not incur contract termination costs or other related costs.

The Company did not incur significant charges in one-time termination benefits during the year ended December 31, 2022.

The following table presents changes in one-time termination benefits during the year ended December 31, 2023.

Accrued balance at January 1, 2023	\$	-
Charges		759
Cash payments		(759)
Accrued balance at December 31, 2023	\$	-

The restructuring charges are included in cost of revenues, research and development and sales, general and administrative in the consolidated statements of operations and comprehensive loss.

10. 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 13, Stockholders' Equity and Additional Paid-in Capital.

The following potentially dilutive securities outstanding at December 31, 2023 and 2022 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	2023	2022
Warrants	14,467,566	118,816
Stock options and unvested stock awards	1,650,288	761,314
K2HV conversion feature	205,396	205,396
	<u>16,323,250</u>	<u>1,085,526</u>

11. LONG-TERM DEBT

	2023	2022
Long-term debt, net of debt discount of \$4,930 (\$6,811 at December 31, 2022)	\$ 50,769	\$ 48,888
Current portion, net of debt discount of \$4,930 (\$0 at December 31, 2022)	(50,769)	-
	<u>\$ -</u>	<u>\$ 48,888</u>

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 \$43.80 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 45,662 common shares at a conversion price of \$43.80 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 additional tranches subject to the achievement of milestones and other customary conditions, (ii) add certain minimum net revenue covenants, (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 next tranche of term loans of up to \$10,000 will be available from April 1, 2024, through June 30, 2024, so long as certain milestones are achieved, no events of default under the Loan Agreement have occurred and are continuing, and the Liquidity Requirement is satisfied. The final 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 45,662 common shares at a conversion price of \$43.80 per share and \$5,000 of the term loans shall be convertible into 159,734 common shares at a conversion price of \$31.302 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 20,833 common shares (the "Original K2HV Warrant") at an exercise price of \$33.60 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 10,417 common shares for a total of 31,250 common shares (the "First Amendment Warrant") with the same exercise price of \$33.60 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 72,680 common shares (the "Second Amendment Warrant") with a warrant exercise price of \$24.08 per share. If and/or when additional tranches are advanced pursuant to the Second Amendment, the Company will issue additional warrants to purchase up to 72,680 common shares 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 various 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 applicable tranche actually funded multiplied by 3.5% and divided by the warrant exercise price of \$24.08, 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 minimus 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 as of December 31, 2023, 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, 2023 was 12.50%. The effective interest rate on the loan of \$50,000, excluding the Original Final Payment and Second Amendment Final Payment, is 16.13%.

The secured term loan maturity date is September 14, 2026, until which the Company is required to pay only interest, or if the milestone for the next tranche of the term loans has been achieved, September 14, 2027. The Loan Agreement, as amended by the Second Amendment, included both financial and non-financial covenants, including quarterly minimum Net Revenue (as defined in the Loan Agreement) targets. The Company was not in compliance with the minimum Net Revenue covenant for the measurement periods ended September 30, 2023 and December 31, 2023, and did not qualify for an exception for this covenant, which constituted an Event of Default (as defined in the Loan Agreement). In anticipation of K2HV declaring an Event of Default as a result of such failure to comply with the Net Revenue covenant, the Company began discussions with K2HV with respect to possible forbearance and other remedies. On October 27, 2023, the Borrowers and K2HV entered into an extension agreement (the “Extension Agreement”), pursuant to which the due date for the Company to deliver the compliance certificate for the period ending September 30, 2023, pursuant to the Loan Agreement, was extended from October 30, 2023, to November 6, 2023, which date was extended again from November 6, 2023, to November 13, 2023, pursuant to a subsequent letter agreement dated November 3, 2023. Pursuant to the Extension Agreement, as amended, K2HV agreed to refrain from declaring an Event of Default under the Loan Agreement and/or the Loan Documents (as defined in the Loan Agreement) prior to November 13, 2023.

On November 13, 2023, the Borrowers entered into a forbearance agreement with the Lenders (the “Forbearance Agreement”), pursuant to which the Lenders agreed to forbear from exercising the Secured Parties’ (as defined in the Loan Agreement) rights with respect to the failure to meet the minimum Net Revenue covenant for the measurement periods ended September 30, 2023, from November 13, 2023, through and including November 28, 2023 (the “Forbearance Period”), subject to compliance by the Borrowers with certain terms and conditions as set forth in the Forbearance Agreement. Such conditions include delivery of cash flow budget and adherence reports, and adherence with such budget and cash flow forecast. On each of November 28, 2023, December 12, 2023, December 26, 2023, January 9, 2024, January 23, 2024, and February 6, 2024, the Loan Parties entered into extensions to the Forbearance Agreement pursuant to which the Lenders agreed to extend the Forbearance Period through and including December 12, 2023, December 26, 2023, January 9, 2024, January 23, 2024, February 6, 2024, and February 20, 2024, respectively, subject to compliance by the Borrowers with the same terms and conditions as set forth in the Forbearance Agreement.

The obligations under the Loan Agreement as amended by the Third Amendment (as defined below) are secured on a senior basis by a lien on substantially all of the assets of the Company and its subsidiaries. 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.

On July 5, 2023, the Borrowers and K2HV entered into (i) an amendment (the “Third Amendment”) to the Loan Agreement, and (ii) an amendment to the Pledge and Security Agreement, dated May 22, 2020, by and among the Company, VBI DE, VBI Cda, K2HV, and Ankura Trust Company, LLC, as collateral trustee for the lenders, pursuant to which the parties have agreed to permit the Bii Collaboration Agreements, the Supply Agreement, and the Letter Agreement, SciVac and Bii Bio. The Company granted to K2HV a security interest in, all of its respective right, title, and interest in and to substantially all of the Company’s intellectual property. In addition, among others, any breach, default or other triggering event by the Company occurring under the Bii Collaboration Agreements resulting in Bii Bio exercising a right to terminate the Bii Collaboration Agreements, will cross default the Third Amendment.

On February 13, 2024, the Loan Parties entered into an amendment (the “Fourth Amendment”) to the Loan Agreement, effective upon entry into certain transactions with Bii Bio, pursuant to which the parties have agreed to, among other things, (i) remove a financial covenant requiring us to maintain minimum net revenue of 75% of projections, (ii) the forbearance by K2HV and the other lenders party thereto, prior to the earlier of (A) December 31, 2024, (B) the date the Side Letter (as defined below) ceases to be in full force and effect prior to the completion of the Essential Activities (as defined below) and (C) the date the Essential Activities (as defined below) are complete (the “Forbearance Expiration Date”) from exercising their remedies with respect to the occurrence of Events of Default (as defined in the Loan Agreement) subject to certain exceptions, and (iii) following the Forbearance Expiration Date, add a financial covenant requiring us to maintain a minimum cash amount equal to our obligations under the Loan Agreement at all times.

The effectiveness of the Fourth Amendment was conditioned upon entry into the Bii Purchase Agreement, the Rehovot Purchase Agreement and the Side Letter (each as defined herein), each of which were entered into by us and the respective parties thereto on February 13, 2024, as described above.

The total initial debt discount related to the Second Amendment is \$7,359, as of December 31, 2023 the unamortized debt discount was \$4,930. 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 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 years ended December 31, 2023 and 2022 was as follows:

	2023	2022
Interest expense	\$ 6,183	\$ 3,515
Amortization of debt discount	1,881	1,707
Extinguishment loss	-	172
Interest income	(1,663)	(1,387)
	<u>\$ 6,401</u>	<u>\$ 4,007</u>

12. 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. 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. The total expense recognized for the years ended December 31, 2023 and 2022 was \$179 and \$170, 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, 2023 and 2022 was \$393 and \$442, 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 years ended December 31, 2023 and 2022 was \$106 and \$5, respectively.

13. STOCKHOLDERS' EQUITY AND ADDITIONAL PAID-IN CAPITAL

Authorized

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

Common Shares Issuances

2023 common share issuances were as follows:

- i. In July 2023, the Company closed an underwritten public offering of 12,445,454 common shares at a price of \$1.65 per share for total gross proceeds of \$20,500;
- ii. On July 5, 2023, the Company closed a registered direct offering of 1,818,182 common shares at a price of \$1.65 per share for total gross proceeds of \$3,000;
- iii. During the second half of the year ended December 31, 2023, as part of the ATM Program, the Company issued 1,046,808 common shares for total gross proceeds of \$738 at an average price of \$0.7048

2022 common share issuances were as follows:

- i. On January 10, 2022, the Company issued 241 common shares upon exercise of stock options at an average exercise price of \$49.43 for gross proceeds of \$12.

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, 2023, there were 28,038 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, 2023, there were 17,195 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, 2023, there were 1,605,055 options outstanding and no 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 692,820 at December 31, 2023.

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, 2023 and 2022.

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 therefore, as of the date such notice of termination is given.

Share Units

The Board of Directors may grant share units, which include RSUs and PSUs, to Eligible Persons on such terms and conditions consistent with the 2016 Plan.

The Board will determine the grant value and the valuation date for each grant of share units. The number of share units to be covered by each grant will be determined by dividing the grant value for such grant by the market value of a common share as of the valuation date, rounded up to the next whole number.

Share units subject to a grant will vest as specified in the grant agreement governing such grant, provided that the participant is employed on the relevant vesting date. RSUs and PSUs will be settled upon, or as soon as reasonably practicable following the vesting thereof, subject to the terms of the grant agreement. In all events, RSUs and PSUs will be settled on or before the earlier of the 90th day following the vesting date and the date that is 2 ½ months after the end of the year in which the vesting occurred. Settlement will be made by way of issuance of one common share for each RSU or PSU, a cash payment equal to the market value of the RSUs or PSUs being settled, or a combination thereof. If the share units would be settled within a blackout period, such settlement will be postponed until the earlier of the 6th trading day following the end of such blackout period and the otherwise applicable date of settlement as determined in accordance with the settlement provision set out above. The Company has not issued any PSUs under this plan at December 31, 2023 and 2022. All RSUs issued under the 2016 Plan at December 31, 2023 and 2022 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, 2023.

Stock-Based Compensation Expense

The table below provides information, as of December 31, 2023, 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	28,038	\$ 126.49
2014 Plan	17,195	151.53
2016 Plan	1,605,055	27.56
	<u>1,650,288</u>	<u>\$ 30.53</u>

Activity related to stock options is as follows:

	Number of Stock Options	Weighted Average Exercise Price
Balance outstanding at December 31, 2021	617,655	\$ 78.90
Granted	171,292	45.24
Exercised	(241)	49.43
Forfeited	(27,474)	77.61
Balance outstanding at December 31, 2022	<u>761,232</u>	<u>\$ 71.26</u>
Granted	993,643	2.02
Forfeited	(104,587)	56.52
Balance outstanding at December 31, 2023	<u>1,650,288</u>	<u>\$ 30.53</u>
Exercisable at December 31, 2023	<u>718,513</u>	<u>\$ 63.81</u>

Exercise Price	Outstanding		Exercisable	
	Number Of Options	Weighted Average Remaining Contractual Life (Years)	Number Of Options	Weighted Average Exercise Price
\$ 0.00 – 0.99	-	-	-	\$ -
1.00 – 1.99	932,500	9.58	94,790	1.30
2.00 – 2.99	8,000	9.33	1,777	2.49
3.00+	709,788	6.32	621,946	73.51
	<u>1,650,288</u>	<u>8.17</u>	<u>718,513</u>	<u>\$ 63.81</u>

The weighted average remaining contractual life of exercisable options was years 6.50 and 6.54 years at December 31, 2023 and 2022, 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, 2021	1,304	\$ 44.10
Vested	(1,199)	44.40
Forfeited	(23)	43.80
Unvested shares outstanding at December 31, 2022	82	\$ 43.80
Vested	(82)	43.80
Unvested shares outstanding at December 31, 2023	-	\$ -

The intrinsic value of outstanding options at December 31, 2023 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 \$0 for the year ended December 31, 2023. There were no options exercised for the year ended December 31, 2023. There were 241 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.

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:

	2023	2022
Volatility	112.44%	93.23%
Risk free interest rate	4.17%	1.75%
Expected term in years	5.74	5.83
Expected dividend yield	0.00%	0.00%
Weighted average fair value per option	\$ 1.65	\$ 33.90

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:

	2023	2022
Research and development	\$ 872	\$ 1,998
General and administration	5,699	7,585
Cost of revenue	90	115
	<u>\$ 6,661</u>	<u>\$ 9,698</u>

There is \$2,684 of unrecognized compensation from all equity awards as of December 31, 2023. This expense will be recognized over a weighted average period of 1.52 years.

Warrants

On September 14, 2022, in connection with the Second Amendment, as described in Note 11, 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.

In July 2023, in connection with the underwritten public offering and registered direct offering, the Company issued common warrants to purchase 14,363,636 common shares with an exercise price of \$1.65. Pursuant to certain anti-dilution provisions of the common warrants, as the consideration paid per common share under the ATM Program was less than the exercise price of such common warrants in effect immediately prior to such issuance (“New Issuance Price”), the exercise price of the warrants (the “Exercise Price”) was reduced to the New Issuance Price. As of December 31, 2023, the Exercise Price in effect was \$0.6057 per share, which resulted in a deemed dividend of \$1,005 as the fair value of the common warrants was greater subsequent to the reduction in Exercise Price than it was immediately prior to such reduction in Exercise Price. The fair values were determined using the Black-Scholes option pricing model.

The value attributed to the common warrants, on date of issuance, was based on the Black-Scholes option pricing model by applying the following assumptions:

	Common warrant
Volatility	118.94%
Risk free interest rate	4.25%
Expected term in years	5
Expected dividend yield	0.00%
Fair value per warrant	\$ 1.38

Activity related to the warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance outstanding at December 31, 2021	46,136	\$ 37.28
Issued	72,680	24.08
Balance outstanding at December 31, 2022	118,816	\$ 29.20
Expired	(14,886)	45.00
Issued	14,363,636	0.61
Balance outstanding at December 31, 2023	14,467,566	\$ 0.79

14. REVENUE, NET AND DEFERRED REVENUE

Revenue, net comprises of the following:

	2023	2022
Product revenue, net	\$ 3,107	\$ 931
License revenue	3,596	-
R&D Service revenue	1,979	151
	<u>\$ 8,682</u>	<u>\$ 1,082</u>

Cost of revenues for the year ended December 31, 2023, for product revenue and R&D services revenue was \$12,507 and de minimis, respectively. Cost of revenues for the year ended December 31, 2022, for product revenue and R&D services revenue was \$11,235 and \$41, 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, 2023:

	Total	2024	2025 and thereafter
Product revenue, net	\$ 5,116	\$ 5,116	\$ -
R&D Service revenue	3,992	2,160	1,832
	<u>\$ 9,108</u>	<u>\$ 7,276</u>	<u>\$ 1,832</u>

The following table presents changes in the deferred revenue balance for the year ended December 31, 2023:

Balance at January 1, 2022	\$ 2,803
Balance at December 31, 2022	\$ 2,613
Amounts received	8,056
Recognition of deferred revenue	(1,952)
Currency translation	391
Balance at December 31, 2023	<u>\$ 9,108</u>
Short Term	\$ 7,276
Long Term	<u>\$ 1,832</u>

Brii Collaboration Agreements – VBI-2601

On December 4, 2018, the Company entered into a Collaboration and License Agreement (the “Brii Collaboration and License Agreement”) with Brii Bio, as amended on April 8, 2021, pursuant to which:

- 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; and
- 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 Bii Bio further amended the Bii Collaboration and License Agreement (the “Bii Second Amendment Collaboration and License Agreement”) whereby:

- the Company and Bii 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
- Bii Bio granted the Company a non-exclusive royalty free license under the Bii 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 Bii Collaboration and License Agreement, as amended by the Bii Second Amendment Collaboration and License Agreement, the Company was responsible for the R&D Services and Bii Bio was responsible for costs relating to the clinical trials for the Licensed Territory.

The initial consideration of the Bii Collaboration and License Agreement consisted of an \$11,000 non-refundable upfront payment. As part of the Bii Collaboration and License Agreement, the Company and Bii Bio entered into a stock purchase agreement. Under the terms of the stock purchase agreement, the Company issued to Bii Bio 76,502 of its common shares valued at \$3,626 (based on the Company’s common share 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 Bii Second Amendment Collaboration and License Agreement.

On July 5, 2023, the Company and Bii Bio entered into the A&R Collaboration Agreement, to, among other things, and subject to the terms and conditions set forth in the A&R Collaboration Agreement, expand the Licensed Territory to the entire world (the “New Licensed Territory”) for Bii Bio’s exclusive rights and licenses to make, have made, use, sell, offer for sale, and import VBI-2601 (“VBI-2601 Licensed Product”). Pursuant to the A&R Collaboration Agreement, the Company granted Bii Bio an exclusive royalty-bearing license, with the right to grant sublicenses through multiple tiers, to (i) perform studies, regulatory and other activities, as may be required to obtain and maintain marketing approval of the VBI-2601 Licensed Products in the New Licensed Territory; and (ii) research, develop, make, have made, distribute, use, sell, offer for sale, have sold, import, export or otherwise commercialize the VBI-2601 Licensed Products for the field of the diagnosis and treatment of hepatitis B in the New Licensed Territory. Except for the rights and licenses expressly granted in the A&R Collaboration Agreement, the Company and Bii Bio retained all rights under their respective intellectual property. Additionally, the A&R Collaboration Agreement constitutes the entire agreement between the VBI and Bii Bio relating to VBI-2601 and supersedes all previous agreements, including the Bii Collaboration and License Agreement and the Bii Second Amendment Collaboration and License Agreement. As a result of the A&R Collaboration Agreement, the unsatisfied performance obligation of \$1,925 under the Bii Collaboration and License Agreement prior to the amendment and restatement was immediately recognized as R&D service revenues during the year ended December 31, 2023.

The initial consideration of the A&R Collaboration Agreement consisted of a \$5,000 non-refundable upfront payment. In addition, prior to the purchase agreement, dated February 13, 2024 (see details below and Note 21), by and between the Company and Bii Bio (the “Bii Purchase Agreement”), the Company was also eligible to receive up to an additional \$227,000 in potential regulatory and net sales milestone payments, along with up to double-digit royalties on commercial sales in the New 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 were recognized under the A&R Collaboration Agreement or have been recognized under the A&R Collaboration Agreement. The \$5,000 of initial consideration of the A&R Collaboration Agreement was allocated to three performance obligations: (i) the VBI-2601 license for the New Licensed Territory; (ii) R&D services related to VBI-2601; and (iii) the technology transfer of VBI-2601. The initial consideration of \$5,000 was allocated as follows: R&D services were allocated \$43, the technology transfer was allocated \$1,597, both performance obligations using an estimated selling price based on an expected cost-plus margin approach, and the residual consideration of \$3,360 was allocated to the VBI-2601 license for the New Licensed Territory.

The A&R Collaboration Agreement will be in effect on a region-by-region basis until the last-to-expire of the latest of the following terms in each region of the New Licensed Territory: (i) expiration, invalidation or lapse of the last Company patent claiming such VBI-2601 Licensed Product, (ii) 10 years from the date of first commercial sale of such VBI-2601 Licensed Product in the applicable region, or (iii) termination or expiration of the Company's obligation to pay third party royalties with respect to sales of such VBI-2601 Licensed Product in such region. Upon expiration (but not an earlier termination) of the A&R Collaboration Agreement in each region of the New Licensed Territory, the Company will grant Bii Bio a perpetual, non-exclusive, fully paid-up, royalty free license, which such license, pursuant to the Bii Purchase Agreement (as defined herein), shall also be irrevocable under the Company's technology related to the VBI-2601 Licensed Products in such region to make and sell VBI-2601 Licensed Products for the field of the diagnosis and treatment of hepatitis B in such region.

Pursuant to the Bii Purchase Agreement, on February 13, 2024, the Company and Bii Bio agreed to amend the A&R Collaboration Agreement to, among other things, subject to the terms and conditions set forth in the A&R Collaboration Agreement, (i) amend the terms the royalty bearing license granted by the Company to Bii Bio for research studies and development of VBI-2601 to be "perpetual and irrevocable", (ii) omit the requirement for Bii Bio to obtain marketing approval and commercialize VBI-2601 in the United States and China, (iii) revise the indemnity requirements such that Bii Bio indemnifies the Company with respect to certain transferred intellectual property after the effective date of the Bii Purchase Agreement and the Company indemnifies Bii Bio prior to such date, (iv) omit the requirement for Bii Bio to make royalty and milestone payments to the Company and (v) omit certain rights of the Company to terminate the A&R Collaboration Agreement and certain other effects of termination of the A&R Collaboration Agreement.

Bii Collaboration Agreements – PreHevbri

On July 5, 2023, the Company and Bii Bio also entered into the Collaboration Agreement, to, among other things, and subject to the terms and conditions set forth in the Collaboration Agreement, acquired an exclusive license for PreHevbri in APAC, excluding Japan ("PreHevbri Licensed Territory"), for Bii Bio's exclusive rights and licenses to make, have made, use, sell, offer for sale, and import PreHevbri ("PreHevbri Licensed Product"). Pursuant to the Collaboration Agreement, the Company granted Bii Bio an exclusive royalty-bearing license, with the right to grant sublicenses through multiple tiers, to (i) perform studies, regulatory and other activities, as may be required to obtain and maintain marketing approval of the PreHevbri Licensed Products in the PreHevbri Licensed Territory; and (ii) research, develop, make, have made, distribute, use, sell, offer for sale, have sold, import, export or otherwise commercialize the PreHevbri Licensed Products for the field of the diagnosis and treatment of hepatitis B in the PreHevbri Licensed Territory. Except for the rights and licenses expressly granted in the Collaboration Agreement, the Company and Bii Bio retained all rights under their respective intellectual property.

The initial consideration of the Collaboration Agreement consisted of a \$2,000 non-refundable upfront payment. In addition, the Company was also eligible to receive up to an additional \$195,000 in potential regulatory and net sales milestone payments, along with up to double-digit royalties on commercial sales in the PreHevbri Licensed Territory, prior to the Bii Purchase Agreement. 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 were recognized under the Collaboration Agreement or have been recognized under the Collaboration Agreement. The \$2,000 of the initial consideration of the Collaboration Agreement was allocated to three performance obligations: (i) the PreHevbri license for the PreHevbri Licensed Territory; (ii) R&D services related to PreHevbri; and (iii) the technology transfer of PreHevbri. The initial consideration of \$2,000 was allocated as follows: the R&D services were allocated \$88, the technology transfer was allocated \$1,597, both performance obligations using an estimated selling price based on an expected cost-plus margin approach, and the residual consideration of \$315 was allocated to the PreHevbri license for the PreHevbri Licensed Territory.

The Collaboration Agreement will be in effect on a region-by-region basis until the last-to-expire of the latest of the following terms in each region of the New Licensed Territory: (i) 10 years from the date of first commercial sale of such PreHevbri Licensed Product in the applicable region, or (ii) termination or expiration of the Company's obligation to pay third party royalties with respect to sales of such PreHevbri Licensed Product in such region. Upon expiration (but not an earlier termination) of the Collaboration Agreement in each region of the PreHevbri Licensed Territory, the Company will grant Bii Bio a perpetual, non-exclusive, fully paid-up, royalty free license, which such license, pursuant to the Bii Purchase Agreement, shall also be irrevocable, under the Company's technology related to the PreHevbri Licensed Products in such region to make and sell PreHevbri Licensed Products for the field of the diagnosis and treatment of hepatitis B in such region.

Pursuant to the Bii Purchase Agreement, on February 13, 2024, the Company and Bii Bio agreed to amend the Collaboration Agreement to, among other things, subject to the terms and conditions set forth in the Collaboration Agreement, (i) amend the terms of the royalty bearing license granted by the Company to Bii Bio for the global development activities of the Licensed Product to be "perpetual and irrevocable", (ii) omit the requirement for Bii Bio to obtain marketing approval for the Licensed Product in certain territories and (iii) omit the requirement for Bii Bio to make royalty and milestone payments to the Company.

The R&D services and technology transfer for the Bii Collaboration Agreements 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.

Upon termination of the Bii Collaboration Agreements 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.

Supply Agreement

On July 5, 2023, in connection with the Bii Collaboration Agreements, the Company and Bii Bio entered into the Supply Agreement related to the clinical and commercial manufacture and supply of VBI-2601 and PreHevbri and any related manufacturing expenditures, as negotiated. Pursuant to the Supply Agreement, the Company received an advance payment of \$5,000 from Bii Bio. The advance payment of \$5,000 will be allocated to the following performance obligations, depending on which performance obligation is requested by Bii Bio, until the advance payment of \$5,000 has been fully utilized: (i) units of VBI-2601 and/or PreHevbri; and (ii) manufacturing expenditures. The advance payment of \$5,000 is included in deferred revenue as of December 31, 2023.

The performance obligation of a unit of VBI-2601 and/or PreHevbri will be satisfied at a point in time using the prices set out in the Supply Agreement and revenue will be recognized upon transfer of control of the performance obligation.

The manufacturing expenditures 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, 2023, performance obligations related to the Bii Collaboration Agreements and the Supply Agreements that remain unsatisfied were \$8,433.

15. COLLABORATIVE ARRANGEMENTS

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.

On April 17, 2023, the Company signed an eighth amendment to the collaboration agreement with the NRC to further broaden the scope to include the development of stable cell lines for our multivalent vaccine candidate against coronaviruses.

This relationship is considered a collaborative relationship and not a customer relationship and is therefore accounted for outside the scope of ASC Topic 606.

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 endemic 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.

Since inception of the CEPI Funding Agreement, the Company has received \$19,327, of which there is a balance remaining of \$3,601 recorded in other current liabilities on the consolidated balance sheet.

Agenus Inc.

On October 12, 2022, the Company entered into a Clinical Collaboration Agreement (“Agenus 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.

This relationship is considered a collaborative relationship and not a customer relationship and is therefore accounted for outside the scope of ASC Topic 606.

The total amount of expenses for collaborative relationships recorded in the years ended December 31, was as follows:

	2023	2022
NRC	\$ 35	\$ 851
CEPI	3,486	3,648
Agenus Inc.	642	3,748
	<u>\$ 4,163</u>	<u>\$ 8,247</u>

Costs associated with collaborative relationships are expensed as incurred in Research and Development expenses and overhead charges are included in General and Administrative.

16. GOVERNMENT GRANTS

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 \$55,976 from the SIF to support the development of our coronavirus vaccine program, VBI-2900, through 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, 2024, 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 December 31, 2023 to March 31, 2027. 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 years ended December 31, 2023 and 2022, the Company recognized \$5,392 and \$6,038, respectively, as a reduction in expenses. As of December 31, 2023 and 2022, the Company had \$55 and \$790, respectively, recorded as deferred government grants, recorded in other current liabilities on the consolidated balance sheet.

17. INCOME TAXES

Components of the Company’s loss from continuing operations before income taxes are as follows:

	2023	2022
Netherlands	\$ (738)	\$ (394)
United States	(7,560)	(3,909)
Canada	(32,360)	(46,364)
Israel	(52,178)	(62,636)
	<u>\$ (92,836)</u>	<u>\$ (113,303)</u>

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:

	2023	2022
Loss before income taxes	\$ (92,836)	\$ (113,303)
Canadian statutory tax rate	26.50%	26.50%
Expected benefit of income tax	(24,602)	(30,025)
Research and development tax credits	(319)	(386)
Change in tax rate	203	1,970
Change in valuation allowance*	17,707	12,562
Difference between Canadian and foreign tax rates	2,042	2,771
Stock based compensation	1,628	2,362
Foreign exchange translation	2,643	10,814
Goodwill impairment	265	-
Permanent statutory to GAAP difference	141	(308)
Other	292	240
	<u>\$ -</u>	<u>\$ -</u>

* 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 2023 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 11.50%. The Israel statutory income rate is approximately 23%. The United States statutory income tax rate is approximately 24% based on current year apportionment.

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

	2023	2022
Net operating losses	\$ 108,574	\$ 98,147
Research and development tax credits	14,655	13,995
Property and equipment	830	1,072
Reserves and other	2,928	2,253
Intangible assets	(9,672)	(15,461)
Allowable capital losses	342	56
Debt obligations	(1,902)	(2,683)
Deferred financing costs	962	1,201
Net deferred tax assets	116,717	98,580
Less: valuation allowance	(116,717)	(98,580)
	<u>\$ -</u>	<u>\$ -</u>

As of December 31, 2023 and 2022, the Company had United States federal net operating loss carryovers ("NOLs") of approximately \$59,524 and \$55,375, 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, 2023. 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, 2023 and 2022, the Company also had Canadian net operating loss carryovers of approximately \$102,475 and \$97,433, respectively, available to offset future taxable income which expire beginning in 2024.

As of December 31, 2023 and 2022, the Company had \$6,964 and \$6,242 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, 2023 and 2022, the Company had unclaimed research and development expenses in Canada of approximately \$28,580 and \$24,997, respectively, which are available to offset future taxable income indefinitely.

As of December 31, 2023 and 2022, the Company had \$204 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, 2023 and 2022, the Company also had Israel net operating loss carryovers of approximately \$291,711 and \$256,305, respectively, which can be carried forward indefinitely.

As of December 31, 2023, the Company had NOLs aggregating approximately \$454,508. The NOLs are available to reduce taxable income of future years and expire as follows:

	Netherlands	United States	Canada	Israel	Total
2025	-	-	862	-	862
2026	-	10	3,590	-	3,600
2027	-	446	4,159	-	4,605
2028	-	718	1,610	-	2,328
2029	-	672	3,016	-	3,688
2030	-	2,556	977	-	3,533
2031	-	3,617	1,207	-	4,824
2032	-	2,962	-	-	2,962
2033	-	3,126	1,411	-	4,537
2034	-	5,626	5,284	-	10,910
2035	-	4,661	1,589	-	6,250
2036	-	5,323	6,995	-	12,318
2037	-	6,017	9,473	-	15,490
2038	-	-	2,353	-	2,353
2039	-	-	7,488	-	7,488
2040	-	-	15,896	-	15,896
2041	-	-	11,682	-	11,682
2042	-	-	13,434	-	13,434
2043	-	-	11,449	-	11,449
No expiration	798	23,790	-	291,711	316,299
	<u>\$ 798</u>	<u>59,524</u>	<u>\$ 102,475</u>	<u>\$ 291,711</u>	<u>\$ 454,508</u>

18. COMMITMENTS AND CONTINGENCIES

Licensing

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. 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.

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).

Royalty payments under the Amended and Restated Ferring License Agreement or the original Ferring License Agreement of \$250 and \$33 were recorded in cost of revenues for the years ended December 31, 2023 and 2022, respectively.

Royalty payments under the SciGen Assignment Agreement of \$155 and \$47 were recorded in cost of revenues for the years ended December 31, 2023 and 2022, respectively.

eVLP Technology

Under a license agreement with UPMC and other licensors relating to eVLP technology, we have an exclusive license to a family of patents that expired 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, 2023, we did not make any milestone payments.

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 (\$518,197). The second claim is a civil action brought by two minors and their parents against SciVac and the Ministry of Health of the State of Israel ("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, January 12, 2023 and July 13, 2023. The next preliminary hearing is scheduled to be held on June 20, 2024.

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. Arie Raziel, requesting compensation due to bodily injury of the minor, who was diagnosed as suffering from an Autism Spectrum Disorder. 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 have not yet been scheduled.

SciVac intends to defend these claims vigorously.

19. 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 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.

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.

The total operating lease cost recorded in the years ended December 31, 2023 and 2022 was as follows:

	2023	2022
Operating lease cost	\$ 1,866	\$ 1,865
Weighted average discount rate		13%
Weighted average remaining lease term		2.36 years

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	
2024	\$ 1,177
2025	686
2026	593
2027	163
	<u>2,619</u>
Effect of discounting	(348)
Total lease liability	2,271
Current portion	(976)
Long term lease liability, net of current portion	<u>\$ 1,295</u>

20. 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.

	2023	2022
United States	\$ 1,845	\$ 695
Israel	167	315
China/Hong Kong	5,585	66
Europe	1,085	6
	<u>\$ 8,682</u>	<u>\$ 1,082</u>

There was no revenue attributed to our country of domicile, Canada, for the years ended December 31, 2023 and 2022.

For the year ended December 31, 2023, the Company had 1 customer that individually accounted for 64% of revenues.

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

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

	2023	2022
Israel	\$ 11,009	\$ 13,892
United States	506	985
Canada (country of domicile)	398	692
	<u>\$ 11,913</u>	<u>\$ 15,569</u>

21. SUBSEQUENT EVENTS

February 2024 Agreements with Brii Bio

On February 13, 2024, the Company entered into a series of agreements with Brii Biosciences Limited (“Brii Bio”), pursuant to which, subject to achievement of certain activities, we would receive up to \$33,000 in consideration from Brii Bio, consideration which will be used to correspondingly reduce our obligations due under the Loan Agreement.

Rehovot Purchase Agreement

On February 13, 2024, the Company and SciVac entered into a purchase agreement (the “Rehovot Purchase Agreement”) with a wholly-owned subsidiary of Brii Bio, to be formed in Israel (“Brii Israel”) prior to the closing, and joined as a party to the agreement prior to the closing as the purchaser, and Brii Biosciences, Inc, a Delaware corporation, pursuant to which, upon achievement of certain activities and closing of the transactions contemplated by the Rehovot Purchase Agreement, subject to the terms and conditions therein, SciVac will sell to Brii Israel certain assets, including SciVac and its affiliates’ interest and rights in certain leases with respect to the vaccine manufacturing facility in Israel, for an aggregate purchase price of \$10,000, which is then required to be paid to K2HV pursuant to the terms of the Fourth Amendment.

The Rehovot Purchase Agreement contains representations and warranties of SciVac and Brii Israel that are typical for transactions of this type. The Rehovot Purchase Agreement also contains covenants on the part of the Company that are typical for transactions of this type.

The closing of the transactions pursuant to the Rehovot Purchase Agreement are subject to the terms and conditions therein, including closing conditions that are typical for transactions of this type and the Company’s completion of the Essential Activities (as defined below). Closing will not occur prior to June 30, 2024.

Brii Purchase Agreement

On February 13, 2024, the Company and VBI Cda entered into a Purchase Agreement with Brii Bio (the “Brii Purchase Agreement”), pursuant to which the Company and VBI Cda will sell, transfer, convey and assign to Brii Bio, substantially all of the intellectual property related to VBI-2601 owned by the Company and VBI Cda, for a secured promissory note in the principal amount up to \$10,000 (the “Note”) to be issued by Brii Bio, which is then required to be assigned to K2HV pursuant to the terms of the Fourth Amendment, in exchange for a reduction in the Company’s obligations under the Loan Agreement equal to the initial principal amount of the Note. The Note was issued to Brii Bio on February 13, 2024. The initial principal amount of the Note is \$2,500, which shall be increased by an aggregate amount equal to \$7,500 upon the Company’s obtaining applicable consents under the Amended and Restated Ferring License Agreement. In the event of certain breaches by the Company of the Brii Purchase Agreement and any such breach is not cured with 30 days, the aggregate principal amount of the Note shall be reduced by an aggregate amount equal to \$2,500.

Brii Side Letter

On February 13, 2024, the Company and Brii Bio entered into a side letter (the “Side Letter”) setting forth certain essential and additional priority activities to transfer manufacturing responsibility for clinical supply and commercial supply of VBI-2601 and PreHevbri for the Brii Territories set forth in the Side Letter (the “Essential Activities”) the Company is required to complete as a condition to the entry into the License Agreement (as defined below) and consummation of the transactions pursuant to the Rehovot Purchase Agreement. The principal amount of the Note shall increase up to \$18,000 upon completion of the Essential Activities and the Company’s obligations under the Loan Agreement shall be reduced by a corresponding amount.

Brii License Agreement

On February 13, 2024, the Company entered into a series of agreements and amendments to existing agreements with Brii Bio. Upon completion of the Essential Activities pursuant to the Side Letter, VBI Cda and Brii Bio will enter into a license agreement (the “Brii License Agreement”) pursuant to which Brii Bio shall issue a secured promissory note in the amount of \$5,000 as consideration for a perpetual, royalty-free, milestone-free, sublicensable, fully-paid, and exclusive license to the GBM program (VBI-1901) for development and commercialization in the APAC region (excluding Japan), which such note is then required to be assigned to K2HV pursuant to the terms of the Fourth Amendment. The entry by VBI Cda and Brii Bio into the Brii License Agreement is subject to the Company completing the Essential Activities.

Loan Agreement and Forbearance Agreement with K2HV

On each of January 9, 2024, January 23, 2024, and February 6, 2024, as discussed in Note 11, the Loan Parties entered into extensions to the Forbearance Agreement. Additionally, on February 14, 2024, as discussed in Note 11, the Loan Parties entered into the Fourth Amendment to the Loan Agreement.

ATM Program

Subsequent to December 31, 2023, the Company sold and issued 2,114,314 common shares under the ATM Program for total gross proceeds of \$1,435 at a weighted average price of \$0.6789 per share.

April 2024 Offering

On April 9, 2024, the Company entered into a securities purchase agreement with certain institutional investors named therein pursuant to which the Company issued and sold 2,272,728 common shares and accompanying warrants to purchase up to 2,272,728 common shares (the “April 2024 Warrants”) at a combined offering price of \$0.88 per common share and accompanying April 2024 Warrant in a registered direct offering (the “April 2024 Offering”). The April 2024 Offering closed on April 11, 2024. The April 2024 Warrants have an exercise price of \$0.76 per share, are immediately exercisable on the date of issuance, and expire five years following the date of issuance. Net proceeds to the Company from the April 2024 Offering, after deducting placement agent fees and estimated offering expenses payable by the Company, were approximately \$1,700.

In connection with the April 2024 Offering, the Company also issued to H.C. Wainwright & Co., LLC or its designees, warrants to purchase up to 136,364 common shares (the “April 2024 Placement Agent Warrants”) as compensation in connection with the April 2024 Offering. The April 2024 Placement Agent Warrants have substantially the same terms and conditions as the April 2024 Warrants, except that the April 2024 Placement Agent Warrants have an exercise price of \$1.10 per share, which represents 125% of the offering price per common share and accompanying April 2024 Warrant and expire five years following the commencement of sales pursuant to the April 2024 Offering.

Exercise of Warrants

In April 2024, warrants for the purchase of 126,250 common shares were exercised at an exercise price of \$0.6057 for total proceeds of \$76.

EXHIBIT INDEX

Exhibit No.	Description
1.1	<u>Open Market Sale AgreementSM, 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).</u>
1.2	<u>Underwriting Agreement dated July 6, 2023 between the Company and Raymond James & Associates, Inc. as Representative of the Several Underwriters (incorporated by reference the Company's Current Report on Form 8-K (SEC File No. 001-37769), filed with the SEC on July 6, 2023).</u>
2.1	<u>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).</u>
3.1	<u>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).</u>
3.2	<u>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).</u>
3.3	<u>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).</u>
4.1	<u>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).</u>
4.2	<u>Form of Underwritten/Registered Direct Warrant (incorporated by reference to the Company's Current Report on Form 8-K (SEC File No. 001-37769), filed with the SEC on July 6, 2023).</u>
4.3	<u>Form of Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (SEC File No. 001-37769), filed with the SEC on April 11, 2024).</u>
4.4	<u>Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K (SEC File No. 001-37769), filed with the SEC on April 11, 2024).</u>
10.1(A)+	<u>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).</u>
10.1(B)+	<u>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).</u>
10.1(C)+	<u>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).</u>
10.2+	<u>Employment Agreement with Jeffrey Baxter, dated May 8, 2014 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).</u>
10.3+	<u>Employment Agreement with David Anderson, dated May 8, 2014 (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).</u>
10.4	<u>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 Supérieure 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).</u>

- 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 Supérieure 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⁽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\).](#)
- 10.10 [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\).](#)
- 10.11 [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\).](#)
- 10.12⁽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\).](#)
- 10.13⁽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\).](#)
- 10.14⁽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\).](#)
- 10.15⁽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\).](#)
- 10.16⁽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\).](#)

- 10.17⁽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\).](#)
- 10.18⁽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\).](#)
- 10.19⁽²⁾⁽³⁾ [Seventh Amendment to the Collaborative Research Agreement, signed February 28, 2023, between National Research Council of Canada and Variation Biotechnologies Inc. \(incorporated by reference to Exhibit 10.52 to the Company's Annual Report on Form 10-K \(SEC File No. 001-37769\) filed with the SEC on March 13, 2023\).](#)
- 10.20⁽²⁾⁽³⁾ [Eighth Amendment to the Collaborative Research Agreement, signed April 17, 2023, between National Research Council of Canada and Variation Biotechnologies Inc \(incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q \(SEC File No. 001-37769\), filed with the SEC on May 15, 2023\).](#)
- 10.21+ [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\).](#)
- 10.22⁽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 Bria 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 \(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 13, 2023\).](#)
- 10.50+ [Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective January 1, 2023 \(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 13, 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. \(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 13, 2023\).](#)
- 10.52+ [Employment Agreement, dated April 3, 2023, by and between VBI Vaccines \(Delaware\) Inc. and Nell Beattie \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K \(SEC File No. 001-37769\), filed with the SEC on April 4, 2023\).](#)

- 10.53⁽²⁾⁽³⁾ [Third Amendment to Loan and Guaranty Agreement, dated July 5, 2023, 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 10.4 to the Company's Quarterly Report on Form 10-Q \(SEC File No. 001-37769\), filed with the SEC on August 14, 2023\).](#)
- 10.54⁽²⁾⁽³⁾ [Collaboration and License Agreement, dated July 5, 2023, by and between VBI Vaccines Inc. and Brii Biosciences \(incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q \(SEC File No. 001-37769\), filed with the SEC on November 14, 2023\).](#)
- 10.55⁽²⁾⁽³⁾ [Amended and Restated Collaboration and License Agreement, dated July 5, 2023, by and between VBI Vaccines Inc. and Brii Biosciences \(incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q \(SEC File No. 001-37769\), filed with the SEC on November 14, 2023\).](#)
- 10.56⁽²⁾⁽³⁾ [Supply Agreement, dated July 5, 2023, by and between VBI Vaccines Inc. and Brii Biosciences \(incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q \(SEC File No. 001-37769\), filed with the SEC on November 14, 2023\).](#)
- 10.57⁽³⁾ [Letter Agreement, dated July 5, 2023, by and between VBI Vaccines Inc. and Brii Biosciences \(incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q \(SEC File No. 001-37769\), filed with the SEC on November 14, 2023\).](#)
- 10.58 [Stock Purchase Agreement, dated July 5, 2023, by and between the Company and Brii Biosciences Limited \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K \(SEC File No. 001-37769\), filed with the SEC on July 5, 2023\).](#)
- 10.59 [Extension Agreement, dated October 27, 2023, by and among VBI Vaccines Inc., Variation Biotechnologies Inc. and K2 HealthVentures LLC \(incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q \(SEC File No. 001-37769\), filed with the SEC on November 14, 2023\).](#)
- 10.60 [Extension Agreement, dated November 3, 2023, by and among VBI Vaccines Inc., Variation Biotechnologies Inc. and K2 HealthVentures LLC \(incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q \(SEC File No. 001-37769\), filed with the SEC on November 14, 2023\).](#)
- 10.61 [Forbearance Agreement, dated November 13, 2023, by and among VBI Vaccines Inc., Variation Biotechnologies Inc. and K2 HealthVentures LLC \(incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q \(SEC File No. 001-37769\), filed with the SEC on November 14, 2023\).](#)
- 10.62* [Extension to Forbearance Agreement, dated November 28, 2023, by and among VBI Vaccines Inc., Variation Biotechnologies Inc. and K2 HealthVentures LLC.](#)
- 10.63* [Extension to Forbearance Agreement, dated December 12, 2023, by and among VBI Vaccines Inc., Variation Biotechnologies Inc. and K2 HealthVentures LLC.](#)
- 10.64* [Extension to Forbearance Agreement, dated December 26, 2023, by and among VBI Vaccines Inc., Variation Biotechnologies Inc. and K2 HealthVentures LLC.](#)
- 10.65* [Extension to Forbearance Agreement, dated January 9, 2024, by and among VBI Vaccines Inc., Variation Biotechnologies Inc. and K2 HealthVentures LLC.](#)
- 10.66* [Extension to Forbearance Agreement, dated January 23, 2024, by and among VBI Vaccines Inc., Variation Biotechnologies Inc. and K2 HealthVentures LLC.](#)
- 10.67* [Extension to Forbearance Agreement, dated February 6, 2024, by and among VBI Vaccines Inc., Variation Biotechnologies Inc. and K2 HealthVentures LLC.](#)
- 10.68+* [Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective January 1, 2024.](#)
- 10.69⁽¹⁾ [Form of Securities Purchase Agreement, dated April 9, 2024, by and among the Company and the investors named therein \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K \(SEC File No. 001-37769\), filed with the SEC on April 11, 2024\).](#)

21.1	<u>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).</u>
23.1*	<u>Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.</u>
24.1*	<u>Power of Attorney (attached to the signature page hereto).</u>
97.1*	<u>Compensation Recovery Policy</u>
31.1*	<u>Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934.</u>
31.2*	<u>Certification of Chief Financial Officer and Head of Corporate Development pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934.</u>
32.1**	<u>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.</u>
32.2**	<u>Certification of Chief Financial Officer and Head of Corporate 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.</u>
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 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 16th day of April, 2024.

VBI VACCINES INC.

By: /s/ Jeffrey R. Baxter
Jeffrey R. Baxter, President and Chief Executive Officer (Principal Executive Officer)

By: /s/ Nell Beattie
Nell Beattie, Chief Financial Officer and Head of Corporate 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 R. Baxter and Nell Beattie, 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: April 16, 2024 /s/ Jeffrey R. Baxter
Jeffrey R. Baxter
President, Chief Executive Officer and
Director (Principal Executive Officer)

Date: April 16, 2024 /s/ Nell Beattie
Nell Beattie
Chief Financial Officer and Head of Corporate Development and Director
(Principal Financial and Accounting Officer)

Date: April 16, 2024 /s/ Steven Gillis
Steven Gillis
Director

Date: April 16, 2024 /s/ Michel De Wilde
Michel De Wilde
Director

Date: April 16, 2024 /s/ Blaine McKee
Blaine McKee
Director

Date: April 16, 2024 /s/ Joanne Cordeiro
Joanne Cordeiro
Director

Date: April 16, 2024 /s/ Damian Braga
Damian Braga
Director

Date: April 16, 2024 /s/ Vaughn Himes
Vaughn Himes
Director

FORBEARANCE AGREEMENT

This FORBEARANCE AGREEMENT (this “**Forbearance Agreement**”) is entered into as of November 13, 2023 (“**Effective Date**”) by and among **VARIATION BIOTECHNOLOGIES INC.**, a Canadian federal corporation (“**Borrower Representative**”), **VBI VACCINES INC.**, a British Columbia corporation (“**Parent**”, and together with Borrower Representative, and any other Person from time to time party to the Agreement (as defined below) as a borrower, collectively, “**Borrowers**”, and each, a “**Borrower**”), each of the parties set forth on the signature page hereto as guarantors (together with any other Person from time to time party to the Agreement as a guarantor, collectively, “**Guarantors**” and each, a “**Guarantor**”), the lenders party hereto (together with any other lender from time to time under the Agreement, collectively, “**Lenders**”, and each, a “**Lender**”) constituting Required Lenders (as defined in the Agreement (as defined below)), and **K2 HEALTHVENTURES LLC**, as administrative agent for Lenders (in such capacity, together with its successors, “**Administrative Agent**”).

RECITALS

A. Reference is made to (i) that certain Loan and Guaranty Agreement, dated as of May 22, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the “**Agreement**”) by and among Borrowers, Guarantors, Lenders, Administrative Agent and ANKURA TRUST COMPANY, LLC, as collateral trustee for Lenders (in such capacity, together with its successors, “**Collateral Trustee**”).

B. Certain Events of Default, as described on Schedule 1 attached hereto, have occurred (the “**Specified Defaults**”).

C. Borrowers have requested a forbearance with respect to the Specified Defaults and the undersigned Lenders, constituting Required Lenders, have agreed, to so forbear subject to the terms and conditions in this Forbearance Agreement.

AGREEMENT

1. Forbearance. Borrowers hereby acknowledge that the Specified Defaults have occurred. Administrative Agent and Lenders, although under no obligation to do so, hereby agree to forbear from exercising (or causing to be exercised) Secured Parties’ rights and remedies under the Loan Documents or applicable law with respect to the Specified Defaults, from the date hereof through and including the Forbearance Expiration Date (as defined on Schedule 2 hereto, and such period, the “**Forbearance Period**”) subject to compliance by Loan Parties with the terms and conditions specified on Schedule 2 hereto of this Forbearance Agreement and the other Loan Documents. The Forbearance Period shall immediately terminate if an Event of Default other than the Specified Defaults occurs, including any Event of Default caused by a breach of the terms of this Forbearance Agreement.

2. Representations. To induce Administrative Agent and Required Lenders to enter into this Forbearance Agreement, each Loan Party hereby represent and warrant as follows:

2.1 The representations and warranties contained in the Agreement and in other Loan Documents are true and correct in all material respects as of the date of this Forbearance Agreement (except for such representations and warranties referring to another date, which representations and warranties are true and correct in all material respects as of such date).

2.2 Other than the Specified Defaults, no Event of Default has occurred and is continuing.

2.3 Each Loan Party has the power and authority to execute and deliver this Forbearance Agreement and to perform its obligations under the Agreement and other Loan Documents to which it is a party.

2.4 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, (a) have been duly authorized by all necessary action on the part of such Loan Party, and (b) do not and will not contravene (i) any material Requirement of Law, (ii) any material contractual restriction in any material agreement with a Person binding on such Loan Party, (iii) any order, judgment or decree of any Governmental Authority binding on such Loan Party, or (iv) the Operating Documents operating of such Loan Party.

2.5 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by, any Governmental Authority, except as already has been obtained or made.

2.6 This Forbearance Agreement has been duly executed and delivered by each Loan Party and is the binding obligation of each Loan Party, enforceable against such Loan Party in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application relating to or affecting creditors' rights and by general equitable principles.

3. Conditions. As a condition to the effectiveness of this Forbearance Agreement, Administrative Agent shall have received, in form and substance satisfactory to Administrative Agent in its sole discretion, the following:

3.1 this Forbearance Agreement, duly executed by the Loan Parties; and

3.2 payment of all fees and Lender Expenses due on the Effective Date in accordance with the Agreement, as amended.

4. Affirmations.

4.1 Each Loan Party hereby reaffirms and ratifies and confirms in all respects, the Agreement and each other Loan Document to which it is a party and agrees and acknowledges that the Agreement and each other Loan Document to which it is a party, remains in full force and effect.

4.2 Each of the Loan Parties agrees and acknowledges that the security interest as granted pursuant to the Pledge and Security Agreement, the Canadian Security Documents or the Israeli Security Documents, as applicable, continues to secure the Obligations from the Closing Date without novation, and this Forbearance Agreement is not intended to be, and shall not constitute, a novation.

4.3 The Guarantors agree and acknowledge the terms of this Forbearance Agreement and confirm that the guaranty pursuant to Section 13 of the Agreement remains in full force and effect as of the date hereof with respect to the Obligations.

5. General release

5.1 For good and valuable consideration, each Loan Party hereby forever relieves, releases, and discharges Administrative Agent, Collateral Trustee and each Lender (collectively, "**Secured Parties**") and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them (in each case, in his, her or its capacity as such with respect to such Secured Party), from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Forbearance Agreement (collectively "**Released Claims**"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

5.2 By entering into this release, each Loan Party recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of such Loan Party hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if such Loan Party should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, such Loan Party shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Each Loan Party acknowledges that it is not relying upon and has not relied upon any representation or statement made by any Secured Party with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

5.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Each Loan Party acknowledges that the release contained herein constitutes a material inducement to Secured Parties to enter into this Forbearance Agreement, and that Secured Parties would not have done so but for Secured Parties' expectation that such release is valid and enforceable in all events.

5.4 Each Loan Party hereby represents and warrants to Secured Parties, and each Secured Party is relying thereon, as follows:

5.4.1 Except as expressly stated in this Forbearance Agreement, neither any Secured Party nor any agent, employee or representative of Secured Parties has made any statement or representation to such Loan Party regarding any fact relied upon by Loan Party in entering into this Forbearance Agreement.

5.4.2 Such Loan Party has made such investigation of the facts pertaining to this Forbearance Agreement and all of the matters appertaining thereto, as it deems necessary.

5.4.3 The terms of this Forbearance Agreement are contractual and not a mere recital.

5.4.4 This Forbearance Agreement has been carefully read by such Loan Party, the contents hereof are known and understood by such Loan Party, and this Forbearance Agreement is signed freely, and without duress, by such Loan Party.

5.4.5 Such Loan Party is the sole and lawful owner of all right, title and interest in and to every claim and every other matter which it releases herein, and that it has not heretofore assigned or transferred, or purported to assign or transfer, to any person, firm or entity any claims or other matters herein released. Each Loan Party shall indemnify Secured Parties, defend and hold it harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

6. **Governing Law.** Sections 11 and 12 of the Agreement is incorporated herein, provided that references to the "Agreement" shall be understood to refer to this Forbearance Agreement.

7. General Provisions

7.1 Unless otherwise defined, all initially capitalized terms in this Forbearance Agreement shall be as defined in the Agreement. The Agreement and this Forbearance Agreement shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. The execution, delivery, and performance of this Forbearance Agreement shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Secured Parties under the Agreement, as in effect prior to the date hereof. Each Loan Party ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement. No course of dealing on the part of Secured Parties or its officers, nor any failure or delay in the exercise of any right by Secured Parties, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Secured Parties' failure at any time to require strict performance by Loan Party of any provision shall not affect any right of Secured Parties thereafter to demand strict compliance and performance. Each Loan Party hereby acknowledges that the Obligations due and owing to Secured Parties are without setoff, recoupment, defense or counterclaim, in law or in equity, of any nature or kind. All security interests granted to Collateral Trustee by a Loan Party under any Loan Document are hereby reaffirmed by such Loan Party. Except as expressly set forth herein, the terms of the Loan Documents remain in effect.

7.2 This Forbearance Agreement and the Loan Documents represent the entire agreement with respect to this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Forbearance Agreement and the Loan Documents merge into this Forbearance Agreement and the Loan Documents.

7.3 This Forbearance Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

7.4 This Forbearance Agreement shall constitute a Loan Document. Accordingly, the provisions of Section 11 of the Agreement shall likewise apply to this Forbearance Agreement.

7.5 Each of Schedule 1 (Specified Defaults) and Schedule 2 (Forbearance Terms) may be modified with the approval of the Required Lenders and Administrative Agent in their sole and absolute discretion, and agreed to by the Loan Parties, by attaching hereto a modified Schedule 1 or Schedule 2, as applicable, duly executed by each of the parties hereto, which modified schedules shall indicate the effective date of such modification. Any such modification shall be effective from the effective date indicated in such modified schedule, and any such modification in any instance, shall not establish any course of dealing or obligate Lenders or Administrative Agent to agree to any future modification thereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Forbearance Agreement to be executed as of the date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES INC., a British Columbia corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VARIATION BIOTECHNOLOGIES (US), INC., a
Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

ADMINISTRATIVE AGENT:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

LENDER:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

SCHEDULE 1 SPECIFIED DEFAULTS

1. Failure to achieve Revenue for the measurement period ended September 30, 2023 in the amount required pursuant to Section 6.10.
-

SCHEDULE 2
FORBEARANCE TERMS

Forbearance Expiration Date: December 12, 2023

Effective Date: November 28, 2023

Forbearance Conditions:

1. **Forbearance Period Termination.** The Borrower shall provide immediate written notice to the Administrative Agent of any event or condition that would result in a termination of the Forbearance Period.

2. **Update Calls.** Loan Parties shall make management available to participate in conference call with Administrative Agent from time to time upon request by Administrative Agent, to participate in discussions on such matters concerning the Loan Parties (including as to financial data, reports, and projections), as Administrative Agent may reasonably request.

3. **13-Week Cash Flow Budget.** Borrower Representative shall deliver to Administrative Agent not later than 5:00 p.m., Eastern Time, on each Wednesday (the "**Delivery Date**") following the Effective Date:

(a) cash flow forecast and sources and uses budget for the 13-week period commencing at such time and in the form agreed to by the Loan Parties and the Administrative Agent prior to the Delivery Date (the "**13-Week Cash Flow Budget**"); and

(b) an accounts payable aging report, in form satisfactory to Administrative Agent.

Notwithstanding anything to the contrary herein, the parties understand and agree that the initial 13-Week Cash Flow Budget due the day after the Effective Date shall be subject to updates for certain expected expenditures not yet incorporated as discussed among the parties prior to the Effective Date, provided that Borrower Representative shall endeavor to provide information regarding such updates as promptly as practicable and Administrative Agent shall not unreasonably withhold approval to such updates.

4. **Budget Variance Report.** Not later than 5:00 p.m., Eastern Time, on every Wednesday, Borrower Representative shall deliver to Administrative Agent a report, in form and substance reasonably satisfactory to Administrative Agent, for the immediately preceding four-week period (or such shorter period commencing on the first week following the Effective Date covered by a 13-Week Cash Flow Budget delivered in accordance with the above) that (i) sets forth the variances for the Loan Parties (as a percentage and as a dollar amount) between the actual cash uses and the corresponding projected amounts reflected in the 13-Week Cash Flow Budget then in effect for the corresponding period.

5. **Other Information Requested.** Borrower Representative shall deliver any other financial or other information with respect to the business of the Loan Parties or other matters upon request by Administrative Agent no later than the Business Day following receipt of such request.

6. **Adherence with 13-Week Cash Flow Budget.** Loan Parties shall not permit total cash uses for any two week period to exceed the amount set forth in the 13-Week Cash Flow Budget for such two week period, as applicable by more than 10% without prior written approval by Administrative Agent, provided that for purposes of the foregoing, Lender Expenses and any legal expenses of the Loan Parties incurred in connection with the Loan Documents or other fees and expenses as approved by Administrative Agent as of the Effective Date or from time to time thereafter may be disregarded.

[APPROVAL OF UPDATED FORBEARANCE TERMS (11.28.23)]

This updated Schedule 2 is approved by the undersigned as of the Effective Date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: CEO

VBI VACCINES INC., a British Columbia corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: CEO

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: CEO

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: CEO

VARIATION BIOTECHNOLOGIES (US), INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: CEO

[APPROVAL OF UPDATED FORBEARANCE TERMS (11.28.23)]

ADMINISTRATIVE AGENT:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora

Name: Anup Arora

Title: Chief Investment Officer and Managing Director

LENDER:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora

Name: Anup Arora

Title: Chief Investment Officer and Managing Director

FORBEARANCE AGREEMENT

This FORBEARANCE AGREEMENT (this “**Forbearance Agreement**”) is entered into as of November 13, 2023 (“**Effective Date**”) by and among VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation (“**Borrower Representative**”), VBI VACCINES INC., a British Columbia corporation (“**Parent**”, and together with Borrower Representative, and any other Person from time to time party to the Agreement (as defined below) as a borrower, collectively, “**Borrowers**”, and each, a “**Borrower**”), each of the parties set forth on the signature page hereto as guarantors (together with any other Person from time to time party to the Agreement as a guarantor, collectively, “**Guarantors**” and each, a “**Guarantor**”), the lenders party hereto (together with any other lender from time to time under the Agreement, collectively, “**Lenders**”, and each, a “**Lender**”) constituting Required Lenders (as defined in the Agreement (as defined below)), and K2 HEALTHVENTURES LLC, as administrative agent for Lenders (in such capacity, together with its successors, “**Administrative Agent**”).

RECITALS

A. Reference is made to (i) that certain Loan and Guaranty Agreement, dated as of May 22, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the “**Agreement**”) by and among Borrowers, Guarantors, Lenders, Administrative Agent and ANKURA TRUST COMPANY, LLC, as collateral trustee for Lenders (in such capacity, together with its successors, “**Collateral Trustee**”).

B. Certain Events of Default, as described on Schedule 1 attached hereto, have occurred (the “**Specified Defaults**”).

C. Borrowers have requested a forbearance with respect to the Specified Defaults and the undersigned Lenders, constituting Required Lenders, have agreed, to so forbear subject to the terms and conditions in this Forbearance Agreement.

AGREEMENT

1. Forbearance. Borrowers hereby acknowledge that the Specified Defaults have occurred. Administrative Agent and Lenders, although under no obligation to do so, hereby agree to forbear from exercising (or causing to be exercised) Secured Parties’ rights and remedies under the Loan Documents or applicable law with respect to the Specified Defaults, from the date hereof through and including the Forbearance Expiration Date (as defined on Schedule 2 hereto, and such period, the “**Forbearance Period**”) subject to compliance by Loan Parties with the terms and conditions specified on Schedule 2 hereto of this Forbearance Agreement and the other Loan Documents. The Forbearance Period shall immediately terminate if an Event of Default other than the Specified Defaults occurs, including any Event of Default caused by a breach of the terms of this Forbearance Agreement.

2. Representations. To induce Administrative Agent and Required Lenders to enter into this Forbearance Agreement, each Loan Party hereby represent and warrant as follows:

2.1 The representations and warranties contained in the Agreement and in other Loan Documents are true and correct in all material respects as of the date of this Forbearance Agreement (except for such representations and warranties referring to another date, which representations and warranties are true and correct in all material respects as of such date).

2.2 Other than the Specified Defaults, no Event of Default has occurred and is continuing.

2.3 Each Loan Party has the power and authority to execute and deliver this Forbearance Agreement and to perform its obligations under the Agreement and other Loan Documents to which it is a party.

2.4 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, (a) have been duly authorized by all necessary action on the part of such Loan Party, and (b) do not and will not contravene (i) any material Requirement of Law, (ii) any material contractual restriction in any material agreement with a Person binding on such Loan Party, (iii) any order, judgment or decree of any Governmental Authority binding on such Loan Party, or (iv) the Operating Documents operating of such Loan Party.

2.5 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by, any Governmental Authority, except as already has been obtained or made.

2.6 This Forbearance Agreement has been duly executed and delivered by each Loan Party and is the binding obligation of each Loan Party, enforceable against such Loan Party in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application relating to or affecting creditors' rights and by general equitable principles.

3. Conditions. As a condition to the effectiveness of this Forbearance Agreement, Administrative Agent shall have received, in form and substance satisfactory to Administrative Agent in its sole discretion, the following:

3.1 this Forbearance Agreement, duly executed by the Loan Parties; and

3.2 payment of all fees and Lender Expenses due on the Effective Date in accordance with the Agreement, as amended.

4. Affirmations.

4.1 Each Loan Party hereby reaffirms and ratifies and confirms in all respects, the Agreement and each other Loan Document to which it is a party and agrees and acknowledges that the Agreement and each other Loan Document to which it is a party, remains in full force and effect.

4.2 Each of the Loan Parties agrees and acknowledges that the security interest as granted pursuant to the Pledge and Security Agreement, the Canadian Security Documents or the Israeli Security Documents, as applicable, continues to secure the Obligations from the Closing Date without novation, and this Forbearance Agreement is not intended to be, and shall not constitute, a novation.

4.3 The Guarantors agree and acknowledge the terms of this Forbearance Agreement and confirm that the guaranty pursuant to Section 13 of the Agreement remains in full force and effect as of the date hereof with respect to the Obligations.

5. General release

5.1 For good and valuable consideration, each Loan Party hereby forever relieves, releases, and discharges Administrative Agent, Collateral Trustee and each Lender (collectively, "**Secured Parties**") and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them (in each case, in his, her or its capacity as such with respect to such Secured Party), from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Forbearance Agreement (collectively "**Released Claims**"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

5.2 By entering into this release, each Loan Party recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of such Loan Party hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if such Loan Party should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, such Loan Party shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Each Loan Party acknowledges that it is not relying upon and has not relied upon any representation or statement made by any Secured Party with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

5.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Each Loan Party acknowledges that the release contained herein constitutes a material inducement to Secured Parties to enter into this Forbearance Agreement, and that Secured Parties would not have done so but for Secured Parties' expectation that such release is valid and enforceable in all events.

5.4 Each Loan Party hereby represents and warrants to Secured Parties, and each Secured Party is relying thereon, as follows:

5.4.1 Except as expressly stated in this Forbearance Agreement, neither any Secured Party nor any agent, employee or representative of Secured Parties has made any statement or representation to such Loan Party regarding any fact relied upon by Loan Party in entering into this Forbearance Agreement.

5.4.2 Such Loan Party has made such investigation of the facts pertaining to this Forbearance Agreement and all of the matters appertaining thereto, as it deems necessary.

5.4.3 The terms of this Forbearance Agreement are contractual and not a mere recital.

5.4.4 This Forbearance Agreement has been carefully read by such Loan Party, the contents hereof are known and understood by such Loan Party, and this Forbearance Agreement is signed freely, and without duress, by such Loan Party.

5.4.5 Such Loan Party is the sole and lawful owner of all right, title and interest in and to every claim and every other matter which it releases herein, and that it has not heretofore assigned or transferred, or purported to assign or transfer, to any person, firm or entity any claims or other matters herein released. Each Loan Party shall indemnify Secured Parties, defend and hold it harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

6. Governing Law. Sections 11 and 12 of the Agreement is incorporated herein, provided that references to the "Agreement" shall be understood to refer to this Forbearance Agreement.

7. General Provisions

7.1 Unless otherwise defined, all initially capitalized terms in this Forbearance Agreement shall be as defined in the Agreement. The Agreement and this Forbearance Agreement shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. The execution, delivery, and performance of this Forbearance Agreement shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Secured Parties under the Agreement, as in effect prior to the date hereof. Each Loan Party ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement. No course of dealing on the part of Secured Parties or its officers, nor any failure or delay in the exercise of any right by Secured Parties, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Secured Parties' failure at any time to require strict performance by Loan Party of any provision shall not affect any right of Secured Parties thereafter to demand strict compliance and performance. Each Loan Party hereby acknowledges that the Obligations due and owing to Secured Parties are without setoff, recoupment, defense or counterclaim, in law or in equity, of any nature or kind. All security interests granted to Collateral Trustee by a Loan Party under any Loan Document are hereby reaffirmed by such Loan Party. Except as expressly set forth herein, the terms of the Loan Documents remain in effect.

7.2 This Forbearance Agreement and the Loan Documents represent the entire agreement with respect to this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Forbearance Agreement and the Loan Documents merge into this Forbearance Agreement and the Loan Documents.

7.3 This Forbearance Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

7.4 This Forbearance Agreement shall constitute a Loan Document. Accordingly, the provisions of Section 11 of the Agreement shall likewise apply to this Forbearance Agreement.

7.5 Each of Schedule 1 (Specified Defaults) and Schedule 2 (Forbearance Terms) may be modified with the approval of the Required Lenders and Administrative Agent in their sole and absolute discretion, and agreed to by the Loan Parties, by attaching hereto a modified Schedule 1 or Schedule 2, as applicable, duly executed by each of the parties hereto, which modified schedules shall indicate the effective date of such modification. Any such modification shall be effective from the effective date indicated in such modified schedule, and any such modification in any instance, shall not establish any course of dealing or obligate Lenders or Administrative Agent to agree to any future modification thereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Forbearance Agreement to be executed as of the date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES INC., a British Columbia corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VARIATION BIOTECHNOLOGIES (US), INC., a
Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

ADMINISTRATIVE AGENT:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

LENDER:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

SCHEDULE 1 SPECIFIED DEFAULTS

1. Failure to achieve Revenue for the measurement period ended September 30, 2023 in the amount required pursuant to Section 6.10.
-

SCHEDULE 2
FORBEARANCE TERMS

Forbearance Expiration Date: December 26, 2023

Effective Date: December 12, 2023

Forbearance Conditions:

1. Forbearance Period Termination. The Borrower shall provide immediate written notice to the Administrative Agent of any event or condition that would result in a termination of the Forbearance Period.

2. Update Calls. Loan Parties shall make management available to participate in conference call with Administrative Agent from time to time upon request by Administrative Agent, to participate in discussions on such matters concerning the Loan Parties (including as to financial data, reports, and projections), as Administrative Agent may reasonably request.

3. 13-Week Cash Flow Budget. Borrower Representative shall deliver to Administrative Agent not later than 5:00 p.m., Eastern Time, on each Wednesday (the “**Delivery Date**”) following the Effective Date:

(a) cash flow forecast and sources and uses budget for the 13-week period commencing at such time and in the form agreed to by the Loan Parties and the Administrative Agent prior to the Delivery Date (the “**13-Week Cash Flow Budget**”); and

(b) an accounts payable aging report, in form satisfactory to Administrative Agent.

Notwithstanding anything to the contrary herein, the parties understand and agree that the initial 13-Week Cash Flow Budget due the day after the Effective Date shall be subject to updates for certain expected expenditures not yet incorporated as discussed among the parties prior to the Effective Date, provided that Borrower Representative shall endeavor to provide information regarding such updates as promptly as practicable and Administrative Agent shall not unreasonably withhold approval to such updates.

4. Budget Variance Report. Not later than 5:00 p.m., Eastern Time, on every Wednesday, Borrower Representative shall deliver to Administrative Agent a report, in form and substance reasonably satisfactory to Administrative Agent, for the immediately preceding four-week period (or such shorter period commencing on the first week following the Effective Date covered by a 13-Week Cash Flow Budget delivered in accordance with the above) that (i) sets forth the variances for the Loan Parties (as a percentage and as a dollar amount) between the actual cash uses and the corresponding projected amounts reflected in the 13-Week Cash Flow Budget then in effect for the corresponding period.

5. Other Information Requested. Borrower Representative shall deliver any other financial or other information with respect to the business of the Loan Parties or other matters upon request by Administrative Agent no later than the Business Day following receipt of such request.

6. Adherence with 13-Week Cash Flow Budget. Loan Parties shall not permit total cash uses for any two week period to exceed the amount set forth in the 13-Week Cash Flow Budget for such two week period, as applicable by more than 10% without prior written approval by Administrative Agent, provided that for purposes of the foregoing, Lender Expenses and any legal expenses of the Loan Parties incurred in connection with the Loan Documents or other fees and expenses as approved by Administrative Agent as of the Effective Date or from time to time thereafter may be disregarded.

[APPROVAL OF UPDATED FORBEARANCE TERMS (12.12.23)]

This updated Schedule 2 is approved by the undersigned as of the Effective Date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES INC., a British Columbia corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VARIATION BIOTECHNOLOGIES (US), INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

[APPROVAL OF UPDATED FORBEARANCE TERMS (12.12.23)]

ADMINISTRATIVE AGENT:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora

Name: Anup Arora

Title: Chief Investment Officer and Managing Director

LENDER:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora

Name: Anup Arora

Title: Chief Investment Officer and Managing Director

FORBEARANCE AGREEMENT

This FORBEARANCE AGREEMENT (this “**Forbearance Agreement**”) is entered into as of November 13, 2023 (“**Effective Date**”) by and among **VARIATION BIOTECHNOLOGIES INC.**, a Canadian federal corporation (“**Borrower Representative**”), **VBI VACCINES INC.**, a British Columbia corporation (“**Parent**”, and together with Borrower Representative, and any other Person from time to time party to the Agreement (as defined below) as a borrower, collectively, “**Borrowers**”, and each, a “**Borrower**”), each of the parties set forth on the signature page hereto as guarantors (together with any other Person from time to time party to the Agreement as a guarantor, collectively, “**Guarantors**” and each, a “**Guarantor**”), the lenders party hereto (together with any other lender from time to time under the Agreement, collectively, “**Lenders**”, and each, a “**Lender**”) constituting Required Lenders (as defined in the Agreement (as defined below)), and **K2 HEALTHVENTURES LLC**, as administrative agent for Lenders (in such capacity, together with its successors, “**Administrative Agent**”).

RECITALS

A. Reference is made to (i) that certain Loan and Guaranty Agreement, dated as of May 22, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the “**Agreement**”) by and among Borrowers, Guarantors, Lenders, Administrative Agent and ANKURA TRUST COMPANY, LLC, as collateral trustee for Lenders (in such capacity, together with its successors, “**Collateral Trustee**”).

B. Certain Events of Default, as described on Schedule 1 attached hereto, have occurred (the “**Specified Defaults**”).

C. Borrowers have requested a forbearance with respect to the Specified Defaults and the undersigned Lenders, constituting Required Lenders, have agreed, to so forbear subject to the terms and conditions in this Forbearance Agreement.

AGREEMENT

1. Forbearance. Borrowers hereby acknowledge that the Specified Defaults have occurred. Administrative Agent and Lenders, although under no obligation to do so, hereby agree to forbear from exercising (or causing to be exercised) Secured Parties’ rights and remedies under the Loan Documents or applicable law with respect to the Specified Defaults, from the date hereof through and including the Forbearance Expiration Date (as defined on Schedule 2 hereto, and such period, the “**Forbearance Period**”) subject to compliance by Loan Parties with the terms and conditions specified on Schedule 2 hereto of this Forbearance Agreement and the other Loan Documents. The Forbearance Period shall immediately terminate if an Event of Default other than the Specified Defaults occurs, including any Event of Default caused by a breach of the terms of this Forbearance Agreement.

2. Representations. To induce Administrative Agent and Required Lenders to enter into this Forbearance Agreement, each Loan Party hereby represent and warrant as follows:

2.1 The representations and warranties contained in the Agreement and in other Loan Documents are true and correct in all material respects as of the date of this Forbearance Agreement (except for such representations and warranties referring to another date, which representations and warranties are true and correct in all material respects as of such date).

2.2 Other than the Specified Defaults, no Event of Default has occurred and is continuing.

2.3 Each Loan Party has the power and authority to execute and deliver this Forbearance Agreement and to perform its obligations under the Agreement and other Loan Documents to which it is a party.

2.4 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, (a) have been duly authorized by all necessary action on the part of such Loan Party, and (b) do not and will not contravene (i) any material Requirement of Law, (ii) any material contractual restriction in any material agreement with a Person binding on such Loan Party, (iii) any order, judgment or decree of any Governmental Authority binding on such Loan Party, or (iv) the Operating Documents operating of such Loan Party.

2.5 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by, any Governmental Authority, except as already has been obtained or made.

2.6 This Forbearance Agreement has been duly executed and delivered by each Loan Party and is the binding obligation of each Loan Party, enforceable against such Loan Party in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application relating to or affecting creditors' rights and by general equitable principles.

3. Conditions. As a condition to the effectiveness of this Forbearance Agreement, Administrative Agent shall have received, in form and substance satisfactory to Administrative Agent in its sole discretion, the following:

3.1 this Forbearance Agreement, duly executed by the Loan Parties; and

3.2 payment of all fees and Lender Expenses due on the Effective Date in accordance with the Agreement, as amended.

4. Affirmations.

4.1 Each Loan Party hereby reaffirms and ratifies and confirms in all respects, the Agreement and each other Loan Document to which it is a party and agrees and acknowledges that the Agreement and each other Loan Document to which it is a party, remains in full force and effect.

4.2 Each of the Loan Parties agrees and acknowledges that the security interest as granted pursuant to the Pledge and Security Agreement, the Canadian Security Documents or the Israeli Security Documents, as applicable, continues to secure the Obligations from the Closing Date without novation, and this Forbearance Agreement is not intended to be, and shall not constitute, a novation.

4.3 The Guarantors agree and acknowledge the terms of this Forbearance Agreement and confirm that the guaranty pursuant to Section 13 of the Agreement remains in full force and effect as of the date hereof with respect to the Obligations.

5. General release

5.1 For good and valuable consideration, each Loan Party hereby forever relieves, releases, and discharges Administrative Agent, Collateral Trustee and each Lender (collectively, "**Secured Parties**") and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them (in each case, in his, her or its capacity as such with respect to such Secured Party), from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Forbearance Agreement (collectively "**Released Claims**"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

5.2 By entering into this release, each Loan Party recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of such Loan Party hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if such Loan Party should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, such Loan Party shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Each Loan Party acknowledges that it is not relying upon and has not relied upon any representation or statement made by any Secured Party with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

5.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Each Loan Party acknowledges that the release contained herein constitutes a material inducement to Secured Parties to enter into this Forbearance Agreement, and that Secured Parties would not have done so but for Secured Parties' expectation that such release is valid and enforceable in all events.

5.4 Each Loan Party hereby represents and warrants to Secured Parties, and each Secured Party is relying thereon, as follows:

5.4.1 Except as expressly stated in this Forbearance Agreement, neither any Secured Party nor any agent, employee or representative of Secured Parties has made any statement or representation to such Loan Party regarding any fact relied upon by Loan Party in entering into this Forbearance Agreement.

5.4.2 Such Loan Party has made such investigation of the facts pertaining to this Forbearance Agreement and all of the matters appertaining thereto, as it deems necessary.

5.4.3 The terms of this Forbearance Agreement are contractual and not a mere recital.

5.4.4 This Forbearance Agreement has been carefully read by such Loan Party, the contents hereof are known and understood by such Loan Party, and this Forbearance Agreement is signed freely, and without duress, by such Loan Party.

5.4.5 Such Loan Party is the sole and lawful owner of all right, title and interest in and to every claim and every other matter which it releases herein, and that it has not heretofore assigned or transferred, or purported to assign or transfer, to any person, firm or entity any claims or other matters herein released. Each Loan Party shall indemnify Secured Parties, defend and hold it harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

6. Governing Law. Sections 11 and 12 of the Agreement is incorporated herein, provided that references to the "Agreement" shall be understood to refer to this Forbearance Agreement.

7. General Provisions

7.1 Unless otherwise defined, all initially capitalized terms in this Forbearance Agreement shall be as defined in the Agreement. The Agreement and this Forbearance Agreement shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. The execution, delivery, and performance of this Forbearance Agreement shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Secured Parties under the Agreement, as in effect prior to the date hereof. Each Loan Party ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement. No course of dealing on the part of Secured Parties or its officers, nor any failure or delay in the exercise of any right by Secured Parties, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Secured Parties' failure at any time to require strict performance by Loan Party of any provision shall not affect any right of Secured Parties thereafter to demand strict compliance and performance. Each Loan Party hereby acknowledges that the Obligations due and owing to Secured Parties are without setoff, recoupment, defense or counterclaim, in law or in equity, of any nature or kind. All security interests granted to Collateral Trustee by a Loan Party under any Loan Document are hereby reaffirmed by such Loan Party. Except as expressly set forth herein, the terms of the Loan Documents remain in effect.

7.2 This Forbearance Agreement and the Loan Documents represent the entire agreement with respect to this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Forbearance Agreement and the Loan Documents merge into this Forbearance Agreement and the Loan Documents.

7.3 This Forbearance Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

7.4 This Forbearance Agreement shall constitute a Loan Document. Accordingly, the provisions of Section 11 of the Agreement shall likewise apply to this Forbearance Agreement.

7.5 Each of Schedule 1 (Specified Defaults) and Schedule 2 (Forbearance Terms) may be modified with the approval of the Required Lenders and Administrative Agent in their sole and absolute discretion, and agreed to by the Loan Parties, by attaching hereto a modified Schedule 1 or Schedule 2, as applicable, duly executed by each of the parties hereto, which modified schedules shall indicate the effective date of such modification. Any such modification shall be effective from the effective date indicated in such modified schedule, and any such modification in any instance, shall not establish any course of dealing or obligate Lenders or Administrative Agent to agree to any future modification thereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Forbearance Agreement to be executed as of the date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES INC., a British Columbia corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VARIATION BIOTECHNOLOGIES (US), INC., a
Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

ADMINISTRATIVE AGENT:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

LENDER:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

SCHEDULE 1 SPECIFIED DEFAULTS

1. Failure to achieve Revenue for the measurement period ended September 30, 2023 in the amount required pursuant to Section 6.10.
-

SCHEDULE 2
FORBEARANCE TERMS

Forbearance Expiration Date: January 9, 2024

Effective Date: December 26, 2023

Forbearance Conditions:

1. Forbearance Period Termination. The Borrower shall provide immediate written notice to the Administrative Agent of any event or condition that would result in a termination of the Forbearance Period.

2. Update Calls. Loan Parties shall make management available to participate in conference call with Administrative Agent from time to time upon request by Administrative Agent, to participate in discussions on such matters concerning the Loan Parties (including as to financial data, reports, and projections), as Administrative Agent may reasonably request.

3. 13-Week Cash Flow Budget. Borrower Representative shall deliver to Administrative Agent not later than 5:00 p.m., Eastern Time, on each Wednesday (the “**Delivery Date**”) following the Effective Date:

(a) cash flow forecast and sources and uses budget for the 13-week period commencing at such time and in the form agreed to by the Loan Parties and the Administrative Agent prior to the Delivery Date (the “**13-Week Cash Flow Budget**”); and

(b) an accounts payable aging report, in form satisfactory to Administrative Agent.

Notwithstanding anything to the contrary herein, the parties understand and agree that the initial 13-Week Cash Flow Budget due the day after the Effective Date shall be subject to updates for certain expected expenditures not yet incorporated as discussed among the parties prior to the Effective Date, provided that Borrower Representative shall endeavor to provide information regarding such updates as promptly as practicable and Administrative Agent shall not unreasonably withhold approval to such updates.

4. Budget Variance Report. Not later than 5:00 p.m., Eastern Time, on every Wednesday, Borrower Representative shall deliver to Administrative Agent a report, in form and substance reasonably satisfactory to Administrative Agent, for the immediately preceding four-week period (or such shorter period commencing on the first week following the Effective Date covered by a 13-Week Cash Flow Budget delivered in accordance with the above) that (i) sets forth the variances for the Loan Parties (as a percentage and as a dollar amount) between the actual cash uses and the corresponding projected amounts reflected in the 13-Week Cash Flow Budget then in effect for the corresponding period.

5. Other Information Requested. Borrower Representative shall deliver any other financial or other information with respect to the business of the Loan Parties or other matters upon request by Administrative Agent no later than the Business Day following receipt of such request.

6. Adherence with 13-Week Cash Flow Budget. Loan Parties shall not permit total cash uses for any two week period to exceed the amount set forth in the 13-Week Cash Flow Budget for such two week period, as applicable by more than 10% without prior written approval by Administrative Agent, provided that for purposes of the foregoing, Lender Expenses and any legal expenses of the Loan Parties incurred in connection with the Loan Documents or other fees and expenses as approved by Administrative Agent as of the Effective Date or from time to time thereafter may be disregarded.

[APPROVAL OF UPDATED FORBEARANCE TERMS (12.26.23)]

This updated Schedule 2 is approved by the undersigned as of the Effective Date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES INC., a British Columbia corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VARIATION BIOTECHNOLOGIES (US), INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

[APPROVAL OF UPDATED FORBEARANCE TERMS (12.26.23)]

ADMINISTRATIVE AGENT:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora

Name: Anup Arora

Title: Chief Investment Officer and Managing Director

LENDER:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora

Name: Anup Arora

Title: Chief Investment Officer and Managing Director

FORBEARANCE AGREEMENT

This FORBEARANCE AGREEMENT (this “**Forbearance Agreement**”) is entered into as of November 13, 2023 (“**Effective Date**”) by and among **VARIATION BIOTECHNOLOGIES INC.**, a Canadian federal corporation (“**Borrower Representative**”), **VBI VACCINES INC.**, a British Columbia corporation (“**Parent**”, and together with Borrower Representative, and any other Person from time to time party to the Agreement (as defined below) as a borrower, collectively, “**Borrowers**”, and each, a “**Borrower**”), each of the parties set forth on the signature page hereto as guarantors (together with any other Person from time to time party to the Agreement as a guarantor, collectively, “**Guarantors**” and each, a “**Guarantor**”), the lenders party hereto (together with any other lender from time to time under the Agreement, collectively, “**Lenders**”, and each, a “**Lender**”) constituting Required Lenders (as defined in the Agreement (as defined below)), and **K2 HEALTHVENTURES LLC**, as administrative agent for Lenders (in such capacity, together with its successors, “**Administrative Agent**”).

RECITALS

A. Reference is made to (i) that certain Loan and Guaranty Agreement, dated as of May 22, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the “**Agreement**”) by and among Borrowers, Guarantors, Lenders, Administrative Agent and ANKURA TRUST COMPANY, LLC, as collateral trustee for Lenders (in such capacity, together with its successors, “**Collateral Trustee**”).

B. Certain Events of Default, as described on Schedule 1 attached hereto, have occurred (the “**Specified Defaults**”).

C. Borrowers have requested a forbearance with respect to the Specified Defaults and the undersigned Lenders, constituting Required Lenders, have agreed, to so forbear subject to the terms and conditions in this Forbearance Agreement.

AGREEMENT

1. Forbearance. Borrowers hereby acknowledge that the Specified Defaults have occurred. Administrative Agent and Lenders, although under no obligation to do so, hereby agree to forbear from exercising (or causing to be exercised) Secured Parties’ rights and remedies under the Loan Documents or applicable law with respect to the Specified Defaults, from the date hereof through and including the Forbearance Expiration Date (as defined on Schedule 2 hereto, and such period, the “**Forbearance Period**”) subject to compliance by Loan Parties with the terms and conditions specified on Schedule 2 hereto of this Forbearance Agreement and the other Loan Documents. The Forbearance Period shall immediately terminate if an Event of Default other than the Specified Defaults occurs, including any Event of Default caused by a breach of the terms of this Forbearance Agreement.

2. Representations. To induce Administrative Agent and Required Lenders to enter into this Forbearance Agreement, each Loan Party hereby represent and warrant as follows:

2.1 The representations and warranties contained in the Agreement and in other Loan Documents are true and correct in all material respects as of the date of this Forbearance Agreement (except for such representations and warranties referring to another date, which representations and warranties are true and correct in all material respects as of such date).

2.2 Other than the Specified Defaults, no Event of Default has occurred and is continuing.

2.3 Each Loan Party has the power and authority to execute and deliver this Forbearance Agreement and to perform its obligations under the Agreement and other Loan Documents to which it is a party.

2.4 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, (a) have been duly authorized by all necessary action on the part of such Loan Party, and (b) do not and will not contravene (i) any material Requirement of Law, (ii) any material contractual restriction in any material agreement with a Person binding on such Loan Party, (iii) any order, judgment or decree of any Governmental Authority binding on such Loan Party, or (iv) the Operating Documents operating of such Loan Party.

2.5 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by, any Governmental Authority, except as already has been obtained or made.

2.6 This Forbearance Agreement has been duly executed and delivered by each Loan Party and is the binding obligation of each Loan Party, enforceable against such Loan Party in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application relating to or affecting creditors' rights and by general equitable principles.

3. Conditions. As a condition to the effectiveness of this Forbearance Agreement, Administrative Agent shall have received, in form and substance satisfactory to Administrative Agent in its sole discretion, the following:

3.1 this Forbearance Agreement, duly executed by the Loan Parties; and

3.2 payment of all fees and Lender Expenses due on the Effective Date in accordance with the Agreement, as amended.

4. Affirmations.

4.1 Each Loan Party hereby reaffirms and ratifies and confirms in all respects, the Agreement and each other Loan Document to which it is a party and agrees and acknowledges that the Agreement and each other Loan Document to which it is a party, remains in full force and effect.

4.2 Each of the Loan Parties agrees and acknowledges that the security interest as granted pursuant to the Pledge and Security Agreement, the Canadian Security Documents or the Israeli Security Documents, as applicable, continues to secure the Obligations from the Closing Date without novation, and this Forbearance Agreement is not intended to be, and shall not constitute, a novation.

4.3 The Guarantors agree and acknowledge the terms of this Forbearance Agreement and confirm that the guaranty pursuant to Section 13 of the Agreement remains in full force and effect as of the date hereof with respect to the Obligations.

5. General release

5.1 For good and valuable consideration, each Loan Party hereby forever relieves, releases, and discharges Administrative Agent, Collateral Trustee and each Lender (collectively, "**Secured Parties**") and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them (in each case, in his, her or its capacity as such with respect to such Secured Party), from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Forbearance Agreement (collectively "**Released Claims**"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

5.2 By entering into this release, each Loan Party recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of such Loan Party hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if such Loan Party should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, such Loan Party shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Each Loan Party acknowledges that it is not relying upon and has not relied upon any representation or statement made by any Secured Party with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

5.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Each Loan Party acknowledges that the release contained herein constitutes a material inducement to Secured Parties to enter into this Forbearance Agreement, and that Secured Parties would not have done so but for Secured Parties' expectation that such release is valid and enforceable in all events.

5.4 Each Loan Party hereby represents and warrants to Secured Parties, and each Secured Party is relying thereon, as follows:

5.4.1 Except as expressly stated in this Forbearance Agreement, neither any Secured Party nor any agent, employee or representative of Secured Parties has made any statement or representation to such Loan Party regarding any fact relied upon by Loan Party in entering into this Forbearance Agreement.

5.4.2 Such Loan Party has made such investigation of the facts pertaining to this Forbearance Agreement and all of the matters appertaining thereto, as it deems necessary.

5.4.3 The terms of this Forbearance Agreement are contractual and not a mere recital.

5.4.4 This Forbearance Agreement has been carefully read by such Loan Party, the contents hereof are known and understood by such Loan Party, and this Forbearance Agreement is signed freely, and without duress, by such Loan Party.

5.4.5 Such Loan Party is the sole and lawful owner of all right, title and interest in and to every claim and every other matter which it releases herein, and that it has not heretofore assigned or transferred, or purported to assign or transfer, to any person, firm or entity any claims or other matters herein released. Each Loan Party shall indemnify Secured Parties, defend and hold it harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

6. Governing Law. Sections 11 and 12 of the Agreement is incorporated herein, provided that references to the "Agreement" shall be understood to refer to this Forbearance Agreement.

7. General Provisions

7.1 Unless otherwise defined, all initially capitalized terms in this Forbearance Agreement shall be as defined in the Agreement. The Agreement and this Forbearance Agreement shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. The execution, delivery, and performance of this Forbearance Agreement shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Secured Parties under the Agreement, as in effect prior to the date hereof. Each Loan Party ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement. No course of dealing on the part of Secured Parties or its officers, nor any failure or delay in the exercise of any right by Secured Parties, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Secured Parties' failure at any time to require strict performance by Loan Party of any provision shall not affect any right of Secured Parties thereafter to demand strict compliance and performance. Each Loan Party hereby acknowledges that the Obligations due and owing to Secured Parties are without setoff, recoupment, defense or counterclaim, in law or in equity, of any nature or kind. All security interests granted to Collateral Trustee by a Loan Party under any Loan Document are hereby reaffirmed by such Loan Party. Except as expressly set forth herein, the terms of the Loan Documents remain in effect.

7.2 This Forbearance Agreement and the Loan Documents represent the entire agreement with respect to this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Forbearance Agreement and the Loan Documents merge into this Forbearance Agreement and the Loan Documents.

7.3 This Forbearance Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

7.4 This Forbearance Agreement shall constitute a Loan Document. Accordingly, the provisions of Section 11 of the Agreement shall likewise apply to this Forbearance Agreement.

7.5 Each of Schedule 1 (Specified Defaults) and Schedule 2 (Forbearance Terms) may be modified with the approval of the Required Lenders and Administrative Agent in their sole and absolute discretion, and agreed to by the Loan Parties, by attaching hereto a modified Schedule 1 or Schedule 2, as applicable, duly executed by each of the parties hereto, which modified schedules shall indicate the effective date of such modification. Any such modification shall be effective from the effective date indicated in such modified schedule, and any such modification in any instance, shall not establish any course of dealing or obligate Lenders or Administrative Agent to agree to any future modification thereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Forbearance Agreement to be executed as of the date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES INC., a British Columbia corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VARIATION BIOTECHNOLOGIES (US), INC., a Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

ADMINISTRATIVE AGENT:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

LENDER:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

SCHEDULE 1 SPECIFIED DEFAULTS

1. Failure to achieve Revenue for the measurement period ended September 30, 2023 in the amount required pursuant to Section 6.10.
-

SCHEDULE 2
FORBEARANCE TERMS

Forbearance Expiration Date: January 23, 2024

Effective Date: January 9, 2024

Forbearance Conditions:

1. Forbearance Period Termination. The Borrower shall provide immediate written notice to the Administrative Agent of any event or condition that would result in a termination of the Forbearance Period.

2. Update Calls. Loan Parties shall make management available to participate in conference call with Administrative Agent from time to time upon request by Administrative Agent, to participate in discussions on such matters concerning the Loan Parties (including as to financial data, reports, and projections), as Administrative Agent may reasonably request.

3. 13-Week Cash Flow Budget. Borrower Representative shall deliver to Administrative Agent not later than 5:00 p.m., Eastern Time, on each Wednesday (the “**Delivery Date**”) following the Effective Date:

(a) cash flow forecast and sources and uses budget for the 13-week period commencing at such time and in the form agreed to by the Loan Parties and the Administrative Agent prior to the Delivery Date (the “**13-Week Cash Flow Budget**”); and

(b) an accounts payable aging report, in form satisfactory to Administrative Agent.

Notwithstanding anything to the contrary herein, the parties understand and agree that the initial 13-Week Cash Flow Budget due the day after the Effective Date shall be subject to updates for certain expected expenditures not yet incorporated as discussed among the parties prior to the Effective Date, provided that Borrower Representative shall endeavor to provide information regarding such updates as promptly as practicable and Administrative Agent shall not unreasonably withhold approval to such updates.

4. Budget Variance Report. Not later than 5:00 p.m., Eastern Time, on every Wednesday, Borrower Representative shall deliver to Administrative Agent a report, in form and substance reasonably satisfactory to Administrative Agent, for the immediately preceding four-week period (or such shorter period commencing on the first week following the Effective Date covered by a 13-Week Cash Flow Budget delivered in accordance with the above) that (i) sets forth the variances for the Loan Parties (as a percentage and as a dollar amount) between the actual cash uses and the corresponding projected amounts reflected in the 13-Week Cash Flow Budget then in effect for the corresponding period.

5. Other Information Requested. Borrower Representative shall deliver any other financial or other information with respect to the business of the Loan Parties or other matters upon request by Administrative Agent no later than the Business Day following receipt of such request.

6. Adherence with 13-Week Cash Flow Budget. Loan Parties shall not permit total cash uses for any two week period to exceed the amount set forth in the 13-Week Cash Flow Budget for such two week period, as applicable by more than 10% without prior written approval by Administrative Agent, provided that for purposes of the foregoing, Lender Expenses and any legal expenses of the Loan Parties incurred in connection with the Loan Documents or other fees and expenses as approved by Administrative Agent as of the Effective Date or from time to time thereafter may be disregarded.

[APPROVAL OF UPDATED FORBEARANCE TERMS (01.09.24)]

This updated Schedule 2 is approved by the undersigned as of the Effective Date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES INC., a British Columbia corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VARIATION BIOTECHNOLOGIES (US), INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

[APPROVAL OF UPDATED FORBEARANCE TERMS (01.09.24)]

ADMINISTRATIVE AGENT:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora

Name: Anup Arora

Title: Chief Investment Officer and Managing Director

LENDER:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora

Name: Anup Arora

Title: Chief Investment Officer and Managing Director

FORBEARANCE AGREEMENT

This FORBEARANCE AGREEMENT (this “**Forbearance Agreement**”) is entered into as of November 13, 2023 (“**Effective Date**”) by and among **VARIATION BIOTECHNOLOGIES INC.**, a Canadian federal corporation (“**Borrower Representative**”), **VBI VACCINES INC.**, a British Columbia corporation (“**Parent**”, and together with Borrower Representative, and any other Person from time to time party to the Agreement (as defined below) as a borrower, collectively, “**Borrowers**”, and each, a “**Borrower**”), each of the parties set forth on the signature page hereto as guarantors (together with any other Person from time to time party to the Agreement as a guarantor, collectively, “**Guarantors**” and each, a “**Guarantor**”), the lenders party hereto (together with any other lender from time to time under the Agreement, collectively, “**Lenders**”, and each, a “**Lender**”) constituting Required Lenders (as defined in the Agreement (as defined below)), and **K2 HEALTHVENTURES LLC**, as administrative agent for Lenders (in such capacity, together with its successors, “**Administrative Agent**”).

RECITALS

A. Reference is made to (i) that certain Loan and Guaranty Agreement, dated as of May 22, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the “**Agreement**”) by and among Borrowers, Guarantors, Lenders, Administrative Agent and ANKURA TRUST COMPANY, LLC, as collateral trustee for Lenders (in such capacity, together with its successors, “**Collateral Trustee**”).

B. Certain Events of Default, as described on Schedule 1 attached hereto, have occurred (the “**Specified Defaults**”).

C. Borrowers have requested a forbearance with respect to the Specified Defaults and the undersigned Lenders, constituting Required Lenders, have agreed, to so forbear subject to the terms and conditions in this Forbearance Agreement.

AGREEMENT

1. Forbearance. Borrowers hereby acknowledge that the Specified Defaults have occurred. Administrative Agent and Lenders, although under no obligation to do so, hereby agree to forbear from exercising (or causing to be exercised) Secured Parties’ rights and remedies under the Loan Documents or applicable law with respect to the Specified Defaults, from the date hereof through and including the Forbearance Expiration Date (as defined on Schedule 2 hereto, and such period, the “**Forbearance Period**”) subject to compliance by Loan Parties with the terms and conditions specified on Schedule 2 hereto of this Forbearance Agreement and the other Loan Documents. The Forbearance Period shall immediately terminate if an Event of Default other than the Specified Defaults occurs, including any Event of Default caused by a breach of the terms of this Forbearance Agreement.

2. Representations. To induce Administrative Agent and Required Lenders to enter into this Forbearance Agreement, each Loan Party hereby represent and warrant as follows:

2.1 The representations and warranties contained in the Agreement and in other Loan Documents are true and correct in all material respects as of the date of this Forbearance Agreement (except for such representations and warranties referring to another date, which representations and warranties are true and correct in all material respects as of such date).

2.2 Other than the Specified Defaults, no Event of Default has occurred and is continuing.

2.3 Each Loan Party has the power and authority to execute and deliver this Forbearance Agreement and to perform its obligations under the Agreement and other Loan Documents to which it is a party.

2.4 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, (a) have been duly authorized by all necessary action on the part of such Loan Party, and (b) do not and will not contravene (i) any material Requirement of Law, (ii) any material contractual restriction in any material agreement with a Person binding on such Loan Party, (iii) any order, judgment or decree of any Governmental Authority binding on such Loan Party, or (iv) the Operating Documents operating of such Loan Party.

2.5 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by, any Governmental Authority, except as already has been obtained or made.

2.6 This Forbearance Agreement has been duly executed and delivered by each Loan Party and is the binding obligation of each Loan Party, enforceable against such Loan Party in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application relating to or affecting creditors' rights and by general equitable principles.

3. Conditions. As a condition to the effectiveness of this Forbearance Agreement, Administrative Agent shall have received, in form and substance satisfactory to Administrative Agent in its sole discretion, the following:

3.1 this Forbearance Agreement, duly executed by the Loan Parties; and

3.2 payment of all fees and Lender Expenses due on the Effective Date in accordance with the Agreement, as amended.

4. Affirmations.

4.1 Each Loan Party hereby reaffirms and ratifies and confirms in all respects, the Agreement and each other Loan Document to which it is a party and agrees and acknowledges that the Agreement and each other Loan Document to which it is a party, remains in full force and effect.

4.2 Each of the Loan Parties agrees and acknowledges that the security interest as granted pursuant to the Pledge and Security Agreement, the Canadian Security Documents or the Israeli Security Documents, as applicable, continues to secure the Obligations from the Closing Date without novation, and this Forbearance Agreement is not intended to be, and shall not constitute, a novation.

4.3 The Guarantors agree and acknowledge the terms of this Forbearance Agreement and confirm that the guaranty pursuant to Section 13 of the Agreement remains in full force and effect as of the date hereof with respect to the Obligations.

5. General release

5.1 For good and valuable consideration, each Loan Party hereby forever relieves, releases, and discharges Administrative Agent, Collateral Trustee and each Lender (collectively, "**Secured Parties**") and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them (in each case, in his, her or its capacity as such with respect to such Secured Party), from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Forbearance Agreement (collectively "**Released Claims**"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

5.2 By entering into this release, each Loan Party recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of such Loan Party hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if such Loan Party should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, such Loan Party shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Each Loan Party acknowledges that it is not relying upon and has not relied upon any representation or statement made by any Secured Party with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

5.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Each Loan Party acknowledges that the release contained herein constitutes a material inducement to Secured Parties to enter into this Forbearance Agreement, and that Secured Parties would not have done so but for Secured Parties' expectation that such release is valid and enforceable in all events.

5.4 Each Loan Party hereby represents and warrants to Secured Parties, and each Secured Party is relying thereon, as follows:

5.4.1 Except as expressly stated in this Forbearance Agreement, neither any Secured Party nor any agent, employee or representative of Secured Parties has made any statement or representation to such Loan Party regarding any fact relied upon by Loan Party in entering into this Forbearance Agreement.

5.4.2 Such Loan Party has made such investigation of the facts pertaining to this Forbearance Agreement and all of the matters appertaining thereto, as it deems necessary.

5.4.3 The terms of this Forbearance Agreement are contractual and not a mere recital.

5.4.4 This Forbearance Agreement has been carefully read by such Loan Party, the contents hereof are known and understood by such Loan Party, and this Forbearance Agreement is signed freely, and without duress, by such Loan Party.

5.4.5 Such Loan Party is the sole and lawful owner of all right, title and interest in and to every claim and every other matter which it releases herein, and that it has not heretofore assigned or transferred, or purported to assign or transfer, to any person, firm or entity any claims or other matters herein released. Each Loan Party shall indemnify Secured Parties, defend and hold it harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

6. Governing Law. Sections 11 and 12 of the Agreement is incorporated herein, provided that references to the "Agreement" shall be understood to refer to this Forbearance Agreement.

7. General Provisions

7.1 Unless otherwise defined, all initially capitalized terms in this Forbearance Agreement shall be as defined in the Agreement. The Agreement and this Forbearance Agreement shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. The execution, delivery, and performance of this Forbearance Agreement shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Secured Parties under the Agreement, as in effect prior to the date hereof. Each Loan Party ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement. No course of dealing on the part of Secured Parties or its officers, nor any failure or delay in the exercise of any right by Secured Parties, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Secured Parties' failure at any time to require strict performance by Loan Party of any provision shall not affect any right of Secured Parties thereafter to demand strict compliance and performance. Each Loan Party hereby acknowledges that the Obligations due and owing to Secured Parties are without setoff, recoupment, defense or counterclaim, in law or in equity, of any nature or kind. All security interests granted to Collateral Trustee by a Loan Party under any Loan Document are hereby reaffirmed by such Loan Party. Except as expressly set forth herein, the terms of the Loan Documents remain in effect.

7.2 This Forbearance Agreement and the Loan Documents represent the entire agreement with respect to this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Forbearance Agreement and the Loan Documents merge into this Forbearance Agreement and the Loan Documents.

7.3 This Forbearance Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

7.4 This Forbearance Agreement shall constitute a Loan Document. Accordingly, the provisions of Section 11 of the Agreement shall likewise apply to this Forbearance Agreement.

7.5 Each of Schedule 1 (Specified Defaults) and Schedule 2 (Forbearance Terms) may be modified with the approval of the Required Lenders and Administrative Agent in their sole and absolute discretion, and agreed to by the Loan Parties, by attaching hereto a modified Schedule 1 or Schedule 2, as applicable, duly executed by each of the parties hereto, which modified schedules shall indicate the effective date of such modification. Any such modification shall be effective from the effective date indicated in such modified schedule, and any such modification in any instance, shall not establish any course of dealing or obligate Lenders or Administrative Agent to agree to any future modification thereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Forbearance Agreement to be executed as of the date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES INC., a British Columbia corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VARIATION BIOTECHNOLOGIES (US), INC., a
Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

ADMINISTRATIVE AGENT:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

LENDER:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

SCHEDULE 1 SPECIFIED DEFAULTS

1. Failure to achieve Revenue for the measurement period ended September 30, 2023 in the amount required pursuant to Section 6.10.
-

SCHEDULE 2
FORBEARANCE TERMS

Forbearance Expiration Date: February 6, 2024

Effective Date: January 23, 2024

Forbearance Conditions:

1. Forbearance Period Termination. The Borrower shall provide immediate written notice to the Administrative Agent of any event or condition that would result in a termination of the Forbearance Period.

2. Update Calls. Loan Parties shall make management available to participate in conference call with Administrative Agent from time to time upon request by Administrative Agent, to participate in discussions on such matters concerning the Loan Parties (including as to financial data, reports, and projections), as Administrative Agent may reasonably request.

3. 13-Week Cash Flow Budget. Borrower Representative shall deliver to Administrative Agent not later than 5:00 p.m., Eastern Time, on each Wednesday (the “**Delivery Date**”) following the Effective Date:

(a) cash flow forecast and sources and uses budget for the 13-week period commencing at such time and in the form agreed to by the Loan Parties and the Administrative Agent prior to the Delivery Date (the “**13-Week Cash Flow Budget**”); and

(b) an accounts payable aging report, in form satisfactory to Administrative Agent.

Notwithstanding anything to the contrary herein, the parties understand and agree that the initial 13-Week Cash Flow Budget due the day after the Effective Date shall be subject to updates for certain expected expenditures not yet incorporated as discussed among the parties prior to the Effective Date, provided that Borrower Representative shall endeavor to provide information regarding such updates as promptly as practicable and Administrative Agent shall not unreasonably withhold approval to such updates.

4. Budget Variance Report. Not later than 5:00 p.m., Eastern Time, on every Wednesday, Borrower Representative shall deliver to Administrative Agent a report, in form and substance reasonably satisfactory to Administrative Agent, for the immediately preceding four-week period (or such shorter period commencing on the first week following the Effective Date covered by a 13-Week Cash Flow Budget delivered in accordance with the above) that (i) sets forth the variances for the Loan Parties (as a percentage and as a dollar amount) between the actual cash uses and the corresponding projected amounts reflected in the 13-Week Cash Flow Budget then in effect for the corresponding period.

5. Other Information Requested. Borrower Representative shall deliver any other financial or other information with respect to the business of the Loan Parties or other matters upon request by Administrative Agent no later than the Business Day following receipt of such request.

6. Adherence with 13-Week Cash Flow Budget. Loan Parties shall not permit total cash uses for any two week period to exceed the amount set forth in the 13-Week Cash Flow Budget for such two week period, as applicable by more than 10% without prior written approval by Administrative Agent, provided that for purposes of the foregoing, Lender Expenses and any legal expenses of the Loan Parties incurred in connection with the Loan Documents or other fees and expenses as approved by Administrative Agent as of the Effective Date or from time to time thereafter may be disregarded.

[APPROVAL OF UPDATED FORBEARANCE TERMS (01.23.24)]

This updated Schedule 2 is approved by the undersigned as of the Effective Date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES INC., a British Columbia corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VARIATION BIOTECHNOLOGIES (US), INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

[APPROVAL OF UPDATED FORBEARANCE TERMS (01.23.24)]

ADMINISTRATIVE AGENT: K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer and Managing Director

LENDER: K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer and Managing Director

FORBEARANCE AGREEMENT

This FORBEARANCE AGREEMENT (this “**Forbearance Agreement**”) is entered into as of November 13, 2023 (“**Effective Date**”) by and among **VARIATION BIOTECHNOLOGIES INC.**, a Canadian federal corporation (“**Borrower Representative**”), **VBI VACCINES INC.**, a British Columbia corporation (“**Parent**”, and together with Borrower Representative, and any other Person from time to time party to the Agreement (as defined below) as a borrower, collectively, “**Borrowers**”, and each, a “**Borrower**”), each of the parties set forth on the signature page hereto as guarantors (together with any other Person from time to time party to the Agreement as a guarantor, collectively, “**Guarantors**” and each, a “**Guarantor**”), the lenders party hereto (together with any other lender from time to time under the Agreement, collectively, “**Lenders**”, and each, a “**Lender**”) constituting Required Lenders (as defined in the Agreement (as defined below)), and **K2 HEALTHVENTURES LLC**, as administrative agent for Lenders (in such capacity, together with its successors, “**Administrative Agent**”).

RECITALS

A. Reference is made to (i) that certain Loan and Guaranty Agreement, dated as of May 22, 2020 (as amended, restated, supplemented or otherwise modified from time to time, the “**Agreement**”) by and among Borrowers, Guarantors, Lenders, Administrative Agent and ANKURA TRUST COMPANY, LLC, as collateral trustee for Lenders (in such capacity, together with its successors, “**Collateral Trustee**”).

B. Certain Events of Default, as described on Schedule 1 attached hereto, have occurred (the “**Specified Defaults**”).

C. Borrowers have requested a forbearance with respect to the Specified Defaults and the undersigned Lenders, constituting Required Lenders, have agreed, to so forbear subject to the terms and conditions in this Forbearance Agreement.

AGREEMENT

1. Forbearance. Borrowers hereby acknowledge that the Specified Defaults have occurred. Administrative Agent and Lenders, although under no obligation to do so, hereby agree to forbear from exercising (or causing to be exercised) Secured Parties’ rights and remedies under the Loan Documents or applicable law with respect to the Specified Defaults, from the date hereof through and including the Forbearance Expiration Date (as defined on Schedule 2 hereto, and such period, the “**Forbearance Period**”) subject to compliance by Loan Parties with the terms and conditions specified on Schedule 2 hereto of this Forbearance Agreement and the other Loan Documents. The Forbearance Period shall immediately terminate if an Event of Default other than the Specified Defaults occurs, including any Event of Default caused by a breach of the terms of this Forbearance Agreement.

2. Representations. To induce Administrative Agent and Required Lenders to enter into this Forbearance Agreement, each Loan Party hereby represent and warrant as follows:

2.1 The representations and warranties contained in the Agreement and in other Loan Documents are true and correct in all material respects as of the date of this Forbearance Agreement (except for such representations and warranties referring to another date, which representations and warranties are true and correct in all material respects as of such date).

2.2 Other than the Specified Defaults, no Event of Default has occurred and is continuing.

2.3 Each Loan Party has the power and authority to execute and deliver this Forbearance Agreement and to perform its obligations under the Agreement and other Loan Documents to which it is a party.

2.4 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, (a) have been duly authorized by all necessary action on the part of such Loan Party, and (b) do not and will not contravene (i) any material Requirement of Law, (ii) any material contractual restriction in any material agreement with a Person binding on such Loan Party, (iii) any order, judgment or decree of any Governmental Authority binding on such Loan Party, or (iv) the Operating Documents operating of such Loan Party.

2.5 The execution and delivery by each Loan Party of this Forbearance Agreement and the performance by each Loan Party of their respective obligations under the Agreement and the other Loan Documents to which it is a party, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by, any Governmental Authority, except as already has been obtained or made.

2.6 This Forbearance Agreement has been duly executed and delivered by each Loan Party and is the binding obligation of each Loan Party, enforceable against such Loan Party in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application relating to or affecting creditors' rights and by general equitable principles.

3. Conditions. As a condition to the effectiveness of this Forbearance Agreement, Administrative Agent shall have received, in form and substance satisfactory to Administrative Agent in its sole discretion, the following:

3.1 this Forbearance Agreement, duly executed by the Loan Parties; and

3.2 payment of all fees and Lender Expenses due on the Effective Date in accordance with the Agreement, as amended.

4. Affirmations.

4.1 Each Loan Party hereby reaffirms and ratifies and confirms in all respects, the Agreement and each other Loan Document to which it is a party and agrees and acknowledges that the Agreement and each other Loan Document to which it is a party, remains in full force and effect.

4.2 Each of the Loan Parties agrees and acknowledges that the security interest as granted pursuant to the Pledge and Security Agreement, the Canadian Security Documents or the Israeli Security Documents, as applicable, continues to secure the Obligations from the Closing Date without novation, and this Forbearance Agreement is not intended to be, and shall not constitute, a novation.

4.3 The Guarantors agree and acknowledge the terms of this Forbearance Agreement and confirm that the guaranty pursuant to Section 13 of the Agreement remains in full force and effect as of the date hereof with respect to the Obligations.

5. General release

5.1 For good and valuable consideration, each Loan Party hereby forever relieves, releases, and discharges Administrative Agent, Collateral Trustee and each Lender (collectively, "**Secured Parties**") and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them (in each case, in his, her or its capacity as such with respect to such Secured Party), from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Forbearance Agreement (collectively "**Released Claims**"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

5.2 By entering into this release, each Loan Party recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of such Loan Party hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if such Loan Party should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, such Loan Party shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Each Loan Party acknowledges that it is not relying upon and has not relied upon any representation or statement made by any Secured Party with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

5.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Each Loan Party acknowledges that the release contained herein constitutes a material inducement to Secured Parties to enter into this Forbearance Agreement, and that Secured Parties would not have done so but for Secured Parties' expectation that such release is valid and enforceable in all events.

5.4 Each Loan Party hereby represents and warrants to Secured Parties, and each Secured Party is relying thereon, as follows:

5.4.1 Except as expressly stated in this Forbearance Agreement, neither any Secured Party nor any agent, employee or representative of Secured Parties has made any statement or representation to such Loan Party regarding any fact relied upon by Loan Party in entering into this Forbearance Agreement.

5.4.2 Such Loan Party has made such investigation of the facts pertaining to this Forbearance Agreement and all of the matters appertaining thereto, as it deems necessary.

5.4.3 The terms of this Forbearance Agreement are contractual and not a mere recital.

5.4.4 This Forbearance Agreement has been carefully read by such Loan Party, the contents hereof are known and understood by such Loan Party, and this Forbearance Agreement is signed freely, and without duress, by such Loan Party.

5.4.5 Such Loan Party is the sole and lawful owner of all right, title and interest in and to every claim and every other matter which it releases herein, and that it has not heretofore assigned or transferred, or purported to assign or transfer, to any person, firm or entity any claims or other matters herein released. Each Loan Party shall indemnify Secured Parties, defend and hold it harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

6. Governing Law. Sections 11 and 12 of the Agreement is incorporated herein, provided that references to the "Agreement" shall be understood to refer to this Forbearance Agreement.

7. General Provisions

7.1 Unless otherwise defined, all initially capitalized terms in this Forbearance Agreement shall be as defined in the Agreement. The Agreement and this Forbearance Agreement shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. The execution, delivery, and performance of this Forbearance Agreement shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Secured Parties under the Agreement, as in effect prior to the date hereof. Each Loan Party ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement. No course of dealing on the part of Secured Parties or its officers, nor any failure or delay in the exercise of any right by Secured Parties, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Secured Parties' failure at any time to require strict performance by Loan Party of any provision shall not affect any right of Secured Parties thereafter to demand strict compliance and performance. Each Loan Party hereby acknowledges that the Obligations due and owing to Secured Parties are without setoff, recoupment, defense or counterclaim, in law or in equity, of any nature or kind. All security interests granted to Collateral Trustee by a Loan Party under any Loan Document are hereby reaffirmed by such Loan Party. Except as expressly set forth herein, the terms of the Loan Documents remain in effect.

7.2 This Forbearance Agreement and the Loan Documents represent the entire agreement with respect to this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Forbearance Agreement and the Loan Documents merge into this Forbearance Agreement and the Loan Documents.

7.3 This Forbearance Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

7.4 This Forbearance Agreement shall constitute a Loan Document. Accordingly, the provisions of Section 11 of the Agreement shall likewise apply to this Forbearance Agreement.

7.5 Each of Schedule 1 (Specified Defaults) and Schedule 2 (Forbearance Terms) may be modified with the approval of the Required Lenders and Administrative Agent in their sole and absolute discretion, and agreed to by the Loan Parties, by attaching hereto a modified Schedule 1 or Schedule 2, as applicable, duly executed by each of the parties hereto, which modified schedules shall indicate the effective date of such modification. Any such modification shall be effective from the effective date indicated in such modified schedule, and any such modification in any instance, shall not establish any course of dealing or obligate Lenders or Administrative Agent to agree to any future modification thereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Forbearance Agreement to be executed as of the date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES INC., a British Columbia corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VARIATION BIOTECHNOLOGIES (US), INC., a
Delaware corporation

By /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

[SIGNATURE PAGE TO FORBEARANCE AGREEMENT]

ADMINISTRATIVE AGENT:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

LENDER:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora
Name: Anup Arora
Title: Chief Investment Officer

SCHEDULE 1 SPECIFIED DEFAULTS

1. Failure to achieve Revenue for the measurement period ended September 30, 2023 in the amount required pursuant to Section 6.10.
-

SCHEDULE 2
FORBEARANCE TERMS

Forbearance Expiration Date: February 20, 2024

Effective Date: February 6, 2024

Forbearance Conditions:

1. Forbearance Period Termination. The Borrower shall provide immediate written notice to the Administrative Agent of any event or condition that would result in a termination of the Forbearance Period.

2. Update Calls. Loan Parties shall make management available to participate in conference call with Administrative Agent from time to time upon request by Administrative Agent, to participate in discussions on such matters concerning the Loan Parties (including as to financial data, reports, and projections), as Administrative Agent may reasonably request.

3. 13-Week Cash Flow Budget. Borrower Representative shall deliver to Administrative Agent not later than 5:00 p.m., Eastern Time, on each Wednesday (the “**Delivery Date**”) following the Effective Date:

(a) cash flow forecast and sources and uses budget for the 13-week period commencing at such time and in the form agreed to by the Loan Parties and the Administrative Agent prior to the Delivery Date (the “**13-Week Cash Flow Budget**”); and

(b) an accounts payable aging report, in form satisfactory to Administrative Agent.

Notwithstanding anything to the contrary herein, the parties understand and agree that the initial 13-Week Cash Flow Budget due the day after the Effective Date shall be subject to updates for certain expected expenditures not yet incorporated as discussed among the parties prior to the Effective Date, provided that Borrower Representative shall endeavor to provide information regarding such updates as promptly as practicable and Administrative Agent shall not unreasonably withhold approval to such updates.

4. Budget Variance Report. Not later than 5:00 p.m., Eastern Time, on every Wednesday, Borrower Representative shall deliver to Administrative Agent a report, in form and substance reasonably satisfactory to Administrative Agent, for the immediately preceding four-week period (or such shorter period commencing on the first week following the Effective Date covered by a 13-Week Cash Flow Budget delivered in accordance with the above) that (i) sets forth the variances for the Loan Parties (as a percentage and as a dollar amount) between the actual cash uses and the corresponding projected amounts reflected in the 13-Week Cash Flow Budget then in effect for the corresponding period.

5. Other Information Requested. Borrower Representative shall deliver any other financial or other information with respect to the business of the Loan Parties or other matters upon request by Administrative Agent no later than the Business Day following receipt of such request.

6. Adherence with 13-Week Cash Flow Budget. Loan Parties shall not permit total cash uses for any two week period to exceed the amount set forth in the 13-Week Cash Flow Budget for such two week period, as applicable by more than 10% without prior written approval by Administrative Agent, provided that for purposes of the foregoing, Lender Expenses and any legal expenses of the Loan Parties incurred in connection with the Loan Documents or other fees and expenses as approved by Administrative Agent as of the Effective Date or from time to time thereafter may be disregarded.

[APPROVAL OF UPDATED FORBEARANCE TERMS (02.06.24)]

This updated Schedule 2 is approved by the undersigned as of the Effective Date set forth above.

BORROWERS:

VARIATION BIOTECHNOLOGIES INC., a Canadian federal corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES INC., a British Columbia corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

GUARANTORS:

SCIVAC LTD., an Israeli corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

VARIATION BIOTECHNOLOGIES (US), INC., a Delaware corporation

By: /s/ Jeffrey Baxter
Name: Jeffrey Baxter
Title: Chief Executive Officer

[APPROVAL OF UPDATED FORBEARANCE TERMS (02.06.24)]

ADMINISTRATIVE AGENT:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora

Name: Anup Arora

Title: Chief Investment Officer and Managing Director

LENDER:

K2 HEALTHVENTURES LLC

By: /s/ Anup Arora

Name: Anup Arora

Title: Chief Investment Officer and Managing Director

AMENDMENT TO CONSULTING AGREEMENT

This Amendment to Consulting Agreement (the “**Amendment**”), effective as of **January 1st, 2024** (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, January 1, 2022 and further amended as of January 1, 2023 (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, 2024 (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/ Jeffrey Baxter

Name: Jeffrey Baxter

Title: Chief Executive Officer

F. DIAZ-MITOMA PROFESSIONAL CORPORATION

/s/ Dr. Francisco Diaz-Mitoma

Name: Dr. Francisco Diaz-Mitoma

Title: President

Schedule A

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 April 16, 2024, on our audits of the consolidated financial statements as of December 31, 2023 and 2022 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 April 16, 2024. 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

April 16, 2024

CERTIFICATION

I, Jeffrey Baxter, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2023 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: April 16, 2024

/s/ Jeffrey Baxter

Jeffrey Baxter

Chief Executive Officer (Principal Executive Officer)

CERTIFICATION

I, Nell Beattie, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2023 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: April 16, 2024

/s/ Nell Beattie

Nell Beattie

Chief Financial Officer and Head of Corporate Development (Principal Financial and Accounting Officer)

CERTIFICATION

In connection with the annual report of VBI Vaccines Inc. (the “Company”) on Form 10-K for the year ended December 31, 2023 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: April 16, 2024

/s/ Jeffrey Baxter

Jeffrey Baxter

Chief Executive Officer (Principal Executive Officer)

CERTIFICATION

In connection with the annual report of VBI Vaccines Inc. (the “Company”) on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission (the “Report”), I, Nell Beattie, Chief Financial Officer and Head of Corporate 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: April 16, 2024

/s/ Nell Beattie

Nell Beattie

Chief Financial Officer and Head of Corporate Development (Principal Financial
and Accounting Officer)

VBI Vaccines Inc. Compensation Recovery Policy

This Compensation Recovery Policy (this “Policy”) of VBI Vaccines Inc. (the “Company”) is hereby adopted as of November 21, 2023, in compliance with Rule 5608 of the Nasdaq Rules. Certain terms used herein shall have the meanings as set for in “Section 3. Definitions” below.

Section 1. Recovery Requirement

Subject to Section 4 of this Policy, in the event the Company is required to prepare an Accounting Restatement, then the Board and Committee hereby direct the Company, to the fullest extent permitted by governing law, to recover from each Executive Officer the amount, if any, of Erroneously Awarded Compensation received by such Executive Officer, with such recovery occurring reasonably promptly after the Restatement Date relating to such Accounting Restatement.

The Board or the Committee may effect recovery in any manner consistent with applicable law including, but not limited to, (a) seeking reimbursement of all or part of Erroneously Awarded Compensation previously received by an Executive Officer, together with any expenses reasonably incurred as described below in connection with the recovery of such Erroneously Awarded Compensation, (b) cancelling prior grants of Incentive-Based Compensation, whether vested or unvested, restricted or deferred, or paid or unpaid, and through the forfeiture of previously vested equity awards, (c) cancelling or setting-off against planned future grants of Incentive-Based Compensation, (d) deducting all or any portion of such Erroneously Awarded Compensation from any other remuneration payable by the Company to such Executive Officer, and (e) any other method authorized by applicable law or contract.

To the extent that an Executive Officer fails to repay all Erroneously Awarded Compensation to the Company when due, the Company shall take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Executive Officer. The applicable Executive Officer shall be required to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

The Company’s right to recovery pursuant to this Policy is not dependent on if or when the Accounting Restatement is filed with the SEC.

Section 2. Incentive-Based Compensation Subject to this Policy

This Policy applies to all Incentive-Based Compensation received by each Executive Officer on or after the Effective Date, including:

- if such Incentive-Based Compensation was received on and after the date such person became an Executive Officer of the Company;
 - if such Executive Officer served as an Executive Officer at any time during the performance period for such Incentive-Based Compensation;
 - while the Company has a class of securities listed on a national securities exchange or a national securities association; and
 - during the three completed fiscal years immediately preceding the date that the Company is required to prepare an Accounting Restatement (including any transition period that results from a change in the Company’s fiscal year that is within or immediately following those three completed fiscal years; provided that a transition period of nine to 12 months is deemed to be a completed fiscal year).
-

This Policy shall apply and govern Incentive-Based Compensation received by any Executive Officer, notwithstanding any contrary or supplemental term or condition in any document, plan or agreement including, without limitation, any employment contract, indemnification agreement, equity or bonus agreement, or equity or bonus plan document.

Section 3. Definitions

For purposes of this Policy, the following terms have the meanings set forth below:

- *Accounting Restatement* - means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error:
 - (i) in previously issued financial statements that is material to the previously issued financial statements (commonly referred to as a “Big R” restatement), or
 - (ii) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (commonly referred to as a “little r” restatement).
 - *Board* - means the Board of Directors of the Company.
 - *Committee* - means the Compensation Committee of the Board.
 - *Effective Date* - means October 2, 2023.
 - *Erroneously Awarded Compensation* - means the amount of Incentive-Based Compensation received that exceeds the amount of Incentive-Based Compensation that otherwise would have been received by the Executive Officer had it been determined based on the restated amounts in the Accounting Restatement (computed without regard to any taxes paid). For Incentive-Based Compensation based on share price or total shareholder return (“TSR”), where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the Accounting Restatement, the Company shall:
 - (i) base the calculation of the amount on a reasonable estimate of the effect of the Accounting Restatement on the share price or TSR upon which the Incentive-Based Compensation received was based; and
 - (ii) retain documentation of the determination of that reasonable estimate and provide such documentation to The Nasdaq Stock Market LLC (“Nasdaq”) or, if a class of securities of the Company is no longer listed on Nasdaq, such other national securities exchange or national securities association on which a class of the Company’s securities is then listed for trading.
 - *Executive Officer* - means the Company’s current and former executive officers, as determined by the Board or the Committee in accordance with the definition of executive officer set forth in Rule 5608(d) of the Nasdaq Rules.
 - *Financial Reporting Measures* - means measures that are determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, and any measures that are derived wholly or in part from such measures. Share price and TSR are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the Company’s financial statements or included in any of the Company’s filings with the SEC.
 - *Incentive-Based Compensation* - means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure (including, without limitation, any cash bonuses, performance awards, restricted stock awards or restricted stock unit awards that are granted, earned or vest based on achievement of a Financial Reporting Measure). The following do not constitute Incentive-Based Compensation for purposes of this Policy:
 - (a) equity awards for which (1) the grant is not contingent upon achieving any Financial Reporting Measure performance goals and (2) vesting is contingent solely upon completion of a specified employment period and/or attaining one or more nonfinancial reporting measures, and
 - (b) bonus awards that are discretionary or based on subjective goals or goals unrelated to Financial Reporting Measures.
-

- *Nasdaq Rules* - means the listing rules of The Nasdaq Stock Market LLC.
- *Received* - An Executive Officer shall be deemed to have “received” Incentive-Based Compensation in the Company’s fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that fiscal period.
- *Restatement Date* - means the earlier to occur of:
 - (i) the date the Board or the Committee (or an officer or officers of the Company authorized to take such action if Board action is not required) concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement and
 - (j) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.
- *SEC* - means the U.S. Securities and Exchange Commission.

Section 4. Exceptions to Recovery

Notwithstanding the foregoing, the Company is not required to recover Erroneously Awarded Compensation to the extent that the Committee, or in the absence of such committee, a majority of the independent directors serving on the Board has made a determination that recovery would be impracticable and that:

- (i) after the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation (which has been documented and such documentation has been provided to Nasdaq), the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered;
- (ii) recovery would violate one or more laws of the home country that were adopted prior to November 28, 2022 (which determination shall be made after the Company obtains an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in a such a violation, and a copy of such opinion is provided to Nasdaq);
- (iii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company and its subsidiaries, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder; or
- (iv) any other exception permitted under Rule 5608(b)(1)(iv) of the Nasdaq Rules.

Section 5. Right to Adjust Unvested Incentive-Based Compensation

If the Board or the Committee, in its sole discretion, determines that the performance metrics of outstanding but unvested Incentive-Based Compensation were established using Financial Reporting Measures that were impacted by the Accounting Restatement, the Board or the Committee, in its sole discretion, may adjust such Financial Reporting Measures or modify such Incentive-Based Compensation, in such manner as the Board or the Committee determines, in its sole discretion, to be appropriate.

Section 6. Additional Actions in Case of Misconduct

If the Board or the Committee learns of any misconduct by an Executive Officer that contributed to the Company's having to restate its financial statements, it shall take, or direct the Company to take, such action as it deems reasonably necessary to remedy the misconduct, prevent its recurrence and, if appropriate, based on all relevant facts and circumstances, take remedial action against the wrongdoer. In determining whether remedial action is appropriate, the Board or the Committee shall take into account such factors as it deems relevant, including whether the misconduct reflected negligence, recklessness, or intentional wrongdoing. Remedial action may include dismissal and initiating legal action against the Executive Officer, termination of employment, and/or forfeiture of existing awards, including, without limitation, awards that do not constitute Incentive-Based Compensation, or clawback of prior amounts paid or shares vested.

In determining what action to take or to require the Company to take, the Board and the Committee may consider, among other things, penalties or punishments imposed by third parties, such as law enforcement agencies, regulators, or other authorities, the impact upon the Company in any related proceeding or investigation of taking remedial action against an Executive Officer, and the cost and likely outcome of taking remedial action. The Board's and the Committee's power to determine the appropriate remedial action is in addition to, and not in replacement of, remedies imposed by such authorities.

Section 7. No Right to Indemnification or Insurance

The Company shall not indemnify any Executive Officer against the loss of Erroneously Awarded Compensation or losses arising from any claims relating to the Company's enforcement of this Policy. In addition, the Company shall not pay or reimburse any Executive Officer for any premiums for a third-party insurance policy purchased by the Executive Officer or any other party that would fund any of the Executive Officer's potential recovery obligations under this Policy.

Section 8. Interpretation and Amendment of this Policy

The Board or the Committee, in its discretion, shall have the sole authority to interpret and make any determinations regarding this Policy. Any interpretation, determination, or other action made or taken by the Committee (or, if applicable, the Board) shall be final, binding, and conclusive on all interested parties. The determination of the Committee (or, if applicable, the Board) need not be uniform with respect to one or more officers of the Company. The Board or the Committee may amend this Policy from time to time in its discretion and shall amend the Policy to comply with any rules or standards adopted by Nasdaq or any national securities exchange on which the Company's securities are then listed.

Section 9. Filing Requirement

The Company shall file this Policy as an exhibit to its Annual Report on Form 10-K and make such other disclosures with respect to this Policy in accordance with the requirements of the federal securities laws, including the disclosure required by applicable SEC rules and regulations.

Section 10. Other Recoupment Rights

The Company intends that this Policy will be applied to the fullest extent of the law. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other remedies available to the Company under applicable law. Without by implication limiting the foregoing, following a restatement of the Company's financial statements, the Company also shall be entitled to recover any compensation received by the Chief Executive Officer and Chief Financial Officer that is required to be recovered by Section 304 of the Sarbanes-Oxley Act of 2002.

Section 11. Successors

This Policy shall be binding and enforceable against all Executive Officers and their respective beneficiaries, heirs, executors, administrators, or other legal representatives.

CORPORATE INFORMATION

DIRECTORS AND EXECUTIVE OFFICERS

Jeffrey R. Baxter, FCMA

President, Chief Executive Officer and Director of the Company

David E. Anderson, Ph.D.

Chief Scientific Officer

Francisco Diaz-Mitoma, M.D. Ph.D. F.R.C.P.C.

Chief Medical Officer

Nell Beattie

Chief Financial Officer and Head of Corporate Development and Director of the Company

John Dillman

Chief Commercial Officer

Avi Mazaltov

Global Head of Manufacturing and SciVac General Manager

Steven Gillis, Ph.D.

*Chairman and Director of the Company
Managing Director of ARCH Venture Partners*

Damian Braga

Director of the Company

Joanne Cordeiro

Director of the Company

Michel De Wilde, Ph.D.

Director of the Company

Vaughn Himes, Ph.D.

*Director of the Company
Chief Technical Officer of Seagen, Inc.*

Blaine H. McKee, Ph.D.

*Director of the Company
President and Chief Executive Officer of Walden Biosciences*

CORPORATE HEADQUARTERS

160 Second Street, Floor 3
Cambridge, MA 02142
Telephone: (617) 830-3031

STOCK LISTING

NASDAQ Capital Market: VBIV

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

EisnerAmper LLP
111 Wood Avenue South
Iselin, NJ 08830-2700

TRANSFER AGENT AND REGISTRAR

Computershare
510 Burrard Street, 2nd Floor
Vancouver, British Columbia V6C 3B9
Telephone: (604) 661-9442

ANNUAL GENERAL MEETING OF SHAREHOLDERS

The 2024 Annual General Meeting of Shareholders will be held at 11:00 a.m. Eastern Time on June 25, 2024, at the offices of the Company, located at 160 Second Street, Floor 3, Cambridge, MA 02142. Shareholders of record on April 26, 2024, are entitled to notice of and to vote at the Annual General Meeting.

COMPANY WEBSITE

www.vbivaccines.com