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, 2020

OR

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

For the transition period from _____ to _____

Commission File Number 001-37769

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

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

222 Third Street, Suite 2241
Cambridge, MA 02142
(Address of principal executive offices)
(Zip Code)

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

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

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

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

None
(Title of class)

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

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

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

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

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

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒

Emerging growth company ☒

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

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

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

As of June 30, 2020, 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 $499,170,016

As of February 26, 2021, the registrant had 254,004,515 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 2021 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, 2020

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

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

- the timing of, and our ability to, obtain and maintain regulatory approvals for our clinical trials, products, and pipeline candidates;
- 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;
- the impact of the ongoing COVID-19 pandemic on our clinical studies, research programs, manufacturing, business plan, regulatory review including site inspections, and the global economy;
- our ability to effectively execute and deliver our plans related to commercialization, marketing, manufacturing capabilities and strategy;
- our ability to maintain a good relationship with our employees;
- the suitability and adequacy of our office, manufacturing, and research facilities and our ability to secure term extensions or expansions of leased space;
- our ability to manufacture, or to have manufactured, any products we develop at a commercially viable scale to the standards and requirements of regulatory agencies;
- the ability of our vendors and suppliers to manufacture and deliver materials 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 prophylactic hepatitis B vaccine and clinical supplies of our hepatitis B immunotherapeutic, VBI-2601;
- our compliance with all laws, rules, and regulations applicable to our business and products;
- our ability to continue as a going concern;

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

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

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

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

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

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

PART I

ITEM 1. BUSINESS

Overview

VBI Vaccines Inc. ("VBI") is a biopharmaceutical company driven by immunology to deliver powerful prevention and treatment of disease. Through its innovative approach to virus-like particles ("VLPs"), including a proprietary enveloped VLP ("eVLP") platform technology, VBI develops vaccine candidates that mimic the natural presentation of viruses, designed to elicit the innate power of the human immune system. VBI is committed to targeting and overcoming significant infectious diseases, including hepatitis B, 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 – Lead Program Candidates

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

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

Indication	Program	Technology	Current Status
Prophylactic Candidates			
● Hepatitis B ("HBV")	3-antigen Vaccine *(Israel brand name Sci-B-Vac®)*	VLP	BLA and MAA Accepted; Approved in Israel
● Cytomegalovirus ("CMV")	VBI-1501	eVLP	Phase I Completed
● Pan-coronavirus	VBI-2901	eVLP	Pre-Clinical
● COVID-19	VBI-2902	eVLP	Pre-Clinical
Therapeutic Candidates			
● Hepatitis B ("HBV")	VBI-2601	VLP	Ongoing Phase Ib/IIa
● Glioblastoma ("GBM") + Other CMV-Associated Cancers	VBI-1901	eVLP	Ongoing Phase I/IIa

A summary of these programs and recent developments follows.

Prophylactic Pipeline

3-antigen HBV Vaccine

A scientifically-differentiated approach to HBV vaccination, our 3-antigen HBV vaccine candidate expresses all three surface antigens of HBV – pre-S1, pre-S2, and S. Published data demonstrate pre-S1 antigens induce key neutralizing antibodies that block virus receptor binding, and T cell responses to pre-S1 and pre-S2 antigens can further boost responses to the S antigen. Our 3-antigen HBV vaccine is further distinguished from other commercially available HBV vaccines because it is produced in mammalian cells (Chinese hamster ovary "CHO" cells) rather than in yeast.

Our 3-antigen hepatitis B vaccine is approved for use and commercially available in Israel, under the brand name Sci-B-Vac®, and successfully completed its pivotal Phase III program in the United States, Europe, and Canada in January 2020. This Phase III program consisted of two Phase III studies – PROTECT and CONSTANT – designed to assess efficacy and safety of VBI's 3-antigen HBV vaccines compared with Engerix-B®, a single-antigen HBV vaccine, and lot-to-lot manufacturing consistency of three consecutive lots of VBI's vaccine. As announced in June 2019 and January 2020, results from these two studies showed VBI's 3-antigen vaccine achieved: (1) non-inferiority of seroprotection rate (SPR) in all adults age 18 and older (VBI: 91.4% vs. Engerix-B: 76.5%); (2) superiority (as defined in the clinical protocol) of SPR in adults age 45 and older (VBI: 89.4% vs. Engerix-B: 73.1%); (3) higher SPR and titers at all time points across all subgroup populations, including age, diabetic status, and obesity; (4) a safety profile consistent with the known safety profile of the vaccine and comparable to that of Engerix-B; and (5) manufacturing consistency.

The completed Phase III studies support the regulatory submissions to the United States Food and Drug Administration ("FDA"); the European Medicines Agency ("EMA"); the United Kingdom Medicines and Healthcare products, Regulatory Agency ("MHRA"); and Health Canada. We submitted our Marketing Authorization Application ("MAA") to the EMA on November 23, 2020, which was accepted for review on December 22, 2020, and the Biologics License Application ("BLA") to the FDA on November 30, 2020, which was accepted for review on January 29, 2021. As part of the review process, the FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of November 30, 2021. The submissions to UK and Health Canada are in process and we expect to complete those regulatory filings in 2021.

On December 7, 2020, we announced a partnership for the commercialization of our 3-antigen HBV vaccine with Syneos Health ("Syneos"), who was selected for their robust and innovative commercialization experience and deep vaccine expertise, including successful partnerships with leading vaccine manufacturers.

VBI-2900: Coronavirus Vaccine Program (VBI-2901 & VBI-2902)

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

On March 31, 2020, we announced a collaboration with the National Research Council of Canada ("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 July 3, 2020, we and the NRC as represented by its Industrial Research Assistance Program ("IRAP") signed a contribution agreement whereby the NRC agreed to contribute up to CAD $1 million for the transfer and scale-up of the technical production process for our prophylactic coronavirus vaccine program.

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

On August 26, 2020, we announced data from three pre-clinical studies conducted to enable selection of optimized clinical candidates for our coronavirus vaccine program. As a result of these studies, VBI selected two vaccine candidates, with the goal of bringing forward candidates that add meaningful clinical and medical benefit to those already approved – be it as a one-dose administration and/or providing broader protection against known and future mutated strains of COVID-19: (1) VBI-2901, a trivalent pan-coronavirus vaccine candidate expressing the COVID-19, SARS, and MERS spike proteins; and (2) VBI-2902, a monovalent vaccine candidate expressing an optimized "prefusion" form of the COVID-19 spike protein. The initial clinical study of the first candidate (VBI-2902) is expected to initiate in March 2021, subject to release of clinical materials and regulatory approval. Work is ongoing to further optimize and manufacture VBI-2901, with the anticipation that a Phase I/II study will begin later in 2021. 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. The amendment also extended the expiry date of the agreement to March 15, 2022.

VBI-1501: Prophylactic CMV Vaccine Candidate

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

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

Therapeutic Pipeline

VBI-2601: HBV Immunotherapeutic Candidate

VBI-2601 (BRII-179) is our novel, recombinant, protein-based immunotherapeutic candidate in development for the treatment of chronic HBV infection, a disease that affects more than 250 million people worldwide. Chronic HBV infection can lead to cirrhosis of the liver, hepatocellular cancer, and other liver disease, making it a life-threatening global health problem. VBI-2601 (BRII-179) is formulated to induce broad immunity against HBV virus, including T-cell immunity which plays an important role in controlling HBV infection.

VBI-2601 (BRII-179) is in an ongoing Phase Ib/IIa study in patients with chronic HBV infection, which initiated enrollment in November 2019, and is being conducted by our partner Brii Biosciences Limited ("Brii Bio") pursuant to a Collaboration and License Agreement ("License Agreement") announced on December 6, 2018. The Phase Ib/IIa study is a randomized, controlled study designed to assess the safety, tolerability, antiviral and immunological activity of VBI-2601 (BRII-179). The study is designed as a two-part dose-escalation study assessing different dose levels of VBI-2601 (BRII-179) with and without an immunomodulatory adjuvant and enrolled 46 patients. The study is being conducted at multiple study sites in New Zealand, Australia, Thailand, South Korea, Hong Kong SAR, and China.

On November 18, 2020, we announced interim data from the low-dose cohorts, which achieved human proof-of-concept, demonstrating restoration of both antibody and T cell responses in chronically-infected HBV patients. The data showed 1) potent re-stimulation of T cell responses to HBV surface antigens in 67% (n=6/9) and 78% (n=7/9) of evaluable patients in the low-dose VBI-2601 unadjuvanted and adjuvanted study arms, respectively; and 2) antibody responses against HBV surface antigens in 60% of evaluable patients (n=6/10) in the unadjuvanted cohort and in 67% (n=6/9) in the adjuvanted cohort. The low-dose, with and without the adjuvant, was well-tolerated with no safety signals observed. Based on the results of this study, Brii Bio is planning to initiate a Phase II clinical study in Q1 2021 to assess the safety and efficacy of the combination of VBI-2601 (BRII-179) and BRII-835 (VIR-2218), a novel, investigational RNA interference therapeutic, in chronically infected HBV patients who are on stable nucleos(t)ide therapies.

VBI-1901: CMV-Associated Cancer Vaccine Immunotherapeutic Candidate

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

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

Data from the ongoing Phase IIa portion of the study was announced throughout 2020, with the latest data presented in November 2020 at the Society for Neuro-Oncology (SNO) 2020 Annual Meeting. This data showed two partial responses ("PRs") and two stable disease ("SD") observed in the VBI-1901 plus GM-CSF vaccinated group, resulting in a disease control rate of 40% (n=4/10). A 56% disease control rate was achieved in the group vaccinated with VBI-1901 plus AS01, with 5 stable disease observations (n=5/9). Presumed pseudoprogression was observed in both vaccinated groups, defined as immune infiltration into the tumor which appears initially as tumor growth but later subsides resulting in tumor growth stabilization and/or shrinkage. In the VBI-1901 plus GM-CSF study arm, a normal baseline CD4+/CD8+ T cell ratio was identified as a biomarker associated with tumor response. In the VBI-1901 plus AS01 study arm, however, tumor responses were seen regardless of this biomarker, suggesting that AS01 may help overcome deficits in immune function.

VBI-1901 continues to be safe and well tolerated at all doses tested, with no safety signals observed.

Based on the data seen to-date, VBI is exploring a randomized, controlled, clinical study with registration potential for the next phase of development, which, subject to approval from regulatory bodies, is expected to begin in 2021.

In addition to the lead program candidates described above, we may also seek to in-license clinical-stage vaccines or vaccine-related technologies that we believe complement our product and pipeline portfolio, in addition to technologies that may supplement our therapeutic and preventative vaccination efforts in both immuno-oncology and infectious disease.

Impact of the COVID-19 Pandemic on Our Business

In December 2019, SARS-CoV-2 was reported to have surfaced in Wuhan, China, and on March 12, 2020, the WHO declared the global outbreak of COVID-19, the disease caused by SARS-CoV-2, to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, Canada, Israel and China, have imposed unprecedented restrictions on travel, quarantines, and other public health safety measures. According to the WHO situation report, dated as of January 5, 2021, approximately 83.3 million cases were reported globally and 1.8 million of these were deadly, making the development of effective vaccines to prevent this disease a major global priority. Multiple vaccine candidates against SARS-CoV-2 are under development, and in December 2020, certain large, multinational pharmaceutical companies were granted authorizations for emergency use by the FDA. In the United States, widespread distribution of the currently available vaccines has begun pursuant to Operation Warp Speed, a partnership among components of the U.S. Department of Health and Human Services, the Centers for Disease Control and Prevention, the National Institutes of Health, the Biomedical Advanced Research and Development Authority, and the Department of Defense, as well as certain private firms and other federal agencies. The treatments for COVID-19, including symptomatic and supportive therapies, among other things, continue to be updated on a rolling basis by healthcare authorities and agencies.

Since early in the pandemic SARS-CoV-2 variants started to emerge and certain of these variants have been identified as having a significant public health impact. In December 2020 the United Kingdom reported to WHO a variant that contains 23 nucleotide substitutions associated with increased transmissibility. Also, in December 2020, South Africa reported to WHO a new variant of SARS-CoV-2 named 501Y.V2. The 501Y.V2 variant is associated with a higher viral load and increased transmissibility, and may be less sensitive to neutralizing antibody responses elicited by currently available COVID-19 vaccines. VBI is closely following changing SARS-CoV-2 characteristics and plans to study the impact of specific mutations that may impact vaccine efficacy and vaccine design. Further investigations are required to understand the impact of specific mutations on viral properties and the effectiveness of vaccines.

The ultimate impact of the global COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to future developments. Relevant factors include but are not limited to the duration of the COVID-19 pandemic, the emergence of new variants, and any additional preventative and protective actions that regulators, or our board of directors or management may determine are needed. We do not yet know the full extent of potential delays or impacts on our business, our vaccine development efforts, healthcare systems, or the global economy as a whole. However, the effects may have a material impact on our operations, liquidity, and capital resources, and we continue to monitor the COVID-19 situation closely.

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

We have two ongoing clinical studies being conducted at clinical sites worldwide: the ongoing Phase Ib/IIa clinical study of VBI-2601 (BRII-179) at multiple study sites in New Zealand, Australia, Thailand, South Korea, Hong Kong SAR, and China, and the ongoing Phase I/IIa clinical study of VBI-1901 at various hospitals in the United States. In addition to the active clinical studies, we have several planned clinical studies expected to begin in 2021, including: a Phase II study of VBI-2601 (BRII-179) to be conducted by Brii Bio at multiple study sites in Asia Pacific countries; a further clinical study with VBI-1901 to be conducted by VBI in the United States; and the clinical evaluation of our coronavirus vaccine candidates in Canada. The enrollment of patients at some of the clinical sites in our studies was suspended due to the COVID-19 pandemic and may again be suspended, and enrollment of patients at other clinical sites may be suspended or delayed as hospitals and clinics where we are conducting or planning to conduct clinical trials may reallocate resources and limit access to or close clinical facilities due to the COVID-19 pandemic. Additionally, if our trial participants are unable to travel to or visit to our clinical study sites as a result of quarantines or other restrictions resulting from the COVID-19 pandemic, we will experience higher drop-out rates or delays in our clinical studies. Government-imposed quarantines and restrictions may also require us to temporarily close our clinical sites, research laboratories, or manufacturing facility. Furthermore, if we determine that our trial participants may suffer from exposure to COVID-19 as a result of their participation in our clinical trials, we may voluntarily close certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. As a result, our expected development timelines for VBI-2601 (BRII-179), VBI-1901, our coronavirus vaccine candidates, and possibly our regulatory timelines for our 3-antigen prophylactic HBV vaccine candidate, may be negatively impacted.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition in other ways, as well. Specifically, we anticipate that the stress of COVID-19 on healthcare systems generally around the globe will negatively impact regulatory authorities and the third parties that we may engage in connection with the development and testing of our coronavirus vaccine candidates.

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

Finally, the FDA announced in March 2020 that it is temporarily postponing regulatory inspections of overseas facilities, such as our manufacturing facility in Rehovot, Israel. This could cause a number of delays and/or issues for our operations, but most importantly, could delay the review of the BLA we submitted for our 3-antigen prophylactic HBV vaccine candidate, which could delay its approval beyond the current PDUFA target action date of November 30, 2021 (which such approval is not guaranteed). Any such delays would have a material adverse impact on our ability to commercialize our HBV vaccine candidate in the United States.

Corporate History

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

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

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

Our registered office is located at Suite 1700, Park Place, 666 Burrard Street, Vancouver British Columbia V6C 2X8. Our principal executive offices are located at 222 Third St. Suite 2241, 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, 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.

Contractual Arrangements

Collaboration and License Agreement with Brii Biosciences – VBI-2601 (BRII-179)

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

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

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

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

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

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

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

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

Ferring and SciGen License Agreements

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

Royalty payments under the Ferring License Agreement of $20 and $38, were recorded in cost of revenues for the year ended December 31, 2020 and 2019, respectively.

Royalty payments under the SciGen Assignment Agreement of $14 and $27 were recorded in cost of revenues for the year ended December 31, 2020 and 2019, respectively.

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

Government contribution agreements

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

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

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

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

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

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

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

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

eVLP Technology

We are engaged in the inbound licensing of key intellectual property ("IP"). 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 IP covering its eVLP vaccine platform (the "Technology"), including patents (the "Acquired Patents") covering the Technology. We paid a purchase price of €400 (approximately $450) for the ePixis shares and approximately $75 in related transaction costs. VBI Cda also agreed to make certain contingent payments to the Sellers as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The parties may terminate the ePixis License Agreement, as amended, by mutual agreement. There is also a cancellation right that may be exercised in the event of breach. UPMC may terminate the ePixis License Agreement if we, among other things, declare bankruptcy; do not put forth reasonable effort or are unable to develop and market the products, and, in particular, if we suspend the development of the products for more than six months; our inability to make the payments required by the ePixis License Agreement; lack of sales of a product, or lack of a signed sub-license agreement within one year from the date of acquiring AMM (Autorisation de mise sur le marché – Regulation of Therapeutic Goods) authorization, or the necessary equivalent authorization for the use of the products; and lack of sales of a product for more than two years after the initial marketing has taken place. During the year-ended December 31, 2016, VBI Cda paid UPMC €200 in milestone payments related to CMV Phase I clinical trial approval and start. During the year ended December 31, 2018, VBI Cda paid UPMC €200, in milestone payments related to the GBM Phase I/IIa clinical trial approval and start. No payments have been made in 2020 or 2019, however we are obligated to make a payment of €50 in 2021 in relation to our prophylactic coronavirus vaccine program and to potentially make additional payments upon the start of any clinical studies.

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.

We operate a proprietary, mammalian cell-derived vaccine manufacturing facility in Rehovot, Israel, which we use to manufacture our 3-antigen prophylactic HBV vaccine, as well as clinical study supply of VBI-2601 (BRII-179). The facility was built in December 2006 and was GMP certified by the IMoH. 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; however, our facility will have to pass FDA inspection as part of the BLA application process for our 3-antigen prophylactic HBV vaccine candidate in the United States. In 2018, we temporarily closed our manufacturing facility for modernization and capacity increase. We re-commenced operations in May 2019, and we received a certificate of GMP compliance from the IMoH on January 27, 2020. In addition to the GMP compliance certification, the IMoH will also need to review and approve the process validation submission and provide approval for us to sell our 3-antigen prophylactic HBV vaccine manufactured at the modernized facility. We increased the capacity of our manufacturing facility to be able to supply commercial quantities of our 3-antigen prophylactic HBV vaccine upon marketing authorization and approval in the U.S., Europe, and Canada.

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.

Commercialization

To date, where approved or available through our active named-patient program, our 3-antigen prophylactic HBV vaccine is distributed through a network of local distributors, and available under the brand name Sci-B-Vac®.

On December 7, 2020, we announced our partnership with Syneos Health ("Syneos") in preparation for the commercialization of our 3-antigen prophylactic HBV vaccine in the U.S., Europe, and Canada, pending regulatory approvals. VBI and Syneos have been working together on the pre-launch strategy and activity since 2019, and have expanded the relationship to build the leadership team and field teams dedicated to VBI, incorporating full-service commercialization solutions. 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.

Customers

Our customers for our 3-antigen prophylactic HBV vaccine are mainly physicians and pharmacists in markets where the product is approved.

Through SciVac, services are also made available to the biotechnology industry in Israel pursuant to an agreement with the Israel Innovation Authority (formerly the Office of the Chief Scientist in Israel) and ancillary to the core vaccine development and manufacturing focus.

In addition to direct sales of our 3-antigen prophylactic HBV vaccine in approved territories, we are also engaged in the development of vaccine platforms and products which may be licensed to major pharmaceutical companies and larger biotechnology companies.

Competitors

Our products and 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 & Co ("Merck"), Janssen Pharmaceutical, Inc ("Janssen"), Mitsubishi Tanabe Pharma Corporation, Takeda Pharmaceutical Company Limited and Pfizer, Inc. ("Pfizer"); mid-size pharmaceutical companies and emerging biotechnology companies including Dynavax Technologies Corporation ("Dynavax"), Novavax Inc., Moderna, Inc., BioNTech SE, and Hookipa Biotech AG; and academic and not-for-profit vaccine researchers and developers including the National Institutes of Health. The industry is typified by extensive collaboration, licensing, and merger and acquisition activity despite the intense competition.

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

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

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

Within the COVID vaccine space, over one hundred vaccine candidates against SARS-CoV-2 are under development, and in December 2020, two vaccines were granted authorizations for emergency use by the FDA – one from Pfizer, Inc./BioNTech SE and one from Moderna, Inc. In February 2021, an additional emergency use authorization was granted to Janssen. Additional emergency use authorizations and approvals are anticipated in 2021 and beyond. Key companies in the space with late-stage clinical or pre-approval vaccine candidates include, Novavax, Inc., AstraZeneca PLC, CureVac N.V., Medicago Inc., GSK, Sanofi S.A., Dynavax, and Valneva SE. 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, Merck's CMV vaccine entered Phase II testing in 2019 and Moderna Inc's CMV vaccine is in Phase II. Additionally, Hookipa Biotech AG is engaged in clinical development of a prophylactic CMV vaccine.

Suppliers, Contractors and Collaborations

Suppliers

We rely on a single source for our supply of vials and certain raw materials required for the manufacturing of our 3-antigen prophylactic 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 prophylactic HBV vaccine and our pipeline candidates and could have a material adverse effect on our business.

Contractors

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

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

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

We rely on a number of contractors to provide services to characterize and release our 3-antigen prophylactic HBV vaccine for Israel and on a named patient basis where it is not approved. 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 prophylactic 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 IP portfolio to which we have an exclusive license. Under the terms of the ePixis License Agreement, as amended, we are required to pay royalties for successful products developed using the IP for as long as patent claims cover the period in a given jurisdiction. This patent portfolio has claims that are expected to remain in force until 2022 in the United States and 2021 in other countries, after which time we are no longer obligated to compensate UPMC for development of vaccines based on the UPMC IP portfolio. After that time, the remaining patent protection of the CMV vaccine candidate will be based on patents and patent applications co-owned with UPMC which, if granted, would provide patent protection extending until 2032. We are currently negotiating extension of the ePixis License Agreement to cover the CMV patents and patent applications. There can be no assurance that any pending patent applications will be granted or, if granted, will be enforceable, and the claims in pending patent applications may be amended to reduce the scope of patent claims.

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

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

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

Collaborations

We also enter into contracts in the normal course of business with vendors for pre-clinical safety and research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice and do not include any minimum purchase commitments, and therefore are cancellable contracts.

- On December 4, 2018, we entered into the License Agreement with Brii Bio, pursuant to which, among other things, the parties agreed to collaborate on the development of a protein based immunotherapeutic candidate for treatment of HBV subject to terms and conditions set forth in the License Agreement as described in "Part I - Item I - Business - Contractual Arrangements". On November 14, 2019 we announced initiation of enrollment in a Phase Ib/IIa Study of VBI-2601 (BRII-179) in patients with chronic HBV infection.

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

- On March 31, 2020, we announced a collaboration with the NRC, Canada's largest federal research and development organization, to develop coronavirus vaccine candidate, targeting COVID-19, SARS, and MERS. 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. The amendment also extended the expiry date of the agreement to March 15, 2022.

Employees

As of December 31, 2020, we had a total of 127 full-time and 6 part-time employees. The SciVac manufacturing site in Israel had 83 full-time employees and 3 part-time employees and the VBI Cda research site employed 36 full-time and 3 part-time employees, as of December 31, 2020. The remaining 9 full-time employees worked out of our headquarters in Cambridge, MA. None of our employees are represented by unions. Our management considers its relationship with our employees to be good.

Facilities and Offices

Our registered office is located at Suite 1700, Park Place, 666 Burrard Street, Vancouver, BC V6C 2X8 with our headquarters located at 222 Third Street, Suite 2241, 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 $1,144 during the fiscal year ended December 31, 2020.

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

Research and Development

We invest heavily in R&D. R&D expenses were $14.9 million and $26.3 million for the years ended December 31, 2020 and 2019, respectively. All R&D was funded by equity financings, term loan financings, collaboration agreements, or government grants and contributions. Our most significant R&D expenses to date have been related to the development of our 3-antigen prophylactic HBV vaccine candidate, followed by the development of our CMV candidate, our GBM vaccine immunotherapeutic candidate, our prophylactic coronavirus vaccine candidates, and the related eVLP platform. Although we have completed the Phase III clinical trial for our 3-antigen prophylactic HBV vaccine candidate, our R&D expenses are expected to increase as we plan to continue to invest in and advance our lead pipeline candidates. In addition, we may bring other pipeline candidates through the clinical development stage and explore other vaccine opportunities and/or collaborations.

Intellectual Property

Patents

Our IP portfolio includes 19 active patent families consisting of 149 fully owned or co-owned or exclusively licensed patents and patent applications. The highlights of our patent portfolio include:

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

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

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

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

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

Trade Secrets

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

Trademarks

We use the Sci-B-Vac trademark in connection with our 3-antigen prophylactic HBV vaccine. We have registered these trademarks in 16 countries. The trademarks are renewable indefinitely, so long as we make the appropriate filings when required. We also have a registration for the LPV mark in Canada.

Governmental Regulation and Product Approval

Vaccine development is a highly regulated field. The manufacturing and marketing of our potential products 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, and the European Medicines Agency in Europe. New products must go through extensive pre-clinical and clinical development prior to product launch. This process can take more than ten years from candidate identification to licensure/marketing approval by health authorities worldwide. Despite efforts to harmonize regulatory requirements in different jurisdictions, there exists a divergence of legal and regulatory requirements in different countries and territories. Delays in regulatory approval to move from one stage of development to another can potentially cause us significant delays and can affect our market capitalization.

United States, Europe and Canada Regulatory Agencies

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

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

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

Pre-clinical Testing

In the United States, drug candidates are tested in animals until adequate proof of safety and efficacy is established. These pre-clinical studies generally evaluate the mechanism of action and pharmacology of the product and assess the potential safety and efficacy of the product. Tested compounds must be produced according to applicable current GMP 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 GMP, 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 GMP 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.

Biologics Price Competition and Innovation Act of 2009 (BPCIA)

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

Fast Track Approval

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

Orphan Drug Designation

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

Foreign Regulation

In addition to regulations in the United States, we are and will continue to be subject to a variety of laws and regulations governing clinical trials and commercial sales and distribution of our products in foreign countries. Whether or not we obtain FDA approval for a product, we must separately obtain approval of a product 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.

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

Under the applicable EU regulatory regime, we may submit marketing authorization applications (MAAs) either under a centralized or decentralized procedure (which also includes the mutual recognition procedure available for companies who already hold national licenses). The decentralized procedures provide for mutual recognition of national approval decisions. These authorizations provide marketing authorizations. The centralized procedure, which is available for medicines, inter alia, produced by biotechnology, intended to treat specific illnesses, or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all EU member states (as well as in Northern Ireland and the European Economic Area (EEA) countries of Iceland, Liechstenstein 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 are 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, once our products are marketed commercially, we will have to comply with the various laws relating to the Medicare, Medicaid, and other federal healthcare programs. These federal laws include, by way of example, the following:

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

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

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

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

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

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or some combination thereof. 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.

We are building out our legal and regulatory compliance capabilities through in-house hiring and external consultants who have extensive experience with the regulatory and commercialization process.

We also use additional regulatory consultants including several former FDA regulators with experience at the Center for Biologics Evaluation & Research ("CBER"), which is the division of FDA that regulates vaccines and other drugs.

Available Information

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

ITEM 1A: RISK FACTORS

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

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

Summary of Risk Factors

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

- We have a history of operating losses, and we cannot guarantee that we can ever achieve sustained profitability;
- We will need additional financing to continue our operations. If we are unable to obtain additional financing on acceptable terms, we may have to curtail or cease our development plans and operations;
- Our success is dependent on the successful clinical development, regulatory approval and commercialization of our product 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 prophylactic HBV vaccine and VBI-2601 at a single location. Any disruption in the operations of our manufacturing facility could adversely affect our business and results of operations;
- Our success depends on our ability to maintain the proprietary nature of our technology.

Risks Related to Our Product Development

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

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

As a result of the COVID-19 pandemic, we are operating in isolated groups, to reduce exposure risk, and with fewer employees on site at both our manufacturing facility in Israel, where we manufacture our 3-antigen prophylactic HBV vaccine and VBI-2601, and at our research and development laboratories in Ottawa, Canada. Our manufacturing facility in Israel and CDMOs that we engage to manufacture our eVLP vaccine candidates are dependent on sourcing raw materials from third party suppliers. The COVID-19 pandemic has impacted lead times and availability of many raw materials, which may adversely impact our ability to manufacture products in a timely manner. For example, unanticipated delays in receipt of release testing materials have impacted the timing of the initiation of our Phase I/II study of our monovalent coronavirus vaccine candidate, VBI-2902. In addition, the FDA announced in March 2020 that it is temporarily postponing regulatory inspections of overseas facilities, such as our manufacturing facility in Rehovot, Israel. This could cause a number of delays and/or issues for our operations, but most importantly, could delay the review of the BLA we submitted for our 3-antigen HBV vaccine candidate, which could delay its approval beyond the current PDUFA target action date of November 30, 2021 (which such approval is not guaranteed). Any such delays would have a material adverse impact on our ability to commercialize our HBV vaccine candidate in the United States.

We have two ongoing clinical studies being conducted at clinical sites worldwide: the ongoing Phase Ib/IIa clinical study of VBI-2601 (BRII-179) at multiple study sites in New Zealand, Australia, Thailand, South Korea, Hong Kong SAR, and China, and the ongoing Phase I/IIa clinical study of VBI-1901 at various hospitals in the United States. In addition to the active clinical studies, we have several planned clinical studies expected to begin in 2021, including: a Phase II study of VBI-2601 (BRII-179) conducted by Brii Bio at multiple study sites in Asia Pacific countries; a further clinical study with VBI-1901 conducted by VBI in the United States; and the clinical evaluation of our coronavirus vaccine candidates in Canada. The enrollment of patients at some of the clinical sites in our studies was suspended and may again be suspended, and enrollment of patients at other clinical sites may be suspended or delayed as hospitals and clinics where we are conducting clinical trials reallocate resources and limit access to or close clinical facilities due to the COVID-19 pandemic. Additionally, if our trial participants are unable to travel to or visit to our clinical study sites as a result of quarantines or other restrictions resulting from the COVID-19 pandemic, we will experience higher drop-out rates or delays in our clinical studies. Government-imposed quarantines and restrictions may also require us to temporarily close our clinical sites, research laboratories, or manufacturing facility. Furthermore, if we determine that our trial participants may suffer from exposure to COVID-19 as a result of their participation in our clinical trials, we may voluntarily close certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. As a result, our expected development timelines for VBI-2601 (BRII-179), VBI-1901, our coronavirus vaccine candidates, and possibly our regulatory timelines for our 3-antigen prophylactic HBV vaccine candidate, may be negatively impacted. We cannot predict the ultimate impact of the COVID-19 pandemic as consequences of such an event are highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical studies, our research programs, and our manufacturing; however, the ongoing COVID-19 pandemic may disrupt or delay our business operations, further divert the attention and efforts of the medical community to coping with COVID-19 and disrupt the marketplace in which we operate, which could have a material adverse effect on our operations.

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

Our pursuit of coronavirus vaccine candidates is at an early stage. We may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all.

In response to the COVID-19 pandemic, on March 30, 2020, we entered into a Collaborative Research Agreement with the NRC, and subsequently amended on December 21, 2020, pursuant to which we collaborated on certain activities to advance development of our trivalent pan-coronavirus vaccine candidate targeting COVID-19, SARS and MERS and our monovalent coronavirus vaccine candidate targeting COVID-19. Our development of the vaccine candidates is in the pre-clinical stage, and we may be unable to develop a vaccine that successfully and safely protects against the viruses in a timely manner, if at all. Furthermore, even if we successfully develop a vaccine, we may encounter difficulties developing and scaling up manufacturing processes suitable for production of sufficient supply for our clinical trials or for commercialization in a cost-effective manner. Due to the number of COVID-19 vaccine candidates in clinical trials, we may also encounter difficulty locating clinical sites with capacity to conduct clinical trials, and therefore, we may experience delays in initiating or enrolling clinical trials of our vaccine candidate. We are also committing financial resources and personnel to the development of a coronavirus vaccine which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of coronavirus as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We submitted the BLA to the FDA and the MAA to the EMA in the fourth quarter of 2020 for our 3-antigen HBV vaccine candidate, which have subsequently been accepted for review by the regulatory authorities. Our registration and commercial timelines for such vaccine candidate depend on further discussions with the FDA and corresponding foreign regulatory agencies. They could have requirements and requests for additional data, beyond what is included in the submissions, or completion of additional clinical trials, including a request to increase the size of the safety data set. Any such requirements or requests could:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The risk of product liability is inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. Our 3-antigen prophylactic HBV vaccine is currently approved for sale 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 during clinical trials were to cause adverse side effects, we may be exposed to substantial liabilities.

In September 2018, two civil claims were brought in the District of Court of the central district in Israel which named our subsidiary SciVac as a defendant. In one claim, two minors, through their parents, allege, among other things: defects in certain batches of our 3-antigen prophylactic HBV vaccine discovered in July 2015; that our 3-antigen prophylactic HBV vaccine was approved for use in children and infants in Israel without sufficient evidence establishing its safety; that SciVac failed to provide accurate information about our 3-antigen prophylactic HBV vaccine 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 our 3-antigen prophylactic HBV vaccine in Israel since April 2011 and seeking damages in a total amount of NIS 1,879,500,000 (not in thousands) ($584.6 million). The second claim is a civil action brought by two minors and their parents against SciVac and IMoH alleging, among other things, that SciVac marketed an experimental, defective, hazardous, or harmful vaccine; that our 3-antigen prophylactic HBV vaccine was marketed in Israel without establishing its safety; and that our 3-antigen prophylactic HBV vaccine 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 and December 3, 2020 to discuss document disclosure. The next preliminary hearing is scheduled to be held on March 24, 2021.

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

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

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

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

Even if we obtain regulatory approval for one or more of our pipeline candidates, we will still face extensive, ongoing regulatory requirements and review, and our products may face future development and regulatory difficulties.

Even if we obtain regulatory approval for one or more of our pipeline candidates in the United States or other regions, which we cannot guarantee, the FDA or other regulatory bodies may still impose significant restrictions on a product's indicated uses or marketing, or impose conditions for approval, or impose ongoing requirements for potentially costly post-approval studies, including Phase IV clinical trials or post-marketing surveillance. As a condition to granting marketing approval of a product, the FDA or other regulatory bodies may require us to conduct additional clinical trials. The results generated in these post-approval clinical trials could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. For example, the labeling for our pipeline candidates, if approved, may include restrictions on use or warnings. 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 Risk Evaluation and Mitigation Strategies ("REMS programs"). If approved, our pipeline candidates will also be subject to ongoing FDA requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record keeping, and reporting of safety and other post-market information. The FDA's exercise of its authority could result in delays or increased costs during product development, clinical trials, and regulatory review, increased costs to comply with additional post-approval regulatory requirements, and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable costs. Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our pipeline candidates once approved, and potentially our other marketed products. Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of our approved products. Accordingly, new data about our products could negatively affect demand because of real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

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

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

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

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

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

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

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

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

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

We incurred significant costs to modernize and increase the capacity of our manufacturing facility in Rehovot, Israel. Any delays in validating the modernization and capacity increase of our facility could adversely affect our ability to supply our vaccines for commercial sale and clinical development.

We invested substantial funds to modernize and increase the capacity of our manufacturing facility in Rehovot, Israel, where we manufacture all clinical and commercial supplies of our 3-antigen prophylactic HBV vaccine and clinical materials of VBI-2601. During the modernization and capacity increase, which started in April 2018, we ceased manufacturing operations at our manufacturing facility. Although the modernization and the capacity increase of our manufacturing facility has been completed and we obtained a certificate of GMP compliance from the IMoH on January 27, 2020, the IMoH will also need to review and approve the process validation submission and provide approval for us to sell our 3-antigen prophylactic HBV vaccine manufactured at the modernized facility. If we are unable to promptly obtain IMoH approval, our ability to commercially sell our 3-antigen prophylactic HBV vaccine could be interrupted, the costs associated with our modernization project would increase, and our sales of our 3-antigen prophylactic HBV vaccine and the timing of our clinical studies related to VBI-2601 could be adversely affected.

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 prophylactic 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 prophylactic 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 prophylactic HBV vaccine and VBI-2601 and future profit margins, if any.

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

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

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

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

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

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

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

In some countries, particularly countries in Europe, the pricing and/or reimbursement of prescription pharmaceuticals is subject to governmental control. In Canada, the prices of patented medicines are subject to price controls. In these countries, pricing negotiations with governmental 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 pipeline candidates is characterized by intense competition and rapid technological advances. For example, if it is approved in the future, our 3-antigen prophylactic HBV vaccine will compete in the United States with approved HBV vaccines marketed by GSK, Dynavax, and Merck and will compete outside the United States with vaccines from GSK, Merck, and several additional established pharmaceutical companies. 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 pipeline candidates may never achieve market acceptance, even if we obtain regulatory approvals.

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

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

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

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

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

If we are unable to manufacture our eVLP pipeline candidates in clinical or commercial quantities, as the case may be, in sufficient yields, with sufficient purity, potency, quality, and identity, then we must find, qualify, and rely on third parties. Any new third-party manufacturers must also receive FDA approval 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 eVLP pipeline candidates.

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

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

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

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

- we may not have the ability to control the activities of our partners and cannot provide assurance that they will fulfill their obligations to us, including with respect to the license, development, and commercialization of pipeline candidates, in a timely manner or at all;
- such partners may not devote sufficient resources to our pipeline candidates 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 in the event we fail to establish agreements as necessary, we could be required to undertake research, development, manufacturing, and commercialization activities solely at our own expense. These activities would significantly increase our capital requirements and, given our lack of sales, marketing and distribution capabilities, significantly delay the commercialization of our pipeline candidates.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Capital Requirements and Financings

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

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

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

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

We have incurred significant net losses and negative operating cash flows since inception. We incurred net losses of approximately $46.2 million and $54.8 million in 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $308.6 million. Our income generating activities have been from sales of our 3-antigen prophylactic HBV vaccine in Israeli markets that have generated a limited number of sales to-date, fees from research and development services, and revenue from partnership collaborations. We expect to incur significant operating losses for the next several years as we support our 3-antigen prophylactic HBV vaccine regulatory submissions and pre-commercialization activities, expand our research and development, advance other pipeline candidates into and through clinical development, including our immunotherapeutic HBV candidate, GBM vaccine immunotherapeutic candidate, prophylactic coronavirus vaccine program candidates, and CMV candidate, complete clinical trials and seek regulatory approval. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, as well as those related to our expectations for the License Agreement, we are unable to predict the extent of any future losses or guarantee when, or if, our company will become profitable or cash flow positive. If we never achieve profitability or positive cash flows, or achieve either later than we anticipate, you may lose some or all of your investment in us.

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

In its report dated March 2, 2021, EisnerAmper LLP, our independent registered public accounting firm, expressed substantial doubt about our ability to continue as a going concern as we have suffered recurring losses from operations and have insufficient liquidity to fund our future operations. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge out liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment. As of December 31, 2020, we had $93.8 million of cash and cash equivalents. In order to have sufficient cash and cash equivalents to fund our operations in the future, we will need to raise additional equity or debt capital and cannot provide any assurance that we will be successful in doing so.

Risks Related to Our Business

Adverse effects resulting from vaccines or immunotherapies or therapies could also negatively affect the perceptions by members of the health care community, including physicians, about the safety and effectiveness of our 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 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 pipeline candidates, it could be attributed to our pipeline candidates or immunotherapy protocols as a whole. In fact, in the past biologics have been associated with certain safety risks and other companies developing biologics have had patients in trials suffer from serious adverse events, including death. Any such attribution could negatively affect the perceptions by members of the health care community, including physicians, about the safety and effectiveness of our pipeline candidates. Our industry is susceptible to rapid technological changes and there can be no assurance that we will be able to overcome any new technological challenges presented by the adverse effects resulting from vaccines or immunotherapy drugs or therapies developed, manufactured or marketed by others.

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

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

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

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

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

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

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

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

In addition to FDA restrictions on marketing and other applicable regulations, if we obtain FDA approval to commercialize any of our current or future product candidates in the United States, our operations may be directly, or indirectly, through our relationships with healthcare providers, customers, and third-party payors, subject to various federal and state fraud and abuse laws, including, without limitation the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Since the Gaza Strip's 2007 coup, by which the terrorist organization Hamas seized control, there have been a number of armed conflicts between Hamas and Israel – in December-January 2008-9, November 2012, July-August 2014 and as recently as May 2019 – in all of which conflicts, rockets were fired from Gaza into Israeli civilian population centers. During the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party backed by Iran and controlling large swathes of Lebanon. These conflicts involved missile strikes against civilian targets in various parts of Israel, including areas in which our Rehovot facilities, employees and some of our consultants are located, and negatively affected business conditions in Israel. Civil unrest and political turbulence has occurred in other countries in the region, including Syria which shares a common border with Israel, and is affecting the political stability of those countries. Since April 2011, a civil war that has been ongoing in Syria has escalated, and evidence indicates that chemical weapons have been used in the region. This instability and any intervention may lead to additional conflicts in the region. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran also has a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, and both the Allawite regime and various rebel militia groups in Syria. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts, terrorist activities, or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital.

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

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

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

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

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

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

Our functional currency is the United States dollar. We incur expenses in New Israeli Shekel, which we refer to as NIS, Canadian Dollars and United States dollars. As a result, we are exposed to the risks that the United States dollar may devalue relative to the Canadian Dollar or NIS, or, if the United States dollar appreciates relative to the Canadian Dollar or NIS, that the inflation rate in the United States may exceed such rate of devaluation of the United States dollar, or that the timing of such devaluation may lag behind inflation in the United States. The average exchange rate for the year ended December 31, 2020, was US$1.00 = NIS 3.4370 and US$1.00 = CAD $1.3399. We cannot predict any future trends in the rate of inflation in the United States or the rate of devaluation, if any, of the United States dollar against the Canadian Dollar or NIS.

Risks Related to Our Intellectual Property

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

Our success in large part depends on our ability to maintain the proprietary nature of our technology. To do so, we must, at significant cost, prosecute patent applications and maintain existing patents, obtain new patents, and pursue trade secret and other intellectual property protection. We also must operate without infringing the proprietary rights of third parties or allowing third parties to infringe our rights. We currently have rights to over 149 fully owned, co-owned, or exclusively licensed patents and patent applications. However, patent issues relating to pharmaceuticals and biologics involve complex legal, scientific, and factual questions.

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

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

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

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

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

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

Our 3-antigen prophylactic HBV vaccine is the only product we currently market (outside of the U.S., Europe, and Canada). Failure to obtain and retain marketing exclusivity or expiration of the market exclusivity could seriously adversely affect the revenue potential for our 3-antigen prophylactic HBV vaccine in the jurisdictions where it is approved for sale.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our consolidated balance sheet contains approximately $62.2 million of intangible assets. For IPR&D assets, which consist of the CMV and GBM programs, the risk of failure is significant, and there can be no certainty that these assets ultimately will yield successful products. The nature of our business is high-risk and requires that we invest in a large number of projects in an effort to achieve a successful portfolio of approved products. Our ability to realize value on these significant investments is often contingent upon, among other things, regulatory approvals and market acceptance. These IPR&D and goodwill assets may become impaired and be written off at some time in the future, which can have a material adverse effect on the financial statements. An example of an event that is indicative of impairment is a projection or forecast that indicates losses or reduced profits associated with an asset or the market capitalization of a company falling below the net equity value. For IPR&D projects, this could result from, among other things, a change in outlook based on clinical trial data, a delay in the projected launch date or additional expenditures to commercialize the product.

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

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

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

Risks Related to Our Indebtedness

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

K2 HealthVentures LLC ("K2" or the "Lender"), pursuant to the Loan and Guaranty Agreement (the "Loan Agreement"), dated May 22, 2020, has a security interest in substantially all of our assets other than intellectual property. As a result, if we default under our obligations to the lender, the lender could foreclose on its security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations. The principal amount of the term loan as of December 31, 2020, was $20 million ($21.4 million including the exit fee).

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

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

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

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

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

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

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

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

Pursuant to the terms of Loan Agreement, the Lender made a term loan to us in aggregate amount of $20 million. In 2020, we made average monthly payments of interest in the amount of approximately $146. We are required to pay interest only until July 1, 2022, and starting July 1, 2022 monthly principal and interest payments $907 until June 2024, when the entire amount is due.

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

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

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

Risks Related to Our Common Shares

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

During the 12-month period ended February 26, 2021, our common shares traded as high as $6.93 per share and as low as $0.69 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 and cash equivalents reserves;
- additions or departures of key personnel;
- operating results that fall below expectations;
- announcements by us relating to any strategic relationship;
- sales of equity securities or issuance of additional debt;
- industry developments;
- changes in state, provincial, or federal regulations affecting us and our industry;
- the continued large fluctuations in major stock market indexes which causes investors to sell our common shares;
- economic, political, and other external factors; and
- period-to-period fluctuations in our financial results.

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

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

Our common shares are listed on The Nasdaq Capital Market. We have in the past, and may in the future, be unable to comply with certain of the listing standards that we are required to meet to maintain the listing of our common shares on The Nasdaq Capital Market. For instance, on August 14, 2019, 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 July 2, 2019 through August 13, 2019, we did not meet the minimum bid price of $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). On January 9, 2020 we received notice from The Nasdaq indicating that the Company has regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2), and the matter is now closed.

If The Nasdaq Capital Market delists our common shares from trading on its exchange for failure to meet the listing standards, an investor would likely find it significantly more difficult to dispose of or obtain our shares, and our ability raise future capital through the sale of our shares could be severely limited. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

We have no immediate plans to pay dividends.

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

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

From time to time, certain of our shareholders may be eligible to sell all or some of their restricted common shares by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate shareholders may sell freely after six months, subject only to the current public information requirement (which disappears after one year). Of the 247,039,010 common shares outstanding as of December 31, 2020, approximately 177,413,200 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, 2020, we had outstanding options, awards, and warrants for the purchase of 15,834,563 common shares. Of this amount, options, awards and warrants for the purchase of 4,515,553 common shares are held by non-affiliates, who may sell these shares in the public markets from time to time, without limitations on the timing, amount or method of sale. If our share price rises, the holders may exercise their options and sell a large number of shares. This could cause the market price of our common shares to decline.

We are an "emerging growth company" and 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 an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, and will remain so until December 31, 2021, and a "smaller reporting company" as defined under the rules promulgated under the Securities Act. For as long as we continue to be an "emerging growth company" and 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 emerging growth companies or smaller reporting companies, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports.

We will remain a smaller reporting company, until the value of our common shares held by non-affiliates is more than $250 million as measured on the last business day of our second fiscal quarter, and our annual revenues are less than $100 million during the most recently completed fiscal year and the value of our common shares held by non-affiliates is no longer less than $700 million measured on the last business day of our second fiscal quarter.

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

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

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

We are governed by the BCBCA and other relevant laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a 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, or DGCL, that may have the greatest such effect include, but are not limited to, the following: (i) for material corporate transactions (such as mergers and amalgamations, other extraordinary corporate transactions or amendments to our articles) the BCBCA generally requires a two-thirds majority vote by shareholders, whereas DGCL generally only requires a majority vote; and (ii) under the BCBCA a holder of 5% or more of our common shares can requisition a special meeting of shareholders, whereas such right does not exist under the DGCL.

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

As of December 31, 2020, approximately 28.2% of our outstanding common shares was controlled by our officers, directors, beneficial owners of 10% or more of our securities and their respective affiliates. As a result, these shareholders, if they acted together, may be able to determine or influence matters that require approval by our shareholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other shareholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a corporate transaction that other shareholders may view as beneficial.

General Risk Factors

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

Our business is highly dependent upon the continued services of our senior management and key scientific and technical personnel. As such, our future success depends on our ability to identify, attract, hire or engage, retain and motivate well-qualified managerial, technical, clinical, and regulatory personnel. Our operations require qualified personnel with expertise in nonclinical pharmacology and toxicology, pharmaceutical development, clinical research, 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.

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

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

Business interruptions could limit our ability to operate our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

ITEM 1B: UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2: PROPERTIES

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

a) Our headquarters, which is currently comprised of approximately 3,475 square feet of office space, is held pursuant to a lease agreement that was entered into on May 31, 2012 with American Twine Limited Partnership, subsequent assigned to American Twine Owner LLC, and currently pursuant to the seventh amendment we have extended the lease to April 30, 2023 with a base rent for the premises of $25 per month, subject to a 3% annual increase. The lease has been amended since it was entered into for the purpose of revising the length, providing for a new base rent and adding additional office space. We are also responsible for the payment of additional rent, including our pro rata share of real estate taxes, operating expenses, as defined in the lease, and betterment assessments, as defined in the lease.

b) Our manufacturing facility, which is currently comprised of approximately of 3,586 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 $34 per month and linked to the CPI. The commitments for existing and additional space are for a term of five years ending January 31, 2022, with a five-year option to extend until January 31, 2027 with an increase of 10%.

   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 $7 per month.

c) VBI Cda's research facility, which is comprised of laboratory and office space, is held pursuant to a sub-sublease that was entered into on September 1, 2014 with Iogen Corporation and subsequently amended to include some additional space with a term ending on December 31, 2022 with the option to extend the term for one additional period of three years. On September 5, 2019, the sub-sublease was assigned by Iogen Corporation to 310 Hunt Club GP Inc. ("the Assignee"). The base and additional rent for the premises is approximately $21 per month through December 31, 2022. On September 4, 2020, VBI Cda entered into a further lease agreement for additional office space at our research facility, which commenced on October 1, 2020 and expires on April 30, 2023. The base and additional rent for the additional premises is approximately $5.8 per month through December 31, 2022. VBI Cda is also responsible for its pro rata share of additional rent, payable monthly, which includes, but is not limited to, operating and maintenance costs, real estate taxes, general maintenance and repair costs, insurance and professional fees. In addition to the base rent and the additional rent, VBI Cda is responsible for the payment of a refundable harmonized sales tax as require by the Excise Tax Act (Canada). Pursuant to the sub-sublease, the additional rent per month will not exceed CAD $20.50 per square foot of rentable premises. VBI Cda was required to provide a security deposit in the amount of CAD $18.80 which the Assignee will hold until the end of the term and may, in the event of a failure by VBI Cda to pay rent as and when due, apply the security deposit to the unpaid rent obligation.

Pursuant to these leases, we made rent payments of $1,144 in 2020.

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 our 3-antigen prophylactic HBV vaccine discovered in July 2015; that our 3-antigen prophylactic HBV vaccine was approved for use in children and infants in Israel without sufficient evidence establishing its safety; that SciVac failed to provide accurate information about our 3-antigen prophylactic HBV vaccine 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 our 3-antigen prophylactic HBV vaccine in Israel from April 2011 and seeking damages in a total amount of NIS 1,879,500,000 (not in thousands) ($584,603). The second claim is a civil action brought by two minors and their parents against SciVac and the Israel Ministry of Health alleging, among other things, that SciVac marketed an experimental, defective, hazardous or harmful vaccine; that our 3-antigen prophylactic HBV vaccine was marketed in Israel without sufficient evidence establishing its safety; and that our 3-antigen prophylactic HBV vaccine was produced and marketed in Israel without approval of a western regulatory body. The claim seeks damages for past and future losses and expenses as well as punitive damages.

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

The District Court has accepted SciVac's motion to suspend reaching a decision on the approval of the class action pending the determination of liability under the civil action. Preliminary hearings for the trial of the civil action began on January 15, 2020, with subsequent preliminary hearings held on May 13, 2020 and December 3, 2020 to discuss document disclosure. The next preliminary hearing is scheduled to be held on March 24, 2021.

ITEM 4: MINE SAFETY DISCLOSURES

Not applicable.

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

Market Information

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

Holders

As of February 25, 2021, we had approximately 819 shareholders of record. This number does not include an indeterminate number of shareholders whose shares are held by brokers in street name.

Dividends

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

Recent Issuances of Unregistered Securities

All sales of unregistered securities during the year ended December 31, 2020, 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: SELECTED FINANCIAL DATA.

Not applicable.

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

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

VBI Vaccines Inc. ("VBI") is a biopharmaceutical company driven by immunology to deliver powerful prevention and treatment of disease. Through its innovative approach to virus-like particles ("VLPs"), including a proprietary enveloped VLP ("eVLP") platform technology, VBI develops vaccine candidates that mimic the natural presentation of viruses, designed to elicit the innate power of the human immune system. VBI is committed to targeting and overcoming significant infectious diseases, including hepatitis B ("HBV"), 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 – Lead Program Candidates

VBI's pipeline is comprised of vaccine and immunotherapeutic candidates developed by virus-like particle technologies to target two distinct, but often related, disease areas – infectious disease and oncology. We prioritize the development of candidates 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 antigens self-assemble into VLPs, which limit the number of potential targets. Notably, the HVB antigens are among those that are able to spontaneously form orderly VLP structures. VBI's proprietary 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.

Indication	Program	Technology	Current Status
Prophylactic Candidates			
● Hepatitis B ("HBV")	3-antigen Vaccine *(Israel brand name Sci-B-Vac®)*	VLP	BLA and MAA Accepted; Approved in Israel
● Cytomegalovirus ("CMV")	VBI-1501	eVLP	Phase I Completed
● Pan-coronavirus	VBI-2901	eVLP	Pre-Clinical
● COVID-19	VBI-2902	eVLP	Pre-Clinical
Therapeutic Candidates			
● Hepatitis B ("HBV")	VBI-2601	VLP	Ongoing Phase Ib/IIa
● Glioblastoma ("GBM") + Other CMV-Associated Cancers	VBI-1901	eVLP	Ongoing Phase I/IIa

A summary of these programs and recent developments follows.

Prophylactic Pipeline

3-antigen HBV Vaccine/Candidate

A scientifically-differentiated approach to HBV vaccination, our 3-antigen HBV vaccine candidate expresses all three surface antigens of HBV – pre-S1, pre-S2, and S. Published data demonstrate pre-S1 antigens induce key neutralizing antibodies that block virus receptor binding, and T cell responses to pre-S1 and pre-S2 antigens can further boost responses to the S antigen. Our 3-antigen HBV vaccine is further distinguished from other commercially available HBV vaccines because it is produced in mammalian cells (Chinese hamster ovary "CHO" cells) rather than in yeast.

Our 3-antigen HBV vaccine is approved for use and commercially available in Israel, under the brand name Sci-B-Vac®, and successfully completed its pivotal Phase III studies in the United States, Europe, and Canada in January 2020 but is still an investigational candidate in such countries and has not yet been approved for commercialization by the applicable regulatory authorities (e.g., FDA, EMA, MHRA, and Health Canada, each defined below). This Phase III program consisted of two Phase III studies – PROTECT and CONSTANT – designed to assess efficacy and safety of VBI's 3-antigen HBV vaccine candidate compared with Engerix-B®, a single-antigen HBV vaccine, and lot-to-lot manufacturing consistency of three consecutive lots of VBI's vaccine candidate. As announced in June 2019 and January 2020, results from these two studies showed VBI's 3-antigen vaccine candidate achieved: (1) non-inferiority of seroprotection rate (SPR) in all adults age 18 and older (VBI: 91.4% vs. Engerix-B: 76.5%); (2) superiority (as defined in the clinical protocol) of SPR in adults age 45 and older (VBI: 89.4% vs. Engerix-B: 73.1%); (3) higher SPR and titers at all time points across all subgroup populations, including age, diabetic status, and obesity; (4) a safety profile consistent with the known safety profile of the vaccine and comparable to that of Engerix-B; and (5) manufacturing consistency.

The completed Phase III studies support the regulatory submissions to the United States Food and Drug Administration ("FDA"); the European Medicines Agency ("EMA"); the United Kingdom Medicines and Healthcare products, Regulatory Agency ("MHRA"); and Health Canada. We submitted our Marketing Authorization Application ("MAA") to the EMA on November 23, 2020, which was accepted for review on December 22, 2020, and the Biologics License Application ("BLA") to the FDA on November 30, 2020, which was accepted for review on January 29, 2021. As part of the review process, the FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of November 30, 2021. However, there is no guarantee that FDA will be able to meet these deadlines or that our BLA will be approved in a timely manner, if at all. The submissions to UK and Health Canada are in process and we expect to complete those regulatory filings in 2021.

On December 7, 2020, we announced a partnership for the commercialization of our 3-antigen HBV vaccine with Syneos Health ("Syneos"), who was selected for their robust and innovative commercialization experience and deep vaccine expertise, including successful partnerships with leading vaccine manufacturers.

VBI-2900: Coronavirus Vaccine Program (VBI-2901 & VBI-2902)

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

On March 31, 2020, we announced a collaboration with the National Research Council of Canada ("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 July 3, 2020, we and the NRC as represented by its Industrial Research Assistance Program ("IRAP") signed a contribution agreement whereby the NRC agreed to contribute up to CAD $1 million for the transfer and scale-up of the technical production process for our prophylactic coronavirus vaccine program.

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

On August 26, 2020, we announced data from three pre-clinical studies conducted to enable selection of optimized clinical candidates for our coronavirus vaccine program. As a result of these studies, VBI selected two vaccine candidates, with the goal of bringing forward candidates that add meaningful clinical and medical benefit to those already approved – be it as a one-dose administration and/or providing broader protection against known and future mutated strains of COVID-19: (1) VBI-2901, a trivalent pan-coronavirus vaccine candidate expressing the COVID-19, SARS, and MERS spike proteins; and (2) VBI-2902, a monovalent vaccine candidate expressing an optimized "prefusion" form of the COVID-19 spike protein. The initial clinical study of the first of the two candidates (VBI-2902) is expected to initiate in March 2021, subject to release of clinical materials and regulatory approval. Work is ongoing to further optimize and manufacture VBI-2901, with the anticipation that a Phase 1/2 study will begin later in 2021. 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. The amendment also extended the expiry date of the agreement to March 15, 2022.

VBI-1501: Prophylactic CMV Vaccine Candidate

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

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

Therapeutic Pipeline

VBI-2601: HBV Immunotherapeutic Candidate

VBI-2601 (BRII-179) is our novel, recombinant, protein-based immunotherapeutic candidate in development for the treatment of chronic HBV infection, a disease that affects more than 250 million people worldwide. Chronic HBV infection can lead to cirrhosis of the liver, hepatocellular cancer, and other liver disease, making it a life-threatening global health problem. VBI-2601 (BRII-179) is formulated to induce broad immunity against HBV virus, including T-cell immunity which plays an important role in controlling HBV infection.

VBI-2601 (BRII-179) is in an ongoing Phase Ib/IIa study in patients with chronic HBV infection, which initiated enrollment in November 2019, and is being conducted by our partner Brii Biosciences Limited ("Brii Bio") pursuant to a Collaboration and License Agreement ("License Agreement") announced on December 6, 2018. The Phase Ib/IIa study is a randomized, controlled study designed to assess the safety, tolerability, antiviral and immunological activity of VBI-2601 (BRII-179). The study is designed as a two-part dose-escalation study assessing different dose levels of VBI-2601 (BRII-179) with and without an immunomodulatory adjuvant and enrolled 46 patients. The study is being conducted at multiple study sites in New Zealand, Australia, Thailand, South Korea, Hong Kong SAR, and China.

On November 18, 2020, we announced interim data from the low-dose cohorts, which achieved human proof-of-concept, demonstrating restoration of both antibody and T cell responses in chronically-infected HBV patients. The data showed 1) potent re-stimulation of T cell responses to HBV surface antigens in 67% (n=6/9) and 78% (n=7/9) of evaluable patients in the low-dose VBI-2601 unadjuvanted and adjuvanted study arms, respectively; and 2) antibody responses against HBV surface antigens in 60% of evaluable patients (n=6/10) in the unadjuvanted cohort and in 67% (n=6/9) in the adjuvanted cohort. The low-dose, with and without the adjuvant, was well-tolerated with no safety signals observed. Based on the results of this study, Brii Bio is planning to initiate a Phase II clinical study in Q1 2021 to assess the safety and efficacy of the combination of VBI-2601 (BRII-179) and BRII-835 (VIR-2218), a novel, investigational RNA interference therapeutic, in chronically infected HBV patients who are on stable nucleos(t)ide therapies.

VBI-1901: CMV-Associated Cancer Vaccine Immunotherapeutic Candidate

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

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

Data from the ongoing Phase IIa portion of the study was announced throughout 2020, with the latest data presented in November 2020 at the Society for Neuro-Oncology (SNO) 2020 Annual Meeting. This data showed two partial responses ("PRs") and two stable disease ("SD") observed in the VBI-1901 plus GM-CSF vaccinated group, resulting in a disease control rate of 40% (n=4/10). A 56% disease control rate was achieved in the group vaccinated with VBI-1901 plus AS01, with 5 stable disease observations (n=5/9). Presumed pseudoprogression was observed in both vaccinated groups, defined as immune infiltration into the tumor which appears initially as tumor growth but later subsides resulting in tumor growth stabilization and/or shrinkage. In the VBI-1901 plus GM-CSF study arm, a normal baseline CD4+/CD8+ T cell ratio was identified as a biomarker associated with tumor response. In the VBI-1901 plus AS01 study arm, however, tumor responses were seen regardless of this biomarker, suggesting that AS01 may help overcome deficits in immune function.

VBI-1901 continues to be safe and well tolerated at all doses tested, with no safety signals observed.

Based on the data seen to-date, VBI is exploring a randomized, controlled, clinical study with registration potential for the next phase of development, which, subject to approval from regulatory bodies, is expected to begin in 2021.

In addition to the lead program candidates described above, we may also seek to in-license clinical-stage vaccines or vaccine-related technologies that we believe complement our product and pipeline portfolio, in addition to technologies that may supplement our therapeutic and preventative vaccination efforts in both immuno-oncology and infectious disease.

At present, our operations are focused on:

- preparing for commercialization of our 3-antigen prophylactic HBV vaccine candidate in the United States, Europe, and Canada, where we may obtain regulatory approval;
- conducting the Phase I/IIa clinical study of our GBM vaccine immunotherapeutic candidate, VBI-1901;
- continuing our development and scaling-up production processes for our two prophylactic coronavirus vaccine candidates VBI-2901 and VBI-2902 using a CDMO located in Canada;
- seeking regulatory approval to conduct clinical trials of VBI-2901 and VBI-2902;
- developing VBI-2601 (BRII-179), our protein-based immunotherapeutic candidate for treatment of chronic HBV, in collaboration with Brii Bio;
- ensuring our recently modernized manufacturing facility in Rehovot, Israel obtains all required regulatory approvals;
- preparing marketing authorization applications for our 3-antigen prophylactic HBV vaccine in the United Kingdom and Canada;
- preparation for further development of VBI-1501, our preventative CMV vaccine candidate;
- continuing the research and development ("R&D") of our pipeline candidates, including the exploration and development of new pipeline candidates;
- implementing operational, 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 and compliance.

VBI's revenue generating activities have been the sale of our 3-antigen prophylactic HBV vaccine in markets where it is approved or available on a named patient basis where it is not approved, though those markets have generated a limited number of sales to-date, various business development transactions, and R&D services generating fees. 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, sales, and manufacturing activities with respect to the advancement of our 3-antigen prophylactic HBV vaccine and new pipeline candidates. As of December 31, 2020, VBI had an accumulated deficit of approximately $308.6 million and stockholders' equity of approximately $171.7 million. Our ability to maintain our status as an operating company and to realize our investment in our IPR&D assets, which consist of our CMV and GBM programs, is dependent upon obtaining adequate cash and cash equivalents to finance our clinical development, manufacturing, our administrative overhead and our research and development activities, and ultimately to profitably monetize our IPR&D. We plan to finance near term future operations with existing cash and cash equivalents reserves. We expect that we will need to secure additional financing to finance our business plans, which may be a combination of proceeds from the issuance of equity securities, the issuance of additional debt, structured asset financings, government or non-governments organization grants or subsidies, and revenues from potential business development transactions, if any. There is no assurance we will manage to obtain these sources of financing, if required. These factors raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared assuming that we will continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should we be unable to continue as a going concern.

We have incurred operating losses since inception, have not generated significant product sales revenue and have not achieved profitable operations. We incurred net losses of $46,230 for the year ended December 31, 2020, and we expect to continue to incur substantial losses in future periods. We anticipate that we will continue to incur substantial operating expenses as we continue our research and development, clinical studies, and as we take steps to commercialize our product. These include expenses related to:

- preparing for commercialization of our 3-antigen prophylactic HBV vaccine in the United States, Europe, and Canada, where we may obtain approval;
- continuing the research and development of our pipeline candidates, including further development of VBI-1901, our cancer vaccine immunotherapeutic candidate, VBI-2601 (BRII-179), our HBV immunotherapeutic candidate, VBI-2900, our coronavirus vaccine program, and VBI-1501, our prophylactic CMV vaccine candidate;
- seeking regulatory approval to conduct clinical trials of VBI-2902;
- developing and scaling up production processes for VBI-2902 to meet the supply requirements for clinical trials and potential commercialization;
- manufacturing our 3-antigen prophylactic HBV vaccine, and obtaining, and maintaining required regulatory approvals at our recently modernized manufacturing facility in Rehovot, Israel;
- preparing marketing authorization applications for the United Kingdom and Canada;
- maintaining, expanding, and protecting our intellectual property portfolio;
- hiring additional clinical, manufacturing, and scientific personnel or contractors;
- implementing operational, financial, and management information systems, and adding human resources support, including additional personnel, to support our product development; and
- developing our internal systems and processes for regulatory affairs and compliance.

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

Long Term Debt

On May 22, 2020, we (along with our subsidiary VBI Cda) entered into a Loan and Guaranty Agreement (the "Loan Agreement") with K2 HealthVentures LLC and any other lender from time to time party thereto (the "Lenders") pursuant to which we received the first tranche secured term loan of $20 million (the "First Tranche Term Loan"). The Lenders agreed to make available the following additional tranches subject to the following conditions and upon the submission of a loan request by us: (1) up to $10 million available between January 1, 2021 and April 30, 2021 upon achievement of certain milestones (the "Second Tranche Term Loan"), (2) $10 million available between the closing date and December 31, 2021, subject to achievement of a certain United States FDA approval, (the "Third Tranche Term Loan"), and (3) a final tranche of up to $10 million that can be made available any time prior to June 30, 2022, subject to the advance of the Third Tranche Term Loan, satisfactory review by the administrative agent of our financial and operating plan, and approval by the Lenders' investment committee (the "Fourth Tranche Term Loan").

Pursuant to the Loan Agreement, the Lenders have the ability to convert, at the Lenders' option, up to $4 million of the secured term loan into common shares of the Company at a conversion price of $1.46 per share ("K2 conversion feature"). On February 3, 2021, the Lenders, pursuant to the Loan Agreement, converted $2 million of the secured term loan into 1,369,863 commons shares at a conversion price of $1.46.

In connection with the Loan Agreement, on May 22, 2020, we issued the Lenders a warrant to purchase up to 625,000 common shares (the "K2 Warrant") at an exercise price of $1.12 (the "Warrant Price"). The number of common shares issuable pursuant to the K2 Warrant, at any given time, is determined by the aggregate principal amount of the loans advanced at that time pursuant to the Loan Agreement multiplied by 3.5% and divided by the Warrant Price. If the full $50 million available in all K2 tranches is advanced pursuant to the Loan Agreement, up to 1,562,500 common shares will be issuable pursuant to the K2 Warrant. The K2 Warrant may be exercised either for cash or on a cashless "net exercise" basis and expires on May 22, 2030.

As a result of the K2 Warrant and K2 conversion feature, the debt was issued at a discount of $3,758. We also incurred, in the quarter ended June 30, 2020, $1,021 of debt issuance costs and are required to make a final payment equal to 6.95% of the aggregate secured term loan principal outstanding on the maturity date of the term loan, or upon earlier prepayment of the term loans in accordance with the Loan Agreement, resulting in an additional discount of $1,390. The total debt discount is $6,169.

The total principal amount of the loan under the Loan Agreement outstanding at December 31, 2020, including the $1,390 final payment discussed above, is $21,390. The principal amount of the loan made under the Loan Agreement accrues interest at an annual rate equal to the greater of (a) 8.25% or (b) prime rate plus 5.00%. The interest rate as of December 31, 2020 was 8.25%. We are required to pay only interest until July 1, 2022. If there is no Event of Default (as defined in the Loan Agreement), and a Third Tranche Term Loan of $10 million is made upon the achievement of a certain milestone then the interest only period is extended to January 1, 2023.

Upon receipt of additional funds under the Loan Agreement, additional common shares will be issuable pursuant to the K2 Warrant as determined by the principal amount of the additional funds advanced multiplied by 3.5% and divided by the Warrant Price, and the final payment will increase by 6.95% of the funds advanced.

Research and Development Services

Pursuant to an agreement with the Israel Innovation Authority (formerly the Office of the Chief Scientist of Israel), we are required to make services available for the biotechnology industry in Israel. These services include relevant activities for development and manufacturing of therapeutic proteins according to international standards and Good Manufacturing Practice ("GMP") quality level suitable for toxicological studies in animals. Service activities include analytics/bio analytics methods for development and process development of therapeutic proteins starting with a candidate clone through manufacturing.

These R&D services are primarily marketed to the Israeli research community in academia and Israeli biotechnology companies in the life sciences lacking the infrastructure or experience in the development and production of therapeutic proteins to the standards and quality required for clinical trials for human use. During the year ended December 31, 2020, we provided services to biotechnology companies including analytical development.

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

Modernization and Capacity Increases of Our Manufacturing Facility

In 2018, we temporarily closed our manufacturing facility in Rehovot, Israel, for modernization and capacity increase. We re-commenced operations in May 2019 and the review of the modernization and the capacity increase by the Israeli Ministry of Health ("IMoH") occurred in December of 2019. We received our certificate of GMP compliance from the IMoH on January 27, 2020. In addition to the GMP compliance certification, the IMoH will also need to review and approve the process validation submission, and provide approval for us to sell our 3-antigen prophylactic HBV vaccine manufactured at the modernized facility. We increased the capacity of our manufacturing facility to be able to supply commercial quantities of our 3-antigen prophylactic HBV vaccine candidate upon FDA, and/or EMA, and/or MHRA, and/or Health Canada approval, and to supply clinical supplies of VBI-2601 (BRII-179).

Third Party License and Assignment Agreements

We currently are dependent on licenses from third parties for certain of our key technologies, including the license granted pursuant to an agreement between Savient Pharmaceuticals Inc. and SciGen Ltd dated June 2004, as subsequently amended (the "Ferring License Agreement") and a license from L'Universite Pierre et Marie Curie, now Sorbonne Université ("UPMC"), Institut National de la Santé et de la Recherche Médicale ("INSERM") and L'école Normale Supérieure de Lyon. Under the Ferring License Agreement, we are committed to pay Ferring royalties equal to 7% of net sales (as defined therein) of HBsAg "Product" (as defined therein). Under an Assignment Agreement between FDS Pharm LLP and SciGen Ltd., dated February 14, 2012 (the "SciGen Assignment Agreement"), we are required to pay royalties to SciGen Ltd. equal to 5% of net sales (as defined in the Ferring License Agreement) of Product. Under the Ferring License Agreement and the SciGen Assignment Agreement, we originally were to pay royalties on a country-by-country basis until the date 10 years after the date of commencement of the first royalty year in respect of such country. In April 2019, we exercised our option to extend the Ferring License Agreement in respect of all the countries that still make up the territory for an additional 7 years by making a one-time payment to Ferring of $100. Royalties under the Ferring License Agreement and SciGen Assignment Agreement will continue to be payable for the duration of the extended license periods. Under our license agreement with UPMC and other licensors relating to eVLP technology, we have an exclusive license to a family of patents that is expected to expire in the United States in 2022 and 2021 in other countries. Under this agreement, we are required to pay UPMC between 0.75% to 1.75% of net sales and certain lump-sum milestone payments. UPMC is also a co-owner of the patent family covering our VBI-1501 CMV vaccine and we are currently negotiating extension of our existing license to cover this patent family.

Financial Overview

Overall Performance

The Company had net losses of approximately $46.2 million and $54.8 million for the years ended December 31, 2020, and 2019, respectively. The Company has an accumulated deficit of $308.6 million as December 31, 2020. The Company had $93.8 million of cash and cash equivalents at December 31, 2020 and net working capital of approximately $114.7 million.

Revenues

Revenues consist primarily of R&D services revenue recognized as part of the License Agreement with Brii Bio. Other revenues relate to the sale of products and services.

Cost of revenues

Cost of revenues consist primarily of costs incurred for manufacturing our 3-antigen prophylactic HBV vaccine, which includes cost of materials, consumables, supplies, contractors and manufacturing salaries. Certain cost of revenues related to the temporary closure of the manufacturing facility, during the modernization and capacity increase, of approximately $348 was allocated to G&A expenses in the year ended December 31, 2019. These costs were not present for the year ended December 31, 2020.

Research and Development Expenses

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

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

We expense R&D costs when we incur them.

General and Administration Expenses

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

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

Impairment Charges

Impairment charges consist of impairment on intangible assets and goodwill, if any.

Interest Expense, net of interest income

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

Results of Operations

Year Ended December 31, 2020 Compared to the Year Ended December 31, 2019

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

	Years ended December 31			
	2020	**2019**	**Change $**	**Change %**
Revenues	**$ 1,061**	**$ 2,221**	**$ (1,160)**	**(52)%**
Expenses:				
Cost of revenues	9,168	7,904	1,264	16%
Research and development	14,859	26,332	(11,473)	(44)%
General and administration	20,651	14,092	6,559	47%
Impairment charges	-	6,292	(6,292)	(100)%
Total operating expenses	44,678	54,620	(9,942)	(18)%
Loss from operations	(43,617)	(52,399)	8,782	(17)%
Interest expense, net of interest income	(2,708)	(2,196)	(512)	23%
Foreign exchange gain (loss)	95	(218)	313	(144)%
Loss before income taxes	(46,230)	(54,813)	8,583	(16)%
Income tax expense	-	-	-	-%
NET LOSS	$ (46,230)	$ (54,813)	$ 8,583	(16)%

Revenues

Revenue composition

	2020	2019
Product revenue	$ 283	$ 536
R&D Service revenue	778	1,685
	$ 1,061	$ 2,221

Revenue by Geographic Region

	Years ended December 31			
	2020	**2019**	**$ Change**	**% Change**
Revenue in Israel	$ 284	$ 455	$ (171)	(38)%
Revenue in China/Hong Kong	724	1,635	(911)	(56)%
Revenue in Europe	53	131	(78)	(60)%
Total Revenue	**$ 1,061**	**$ 2,221**	**$ (1,160)**	**(52)%**

Revenue for the year ended December 31, 2020 was $1,061 as compared to $2,221 for the year ended December 31, 2019. The revenue decreased by $1,160 or 52%, as a result of decreased R&D services revenue and a decrease in product revenue. The decrease in R&D services revenue is due to less work required as part of the License Agreement with Brii Bio for the year ending December 31, 2020 compared to the year ending December 31, 2019. The decrease in product revenue for the year ending December 31, 2020 compared to the year ending December 31, 2019 was due to limited product availability as we prepared for our regulatory submissions for our 3-antigen prophylactic HBV vaccine, which occurred in the fourth quarter of 2020.

Cost of Revenues

Cost of revenues for the year ended December 31, 2020 was $9,168 as compared to $7,904 for the year ended December 31, 2019. The increase in the cost of revenues of $1,264, or 16%, is due to the re-commencement of manufacturing in Israel, subsequent to the temporary closure of our manufacturing facility in Rehovot, which occurred in May 2019, and increased labor costs; offset by a reduction in costs of revenues related to the License Agreement with Brii Bio discussed above.

Research and Development Expenses

R&D expenses for the year ended December 31, 2020 were $14,859 as compared to $26,332 for the year ended December 31, 2019. The decrease in R&D expenses of $11,473, or 44%, is primarily due to a decrease in the costs related to our 3-antigen prophylactic HBV vaccine Phase III clinical studies. During the year ended December 31, 2020 both of our 3-antigen prophylactic HBV vaccine Phase III clinical studies were complete whereas during the year ended December 31, 2019, both studies were ongoing with the PROTECT topline data released mid- June 2019 and CONSTANT topline data released early January 2020. The decrease in R&D expenses was offset by increased analytical development, manufacturing and clinical costs associated with our eVLP vaccine candidates, more specifically, our prophylactic coronavirus vaccine program.

General and Administration

G&A expenses for the year ended December 31, 2020 were $20,651 as compared to $14,092 for the year ended December 31, 2019. The G&A expense increase of $6,559 or 47%, is primarily due to an increase in pre-commercialization activities related to our 3-antigen prophylactic HBV vaccine, increased insurance costs and increased labor costs.

Impairment Charges

Impairment charges for the year ended December 31, 2020 were $0 as compared to $6,292 for the year ended December 31, 2019. There was an impairment charge for the year ended December 31, 2019 related to goodwill of $6,292.

Loss from Operations

Net loss from operations for the year ended December 31, 2020 was $43,617 as compared to $52,399 for the year ended December 31, 2019. The $8,782 decrease in the net loss from operations resulted primarily from decreased R&D expenses offset by the increased cost of revenues and G&A expenses as discussed above.

Interest Expense, Net of Interest Income

Interest expense, net of interest income, increased by $512 as a result of increased amortization of the debt discount as a result of the debt financing that occurred in May 2020, and decreased interest income earned on cash and cash equivalent balances during the year ended December 31, 2020, compared to interest earned during the year ended December 31, 2019, as a result of the reduced interest rates.

Foreign Exchange Gain/Loss

Foreign exchange gain for the year ended December 31, 2020 was $95 compared to a foreign exchange loss of $218 for the year ended December 31, 2019. The change is a result of the changes in the exchange rate in which the foreign currency transactions were denominated for each of those periods.

Income Tax Expense

We did not incur any income tax expense for the year ended December 31, 2019 and for the year ended December 31, 2020.

Net Loss

The net loss decreased by $8,583, or 16%, from $54,813 for the year ended December 31, 2019 to $46,230 for the year ended December 31, 2020. The decrease in net loss is mainly attributable to the decrease in net loss from operations, discussed above.

Liquidity and Capital Resources

	Year ended December 31			
	2020	2019	$ Change	% Change
Cash and cash equivalents	$ 93,825	$ 44,213	$ 49,612	112%
Current Assets	132,041	46,963	85,078	181%
Current Liabilities	17,348	29,757	(12,409)	(42)%
Working Capital	114,693	17,206	97,487	567%
Accumulated Deficit	(308,618)	(262,388)	(46,230)	18%

As of December 31, 2020, we had cash and cash equivalents of $93,825 as compared to $44,213 as of December 31, 2019. As of December 31, 2020, we had working capital of $114,693 as compared to working capital of $17,206 at December 31, 2019. Working capital is calculated by subtracting current liabilities from current assets.

The report of our independent registered public accounting firm on our consolidated financial statements for the year ended December 31, 2012 contains an explanatory paragraph indicating that there is substantial doubt as to our ability to continue as a going concern. VBI has incurred significant net losses and negative operating cash flows since inception and expects to continue incurring losses and negative cash flows from operations as we carry out our planned clinical, regulatory, R&D, sales, and manufacturing activities with respect to the advancement of our 3-antigen prophylactic HBV vaccine and new pipeline candidates. As of December 31, 2020, VBI had an accumulated deficit of approximately $308.6 million and stockholders' equity of approximately $171.7 million.

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern; however, the above conditions raise substantial doubt about our ability to do so. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should we be unable to continue as a going concern. Our long-term success and ability to continue as a going concern is dependent upon obtaining sufficient capital to fund our planned clinical, regulatory, and research and development of our products and 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.

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

In May 2020, we refinanced our existing term loan facility with Perceptive Credit Holdings, LP ("Perceptive") and entered into the Loan Agreement with K2 for net proceeds of $4.5 million.

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

On July 31, 2020, we entered into an Open Market Sale Agreement[SM] with Jefferies LLC ("Jefferies"), pursuant to which we may offer and sell its common shares having an aggregate price of up to $125 million from time to time through Jefferies, acting as agent or principal (the "ATM Program"). Common shares are offered pursuant to a sales agreement prospectus included in the Company's automatic shelf registration on Form S-3 filed with the United States Securities and Exchange Commission ("SEC") on July 31, 2020. During the third and fourth quarter of 2020, we issued 15,638,706 common shares under the ATM Program, for total gross proceeds of $64,685 at an average price of $4.14. We incurred $2,101 of shares issuance costs related to the common shares issued resulting in net proceeds of $62,584. As of December 31, 2020, approximately $60,315 of common shares remained available for issuance under the ATM Program. Subsequent to December 31, 2020 and up to February 26, 2021, we issued 5,566,432 common shares under the ATM Program for total gross proceeds of $21,448 at an average price of $3.85. We incurred $643 of share issuance costs related to the common shares issued resulting in net proceeds of $20,805.

On September 16, 2020, we and Her Majesty the Queen in Right of Canada as represented by the Minister of Industry ("ISED") signed a contribution agreement (the "Contribution Agreement") for a contribution from the Strategic Innovation Fund ("SIF") whereby ISED agrees to contribute up to CAD $55,976 to support the development of our coronavirus vaccine program, through Phase II clinical studies, for a period commencing on April 15, 2020 and ending in or before the first quarter of 2022. In connection with execution of the Contribution Agreement, the Company obtained a consent of K2, 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.

During the year ended December 31, 2020, we had cash outflows to support the development of our coronavirus program of CAD $5,894 whereby ISED is expected to contribute CAD $4,420 which is included in other current assets on the consolidated balance sheet. In January 2021, we received CAD $1,326 of the ISED contribution.

During the fourth quarter of 2020, we issued 201,158 common shares upon exercise of the National Warrants at an exercise price of $1.50 for gross proceeds of $302. Subsequent to December 31, 2020 and up to February 26, 2021, additional National Securities Warrants to purchase 29,210 commons shares were exercised.

In September 2019, we received aggregate gross proceeds of $40.25 million from an underwritten public offering of an aggregate of 80,500,000 common shares at a price of $0.50 per share. After deducting the underwriting discounts and commissions and offering expenses, net proceeds from the offering were $37.4 million. Net proceeds from the offering are being used to support our pipeline programs, to continue the advancement of our clinical development and research programs and for other general corporate purposes.

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

We expect to finance our future cash needs through public or private equity offerings, potential additional proceeds from the long-term debt from the Lenders pursuant to the Loan Agreement, debt financings, government or non-government organization grants or subsidies, structured asset financings, or business development transactions. In addition to the First Tranche Term Loan, the Lenders agreed to make available subject to the conditions discussed above and upon the submission of a loan request by the Company, the Second Tranche Term Loan, the Third Tranche Term Loan, and the Fourth Tranche Term Loan. Pursuant to the Contribution Agreement, we expect receive up to CAD $55,976 as government grant to support the development of the Company's coronavirus vaccine program, though Phase II clinical studies. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. Additional equity, debt, structured asset financing, government or non-government organization grants or subsidies, or business development transactions may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our R&D programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain pipeline candidates that we might otherwise seek to develop or commercialize independently.

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

Year Ended December 31, 2020 Compared to the Year Ended December 31, 2019

Net cash flows used in Operating Activities

The Company incurred net losses of $46,230 and $54,813 in the years ended December 31, 2020 and 2019, respectively. The Company used $47,050 and $48,712 in cash for operating activities during the years ended December 31, 2020 and 2019, respectively. The decrease in cash outflows is largely as a result of a decrease in net loss offset by an increase in net changes in working capital items, specifically inventory, accounts payable, prepaid expenses, other current assets, and deferred revenue.

Net cash flows used in Investing Activities

The Company's net cash used in investing activities for the year ended December 31, 2020 consisted primarily of the purchase of short-term investments from the cash proceeds received from the issuance of commons shares which occurred in April 2020 and the purchase of property and equipment. Our net cash used in investing activities for the year ended December 31, 2019 consisted only of purchases of property and equipment of $3,673.

Net cash flows provided by Financing Activities

Cash flows provided by financing activities increased by $84,977, from $37,415 for the year ended December 31, 2019 to $122,392 for the year ended December 31, 2020. In 2020, the Company closed an underwritten public offering and entered into an Open Market Sale Agreement with Jeffries, for gross proceeds of $122,185 offset by $5,612 of share issuance costs. Also, the Company refinanced its existing term loan facility with Perceptive and entered into the Loan Agreement with K2 for proceeds of $20,000 offset by debt offering costs of $1,021 and repayment of the term loan facility with Preceptive of $15,300. In addition, the Company received proceeds of $2,139 from the issuance of commons shares upon exercise of warrants. During the year ended December 31, 2019 the Company received $40,250 from the proceeds from the issuance of common shares for cash offset by $2,835 of cash issuance costs.

Off-Balance Sheet Arrangements

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

Net Operating Loss Carryforwards

At December 31, 2020, the Company had net operating loss carryovers ("NOL's") aggregating approximately $285.7 million. The NOL's are available to reduce taxable income of future years and expire as follows:

	United States	Canada	Israel	Total
2024	$ -	$ 476	$ -	$ 476
2025	-	1,480	-	1,480
2026	10	3,732	-	3,742
2027	446	4,324	-	4,770
2028	718	1,674	-	2,392
2029	672	3,135	-	3,807
2030	2,556	1,015	-	3,571
2031	3,617	1,255	-	4,872
2032	2,962	-	-	2,962
2033	3,126	1,467	-	4,593
2034	5,626	5,493	-	11,119
2035	4,661	1,651	-	6,312
2036	5,323	8,762	-	14,085
2037	6,017	9,848	-	15,865
2038	-	2,446	-	2,446
2039	-	7,785	-	7,785
2040	-	14,749	-	14,749
No expiration	18,274	-	162,411	180,685
Total losses	**$ 54,008**	$ **69,292**	$ **162,411**	$ **285,711**

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, 2020, 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, 2020, there were no significant changes to our critical accounting policies, which are discussed in Note 2 to our Consolidated Financial Statements.

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

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

Revenue Recognition

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

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

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

Product Sales

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

Collaborative Arrangements

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

Collaborative arrangements with partners which are within the scope of ASC 606 typically include payment to us of one of more of the following: (i) license fees; (ii) R&D services to be performed as part of the contract; (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 R&D services to be performed by the Company. For performance obligations that include R&D services, the Company generally recognizes revenue allocated to such performance obligations based on an appropriate measure of progress. The Company utilizes judgment to determine the appropriate method of measuring progress for purposes of recognizing revenue, which is generally an input measure such as costs incurred. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Royalties

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

Income Taxes

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

Intangible Assets and Goodwill

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

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

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

Accrued Clinical Expenses

When preparing our financial statements, we are required to estimate our accrued clinical 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 clinical 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 a trial or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued clinical expenses have approximated actual expense incurred.

Long Term Debt

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

Trends, Events and Uncertainties

As with other companies that are in the process of commercializing novel vaccines, 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. Furthermore, other than as discussed in this report, we have no committed source of financing and may not be able to raise money as and when we need it to continue our operations. If we cannot raise funds as and when we need them, we may be required to severely curtail, or even to cease, our operations.

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

Recent Accounting Pronouncements

See Note 3 of Notes to Consolidated Financial Statements.

Related Parties

During the year ended December 31, 2019, the Company entered into a car loan lease with an officer of the Company, as part of their compensation arrangement, for $56, repayable over 3 years. The total amount of the car loan lease at December 31, 2020, is $43.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") was enacted in the United States Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth public companies.

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, 2020, and 2019, we had cash and cash equivalents of $93.8 million and $44.2 million, respectively, and short-term investments of $25.3 million and $0, respectively, which have been deposited in high interest rate bank accounts or redeemable guaranteed investment certificates, for a total of $119.1 million and $44.2 million, respectively. Our cash and cash equivalents and short-term investments holdings are in accordance with our investment policy approved by our board of directors, which specifies the categories, allocations and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash and cash equivalents have significant risk of default or illiquidity.

As of December 31, 2020, and 2019 we had long-term debt outstanding of $21.4 million and $15.3 million, respectively. The debt bears interest at the greater of (a) 8.25% or (b) prime rate plus 5.00%. The interest rate at December 31, 2020 and 2019 was 8.25% and 12.75%, respectively. Our interest rate risk exposure is primarily due to prime rate fluctuations.

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

Foreign Currency Risk

We are also exposed to market risk related to change in foreign currency exchange rates. We have operations in Israel, Canada, and the United States and therefore we incur expenses in NIS, Canadian Dollars, and United States dollars. We also contract with certain vendors that are located in Europe which have contracts denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with our foreign operations and certain agreements. We do not currently hedge our foreign exchange rate risk. As of December 31, 2020, and December 31, 2019, we had minimal liabilities denominated in foreign currencies.

ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

Not applicable.

ITEM 9A: CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer and Head of Business Development (our principal financial and accounting officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Form 10-K. The evaluation was undertaken in consultation with our accounting personnel and external consultants. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer and Head of Business Development concluded that, as of December 31, 2020, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Management's Report on Internal Control over Financial Reporting

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

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

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

Our Chief Executive Officer and our Chief Financial Officer and Head of Business Development assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management evaluated the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework (2013)*.

Based on our assessment, our Chief Executive Officer and our Chief Financial Officer and Head of Business Development determined that, as of December 31, 2020, 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.

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 2021 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates (the "Proxy Statement").

ITEM 11: EXECUTIVE COMPENSATION

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

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

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

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

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

ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

PART IV

ITEM 15: EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. **Financial Statements**

The following financial statements are included herein:

- Report of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of December 31, 2020 and 2019
- Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2020 and 2019
- Consolidated Statements of Stockholders' Equity - For the Years Ended December 31, 2020 and 2019
- Consolidated Statements of Cash Flows - For the Years Ended December 31, 2020 and 2019
- Notes to Consolidated Financial Statements

2. **Exhibits**

See Index to Exhibits

ITEM 16: FORM 10-K SUMMARY.

Not applicable.

VBI Vaccines Inc.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of VBI Vaccines Inc. and Subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations, 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, 2020 and 2019, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has an accumulated deficit as of December 31, 2020 and cash outflows from operating activities for the year-ended December 31, 2020 and, as such, will require significant additional funds to conduct clinical and non-clinical trials, achieve regulatory approvals, and subject to such approvals, commercially launch its products. These factors raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1.The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matters

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

Valuation of In-Process Research and Development

As described in Notes 2 and 7 to the consolidated financial statements, the Company's consolidated In-Process Research & Development ("IPR&D") indefinite-lived intangible asset balance was approximately $62.2 million as of December 31, 2020, related to both cytomegalovirus ("CMV") and glioblastoma ("GBM") programs. The Company performs impairment testing of indefinite-lived intangible assets on August 31st each year, and tests indefinite-lived intangible assets for impairment between annual tests if events or circumstances indicate that the assets might be impaired. The impairment test compares the carrying amount of the IPR&D asset to its estimated fair value. If the carrying amounts exceeds the fair value of the asset, such excess is recorded as an impairment loss. There was no IPR&D impairment loss determined as a result of the Company's annual testing on August 31, 2020. The fair value of the IPR&D assets included in the impairment test was determined using the income approach method and is considered Level 3 in the fair value hierarchy. Some of the more significant estimates and assumptions inherent in the estimate of the fair value of IRP&D assets include the amount and timing of costs to develop the IPR&D into viable products, the amount and timing of future cash inflows, the discount rate, and the probability of technical and regulatory success applied to the cash flows. The valuation of IP&D assets was also identified as a critical accounting estimate by management.

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

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

As described in Note 2 to the consolidated financial statements, at each balance sheet date the Company estimates its accrued clinical 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 trial 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 clinical trial expenses of $5.8 million is included in accrued expenses and other current liabilities on the December 31, 2020 consolidated balance sheet. The amounts recorded for clinical trial expenses represent the Company's estimate of the unpaid clinical trial expenses based on the information available to the Company at that time. The estimation of clinical trial expenses was also identified as a critical accounting estimate by management.

We identified the accrual for clinical trial 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 clinical trial 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, reading agreements and contract amendment with vendors in connection with conducting clinical trials, and evaluating the significant assumptions described above and the methods used in developing the clinical trial estimates and calculating the amounts that were unpaid at the balance sheet date. We confirmed the assumptions directly with the third parties involved in performing the clinical trial services on behalf of the Company. We also made direct inquiries of financial and clinical client personnel regarding status and progress to completion of clinical trials and description of future commitments, and verified amounts paid to date under each contract by vouching to invoices and payment support. We also assessed the historical accuracy of management's estimates, and compared the current estimate of expenses incurred to estimates previously made by management.

Accounting for Loan Agreement with K2 HealthVentures LLC

As described in Note 10 and 12 to the consolidated financial statements, the Company entered into a Loan Agreement with K2 HealthVentures LLC and any other lender from time to time party thereto, pursuant to which the Company received the first tranche of $20 million and may receive additional tranches totaling $30 million, subject to certain conditions. Pursuant to the Loan Agreement, the Lenders have the ability to convert up to $4 million of the secured term loan into common shares of the Company. In connection with the Loan Agreement, the Company issued the Lenders a warrant to purchase up to 625,000 common shares. The fair value of the warrant and conversion feature were determined based on the Black-Scholes pricing model. Estimates and assumptions impacting the fair value measurement using Black-Scholes include the number of shares for which the instruments are exercisable, remaining contractual term, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying common shares. The fair value of the debt was determined using the discounted cash flow method, for which the most significant estimate is the discount rate. The total proceeds attributed to the warrant was based on the relative fair value of the warrant as compared to the sum of the fair values of the warrant, conversion feature, and debt. The effective conversion price of the conversion feature was determined to be less than the fair value of the underlying common stock at the date of the commitment, resulting in a beneficial conversion feature ("BCF") at that date. The intrinsic value of the BCF was recorded to additional paid-in capital. These valuation techniques involve levels of estimation and judgment that are significant with increasingly complex instruments or pricing models. In general, the assumptions used in calculating the fair value of each instrument represents management's best estimates, but the estimates involve inherent uncertainties and the application of management judgment.

We identified the accounting for the loan agreement with K2 Health Ventures LLC as a critical audit matter due to the complexity involved in the Company's interpretation and application of accounting guidance, as well as the valuation, which involved the application of significant judgment and estimation on the part of management. This in turn led to a high degree of auditor subjectivity. We also applied significant judgment in performing our audit procedures and involved a valuation specialist to evaluate the audit evidence obtained from those procedures, in particular to evaluate the reasonableness of management's valuation models, as well as the inputs used within the models.

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 relating to the Company's methods, significant assumptions, and inputs used to value each instrument resulting from the Loan Agreement. Our procedures also included, among others, assessing whether management has appropriately classified the various instruments as liability or equity in accordance with Accounting Standards Codification ("ASC") 480 Distinguishing liabilities from equity, involvement of a valuation specialist in evaluating management's valuation model used, and evaluating the reasonableness of the observable inputs to the models, including the discount rate, and reperfoming the calculation. In addition, to evaluate the reasonableness of management's prices, we also involved a valuation specialist to develop an independent range of prices.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
Iselin, New Jersey
March 2, 2021

VBI Vaccines Inc. and Subsidiaries

Consolidated Balance Sheets
(in thousands, except share amounts)

	December 31, 2020	December 31, 2019
CURRENT ASSETS		
Cash and cash equivalents	**$ 93,825**	$ 44,213
Short-term investments	**25,276**	-
Accounts receivable, net	**77**	201
Inventory, net	**2,152**	1,075
Prepaid expenses	**1,569**	1,024
Other current assets	**9,142**	450
Total current assets	**132,041**	46,963
NON-CURRENT ASSETS		
Other long-term assets	**639**	620
Property and equipment, net	**10,721**	10,195
Right of use assets	**1,554**	1,459
Intangible assets, net	**62,156**	60,756
Goodwill	**2,261**	2,208
Total non-current assets	**77,331**	75,238
TOTAL ASSETS	**$ 209,372**	$ 122,201
CURRENT LIABILITIES		
Accounts payable	**$ 3,734**	$ 1,127
Other current liabilities	**12,415**	12,261
Current portion of deferred revenues	**255**	882
Current portion of lease liability	**944**	642
Current portion of long-term debt, net of debt discount – related party	**-**	14,845
Total current liabilities	**17,348**	29,757
NON-CURRENT LIABILITIES		
Lease liability, net of current portion	**619**	817
Long-term debt, net of debt discount	**16,329**	-
Liabilities for severance pay	**522**	463
Deferred revenues, net of current portion	**2,849**	2,909
Total non-current liabilities	**20,319**	4,189
COMMITMENTS AND CONTINGENCIES (NOTES 14 and 15)	-	-
STOCKHOLDERS' EQUITY		
Common shares (unlimited authorized; no par value) (2020 issued and outstanding – 247,039,010; 2019 - issued and outstanding 178,257,199)	**403,528**	284,965
Additional paid-in capital	**75,530**	66,430
Accumulated other comprehensive income (loss)	**1,265**	(752)
Accumulated deficit	**(308,618)**	(262,388)
Total stockholders' equity	**171,705**	88,255
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 209,372**	$ 122,201

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	
	2020	2019
Revenues	**$ 1,061**	$ 2,221
Operating expenses:		
Cost of revenues	**9,168**	7,904
Research and development	**14,859**	26,332
General and administration	**20,651**	14,092
Impairment charges	**-**	6,292
Total operating expenses	**44,678**	54,620
Loss from operations	**(43,617)**	(52,399)
Interest expense, net of interest income (including related party - see Note 10)	**(2,708)**	(2,196)
Foreign exchange gain (loss)	**95**	(218)
Loss before income taxes	**(46,230)**	(54,813)
Income tax expense	**-**	-
NET LOSS	**$ (46,230)**	$ (54,813)
Other comprehensive income	**2,017**	3,406
COMPREHENSIVE LOSS	**$ (44,213)**	$ (51,407)
Net loss per share of common shares, basic and diluted	**$ (0.21)**	$ (0.46)
Weighted-average number of common shares outstanding, basic and diluted	**218,268,979**	119,446,377

See accompanying Notes to Consolidated Financial Statements

VBI Vaccines Inc. and Subsidiaries

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

	Number of Common Shares	Share Capital	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
BALANCE AS OF DECEMBER 31, 2018	**97,343,777**	**$ 246,417**	**$ 63,449**	**$ (4,158)**	**$ (207,575)**	**$ 98,133**
Common shares issued in financing transaction	**80,500,000**	**37,415**	**-**	**-**	**-**	**37,415**
Warrant modification in connection with debt amendment	**-**	**-**	**179**	**-**	**-**	**179**
Stock-based compensation	**413,422**	**1,133**	**2,802**	**-**	**-**	**3,935**
Net loss	-	-	-	-	**(54,813)**	**(54,813)**
Currency translation adjustments	**-**	**-**	**-**	**3,406**	**-**	**3,406**
BALANCE AS OF DECEMBER 31, 2019	**178,257,199**	**$ 284,965**	**$ 66,430**	**$ (752)**	**$ (262,388)**	**$ 88,255**
Common shares issued in financing transactions, net of share issuance costs	**67,911,432**	**116,478**	**-**	**-**	**-**	**116,478**
Common shares issued upon exercise of warrants	**751,158**	**2,139**	**-**	**-**	**-**	**2,139**
Common shares issued upon exercise of options	**750**	**1**	**-**	**-**	**-**	**1**
Warrants issued in connection with financing transactions	**-**	**(453)**	**1,634**	**-**	**-**	**1,181**
Conversion feature issued in debt financing transaction	**-**	**-**	**2,577**	**-**	**-**	**2,577**
Stock-based compensation	**118,471**	**398**	**4,889**	**-**	**-**	**5,287**
Net loss	**-**	**-**	**-**	**-**	**(46,230)**	**(46,230)**
Unrealized holding gains on short-term investments	**-**	**-**	**-**	**71**	**-**	**71**
Currency translation adjustments	**-**	**-**	**-**	**1,946**	**-**	**1,946**
BALANCE AS OF DECEMBER 31, 2020	**247,039,010**	**$ 403,528**	**$ 75,530**	**$ 1,265**	**$ (308,618)**	**$ 171,705**

See accompanying Notes to Consolidated Financial Statements

VBI Vaccines Inc. and Subsidiaries

Consolidated Statements of Cash Flows
(in thousands)

	For the Years Ended in December 31	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	**$ (46,230)**	$ (54,813)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	**1,652**	1,204
Impairment charges	**-**	6,292
Stock-based compensation	**5,287**	3,935
Amortization of debt discount	**1,569**	998
Inventory reserve	**1,015**	300
Interest accrued on short-term investments	**(205)**	-
Net change in operating working capital items:		
Change in accounts receivable	**130**	(136)
Change in inventory	**(1,946)**	(385)
Change in prepaid expenses	**(511)**	326
Change in other current assets	**(8,409)**	57
Change in other long-term assets	**11**	6
Change in operating right of use assets	**988**	982
Change in accounts payable	**2,059**	(5,175)
Change in deferred revenues	**(771)**	(1,694)
Change in other current liabilities	**(711)**	374
Payments made on operating lease liabilities	**(978)**	(983)
Net cash flows used in operating activities	**(47,050)**	(48,712)
INVESTING ACTIVITIES		
Purchase of short-term investments	**(25,000)**	-
Purchase of property and equipment	**(1,000)**	(3,673)
Net cash flows used in investing activities	**(26,000)**	(3,673)
FINANCING ACTIVITIES		
Proceeds from issuance of common shares for in financing transactions	**122,185**	40,250
Share issuance costs	**(5,612)**	(2,835)
Proceeds from issuance of common shares upon exercise of warrants	**2,139**	-
Proceeds from issuance of common shares upon exercise of stock options	**1**	-
Proceeds from debt financing	**20,000**	-
Debt issuance costs	**(1,021)**	-
Repayment of long-term debt	**(15,300)**	-
Net cash flows provided by financing activities	**122,392**	37,415
Effect of exchange rates on cash and cash equivalents	**270**	(87)
CHANGE IN CASH AND CASH EQUIVALENTS FOR THE YEAR	**$ 49,612**	$ (15,057)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	**$ 44,213**	$ 59,270
CASH AND CASH EQUIVALENTS, END OF YEAR	**$ 93,825**	$ 44,213
Supplementary information:		
Interest paid	**$ 1,608**	$ 2,033
Non-cash investing and financing:		
Warrant modification in connection with debt amendment	**$ -**	$ 179
Warrants issued in connection with financing transactions	**1,634**	-
K2 conversion feature in connection with financing activities	**2,577**	-
Capital expenditures included in accounts payable and other current liabilities	**439**	**33**
Share issuance costs included in accounts payable and other current liabilities	**(95)**	-
Unrealized holding gains on short term investment	**(71)**	**-**

See accompanying Notes to Consolidated Financial Statements

1. NATURE OF BUSINESS AND CONTINUATION OF BUSINESS

Corporate Overview

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

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

The Company's registered office is located at Suite 1700, Park Place, 666 Burrard Street, Vancouver, BC V6C 2X8 with its principal office located at 222 Third Street, Suite 2241, Cambridge, MA 02142. In addition, the Company has manufacturing facilities located in Rehovot, Israel and research facilities located in Ottawa, Ontario, Canada.

Principal Operations

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

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

Liquidity and Going Concern

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

The Company has an accumulated deficit of $308,618 as of December 31, 2020 and cash outflows from operating activities of $47,050, for the year-ended December 31, 2020.

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

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

In May 2020, the Company refinanced its existing term loan facility with Perceptive Credit Holdings, LP and entered into a Loan and Guaranty Agreement (the "Loan Agreement") with K2 HealthVentures LLC for net proceeds of $4.5 million. The refinanced long-term debt has a maturity date of June 1, 2024. See Note 10 for more details.

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

On July 31, 2020, the Company entered into an Open Market Sale Agreement^{SM} with Jefferies LLC ("Jefferies"), pursuant to which we may offer and sell our common shares having an aggregate price of up to $125 million from time to time through Jefferies, acting as agent or principal (the "ATM Program"). Common shares are offered pursuant to a sales agreement prospectus included in the Company's automatic shelf registration on Form S-3 filed with the United States Securities and Exchange Commission ("SEC") on July 31, 2020. During the third and fourth quarter of 2020, the Company issued 15,638,706 common shares under the ATM Program, for total gross proceeds of $64,685 at an average price of $4.14 We incurred $2,101 of shares issuance costs related to the common shares issued resulting in net proceeds of $62,584. As of December 31, 2020, approximately $60,315 of common shares remained available for issuance under the ATM Program.

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

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

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

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Consolidation

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

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

Cash and cash equivalents

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

Short-term investments

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

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

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

Foreign currency

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

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

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

Use of Estimates

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

Concentration of Credit Risk

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

The Company has not experienced any losses in cash and accounts receivable for years ended December 31, 2020 and 2019, respectively.

Inventory

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

Property and equipment

Property and equipment are recorded at cost less accumulated depreciation.

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

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

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

Impairment of long-lived assets

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

The Company did not record an impairment for long-lived assets during the year ended December 31, 2019 or 2020.

In-Process Research and Development Assets and Goodwill

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

The IPR&D assets, which consist of CMV and GBM projects, 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 is amortized over its estimated useful life. The impairment test compares the carrying amount of the IPR&D asset to its fair value. If the carrying amount exceeds the fair value of the asset, such excess is recorded as an impairment loss. There was no IPR&D impairment determined as a result of the Company's annual testing on August 31, 2020. The fair value of the IPR&D assets included in the impairment test was determined using the income approach method and is considered Level 3 in the fair value hierarchy. Some of the more significant estimates and assumptions inherent in the estimate of the fair value of IPR&D assets include the amount and timing of costs to develop the IPR&D into viable products, the amount and timing of future cash inflows, the discount rate, and the probability of technical and regulatory success applied to the cash flows. The discount rate used was 11% and the cumulative probability of technical and regulatory success to achieve approval to market the products ranged from approximately 6% to 17%.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. When evaluating goodwill for impairment, we may first perform an assessment qualitatively whether it is more likely than not that a reporting unit's carrying amount exceeds its fair value, referred to as a "step zero" approach. Subsequently (if necessary after step zero), if the carrying value of a reporting unit exceeded its fair value an impairment would be recorded. We would perform our goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. There was no goodwill impairment determined as a result of the Company's annual testing on August 31, 2020. The Company recorded an impairment of goodwill of $6,292 for the year ended December 31, 2019 and is included in impairment charges in the consolidated statements of operations and comprehensive loss. The Company consists of a single reporting unit and used 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 stock as of each testing date.

Other Intangible Assets

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

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

Long Term Debt

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

Research and development

All costs of research and development are expensed as incurred.

When preparing our financial statements, we are required to estimate our accrued clinical 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 clinical 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 a trial or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued clinical 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.

Revenue recognition

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

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

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

Product sales

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

Collaborative Arrangements

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

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

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

License fees

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

R&D Services

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

Royalties

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

Employee benefits

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

Obligations for employee benefits are recognized as a component of operating expenses in the consolidated statement of operations and comprehensive loss in the periods during which services are rendered by employees. The Company records its obligation with respect to employee severance payments as if it was payable at each balance sheet date.

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, 2020 and 2019. 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 and cash equivalents, short-term investments, accounts receivable, other current assets, accounts payable and other current liabilities. The Company believes that the carrying value of its current financial instruments approximates their fair values due to the short-term nature of these instruments. The Company does not hold any derivative financial instruments.

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

The fair value of our outstanding debt, including the current portion, is estimated to be approximately $20,117 and $15,272 at December 31, 2020 and 2019, respectively. The fair value of the outstanding debt is considered to be Level 3 in the fair value hierarchy and was estimated by discounting to present value the scheduled coupon payments and principal repayment, using an appropriate fair market yield.

Loss per share

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

Leases

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

Stock-based compensation

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

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

3. NEW ACCOUNTING PRONOUNCEMENTS

Recently Adopted Accounting Standards

Intangibles – Goodwill and Other, Internal-Use Software

In August 2018, the FASB issued ASU 2018-15: Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customers' accounting for implementation costs incurred in a cloud computing arrangement that is a service contract. This ASU aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. Accordingly, the amendments require an entity (customer) in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. Our adoption of this ASU, effective January 1, 2020, was applied prospectively and did not have a material impact on our consolidated financial statements and the related footnote disclosures.

Recently Issued Accounting Standards, not yet Adopted

None

4. INVENTORY, NET

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

	2020	2019
Finished goods	$ -	$ 58
Work-in-process	390	237
Raw materials	1,762	780
	$ 2,152	$ 1,075

The Company recorded a provision of approximately $1,015 and $300 during the year ended December 31, 2020 and 2019, 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:

	2020	2019
Government receivables	$ 7,830	$ 238
Other current assets	1,312	212
	$ 9,142	$ 450

6. PROPERTY AND EQUIPMENT

	December 31, 2020		
	Cost	Accumulated Depreciation	Net Book Value
Machinery and equipment	$ 5,352	$ (1,795)	$ 3,557
Furniture and office equipment	218	(64)	154
Computer equipment and software	590	(428)	162
Leasehold improvements	8,171	(1,323)	6,848
	$ 14,331	$ (3,610)	$ 10,721

	December 31, 2019		
	Cost	Accumulated Depreciation	Net Book Value
Machinery and equipment	$ 4,578	$ (1,318)	$ 3,260
Furniture and office equipment	175	(47)	128
Computer equipment and software	518	(326)	192
Leasehold improvements	7,684	(1,069)	6,615
	$ 12,955	$ (2,760)	$ 10,195

Depreciation expense for the years ended December 31, 2020, and 2019 was $1,588 and $1,142, respectively.

7. INTANGIBLE ASSETS AND GOODWILL

	December 31, 2020				
	Gross Carrying amount	**Accumulated Amortization**	**Cumulative Impairment Charge**	**Cumulative Currency Translation**	**Net Book Value**
License	**$ 669**	**$ (590)**	**$ -**	**$ 44**	**$ 123**
IPR&D assets	**61,500**	**-**	**(300)**	**833**	**62,033**
	$ 62,169	**$ (590)**	**$ (300)**	**$ 877**	**$ 62,156**

	December 31, 2019				
	Gross Carrying amount	Accumulated Amortization	Cumulative Impairment Charge	Cumulative Currency Translation	Net Book Value
License	$ 669	$ (521)	$ -	$ 30	$ 178
IPR&D assets	61,500	-	(300)	(622)	60,578
	$ 62,169	$ (521)	$ (300)	$ (592)	$ 60,756

The license is held in Israel at SciVac. Amortization expenses for the years ended December 31, 2020 and 2019 amounted to $64 and $62, respectively. Amortization is expected to be approximately $60 per year until its fully amortized. These amounts do not include any amortization related to the IPR&D assets, which will not begin amortizing until the Company commercializes its products.

The IPR&D assets are in VBI Cda and the change in carrying value for IPR&D assets from December 31, 2019 relates to currency translation adjustments which increased by $1,455 for the year ended December 31, 2020. The change in carrying value from December 31, 2018 to December 31, 2019 relates to currency translation adjustments which increased IPR&D assets by $2,552.

	December 31, 2020			
	Gross Carrying Amount	**Cumulative Impairment Charge**	**Cumulative Currency Translation**	**Net Book Value**
Goodwill	**$ 8,714**	**$ (6,292)**	**$ (161)**	**$ 2,261**

	December 31, 2019			
	Gross Carrying Amount	Cumulative Impairment Charge	Cumulative Currency Translation	Net Book Value
Goodwill	$ 8,714	$ (6,292)	$ (214)	$ 2,208

The goodwill is in VBI Cda and the change in carrying value from December 31, 2019 relates to currency translation adjustments which increased goodwill by $53 for the year ended December 31, 2020. The change in carrying value for goodwill from December 31, 2018 relates to currency translation adjustments which increased by $235 for the year ended December 31, 2019, excluding the effect of the impairment charge of $6,292.

8. OTHER CURRENT LIABILITIES

Other current liabilities consisted of the following:

	December 31,2020	December 31,2019
Accrued research and development expenses (including clinical trial accrued expenses)	**$ 5,842**	$ 9,247
Accrued professional fees	**1,547**	446
Payroll and employee-related costs	**3,844**	2,184
Other current liabilities	**1,182**	384
Total other current liabilities	**$ 12,415**	$ 12,261

9. LOSS PER SHARE OF COMMON SHARES

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

The following potentially dilutive securities outstanding at December 31, 2020 and 2019 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	2020	2019
Warrants	**3,197,666**	2,618,824
Stock options and unvested stock awards	**12,636,897**	6,629,705
K2 conversion feature	**2,739,726**	-
	18,574,289	9,248,529

10. LONG-TERM DEBT

	2020	2019*
Long-term debt, net of debt discount of $5,061 ($455 at December 31 2019*)	**$ 16,329**	$ 14,845
Less: current portion, net of debt discount of $0 ($455 at December 31, 2019)	**-**	14,845
	$ 16,329	$ -

* 2019 long term debt was due to Perceptive Credit Holdings LP, a related party.

On May 22, 2020, the Company (along with its subsidiary VBI Cda) entered into the Loan Agreement with K2 HealthVentures LLC and any other lender from time to time party thereto (the "Lenders") pursuant to which we received the first tranche secured term loan of $20 million (the "First Tranche Term Loan"). The Lenders agreed to make available the following additional tranches subject to the following conditions and upon the submission of a loan request by the Company: (1) up to $10 million available between January 1, 2021 and April 30, 2021 upon achievement of certain milestones (the "Second Tranche Term Loan"), (2) $10 million available between the closing date and December 31, 2021, subject to achievement of a certain U.S. Food and Drug Administration approval (the "Third Tranche Term Loan"), and (3) a final tranche of up to $10 million that can be made available any time prior to June 30, 2022, subject to the advance of the Third Tranche Term Loan, satisfactory review by the administrative agent of our financial and operating plan, and approval by the Lenders' investment committee (the "Fourth Tranche Term Loan"). Pursuant to the Loan Agreement, the Lenders have the ability to convert, at the Lenders' option, up to $4 million of the secured term loan into common shares of the Company at a conversion price of $1.46 per share ("K2 conversion feature").

In connection with the Loan Agreement, on May 22, 2020, the Company issued the Lenders a warrant to purchase up to 625,000 common shares (the "K2 Warrant") at an exercise price of $1.12 (the "Warrant Price"). The number of common shares issuable pursuant to the K2 Warrant, at any given time, is determined by the aggregate principal amount of the loans advanced at that time pursuant to the Loan Agreement multiplied by 3.5% and divided by the Warrant Price. If the full $50 million available in all K2 tranches is advanced pursuant to the Loan Agreement, up to 1,562,500 common shares will be issuable pursuant to the K2 Warrant. The K2 Warrant may be exercised either for cash or on a cashless "net exercise" basis and expires on May 22, 2030.

The total proceeds attributed to the K2 Warrant was $1,181 based on the relative fair value of the K2 Warrant as compared to the sum of the fair values of the K2 Warrant, K2 conversion feature and debt. The effective conversion price of the K2 conversion feature of $1.52 was determined to be less than the fair value of the underlying common stock at the date of commitment, resulting in a beneficial conversion feature ("BCF") at that date. The intrinsic value of the BCF was $2,577 and recorded to additional paid-in capital. The K2 warrant and the K2 conversion feature resulted in the debt being issued at a discount. The Company also incurred $1,021 of debt issuance costs and is required to make a final payment equal to 6.95% of the aggregate secured term loan principal outstanding on the maturity date of the term loan, or upon earlier prepayment of the term loans in accordance with the Loan Agreement, resulting in an additional discount of $1,390. The total debt discount is $6,169. See Note 10 for more detail on assumptions used in the valuation of the K2 Warrant.

Upon receipt of additional funds under the Loan Agreement, additional common shares will be issuable pursuant to the K2 Warrant as determined by the principal amount of the additional funds advanced multiplied by 3.5% and divided by the Warrant Price, and the final payment will increase by 6.95% of the funds advanced.

The total principal amount of the loan under the Loan Agreement outstanding at December 31, 2020, including the $1,390 final payment discussed above, is $21,390. The principal amount of the loan made under the Loan Agreement accrues interest at an annual rate equal to the greater of (a) 8.25% or (b) prime rate plus 5.00%. The interest rate as of December 31, 2020 was 8.25%. The Company is required to pay only interest until July 1, 2022. If there is no Event of Default (as defined in the Loan Agreement) and a Third Tranche Term Loan of $10 million is made upon the achievement of a certain milestone then the interest only period is extended to January 1, 2023.

Upon the occurrence of an Event of Default, and during the continuance of an Event of Default, the applicable rate of interest, described above, will be increased by 5.00% per annum. The secured term loan maturity date is June 1, 2024, and the Loan Agreement includes both financial and non-financial covenants. The Company was in compliance with these covenants as of December 31, 2020.

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

Approximately $14.5 million of the proceeds received were used to repay the Company's Amended Credit Facility (as defined below) with Perceptive Credit Holdings, LP, a related party ("Perceptive"), which was due on June 30, 2020. The early repayment resulted in a loss on extinguishment of debt of $84, which is included in interest expense, net of interest income on the consolidated statement of operations and comprehensive loss.

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

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

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

The total debt discount related to the Loan Agreement with K2 HealthVentures LLC and the Amended Credit Facility with Perceptive of $6,169 and $4,018, respectively. As of December 31, 2020, and 2019, the unamortized debt discount was $5,061 and $455, respectively. The debt discount is being charged to interest expense, net of interest income in the consolidated statement of operations and comprehensive loss using the effective interest method over the term of the debt. The effective interest rate is 17.7%.

Interest expense, net of interest income recorded for the year ended December 31, 2020 and 2019 was as follows:

	December 31	
	2020	2019
Interest expense	**$ 1,752**	**$ 2,033**
Amortization of debt discount	**1,569**	**998**
Interest income	**(613)**	**(835)**
Total interest expense, net of interest income	**$ 2,708**	**$ 2,196**

Interest expense and amortization of debt discount for the year ended December 31, 2020 includes $723 and $461, respectively, incurred to a related party. Interest expense and amortization of debt discount for the year ended December 31, 2019 was fully incurred to a related party.

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

	Principal payments on Loan Agreement and final payment
2021	-
2022	$ 4,683
2023	9,978
2024	6,729
Total	$ 21,390

11. EMPLOYEE BENEFITS

Defined contribution plan

The Company operates a defined contribution retirement benefit plan for all qualifying employees in accordance with corresponding federal and state/provincial law. For VBI DE and VBI Cda employees, the respective companies contribute up to 1.5% of the employee's salary to a retirement benefit, which contribution is based on a 25% match of participating employee contributions. Such expense is not significant for any of the periods presented.

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, 2020 and 2019 was $292 and $263, 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.

There were no severance payments pursuant to the aforementioned statutory or contractual obligations as of December 31, 2020.

Included in research and development expenses for the year ended December 31, 2019 is $24 of severance payments pursuant to the aforementioned statutory or contractual obligations.

12. STOCKHOLDERS' EQUITY AND ADDITIONAL PAID-IN CAPITAL

Authorized

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

Common shares issuances

2019 common share issuances were as follows:

i. On February 20, 2019, the Company issued 143,110 stock awards pursuant to the 2016 Plan. Pursuant to Israeli tax requirements, the common shares were issued to a trustee on behalf of SciVac employees.

ii. On February 20, 2019, the Company issued 35,000 stock awards to service providers pursuant to the 2016 Plan.

iii. On February 20, 2019, the Company issued 140,000 stock awards pursuant to the 2016 Plan.

iv. On June 17, 2019, 25% of the stock awards granted on June 24, 2016 vested and the Company issued 95,312 shares of the Company's common shares.

v. In September 2019, the Company closed an underwritten public offering of 80,500,000 common shares at a price of $0.50 per share for total gross proceeds of $40,250. The Company incurred $2,835 of share issuance costs.

2020 common shares issuances were as follows:

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

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

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

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

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

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

Stock option plans

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

2006 VBI US Stock Option Plan

The 2006 VBI US Stock Option Plan (the "2006 Plan"), was approved by and was previously administered by the VBI US board of directors which designated eligible participants to be included under the 2006 Plan, and designated the number of options, exercise price and vesting period of the new options. The 2006 Plan was not approved by the stockholders of VBI US. The 2006 Plan was superseded by the 2014 Plan (as defined below) following the PLCC Merger and no further options will be issued under the 2006 Plan. As of December 31, 2020, there were 990,449 options outstanding under the 2006 Plan.

2013 Stock Incentive Plan

The 2013 Equity Incentive Plan (the "2013 Plan") was approved by and was previously administered by the VBI DE board of directors which designated eligible participants to be included under the 2013 Plan, and designated the number of options, exercise price and vesting period of the new options. The 2013 Plan was approved by the VBI DE shareholders on November 8, 2013. No further options will be issued under the 2013 Plan. As of December 31, 2020, there are no options outstanding under the 2013 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, 2020, there were 521,242 options outstanding under the 2014 Plan.

2016 VBI Equity Incentive Plan

The 2016 Plan 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, 2020, there were 10,995,850 options outstanding and 129,356 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 10,731,577 at December 31, 2020.

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, 2020 and 2019.

Under the 2016 Plan unless otherwise designated by the Board of Directors, 25% of the options will vest on each of the first four anniversaries of the grant date. The term of options will be for a maximum of 10 years, unless exercised or terminated earlier in accordance with the terms of the 2016 VBI Plan or the applicable grant agreement.

Upon a participant's termination of employment due to death, or in the case of disability: (a) the outstanding options that were granted prior to the year that includes the participant's death or disability that have not become vested prior to such date will continue to vest and, upon vesting, be exercisable during the 36-month period following such date; and (b) the outstanding options that have become vested prior to the participant's death or disability will continue to be exercisable during the 36-month period following such date.

In the case of a participant's termination of employment or contract for services without cause: (a) the outstanding options that have not become vested prior to the participant's termination will continue to vest and, upon vesting, be exercisable during the 120-day period following such date; and (b) the outstanding options that have become vested prior to the participant's termination will continue to be exercisable during the 120-day period following such date.

In the case of a participant's termination due to resignation (including voluntary withdrawal of services by a non-employee participant): (a) the outstanding options that have not become vested prior to the date of notice of resignation will be forfeited and cancelled as of such date; and (b) the outstanding options that have become vested prior to the date of notice of resignation will continue to be exercisable during the 90-day period following such date.

In the case of a participant's termination of employment or contract for services for cause, any and all then outstanding unvested options granted to such participant will be immediately forfeited and cancelled, without any consideration therefor, as of the date such notice of termination is given.

Share Units

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

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

Share units subject to a grant will vest as specified in the grant agreement governing such grant, provided that the participant is employed on the relevant vesting date. RSUs and PSUs will be settled upon, or as soon as reasonably practicable following the vesting thereof, subject to the terms of the grant agreement. In all events, RSUs and PSUs will be settled on or before the earlier of the 90th day following the vesting date and the date that is 2 ½ months after the end of the year in which the vesting occurred. Settlement will be made by way of issuance of one common share for each RSU or PSU, a cash payment equal to the market value of the RSUs or PSUs being settled, or a combination thereof. If the share units would be settled within a blackout period, such settlement will be postponed until the earlier of the 6th trading day following the end of such blackout period and the otherwise applicable date of settlement as determined in accordance with the settlement provision set out above. The Company has not issued any PSUs under this plan at December 31, 2020 and 2019. All RSUs issued under the plan at December 31, 2020 and 2019 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, 2020.

Stock-based compensation expense

The table below provides information, as of December 31, 2020, regarding the 2006 Plan, the 2013 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	990,449	$ 4.02
2014 Plan	521,242	$ 5.09
2016 Plan	11,125,206	$ 2.10
Total	12,636,897	$ 2.37

Activity related to stock options is as follows:

	Number of Stock Options	Weighted Average Exercise Price
Balance outstanding at December 31, 2018	3,479,676	$ 4.14
Granted	3,870,000	$ 1.69
Exercised	-	$ -
Forfeited	(877,968)	$ 3.40
Balance outstanding at December 31, 2019	**6,471,708**	**$ 2.79**
Granted	**6,075,900**	**$ 1.95**
Exercised	**(750)**	**$ 1.64**
Forfeited	**(39,317)**	**$ 2.59**
Balance outstanding at December 31, 2020	**12,507,541**	**$ 2.38**
Exercisable at December 31, 2020	**6,289,230**	**$ 2.76**

	Outstanding		Exercisable	
Exercise Price	Number Of Options	Weighted Average Remaining Contractual Life (Years)	Number Of Options	Weighted Average Exercise Price
$ 0.00 – 3.49	9,882,286	8.65	3,817,956	$ 1.70
$ 3.50 – 4.49	1,934,266	5.88	1,780,285	$ 4.15
$ 4.50 – 5.49	668,101	4.32	668,101	$ 4.90
$ 5.50+	22,888	3.57	22,888	$ 8.17
	12,507,541	7.93	6,289,230	$ 2.76

The weighted average remaining contractual life of exercisable options was 6.98 years and 6.81 years at December 31, 2020 and 2019, respectively.

Information relating to restricted stock units is as follow:

	Number of Stock Awards	Weighted Avg Fair Value at Grant Date
Unvested shares outstanding at January 1, 2019 and December 31, 2018	268,570	4.13
Granted	330,000	$ 1.65
Vested	(421,544)	$ 2.73
Forfeited	(19,029)	$ 3.43
Unvested shares outstanding at December 31, 2019	**157,997**	**$ 2.77**
Granted	**125,000**	**$ 1.46**
Vested	**(140,167)**	**$ 2.79**
Forfeited	**(13,474)**	**$ 1.53**
Unvested shares outstanding at December 31, 2020	**129,356**	**$ 1.62**

The intrinsic value of outstanding options at December 31, 2020 was $9,314 (the intrinsic value of vested options was $4,085 and the intrinsic value of those expected to vest was $5,229). The fair value of the vested RSU's was $389 for the year ended December 31, 2020. There were 750 options exercised for the year ended December 31, 2020 and the intrinsic value of exercised options was $2 for the year ended December 31, 2020. There were no options exercised for the year ended December 31, 2019.

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:

	2020	2019
Volatility	**91.59%**	118.62%
Risk free interest rate	**1.19%**	2.46%
Expected term in years	**5.81**	5.78
Expected dividend yield	**0.00%**	0.00%
Weighted average fair value per option	**$ 1.42**	$ 1.45

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:

	2020	2019
Research and development	**$ 1,088**	$ 796
General and administration	**4,143**	3,080
Cost of revenue	**56**	59
Total stock-based compensation expense	**$ 5,287**	$ 3,935

There is $8,847 of unrecognized compensation from all equity awards as of December 31, 2020. This expense will be recognized over a weighted average period of 2.01 years.

Warrants

In April 2020, the Company engaged National to provide financial advisory services in connection with the April 2020 underwritten public offering, discussed above. As consideration for such services, the Company issued to National or its designees warrants to purchase up to an aggregate of 705,000 common shares, subject to the terms and conditions set forth in the form of warrant agreement. The National Warrants are exercisable immediately upon issuance and terminate three years following issuance and have an exercise price of $1.50 per share.

On May 22, 2020, in connection with the Loan Agreement, as described in Note 10, the Company issued a warrant, the K2 Warrant, to purchase up to an aggregate of 625,000 common shares, subject to terms and conditions set forth in the form of warrant agreement. The K2 Warrant expires on May 22, 2030 and has an exercise price of $1.12 per share.

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

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

During the year ended December 31, 2019, the Company amended the exercise price of certain warrants issued on July 25, 2014 and December 6, 2016, as described in Note 10.

The value attributed to the National Warrants and the K2 Warrant were based on the Black-Scholes option pricing model by applying the following assumptions:

	National Warrants	**K2 Warrant**
Volatility	**103.13%**	**95.00%**
Risk free interest rate	**0.26%**	**0.66%**
Expected term in years	**3**	**10**
Expected dividend yield	**0.00%**	**0.00%**
Fair value per warrant	**$ 0.64**	**$ 2.25**

Activity related to the warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance outstanding at January 1, 2019	2,618,824	$ 3.57
Balance outstanding at December 31, 2019	2,618,824	$ 2.87
Issued	1,330,000	$ 1.32
Exercised	(751,158)	$ 2.85
Balance outstanding at December 31, 2020	3,197,666	**$ 2.23**

13. REVENUE AND DEFERRED REVENUE

Revenue is comprised of the following:

	2020	2019
Product revenue	**$ 283**	$ 536
R&D Service revenue	**778**	1,685
	$ 1,061	$ 2,221

Cost of revenues for the year ended December 31, 2020 for product revenue and R&D services revenue is $8,692 and $476, respectively. Cost of revenues for the year ended December 31, 2019 for product revenue and R&D services revenue is $6,763 and $1,141, 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, 2020:

	Total	**2020**	**2021 and thereafter**
Product revenue	**$ 469**	**$ -**	**$ 469**
R&D Service revenue	**2,635**	**255**	**2,380**
Total	**$ 3,104**	**$ 255**	**$ 2,849**

The following table presents changes in the deferred revenue balance for the year ended December 31, 2020:

Balance at December 31, 2019	**$ 3,791**
Amounts received in 2020	**11**
Recognition of deferred revenue	**(735)**
Currency translation	**37**
Balance at December 31, 2020	**$ 3,104**
Short Term	**$ 255**
Long Term	**$ 2,849**

Collaboration and License Agreement – Brii Bio

On December 4, 2018, we entered into the License Agreement with Brii Bio, whereby:

- the Company and Brii Bio agreed to collaborate on the development of a HBV recombinant protein-based immunotherapeutic in the licensed territory, which consists of China, Hong Kong, Taiwan and Macau (collectively, the "Licensed Territory"), and to conduct a Phase II collaboration clinical trial for the purpose of comparing VBI-2601 (BRII-179), which is a recombinant protein-based immunotherapeutic developed by VBI for use in treating chronic HBV, with a novel composition developed jointly with Brii Bio (either being the "Licensed Product"); and
- 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

Pursuant to the License Agreement, the Company is responsible for the R&D Services and Brii Bio is responsible for costs relating to the clinical trials for the Licensed Territory.

The initial consideration of the License Agreement consisted of an $11 million non-refundable upfront payment. As part of License Agreement, the Company and Brii Bio entered into a stock purchase agreement. Under the terms of the stock purchase agreement, the Company issued to Brii Bio 2,295,082 shares of its common stock valued at $3.6 million (based on the Company's common stock price on December 4, 2018). The remaining $7.4 million, deemed to be the initial transaction price, was allocated to two performance obligations: i) the VBI-2601 (BRII-179) license and ii) R&D services. The R&D services were allocated $4.8 million of the transaction price using an estimated selling price based on an expected cost plus a margin approach and the remaining transaction price of $2.6 million was allocated to the VBI-2601 (BRII-179) license using the residual method.

In addition, the Company is also eligible to receive an additional $117.5 million in potential regulatory and sales milestone payments, along with royalties on commercial sales in the Licensed Territory. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. Therefore, no variable consideration was included in the initial transaction price and no such amounts have been recognized to date.

On December 4, 2018, the Company recognized the VBI-2601 (BRII-179) license when it was granted as it was determined to be distinct and Brii Bio was able to use and benefit from the license. The R&D Services will be satisfied over time as services are rendered using the "cost-to-cost" input method as this method represents the most accurate depiction of the transfer of services based on the types of costs expected to be incurred. As of December 31, 2020, R&D services related to Brii Bio that remain unsatisfied are $2.4 million, out of the $3.1 million total deferred revenue.

Upon termination of the Collaboration and License Agreement prior to the end of the term, there is no obligation for refund and any amounts in deferred revenue related to unsatisfied performance obligations will be immediately recognized.

14. COLLABORATIVE ARRANGEMENTS

GlaxoSmithKline Biologicals S.A. ("GSK")

On September 10, 2019, the Company entered into a Clinical Collaboration Agreement ("Collaboration Agreement") pursuant to which we will investigate the use of GSK's proprietary $AS01_B$ adjuvant system in our ongoing study of VBI-1901. As a result of the Collaboration Agreement, a second study arm was added to Part B of the ongoing Phase Ib/IIa clinical study to accommodate the $AS01_B$ adjuvant.

This relationship is considered a collaborative relationship and not a customer relationship and is therefore accounted for outside the scope of ASC Topic 606. Costs associated with the second study arm will be expensed as incurred in Research and Development expenses; costs for the year ended December 31, 2020 and 2019 are $669 and de minimis, respectively.

National Research Council of Canada ("NRC")

On March 31, 2020, the Company announced a collaboration with the NRC, Canada's largest federal research and development organization, to develop a pan-coronavirus vaccine candidate, targeting COVID-19, SARS, and MERS. The NRC and the Company are collaborating to evaluate and select promising coronavirus vaccine candidates. The collaboration combines the Company's viral vaccine expertise, eVLP technology platform, and modified coronavirus antigens with the NRC's proprietary SARS-CoV-2 antigens and assay development capabilities to select the most immunogenic vaccine candidate for further development.

On December 21, 2020, 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. The amendment also extended the expiry date of the agreement to March 15, 2022.

This relationship is considered a collaborative relationship and not a customer relationship and is therefore accounted for outside the scope of ASC Topic 606. Costs associated with the collaboration will be expensed as incurred in Research and Development expenses; costs for the year ended December 31, 2020 are $454.

Brii Biosciences Limited

On December 4, 2018, we entered into a License Agreement with Brii Bio, as described in Note 13.

15. GOVERNMENT GRANTS

Grants are recognized in research and development expenses in the consolidated statement of operations and comprehensive loss are as follows:

	2020 $ CAD	2020 $ USD
IRAP		
IRAP, grant value	**$ 1,000**	$ **737**
IRAP, cash received	**674**	**482**
IRAP, grant receivable	**326**	**255**
IRAP, total grant claimed	**1,000**	**737**
IRAP, remaining grant value to be claimed	**-**	**-**
SIF		
SIF, grant value up to	**$ 55,976**	**$ 42,487**
SIF, cash received	**-**	-
SIF, grant receivable	**4,420**	**3,468**
SIF, total grant claimed	**4,420**	**3,468**
SIF, remaining grant value to be claimed	**$ 51,556**	**$ 39,019**

The amount of government grants recognized in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2020 related to our government grants is CAD $4,369 (USD $3,261), with the remaining CAD $1,051 (USD $825) recognized as a deferred government grant included other current liabilities.

See Note 1 for description of our government grants.

16. INCOME TAXES

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

	2020	2019
United States	**$ (8,343)**	$ (9,079)
Canada	**(16,480)**	(15,537)
Israel	**(21,407)**	(30,197)
Total	**$ (46,230)**	$ (54,813)

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:

	2020	2019
Loss before income taxes	**$ (46,230)**	$ (54,813)
Canadian statutory tax rate	26.50%	26.50%
Expected benefit of income tax	**12,251**	14,525
Research and development tax credits	**188**	300
Change in valuation allowance*	**(15,094)**	(10,873)
Difference between Canadian and foreign tax rates	**(663)**	(982)
Impairment of Goodwill	**-**	(1,667)
Stock based compensation	**(792)**	(1,042)
Non – deductible portion of capital losses	**-**	(217)
Foreign exchange translation	**2,366**	-
Permanent statutory to GAAP difference	**1,272**	-
Other	**472**	(44)
Income tax expense	**$ -**	$ -

* A portion of the change in valuation allowance is recognized in equity, therefore the overall change in the valuation allowance will not equal the amount recognized in tax expense.

For 2020 the Canadian statutory income tax rate of approximately 26.5% is comprised of federal income tax at approximately 15% and provincial income tax at approximately 11.5%. The Israel statutory income rate is approximately 23%.

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

	2020	2019
Deferred tax assets (liabilities):		
Net operating losses	**$ 70,472**	$ 54,337
Research and development tax credits	**11,163**	12,605
Property and equipment	**641**	431
Reserves and other	**1,603**	1,859
Intangible assets	**(16,471)**	(16,249)
Debt obligations	**(1,531)**	-
Deferred financing costs	**2,348**	-
Net deferred tax assets	**68,225**	52,983
Less: valuation allowance	**(68,225)**	(52,983)
Net deferred tax assets (liabilities)	**$ -**	$ -

As of December 31, 2020, the Company had United States federal net operating loss carryovers ("NOLs") of approximately $54.0 million (2019 - $49.8 million), including $29.0 million 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, 2020. 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, 2020, the Company also had Canadian net operating loss carryovers of approximately $69.3 million (2019 – $52.3 million) available to offset future taxable income which expire beginning in 2024. As of December 31, 2020, the Company also had Israel net operating loss carryovers of approximately $162.4 million (2019 - $116.8 million), which can be carried forward indefinitely.

At December 31, 2020, the Company had $5.9 million (2019 - $5.5 million), of investment tax credits available to carry forward and reduce future years' Canadian income taxes which expire beginning in 2026.

As of December 31, 2020, the Company had unclaimed research and development expenses in Canada of approximately $21.8 million (2019 – $19.9 million), which are available to offset future taxable income indefinitely.

At December 31, 2020, the Company had NOLs aggregating approximately $285.7 million. The NOLs are available to reduce taxable income of future years and expire as follows:

	United States	Canada	Israel	**Total**
2024	$ -	$ 476	$ -	$ 476
2025	-	1,480	-	1,480
2026	10	3,732	-	3,742
2027	446	4,324	-	4,770
2028	718	1,674	-	2,392
2029	672	3,135	-	3,807
2030	2,556	1,015	-	3,571
2031	3,617	1,255	-	4,872
2032	2,962	-	-	2,962
2033	3,126	1,467	-	4,593
2034	5,626	5,493	-	11,119
2035	4,661	1,651	-	6,312
2036	5,323	8,762	-	14,085
2037	6,017	9,848	-	15,865
2038	-	2,446	-	2,446
2039	-	7,785	-	7,785
2040	-	14,749	-	14,749
No expiration	18,274	-	162,411	180,685
Total losses	**$ 54,008**	**$ 69,292**	**$ 162,411**	**$ 285,711**

17. COMMITMENTS AND CONTINGENCIES

Licensing

(a) In connection with the acquisition of the ePixis technology in 2011, VBI Cda also agreed to make certain contingent payments as follows:

Upon the completion of a "Successful Technology Transfer", as defined in the Sale and Purchase Agreement ("SPA"), to a contract manufacturing organization, VBI Cda paid €102 (approximately $110 and referred to as the "Transfer Payment") to the Sellers during the second quarter of 2015. The Transfer Payment related to the achievement of the first milestone, which occurred during the three months ended June 30, 2015.

The Company is committed to make further contingent payments pursuant to defined milestones in the SPA depending on whether there continue to exist any issued and valid claims on the acquired patents. Contingent payments include:

- Upon first approval in the United States or the European Union: €500 to €1,000;
- Upon commercialization when cumulative net sales equals or exceeds:
  - €25,000: €750 to €1,500; and,
  - €50,000: €1,000 to €2,000;

- Upon commercialization by one or more sublicenses when cumulative net sales equals or exceeds:
    - €25,000: €375 to €750;
    - €50,000: €375 to €750;
    - €75,000: €500 to €1,000;
    - €100,000: €500 to €1,000,
    - VBI will be obligated to pay to the Sellers the balance still owing on the total €3,500 when either cumulative net sales of €50,000 by VBI or €100,000 by VBI and its sublicenses is achieved.

The Company is further committed to pay all costs of protecting the patents and make contingent payments to the licensor of the acquired patents pursuant to defined milestones in an amendment to the related license agreement which include: royalty fees ranging between 0.75% and 1.75% depending on the level of net sales; and, lump sum payments ranging from €50 to €1,000 depending on the stage of clinical development and ultimately commercial approval. Additionally, 5% to 25% of any sublicensing fees depending on stage of clinical development are also payable to the licensor.

During the year ended December 31, 2016, VBI Cda paid €200, in milestone payments related to CMV Phase I clinical trial approval and start. During the year ended December 31, 2017 and 2018, VBI Cda paid €50 and €150, respectively, in milestone payments related to the GBM Phase I/IIa clinical trial approval and start. No payments have been made in 2020 or 2019, however, we have accrued in other current liabilities, a payment of €50 in relation to our prophylactic coronavirus vaccine program.

(b) The Company's manufactured and marketed product, our 3-antigen prophylactic HBV vaccine, is a recombinant trivalent HBV vaccine whose sales and territories are governed by the Savient Pharmaceuticals Inc and SciGen Ltd., dated June 2014 ("Ferring License Agreement"). Under the Ferring License Agreement the Company is committed to pay Ferring royalties equal to 7% of net sales (as defined therein) of the HBsAg "Product" (as defined therein). Under an Assignment Agreement between FDS Pharm LLP and SciGen Ltd., dated February 14, 2012 (the "SciGen Assignment Agreement"), we are required to pay royalties to SciGen Ltd. equal to 5% of net sales (as defined in the Ferring License Agreement) of Product.

Royalty payments under the Ferring License Agreement of $20 and $38, were recorded in cost of revenues for the year ended December 31, 2020 and 2019, respectively.

Royalty payments under the SciGen Assignment Agreement of $14 and $27 were recorded in cost of revenues for the year ended December 31, 2020 and 2019, respectively.

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

Under the Ferring License Agreement and the SciGen Assignment Agreement, we originally were to pay royalties on a country-by-country basis until the date 10 years after the date of commencement of the first royalty year in respect of such country. In April 2019, we exercised our option to extend the Ferring License Agreement in respect of all the countries that still make up the territory for an additional 7 years by making a one-time payment to Ferring of $100. Royalties under the Ferring License Agreement and SciGen Assignment Agreement will continue to be payable for the duration of the extended license periods.

Legal Proceedings

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

On September 13, 2018, two civil claims were brought in the District Court of the central district in Israel naming our subsidiary SciVac as a defendant. In one claim, two minors, through their parents, allege, among other things: defects in certain batches of our 3-antigen prophylactic HBV vaccine discovered in July 2015; that our 3-antigen prophylactic HBV vaccine was approved for use in children and infants in Israel without sufficient evidence establishing its safety; that SciVac failed to provide accurate information about our 3-antigen prophylactic HBV vaccine 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 our 3-antigen prophylactic HBV vaccine in Israel from April 2011 and seeking damages in a total amount of NIS 1,879,500,000 (not in thousands) ($584,603). The second claim is a civil action brought by two minors and their parents against SciVac and the Israel Ministry of Health alleging, among other things, that SciVac marketed an experimental, defective, hazardous or harmful vaccine; that our 3-antigen prophylactic HBV vaccine was marketed in Israel without sufficient evidence establishing its safety; and that our 3-antigen prophylactic HBV vaccine was produced and marketed in Israel without approval of a western regulatory body. The claim seeks damages for past and future losses and expenses as well as punitive damages.

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

The District Court has accepted SciVac's motion to suspend reaching a decision on the approval of the class action pending the determination of liability under the civil action. Preliminary hearings for the trial of the civil action began on January 15, 2020, with subsequent preliminary hearings held on May 13, 2020 and December 3, 2020 to discuss document disclosure. The next preliminary hearing is scheduled to be held on March 24, 2021.

18. LEASES

The Company has entered into various non-cancelable lease agreements for its office, lab and manufacturing facilities, which are classified as operating leases. The office facility lease agreement in the United States expired on April 30, 2020, with no option to extend. Effective April 30, 2020, the Company entered into the seventh amendment to the lease agreement for the office facilities in the United States, which extends the lease for a term of three years expiring on April 30, 2023.

Our manufacturing facility lease agreement expires on January 31, 2022 which includes one five-year option to extend until January 31, 2027. The lease agreement for our research facility in Canada, which comprises of office and laboratory space, had an initial term ending on December 31, 2019 with the option to extend the term for two periods of three years. Effective September 5, 2019, the term of the lease was extended until December 31, 2022, with an option to extend the lease for one additional period of three years.

Effective as of September 4, 2020, the Company entered into a further lease agreement for additional office space at its research facility in Canada, the term of which commenced on October 1, 2020 and expires on April 30, 2023.

Options to extend are not recognized as part of the lease liabilities or recognized as right to use assets. There are no residual value guarantees, no variable lease payments, and no restrictions or covenants imposed by leases. The discount rate used in measuring the lease liabilities and right of use assets was determined by reviewing our incremental borrowing rate at the initial measurement date.

Lease cost:		
2020 operating lease costs:	$	1,231
2019 operating lease costs:		1,128
Other information:		
Weighted average remaining lease term		1.84 years
Weighted average discount rate		12%

Operating lease costs are included in general and administrative (“G&A”) expenses in the statement of operation and comprehensive loss.

Operating cash flow supplemental information as of December 31, 2020:

During the year ended December 31, 2020, the Company entered into new lease agreements and recognized a ROU asset of $836.

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

Year ending December 31		
2021	**$**	**1,078**
2022		**513**
2023		**115**
Total	**$**	**1,706**
Effect of discounting		**(143)**
Total lease liability	**$**	**1,563**
Less: current portion		**(944)**
Long term lease liability	**$**	**619**

19. SEGMENT INFORMATION

The Company's Chief Executive Officer ("CEO") has been identified as the chief operating decision maker. The CEO evaluates the performance of the Company and allocates resources based on the information provided by the Company's internal management system at a consolidated level. The Company has determined that it has only one operating segment.

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

	2020	2019
Revenue in Israel	**$ 284**	$ 455
Revenue in China/Hong Kong	**724**	1,635
Revenue in Europe	**53**	131
Total	**$ 1,061**	$ 2,221

There was no revenue attributed to our country of domicile, Canada, for years ended December 31, 2020 and 2019.

For the year ended December 31, 2020, the Company had 3 customers that individually accounted for 68%, 10% and 10% of revenues.

For the year ended December 31, 2019, the Company had 2 customers that individually accounted for 74% and 13% of revenues.

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

	2020	2019
Tangible long-lived assets in Israel	**$ 10,998**	$ 11,062
Tangible long-lived assets in United States	**644**	112
Tangible long-lived assets in Canada (country of domicile)	**633**	480
Total	**$ 12,275**	$ 11,654

20. RELATED PARTY TRANSACTIONS

During the year ended December 31, 2019, the Company entered into a car loan lease with an officer of the Company, as part of their compensation arrangement, for $56, repayable over 3 years. The total amount of the car loan lease at December 31, 2020, is $43.

See Note 10 for the Company's long-term debt that was with a lender that was affiliated with the Company's largest shareholder and was a related party; on May 22, 2020 the long-term debt with the affiliated lender was repaid.

21. SUBSEQUENT EVENTS

On January 27, 2021, the Company approved the grant of 5,540,000 stock options to existing employees and directors pursuant to the 2016 Plan. Options granted to directors vest monthly over 12 months. Options granted to employees vest 25% on the one-year anniversary of the grant date, with the remaining 75% vesting on a monthly basis over 24 months. All options granted automatically expire on January 27, 2031.

On February 3, 2021, pursuant to the Loan Agreement, K2 HealthVentures LLC, converted $2,000 of the secured term loan into 1,369,863 commons shares at a conversion price of $1.46.

Subsequent to December 31, 2020, pursuant to the Open Market Sale Agreement[SM] with Jeffries, the Company issued 5,566,432 common shares under the ATM Program for total gross proceeds of $21,448 at an average price of $3.85. We incurred $643 of share issuance costs related to the common shares issued resulting in net proceeds of $20,805.

Subsequent to December 31, 2020, the Company issued 29,210 common shares upon exercise of National Warrants at an exercise price of $1.50 for gross proceeds of $44.

EXHIBIT INDEX

Exhibit No.	Description
1.1	Open Market Sale Agreement[SM], dated July 31, 2020, by and between VBI Vaccines, Inc. and Jefferies LLC (incorporated by reference to Exhibit 1.2 to the registration statement on Form S-3 (SEC File No. 333-240266), filed with the SEC on July 31, 2020.
2.1	Sale and Purchase Agreement, dated as of July 18, 2011, by and between Variation Biotechnologies, Inc., EPixis SA and the Persons Listed on Schedule 1 therein (incorporated by reference to Exhibit 2.4 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).
3.1	Articles (incorporated by reference to Exhibit 3.1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on December 23, 2015).
3.2	Notice of Articles (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).
3.3	Form of Notice of Alteration (incorporated by reference to Exhibit 3.3 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761) filed with the SEC on February 5, 2016).
4.1	Warrant dated July 25, 2014 issued to PCOF 1, LLC (incorporated by reference to Exhibit 4.1 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
4.2	Form of Initial Term Note (incorporated by reference to Exhibit 4.3 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
4.3	Form of Delayed Draw Warrant (incorporated by reference to Exhibit 4.2 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
4.4	Form of Delayed Draw Note (incorporated by reference to Exhibit 4.4 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
4.5	Form of Term Note (incorporated by reference to Exhibit A to Exhibit 99.1 to the report on Form 6-K (SEC File No. 000-37769), filed with the SEC on December 16, 2016).
4.6	Form of Second Closing Effective Date Warrant held of record by Perceptive Credit Holdings, LP (incorporated by reference to Exhibit E to Exhibit 99.1 to the report on Form 6-K (SEC File No. 000-37769), filed with the SEC on December 16, 2016).
4.7*	Description of Securities.
10.1(A)+	2016 VBI Vaccines Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).
10.1(B)+	2016 VBI Vaccines Equity Incentive Plan forms of award agreements (incorporated by reference to Exhibit 10.2 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).

10.2+	VBI DE 2014 Equity Incentive Plan (incorporated by reference to Annex C to VBI DE's definitive proxy statement on Schedule 14A (SEC File No. 000-18188), filed with the SEC on June 30, 2014).
10.3+	2006 VBI US Stock Option Plan (incorporated by reference to Exhibit 10.2 to the registration statement on Form S-8 (SEC File No. 333-198247), filed with the SEC on August 20, 2014).
10.4	License Agreement, dated June 2004, by and between Savient Pharmaceuticals, Inc. and SciGen, Ltd., as amended (incorporated by reference to Exhibit 99.2 to the report on Form 6-K (SEC File No. 000-13248), filed with the SEC on July 20, 2015).
10.5+	Employment Agreement with Jeff Baxter, dated May 8, 2014 (incorporated by reference to Exhibit 10.5 to VBI DE's current report on form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
10.6+	Employment Agreement with David Anderson, dated May 8, 2014 (incorporated by reference to Exhibit 10.6 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
10.7	Pledge and Security Agreement, dated July 25, 2014, by Variation Biotechnologies (US) Inc. and certain Guarantors in favor of PCOF 1, LLC (incorporated by reference to Exhibit 10.8 to VBI's Annual Report on Form 10-K, filed with the SEC on February 26, 2016).
10.8	Form of Securities Purchase Agreement, by and among Paulson Capital (Delaware) Corp., Variation Biotechnologies (US), Inc. and certain investors (incorporated by reference to Exhibit 10.3 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).

10.9	Form of Securities Purchase Agreement, dated as of August 13, 2015, by and between VBI Vaccines Inc. and certain accredited investors (incorporated by reference to Exhibit 10.1 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on August 18, 2015).
10.10	License Agreement, dated May 31, 2012, by and among University Pierre and Marie Curie, The National Institute of Health and Medical Research Public National Scientific and Technological and Ecole Normale Superieure de Lyon, and Epixis SA (incorporated by reference to Exhibit 10.45 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).
10.11	Amendment to License Agreement by and among University Pierre and Marie Curie, The National Institute of Health and Medical Research Public National Scientific and Technological and Ecole Normale Superieure de Lyon, and Epixis SA (incorporated by reference to Exhibit 10.46 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).
10.12	Lease Agreement, dated May 31, 2012, by and between American Twine Limited Partnership and Variation Biotechnologies (US), Inc., as amended (incorporated by reference to Exhibit 10.47 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).
10.13	Sub-Sublease, dated September 1, 2014, by and between Iogen Corporation and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.48 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).
10.14	Amendment of Sub-sublease, dated March 18, 2016, by and between Iogen Corporation and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.1 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on March 21, 2016).
10.15+	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).
10.16+	Offer letter with Nell Beattie, dated June 22, 2015 (incorporated by reference to Exhibit 10.43 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).
10.17	Amended and Restated Credit Agreement and Guaranty, dated as of December 6, 2016, by and among Variation Biotechnologies (US), Inc., the Guarantors party thereto, and Perceptive Credit Holdings, LP (incorporated by reference to Exhibit 99.1 to the report on Form 6-K (SEC File No. 000-37769), filed with the SEC on December 16, 2016).

10.18	Supplement, dated as of December 6, 2016, to the Pledge and Security Agreement, dated as of July 25, 2014, among the Grantors in favor of Perceptive Credit Holdings, LP (incorporated by reference to Exhibit 99.2 to the report on Form 6-K (SEC File No. 000-37769), filed with the SEC on December 16, 2016).
10.19	Form of Share Purchase Agreement, dated as of June 20, 2016, by and among VBI Vaccines Inc. and each investor identified on the signature pages thereto (incorporated by reference to Exhibit 10.48 to the Annual Report on Form 10-K/A (SEC File No. 001-37769), filed with the SEC on May 15, 2017).
10.20	Form of Share Purchase Agreement, dated as of December 5, 2016, by and among VBI Vaccines Inc. and each investor identified on the signature pages thereto (incorporated by reference to Exhibit 10.49 to the Annual Report on Form 10-K/A (SEC File No. 001-37769), filed with the SEC on May 15, 2017).
10.21	Amendment to Amended and Restated Credit Agreement and Guaranty, dated September 28, 2017, by and among Variation Biogtechnologies (US), Inc., the guarantors party thereto and Perceptive Credit Holdings, LP (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (SEC File No. 001-37769) filed with the SEC on October 2, 2017).
10.22	Form of Subscription Agreement, dated September 26, 2017, between the Company and the investor parties thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (SEC File No. 001-37769) filed with the SEC on October 27, 2017).
10.23	Form of Warrant, dated October 30, 2017 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (SEC File No. 001-37769) filed with the SEC on October 31, 2017).
10.24+	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).
10.25	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).

10.26	Amendment to lease agreement among American Twine Limited Partnership and Variation Biotechnologies (US), 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 1, 2018)
10.27+	Employment Agreement, dated August 14, 2018, by and between VBI Vaccines (Delaware) Inc. and Christopher McNulty (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K (SEC File No. 001-37769) filed with the SEC on August 20, 2018)
10.28(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).
10.29	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).
10.30	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).
10.31+	Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective January 1, 2019 (incorporated by reference to Exhibit 10.65 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on February 25, 2019).
10.32	Waiver Agreement, dated February 14, 2019, by and among Variation Biotechnologies (US), Inc., the Guarantors party thereto, and Perceptive Credit Holdings, LP (incorporated by reference to Exhibit 10.66 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on February 25, 2019).
10.33	Amendment No. 2 to Amended and Restated Credit Agreement and Guaranty and Amendment to Warrant dated, July 17, 2018, by and among Variation Biotechnologies (US), Inc., the guarantors party thereto and Perceptive Credit Holdings, LP (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 July 19, 2018)
10.34	Amendment No. 3 to Amended and Restated Credit Agreement and Guaranty and Amendment to Warrant, dated January 31, 2019, by and among Variation Biotechnologies (US), Inc., the Guarantors party thereto, and Perceptive Credit Holdings, LP (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 February 5, 2019)
10.35	Waiver Agreement, dated February 25, 2020, by and among Variation Biotechnologies (US), Inc., the Guarantors party thereto, and Perceptive Credit Holdings, LP (incorporated by reference to Exhibit 10.43 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 5, 2020).
10.36[2]	Collaborative Research Agreement between National Research Council of Canada and Variation Biotechnologies Inc effective March 30, 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 6, 2020).
10.37	Seventh Amendment to lease agreement among American Twine Owner LLC and Variation Biotechnologies (US), Inc. (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 6, 2020).
10.38	Sixth Amendment to lease agreement among American Twine Limited Partnership and Variation Biotechnologies (US) Inc. (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 May 6, 2020).
10.39	Fifth Amendment to lease agreement among American Twine Limited Partnership and Variation Biotechnologies (US) 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 6, 2020).
10.40	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).
10.41	Form of Warrant Agreement issued to National Securities Corporation or its designees (incorporated by reference to Exhibit 4.1 to the annual report on Form 8-K (SEC File No. 001-37769), filed with the SEC on April 27, 2020).
10.42[2]	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).
10.43	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).
10.44	Lease agreement dated September 4, 2020, between 310 Hunt Club Limited and Variation Biotechnologies Inc. (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (SEC File No. 001-37769), filed with the SEC on November 2, 2020).
10.45	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).
10.46+*	Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective January 1, 2021.
10.47*[2]	Amendment One to Collaborative Research Agreement between National Research Council of Canada and Variation Biotechnologies Inc. effective December 21, 2020.
10.48*	Assignment Agreement, dated February 14, 2012, between FDS Pharma LLP and SciGen Ltd.

10.49*	Assignment Agreement, dated October 16, 2012, by and among FDS Pharma LLP, SciGen Ltd., and SciGen (I.L.) Ltd.
10.50*	Amendment to the Assignment Agreement, dated February 14, 2013, by and among SciGen Ltd., SciGen (I.L.) Ltd.
10.51*[2]	Master Commercial Services Agreement between InVentiv Commercial Services, LLC and VBI Vaccines Inc.
21.1*	VBI Vaccines Inc. – List of Subsidiaries
23.1*	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.
24.1*	Powers of Attorney (attached to the signature page hereto).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of Chief Financial Officer and Head of Business Development pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934.

32.1**	Certification of Chief Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
32.2**	Certification of Chief Financial Officer and Head of Business Development pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

* 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 portions of this exhibit have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. The omitted information is (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed. The Company agrees to furnish supplementally an unredacted copy of the exhibit 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 2nd day of March, 2021.

VBI VACCINES INC.

By: */s/ Jeffrey Baxter*
Jeffrey R. Baxter, President and Chief Executive Officer

By: */s/ Christopher McNulty*
Christopher McNulty, Chief Financial Officer and Head of Business Development (Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jeffrey Baxter and Christopher McNulty, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: March 2, 2021 */s/ Jeffrey Baxter*
Jeffrey Baxter, President, Chief Executive Officer and Director (Principal Executive Officer)

Date: March 2, 2021 */s/ Christopher McNulty*
Christopher McNulty, Chief Financial Officer and Head of Business Development and Director (Principal Financial and Accounting Officer)

Date: March 2, 2021 */s/ Steven Gillis*
Steven Gillis,
Director

Date: March 2, 2021 */s/ Michel De Wilde*
Michel De Wilde
Director

Date: March 2, 2021 */s/ Blaine McKee*
Blaine McKee
Director

Date: March 2, 2021 */s/ Joanne Cordeiro*
Joanne Cordeiro
Director

Date: March 2, 2021 */s/ Damian Braga*
Damian Braga
Director

Exhibit 4.7

DESCRIPTION OF VBI VACCINES INC. COMMON SHARES

The following description of the capital stock of VBI Vaccines Inc. (the "Company," "VBI," "we," "our," or "us") is a summary of the rights of our common shares and certain provisions of our Articles as currently in effect. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Articles, copies of which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our Articles and the applicable provisions of British Columbia Business Corporations Act (the "BCBCA"), for additional information.

Description of Common Shares

We are authorized to issue an unlimited number of common shares with no par value. 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, or DGCL, that may have the greatest such effect include, but are not limited to, the following: (i) for material corporate transactions (such as mergers and amalgamations, other extraordinary corporate transactions or amendments to our articles), the BCBCA generally requires a two-thirds majority vote by shareholders, whereas DGCL generally only requires a majority vote; and (ii) under the BCBCA, one or more shareholders who, in the aggregate, hold 5% or more of our common shares can requisition a special meeting of shareholders, whereas such right does not exist under the DGCL.

Holders of our common shares are entitled to such dividends as may be declared by our board of directors out of funds legally available for such purpose. The BCBCA provides that we may declare or pay dividends unless there are reasonable grounds for believing that (a) the Company is insolvent, or (b) the payment of the dividend would render the Company insolvent.

Each holder of our common shares is entitled to one vote for each such share outstanding in the holder's name. No holder of common shares is entitled to cumulate votes in voting for directors.

In the event of our liquidation, dissolution or winding up, the holders of our common shares are entitled to receive pro rata our assets which are legally available for distribution, after payments of all debts and other liabilities.

Our directors may, subject to our Articles and the BCBCA, issue, allot, sell, grant options on or otherwise dispose of the unissued shares, and issued shares held by the Company, at the times, to the persons, including directors, in the manner, on the terms and conditions and for the issue prices that the directors, in their absolute discretion, may determine by board resolution. Shares may be issued in consideration for past services, property or money. Shares must not be issued until they are fully paid. There are no preemptive, redemption, purchase or conversion rights attaching to our common shares. There are no sinking fund provisions applicable to our common shares. Our common shares are issued in fully registered form, although we are able to issue fractional shares.

Since we are authorized to issue an unlimited number of common shares with no par value, the authorized but unissued common shares are available for future issuance without any further vote or action by our shareholders. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions, and employee benefit plans. The existence of authorized but unissued common shares could render more difficult or discourage an attempt to obtain control over us by means of a proxy contest, tender offer, merger or otherwise.

Securities Act of 1933, as amended.

Anti-takeover Effects of Provisions of VBI's Articles and BCBCA, Alterations

The BCBCA does not contain a provision comparable to Section 203 of the Delaware General Corporation Law (DGCL) with respect to business combinations.

Under the BCBCA and our Articles, certain extraordinary company alterations, such as changes to authorized share structure, continuances, into or out of province, certain amalgamations, sales, leases or other dispositions of all or substantially all of the undertaking of a company (other than in the ordinary course of business) liquidations, dissolutions, and certain arrangements are required to be approved by ordinary or special resolution as applicable.

An ordinary resolution is a resolution (i) passed at a shareholders' meeting by a simple majority, or (ii) passed, after being submitted to all of the shareholders, by being consented to in writing by shareholders who, in the aggregate, hold shares carrying at least two-thirds of the votes entitled to be cast on the resolution. A special resolution is a resolution (i) passed by not less than two-thirds of the votes cast by the shareholders who voted in respect of the resolution at a meeting duly called and held for that purpose or (ii) signed by all shareholders entitled to vote on the resolution.

Under the BCBCA, an action that prejudices or interferes with a right or special right attached to issued shares of a class or series of shares must be approved by a special separate resolution of the holders of the class or series of shares being affected.

Under the BCBCA, arrangements are permitted and a company may make any proposal it considers appropriate "despite any other provision" of the BCBCA. In general, a plan of arrangement is approved by a company's board of directors and then is submitted to a court for approval. It is not unusual for a company in such circumstances to apply to a court initially for an interim order governing various procedural matters prior to calling any security holder meeting to consider the proposed arrangement. Plans of arrangement involving shareholders must be approved by a special resolution of shareholders, including holders of shares not normally entitled to vote. The court may, in respect of an arrangement proposed with persons other than shareholders and creditors, require that those persons approve the arrangement in the manner and to the extent required by the court. The court determines, among other things, to whom notice shall be given and whether, and in what manner, approval of any person is to be obtained and also determines whether any shareholders may dissent from the proposed arrangement and receive payment of the fair value of their shares. Following compliance with the procedural steps contemplated in any such interim order (including as to obtaining security holder approval), the court would conduct a final hearing and approve or reject the proposed arrangement.

The BCBCA does not contain a provision comparable to Section 251(h) of the DGCL.

Election and removal of directors

According to our Articles, all directors cease to hold office immediately before the election or appointment of directors at every annual general meeting, but are eligible for re-election or re- appointment. Under Section 14.10 of VBI's Articles, shareholders of VBI may remove any director before the expiration of his or her term of office by a special resolution of shareholders. This system of electing and removing directors generally makes it more difficult for shareholders to replace a majority of our directors.

Shareholder action; advance notification of stockholder nominations and proposals

Under the BCBCA, one or more shareholders holding in the aggregate at least 5% of our common shares may requisition that the directors call a meeting of shareholders for the purpose of transacting any business that may be transacted at a general meeting. Upon receiving a requisition that complies with the technical requirements set out in the BCBCA, the directors must, subject to certain limited exceptions, call a meeting of shareholders to be held not more than 4 months after receiving the requisition. If the directors do not call such a meeting within 21 days after receiving the requisition, the requisitioning shareholders or any of them holding in aggregate more than 2.5% of the issued shares of the Company that carry the right to vote at general meetings may call the meeting.

Under the BCBCA, shareholder proposals may be made by registered or beneficial owners of shares entitled to vote at general meetings of shareholders who have been the registered or beneficial owner of such shares for an uninterrupted period of at least two years before the date of signing of the proposal, and who together in the aggregate constitute at least 1% of the issued shares that carry on the right to vote at general meetings or have a fair market value of shares in excess of CAD$2,000. Those registered or beneficial holders must, alongside the proposal, submit and sign a declaration providing the requisite information under the BCBCA. To be a valid proposal, the proposal must be submitted at least three months before the anniversary of the previous year's annual reference date (which is generally the date of the annual general meeting).

Under the advance notice provisions contained in Section 10.9 of VBI's Articles, subject only to the BCBCA, only persons who are nominated in accordance with the procedures set forth therein shall be eligible for election as directors of the Company. Nominations of persons for election to the Board may be made at any annual meeting of shareholders, or at any special meeting of shareholders if one of the purposes for which the special meeting was called was the election of directors: (a) by or at the direction of the Board, including pursuant to a notice of meeting; (b) by or at the direction or request of one or more shareholders pursuant to a proposal made in accordance with the provisions of the BCBCA, or a requisition of the shareholders made in accordance with the provisions of the BCBCA; or (c) by any person (a "Nominating Shareholder"): (A) who, at the close of business on the date of the giving of the notice and on the record date for notice of such meeting, is entered in the securities register as a holder of one or more shares carrying the right to vote at such meeting or who beneficially owns shares that are entitled to be voted at such meeting; and (B) who complies with the notice procedures set forth in our Articles.

In addition to any other applicable requirements, for a nomination to be made by a Nominating Shareholder, the Nominating Shareholder must have given timely notice thereof in proper written form to the Secretary of the Company at the principal executive offices of the Company.

To be timely, a Nominating Shareholder's notice to the Secretary of the Company must generally be made: (a) in the case of an annual meeting of shareholders, not less than 30 nor more than 65 days prior to the date of the annual meeting of shareholders; and (b) in the case of a special meeting (that is not also an annual meeting) called for a purpose that includes electing directors, not later than the close of business on the 15th day following the day on which public announcement of the date of the meeting is first made.

These provisions may have the effect of deterring unsolicited offers to acquire the Company or delaying changes in control of our management. These provisions could also have the effect of delaying until the next shareholder meeting any shareholder actions, even if they are favored by the holders of a majority of our outstanding voting securities.

Amendment to Articles

Under the BCBCA, a company may amend its articles or notice of articles by (i) the type of resolution specified in the BCBCA, (ii) if the BCBCA does not specify a type of resolution, then by the type specified in the company's articles, or (iii) if the company's articles do not specify a type of resolution, then by special resolution. The BCBCA permits many substantive changes to a company's articles (such as a change in the company's authorized share structure or a change in the special rights or restrictions that may be attached to a certain class or series of shares) to be changed by the resolution specified in that company's articles.

Our Articles provide that, subject to the BCBCA, certain alterations to our share structure be done by way of directors' resolution. Any creation, variation or deletion of special rights and restrictions attached to a series or class of shares must be done by way of special resolution.

Our Articles also provide that, the shareholders may from time to time, by ordinary resolution, make any alteration to our notice of articles and articles as permitted by the BCBCA.

Limitation of Liability and Indemnification

Section 21.2 of VBI's Articles requires VBI, subject to the BCBCA, to indemnify a director, former director or alternate director and his or her heirs and legal representatives against all eligible penalties to which such person is or may be liable and after the disposition of an eligible proceeding pay the expenses actually and reasonably incurred by such person in respect of that proceeding.

Pursuant to Section 21.3 of VBI's Articles, VBI may indemnify any person subject to the restrictions of the BCBCA.

Pursuant to Section 162 of the BCBCA, prior to the final disposition, VBI may pay, as they are incurred, the expenses actually and reasonably incurred by an eligible party, or the heirs and personal or other legal representatives in respect of that proceeding, if VBI first receives from such person a written undertaking that if the indemnification is ultimately determined to be prohibited pursuant to the BCBCA, such person will repay the amounts advanced.

Indemnification under the BCBCA is prohibited if any of the following circumstances apply: (1) if the indemnity or payment is made under an earlier agreement and at the time the agreement to indemnify or pay expenses was made the company was prohibited from doing so under its memorandum or articles; (2) if the indemnity or payment is made otherwise than under an earlier agreement and at the time the indemnity or payment is made, the company is prohibited from doing so under its memorandum or articles; (3) if, in relation to the subject matter of the eligible proceeding, the eligible party did not act honestly and in good faith with a view to the best interests of the company or the associated corporation; or (4) in the case of an eligible proceeding other than a civil proceeding, if the eligible party did not have reasonable grounds for believing that the eligible party's conduct in respect of which the proceeding was brought was lawful.

If an eligible proceeding is brought against an eligible party, or the heirs and personal or other legal representatives in respect of that proceeding, by or on behalf of VBI or an associated corporation, VBI must not indemnify that person for any penalties such person is or may be liable for and must not pay the expenses of that person in respect of the proceeding.

In addition, on the application of VBI or an eligible party, a court may: (a) order VBI to indemnify an eligible party against any liability incurred by the eligible party in respect of an eligible proceeding; (b) order VBI to pay some or all of the expenses incurred by an eligible party in respect of an eligible proceeding; (c) order the enforcement of, or any payment under, an agreement of indemnification entered into by VBI; (d) order VBI to pay some or all of the expenses actually and reasonably incurred by any person in obtaining an order under the BCBCA; (e) make any other order the court considers appropriate.

Control Block Distributions

Under applicable securities laws in Canada, any person (or group of persons) who owns a sufficient number of any of the securities of an issuer so as to affect materially the control of that issuer is considered to be a "control person". For such purposes, any person who has or acquires control or direction over more than 20% of the voting securities of an issuer will be deemed, in the absence of evidence to the contrary, to be a "control person". Any "trade" of securities by a control person is considered to be a "distribution", and accordingly, the disposition of such securities must be qualified by a prospectus, absent an available exemption.

Certain Takeover Bid Requirements

Any offer made by a person (an "offeror") to acquire outstanding shares of a Canadian entity that, when aggregated with the offeror's holdings (and those of persons or companies acting jointly with the offeror), would constitute 20% or more of the outstanding shares, would be subject to the take-over provisions of Canadian securities laws, unless the offer constitutes an exempt transaction.

In addition to those take-over bid requirements noted above, the acquisition of shares may trigger the application of additional statutory regimes including amongst others, the *Investment Canada Act* and the *Competition Act* (Canada).

Listing

Our common shares are listed for trading on the NASDAQ Capital Market under the symbol "VBIV."

Transfer Agent and Registrar

The transfer agent and registrar for our common shares is Computershare. Its address is 510 Burrard Street, 2nd Floor, Vancouver, British Columbia V6C 3B9, and its telephone number is (604) 661-9442.

This summary is not a comprehensive description of relevant or applicable considerations regarding such requirements and, accordingly, is not intended to be, and should not be interpreted as, legal advice to any prospective purchaser and no representation with respect to such requirements to any prospective purchaser is made. Prospective investors should consult their own Canadian legal advisors with respect to any questions regarding securities law in the provinces and territories of Canada.

Exhibit 10.46

AMENDMENT TO CONSULTING AGREEMENT

This Amendment to Consulting Agreement (the "**Amendment**"), effective as of **January 1st, 2021** (the "**Effective Date**"), is by and between Variation Biotechnologies Inc., a corporation incorporated pursuant to the laws of Canada (the "**Company**") having an address of 310 Hunt Club Road East, Ottawa, Ontario K1V 1C1 and F. Diaz-Mitoma Professional Corporation (Ontario corporation number 002356634) having an address of 210 Barrow Crescent, Kanata, Ontario K2L 2C7 ("**Consultant**"). The Consultant and Company are sometimes referred to as a "**Party"** and are collectively referred to as the "**Parties"**.

WHEREAS, the Company and Consultant are parties to a certain Consulting Agreement dated July 1, 2016, amended as of January 1, 2017, amended January 1, 2018, amended January 1, 2019, and further amended as of January 1, 2020 (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, 2021 (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 **$46,000.00 CAD** per month (plus any HST or GST payable).

3. **Replacement of Appendix C.** As of the Effective Date, Appendix C of the Consulting Agreement shall be deleted in its entirety and replaced with the version of Appendix C attached as Schedule A to this Amendment.

4. Consulting Agreement to Remain in Full Effect. Except as amended by this Amendment, the Consulting Agreement shall continue to be in full force and effect, without amendment, and is hereby ratified and confirmed. The Consulting Agreement shall henceforth be read and construed in conjunction with this Amendment.

5. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the Province of Ontario and the federal laws of Canada applicable therein.

6. Further Assurances. Each Party shall do such further acts and execute such further documents as may be required to give effect to this Amendment and carry out the intent thereof.

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

8. Execution and Counterparts. This Amendment may be executed in counterparts, including counterpart signature pages or counterpart facsimile or scanned signature pages (each of which shall be deemed an original), all of which together shall constitute one and the same instrument.

(*Signature page follows.*)

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed by their respective authorized officers as of the Effective Date.

VARIATION BIOTECHNOLOGIES INC.

/s/ Jeff Baxter

Name: Jeff Baxter
Title: Chief Executive Officer

F. DIAZ-MITOMA PROFESSIONAL CORPORATION

/s/ Francisco Diaz-Mitoma

Name: Dr. Francisco Diaz-Mitoma
Title: President

Schedule A

Appendix C – Performance Incentives

1. Bonus payable as of January 31, 2021 – CAD **$265,500**

1. The Company shall cause VBI Vaccines Inc., a British Columbia corporation (the "**Parent**") to grant to Francisco Diaz-Mitoma, as designee of Consultant, **500,000** stock options (the "**Options**"), each Option exercisable for one common share of Parent, to be granted effective as of **January 27, 2021**, which was the date on which the board of directors of Parent approved such grant, and to be subject to the provisions of the Plan. Conditions regarding the Options and their exercise, including the exercise price, the term of the Options and the timing of vesting shall be set out in an Option Agreement between the Parent and Francisco Diaz-Mitoma. The common shares issuable upon exercise of the Options shall bear the appropriate legend to indicate such shares are "control securities" as defined in General Instruction C.1(a) of Form S-8.

National Research Council Canada | Conseil national de recherches Canada

Amendment One to Collaborative Research Agreement

PLEASE NOTE: CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Business Confidential – Protected *B*

THIS IS AN AMENDING AGREEMENT

BETWEEN: **NATIONAL RESEARCH COUNCIL OF CANADA**
a departmental corporation forming part of the Government of Canada
created by the *National Research Council Act* (R.S.C. 1985, c. N-15), and
an agent of Her Majesty the Queen in Right of Canada
whose head office address is:
1200 Montreal Road
Ottawa, Ontario K1A 0R6 (called the **"NRC"**)

AND: ***VARIATION BIOTECHNOLOGIES INC.***
a *Company incorporated under the Canada Business Corporations Act under number 393728-3 whose Registered Office Address is located in:*

300 Hunt Club Road East, 2nd Floor
Ottawa, Ontario K1V 1C1 (called the **"Collaborator" or "VBI"**)

(Collectively known as the "**Parties**")

WHEREAS the parties entered into an Agreement signed by the NRC on 3*0 March 2020* (called the **"Original Agreement"**) by which the Parties agreed to collaborate in a "Project", described as: ***COVID-19 vaccine evaluation***.

WHEREAS the parties wish to amend the Original Agreement. In consideration of the mutual covenants hereunder, the parties agree as follows

1. The Original Agreement shall be read with the amended terms stated below. With respect to all other terms, the Parties confirm the Original Agreement.

2. The Budget attached hereto includes the work scheduled to be performed pursuant to the Original Agreement (Tasks 1, 2, 3 and 4) and additional work related to vaccine evaluation which was not included in the Original Agreement.

3. The attached "**SCHEDULE OF PAYMENTS**" is in addition to the "**SCHEDULE OF PAYMENTS"** from the Original Agreement.

4. The attached "**NEW STATEMENT OF WORK AND DELIVERABLES"** is in addition to the "**STATEMENT OF WORK AND DELIVERABLES**" in the Original Agreement.

5. The estimated total value of this Project amendment is: **minimum of $[***](Tasks 1.5, 1.6 1.8 and 1.9)** (immediate priority) to a **maximum of $[***] (Tasks 1.5 – 1.9)** (includes [***] tasks) as stated in the Statement of Work.

6. The Collaborator is a Canadian Small and Medium Enterprise (SME) or a Canadian educational institution, including a community college, CEGEP, polytechnic or university, and benefits from a Fee Reduction of **minimum of $[***] (Tasks 1.5, 1.6, 1.8 and 1.9) to a maximum of $[***] (Tasks 1.5 - Tasks 1.9)**. The Collaborator hereby warrants that, at the time of signing this Agreement, it is a SME and has 500 or fewer full-time equivalent employees, or it is a Canadian educational institution.

7. The amount that the Collaborator will pay to the NRC in cash for this amendment is: **minimum of $[***] (Tasks 1.5, 1.6 1.8 and 1.9)** (immediate priority) to a **maximum of $[***] (Tasks 1.5 – 1.9)** (includes [***] tasks) as stated in the Statement of Work.

8. The estimated value of the NRC's in-kind contribution for this amendment is: ***minimum $[***] (Tasks 2.1, 2.2, 2.3, 2.4 and Task 2.6) to a maximum $[***] (Tasks 2.1 - Tasks 2.6)***.

9. The expiry date as stated in the Original Agreement as "30 November 2020" is now amended to be "15 March 2022".

10. This Agreement may be executed in one or more counterparts and by the different parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one valid and binding Agreement. A portable document format (PDF) copy of an executed counterpart signature page will be as valid as an originally executed counterpart for purposes of signing this Agreement.

SIGNED by the Collaborator at Ottawa, Ontario

VARIATION BIOTECHNOLOGIES INC.

Date: 21 DEC 2020

Per: */s/ Jeff Baxter*
Jeff Baxter
CEO

SIGNED by the NRC at Ottawa, Ontario

NATIONAL RESEARCH COUNCIL OF CANADA

Date: 21 DEC 2020

Per: */s/ Lakshimi Krishnan*
Lakshmi Krishnan, Ph.D.
A/Vice President, Life Sciences

ANNEX SP – SCHEDULE OF PAYMENTS TO NRC

Billing address: See page 1

Billing contact:

Name: Andrea McRae
Title: Project Manager
Telephone: [***]
Email: [***]

SP-1 The Collaborator shall be invoiced as follows:

Invoicing Schedule (Estimated Dates)	**Amount Due***
1. Invoice to be issued on ***signature of this amendment for Tasks 1.5 – 1.6***	**$[***]**
2. Invoice to be issued on ***completion of Tasks 1.8 – 1.9***	***$[***]***
3. Invoice to be issued upon **confirmation by client – Task 1.7**	***$[***]***

*Plus applicable taxes

SP-2 All amounts shall be due 30 days from the date of the invoice.

SP-3 Payments must be made to: "Receiver General - National Research Council of Canada" and addressed to:

Accounts Receivable
National Research Council of Canada
1200 Montreal Road
Ottawa, Ontario, K1A 0R6
CANADA

SP-4 Payments can be made by cheque, MasterCard, Visa or American Express; or by wire transfer. Wire transfer information is available upon request. The Collaborator is responsible for all bank charges associated with wire transfers. Any inquiries may be directed to: AccountsReceivable@nrc-cnrc.gc.ca.

SP-5 The Collaborator shall provide any Invoicing Reference Number at the time of Agreement signature or promptly thereafter. The NRC will not delay or cancel invoicing nor defer accrual of interest due to the Collaborator's failure to provide an Invoicing Reference Number.

SP-6 The NRC may suspend its performance of any obligations under this Agreement so long as any payment is overdue for any reason.

SP-7 If this Agreement is amended to increase the scope of the Services, the NRC reserves the right to calculate costing for its additional Project activities at its rates that are in effect at that time. Any such cost increases shall be approved, in writing, by both Parties.

SP-8 If the NRC expects that the value of its estimated contribution will be exceeded by more than *10%*, it shall promptly notify the other Party. The Parties shall then negotiate a further agreement on costs or payments, and either Party may suspend the performance of any obligations, other than confidentiality, intellectual property and accrued obligations to pay, until a further agreement is reached. If the Parties fail to agree on an amendment within 60 days of the notice, then this Agreement shall terminate on the 60th day after the notice, unless the Parties agree otherwise in writing.

SP-9 If a surplus of prepayment remains as a result of premature termination, it will be refunded.

SP-10 If an instrument tendered in payment or settlement of an amount due to the NRC is dishonoured for any reason, the NRC will invoice an additional administrative charge of CAD 25 and this amount will be due as invoiced.

SP-11 Interest is payable on all overdue amounts. Interest is calculated and compounded monthly at the average bank rate plus 3% and accrues during the period beginning on the due date and ending on the day before the day on which payment is received by the NRC. For purposes of this paragraph "**bank rate**" means the rate of interest established periodically by the Bank of Canada as the minimum rate at which the Bank of Canada makes short term advances to members of the Canadian Payments Association, and "**average bank rate**" means the weighted arithmetic average of the bank rates that are established during the month before the month in respect of which interest is being calculated.

(Rate information may be found at http://www.tpsgc-pwgsc.gc.ca/recgen/txt/tipp-ppir-eng.html. *This site provides information on the rate used by departments of the Government of Canada to calculate the interest on overdue accounts payable and is the same rate used by the NRC to charge interest on overdue accounts receivable under the Interest and Administrative Charges Regulations, SOR/96-188. This web site address, and the information set out there, is provided here for convenience. In case of rate discrepancy, the rates quoted by the Bank of Canada shall prevail.)*

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REVISED & EXPANDED STATEMENT OF WORK AND DELIVERABLES

Amendment to VBI-NRC Collaborative Research Agreement A-0035546: Multivalent Coronavirus vaccine development

The Client and NRC hereby agree to amend the workplan from the Original Agreement and expand to include a broader workplan relating to evaluation and manufacture of Client's COVID-19 vaccines as set out below.
With the completion of the Stage 1 (Establish potency of VBI monovalent and multivalent coronavirus eVLP vaccine preparations) in the original workplan, VBI and NRC have agreed to expand the R&D collaboration to include follow-on pre-clinical evaluation, bioprocess optimization and scale-up work as well as additional productions for clinical trials.

The following activities, Stage 2, are meant to encompass the further scope for the workplan. Indicated budget figures are high-level estimates. Follow-on discussions between NRC and VBI will further refine the scope and associated budget. However, no increases to the amounts shown in the Budget will be effective unless agreed in writing by Client.

Note: VBI will be responsible to provide the plasmids needed for all productions.

Stage 1: Candidate Identification & Immunogenicity

The Client and NRC have agreed that the original workplan has been modified to accommodate 3 larger studies (29B609, 29B619 and 29B621) which included additional PRNT and ELISPOT work. The final price for these 3 studies is equivalent to the full maximum price for agreement A-00355546: [***]. The parties also agree to amend and extend this stage of work as follows:

1.5 Task 1.5: 29B634 **estimated budget: $[***]** (anticipated duration: [***]weeks)
1.6 Task 1.6: Additional [***]: [***]for [***]work done at [***]**estimated budget: $[***]** (anticipated duration: [***]weeks)
1.7 Task 1.7: Optional [***] studies for immunogenicity to be conducted at the request of Client (up to [***]mouse studies, n=[***]) $[***] per study x [***] = ***estimated budget: $[***]*** *(anticipated duration: [***] weeks for each study)*
1.8 Task 1.8 Phase I Clinical sample testing [***]for clinical samples

- n= [***]***estimated budget $[***]*** *(anticipated duration [***] weeks)*

1.9 OPTION: Task 1.9 Phase II Clinical sample testing [***] for clinical samples

- n= [***]***estimated budget $[***]*** *(anticipated duration [***] weeks)*

Total estimated budget for new and amended tasks in Stage 1: $[***]

Stage 2: Tech Transfer & Process Development Activities

The approach for the following activities is to transfer the existing VBI manufacturing process to NRC at [***], and also to scale up the modified process to [***] (implementing [***] developed in Task 2.1 below) to produce product for use in later stage clinical trials. NRC will discuss approach together with VBI and further discussion may, with the agreement of the parties, change the scope for process modification. Nevertheless, process modification will be kept to a minimum in order to accelerate timelines. Given the at risk nature of this development, NRC is proposing to complete these development activities at risk and in consideration of future Retained Doses as per Exhibit B.

2.1. Task 2.1: [***] (SOW already submitted but additional work is already anticipated) – See Annex C
Revised estimated budget: $[***] (anticipated duration: [***]weeks)

2.2. Task 2.2 Process transfer to [***]: Transfer of current process for [***]. This includes: 2.2.1. [***].
Estimated budget: $[***] *(anticipated duration: [***]weeks [***])*

2.3. Task 2.3 Analytics:
[***]**Estimated budget:** $[***].

2.4 Task 2.4 Modified process scale up [***]**.**

2.5 Task 2.5 Optional - [***]

Total estimated budget for core tasks: $[***]

Given the COVID situation, there are a number of constraints on timelines in particular:

1) *With current procurement challenges, many items for larger scale and Clinical material production may need to be purchased at-risk in an attempt to reduce long lead times for some consumables (media, columns, etc). Despite best efforts, some items may have lead times which impact timelines for the described work. VBI may choose to procure these directly in order to expedite timelines.*
2) *There are public health and NRC Corporate restrictions on the number of people permitted to work on-site and this may impact timelines although NRC and VBI will endeavour to minimize this wherever possible.*

Budget Summary: VBI-2900 eVLP vaccine candidates against coronaviruses

Work Task	Task Value	NRC Co-investment	CAN SME Fee Reduction	NRC Task Price*
STAGE 1: Candidate Identification				
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
Stage 1 - Total Minimum (without option)	[***]	[***]	[***]	[***]
Stage 1 – Total Maximum (with option)	[***]	[***]	[***]	[***]

Work Task	Task Value	NRC Co-investment	CAN SME Fee Reduction	NRC Task Price*
STAGE 2: Tech Transfer & Process Devt				
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
Stage 2 Total Minimum	[***]	[***]	[***]	[***]
Stage 2 Total Maximum (with options)*				
Clinical Trial Material – ANNEX A				
[***]	TBD			TBD
[***]	TBD			TBD
ANNEX A Subtotal	TBD	0		TBD

Annex A - Production of Clinical Trial Material

Annex B – Stage 4 - Additional Production

Annex C: Scope of Work for the Polishing Step for eVLP Purification.

ASSIGNMENT AGREEMENT

This ASSIGNMENT AGREEMENT is entered into on February 14 2012, by and between:

1. **FDS Pharma LLP,** a **Limited Liability Company** company incorporated under the laws of Great Britain with its registered seat at Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW, United Kingdom (the "**New Licensee**" or **"FDS Pharma"**), represented by Dimitry Genkin, Director of General Partner, and

2. **SCIGEN LTD.** a public company incorporated under the laws of Singapore, with its registered seat at 152 Beach Road, Suite 26-07/08, Gateway East, Singapore 189721 (**"Scigen"**), represented by Sławomir Ziegert, President and CEO.

RECITALS

1. On 3 June 2004 Scigen and **SAVIENT PHARMACEUTICALS, INC.** a Delaware corporation, with its registered seat at 14th Floor, One Tower Center, East Brunswick, New Jersey 08816, USA (**"Savient"**) entered into a license agreement (the "**License Agreement**"), as amended by a certain amendment to the License Agreement effective 24 January 2005 and a second amendment to the License Agreement effective 15 March 2005, and a third amendment to the License Agreement effective 15 June 2005, whereunder Savient granted to Scigen certain rights and licenses with regard to the manufacture, marketing, sale and distribution of the Product, as defined in the License Agreement.

2. On 18 July 2005 as a result of a transaction the Licence Agreement was assigned by Savient to Ferring International Center S.A., a corporation duly incorporated under the laws of Switzerland, having its principal place of business at Ch. De la Vergognausaz 50, 1162 Saint-Prex, Switzerland (**"Ferring"**).

3. The Product, as defined in the License Agreement, has been manufactured in the Facility, as defined in the License Agreement, by SciGen (I.L.) Ltd., Scigen's affiliate and the owner of the Facility.

4. Scigen has agreed to assign all of its rights, obligations and liabilities under the License Agreement to FDS Pharma. Further, FDS Pharma has agreed to purchase all the shares in the share capital of SciGen (I.L.) Ltd.

5. According to Section 23.4 of the License Agreement, in case the rights, obligations and liabilities under the License Agreement are assigned to a party acquiring all of the assigning party's business to which the License Agreement relates, no consent of Savient (or Ferring, who has assumed all rights and obligations of Savient in the License Agreement) is required to such assignment.

6. Scigen and FDS Pharma have entered into this agreement on the terms set out below.

7. All definitions and capitalised terms will have the same meaning as defined in the License Agreement, unless specified otherwise in this Agreement.

8. On 10 November 2011 the Parties signed Share Purchase Agreement to purchase one thousand (1,000) Ordinary Shares of the SciGen (I.L.) Ltd. with the nominal value of NIS 1.00 representing one hundred (100) per cent of the outstanding shares of SciGen (I.L.) Ltd. ("SPA").

9. SPA provides that the sale of shares shall take place following fulfilment of particular conditions by both Parties, e.g delivery by Scigen the Acknowledgment duly executed by Savient ("Closing").

1. Undertakings

1.1. Scigen hereby assigns, with immediate effect, all the rights, obligations and liabilities under the License Agreement.

1.2. FDS Pharma hereby undertakes to Scigen that it shall, with immediate effect, assume all the rights, obligations and liabilities under the License Agreement to such extent as if FDS Pharma had been a party to the License Agreement.

2. Price

2.1. FDS Pharma shall pay to Scigen the amount of USD 1,650,000.00 (one million six hundred fifty thousand) for the assignment contemplated herein.

2.2. The amount indicated above is net of VAT and any additional sales taxes which may be levied according to the binding tax regulations of jurisdiction applicable to FDS Pharma. Such taxes, if applicable, will increase the price and will be borne by FDS Pharma.

2.3. The price shall be paid to Scigen's account as follows:

2.3.1. USD 150,000.00 (one hundred fifty thousand) at Closing

2.3.2. USD 500.000.00 (five hundred thousand) at the first anniversary of Assignment Agreement

2.3.3. USD 1,000,000,00 (one million) 18 months after the date of Assignment Agreement.

2.4. The payments stipulated under points 2.3.2 and 2.3.3 will be secured by the FDS Pharma by establishing of pledges to the benefit of Scigen resulting from the Pledge Agreement 1 and Pledge Agreement 2, as defined in the SPA.

2.5. Additionally, Scigen will be entitled to receive a 5% royalty payment on Product Net Sales, paid on quarterly basis within 30 days after the end of each calendar quarter from the date of this Agreement. For the purpose of reporting of the Net Sales and royalties due to SciGen, FDS Pharma shall be bound by obligation towards Scigen as defined in the section 10 of the Licence Agreement.

3. Release of Scigen

FDS Pharma hereby releases and discharges Scigen from all future obligations and liabilities under the License Agreement which have been assumed by FDS Pharma, and Scigen hereby waives any rights of action it may have under the License Agreement in respect of such future obligations and liabilities. For the avoidance of doubt, the parties hereto agree that this waiver shall not apply to rights of ownership in tangible or intangible property acquired by Scigen under the License Agreement prior to the date hereof.

4. Release of FDS Pharma

Scigen herby releases and discharges FDS Pharma from all obligations and liabilities under the License Agreement, which have accrued or been accumulated prior to the date of this Agreement.

5. Governing Law

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

6. Disputes

All disputes arising out of or relating to this agreement, including any disputes concerning the validity and interpretation of this agreement, which the parties to this agreement are not able to solve in an amicable way, will be finally settled under the Rules of Arbitration of the International Chamber of Commerce (the "**ICC Rules**"). The place of the arbitration will be Vienna, Austria and the language of the arbitration will be English. The dispute shall be decided by three arbitrators. The chairman of the Arbitral Tribunal shall be appointed by the co-arbitrators from amongst lawyers qualified in the laws of the State of New Jersey, United States of America.

7. Counterparts

This agreement has been executed in the English language, in two (2) counterparts, one (1) copy for each party hereto.

IN WITNESS whereof the parties hereby duly executed this agreement on the date and year written above.

SIGNED and DELIVERED for and on behalf of FDS Pharma by	
Signed:	
Name:	Dmitry Gerasin
Title:	Director of General Partner
Date:	14 February 2012

SIGNED and DELIVERED for and on behalf of Scigen by	
Signed:	
Name:	
Title:	
Date:	

Scigen herby releases and discharges FDS Pharma from all obligations and liabilities under the License Agreement, which have accrued or been accumulated prior to the date of this Agreement.

5. Governing Law

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

6. Disputes

All disputes arising out of or relating to this agreement, including any disputes concerning the validity and interpretation of this agreement, which the parties to this agreement are not able to solve in an amicable way, will be finally settled under the Rules of Arbitration of the International Chamber of Commerce (the "ICC Rules"). The place of the arbitration will be Vienna, Austria and the language of the arbitration will be English. The dispute shall be decided by three arbitrators. The chairman of the Arbitral Tribunal shall be appointed by the co-arbitrators from amongst lawyers qualified in the laws of the State of New Jersey, United States of America.

7. Counterparts

This agreement has been executed in the English language, in two (2) counterparts, one (1) copy for each party hereto.

IN WITNESS whereof the parties hereby duly executed this agreement on the date and year written above.

SIGNED and DELIVERED for and on behalf of FDS Pharma by:	
Signed:	
Name:	
Title:	
Date:	

SIGNED and DELIVERED for and on behalf of Scigen by:	
Signed:	Stanomir Ziegert
Name:	STANOMIR ZIEGERT
Title:	CEO
Date:	

CH

FERRING
PHARMACEUTICALS

January 30, 2012

From:

Ferring International Center S.A.
Ch. De la Vergognausaz 50
1162 Saint-Prex
Switzerland

To:

SCIGEN LTD.
152 Beach Road, Suite 26-07/08
Gateway East
Singapore 189721

ACKNOWLEDGMENT AND CONSENT

We, the undersigned, acting in the name and on behalf of Ferring International Centre SA, who legally assumed any and all rights, liabilities and undertakings of Savient Pharmaceuticals, Inc., under that certain Three-Way Agreement, dated June 15, 2005 by and among SciGen Ltd., SciGen (I.L.) Ltd. and Savient Pharmaceuticals, Inc. (the **"Three-Way Agreement"**), hereby confirm that we have been notified by SciGen Ltd. that all of its rights, obligations and liabilities under the Three-Way Agreement, will be assigned by January 31, 2012 to FDS Pharma LLP, the purchaser of all the shares in SciGen (I.L.) Ltd and the Assignee of the License Agreement dated 3 June 2004 with amendments ("Assignment").

Therefore, we, the undersigned, acting in the name and on behalf of Ferring International Centre SA, hereby consent to the Assignment and acknowledge that as of the effective date of the Assignment, FDS Pharma LLP shall assume all the rights, obligations and liabilities of SciGen Ltd. under the Three-Way Agreement.

Peter Wilden
Chief Financial Officer

Edgar Koster
Sr. VP Global Operational Management

CH

FERRING
PHARMACEUTICALS

30, January 2012

From:

Ferring International Center S.A.
Ch. De la Vergognausaz 50
1162 Saint-Prex
Switzerland

To:

SCIGEN LTD.
152 Beach Road, Suite 26-07/08
Gateway East
Singapore 189721

We, the undersigned, acting in the name and on behalf of Ferring International Center S.A., who is the sole legal and beneficial owner of all unencumbered intellectual property rights for Product and Technology, as defined in the License Agreement, hereby confirm that we have been notified by Scigen Ltd. that all of its rights, obligations and liabilities under the License Agreement dated 3 June 2004 concluded between Scigen Ltd. and Ferring International Center S.A., as amended by a certain amendment to the License Agreement effective 24 January 2005 and a second amendment to the License Agreement effective 15 March 2005, and a third amendment to the License Agreement effective 15 June 2005, are to be assigned by 31 January 2012 to FDS Pharma LLP, a Limited Liability Company incorporated under the laws of Great Britain with its registered seat at Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW, United Kingdom, the purchaser of all the shares in SciGen Israel Ltd., in accordance with Section 23.4 of the License Agreement ("Assignment").

Therefore, we, the undersigned, acting in the name and on behalf of Ferring International Center S.A., hereby consent to the Assignment and acknowledge that as of the effective date of the Assignment, FDS Pharma shall assume all the rights, obligations and liabilities of SciGen Ltd. under the License Agreement.

Peter Wilden
Chief Financial Officer

Edgar Koster
Sr. VP Global Operational Management

ASSIGNMENT AND ASSUMPTION AGREEMENT

This Assignment and Assumption Agreement (the "**Assignment and Assumption**") is made and entered into as of October 16, 2012, by and among **FDS Pharma LLP,** a limited liability partnership organized under the laws of Great Britain, with its registered seat at Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW, United Kingdom ("**FDS Pharma**"), **SciGen Ltd.**, a public company incorporated under the laws of Singapore, with its registered seat at 152 Beach Road, Suite 26-07/08, Gateway East, Singapore 189721 ("**Scigen**") and **SciGen (I.L.) Ltd.**, a private company incorporated under the laws of Israel, with company registration no. 51- 367955-5, with its registered office at Gad Feinstein Rd., Rehovot 76100, Israel (the "**Company**").

FDS Pharma, Scigen and the Company may sometimes be referred to individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS, on June 3, 2004, Scigen and Savient Pharmaceuticals, Inc. ("**Savient**") entered into a License Agreement, which was subsequently amended four times effective, respectively on 24 January 2005, 15 March 2005, 15 June 2005 and 14 February 2012 (the "**License Agreement**") whereby Scigen was granted certain rights and licenses with regards to the manufacture, marketing, sale and distribution of the "**Product**", as defined in the License Agreement; and

WHEREAS, on July 18, 2005, the License Agreement was assigned by Savient to Ferring International Center S.A., ("**Ferring**");

WHEREAS, the Product is being manufactured in the "**Facility**", as defined in the License Agreement, by the Company, which is the owner of the Facility;

WHEREAS, on February 14, 2012, FDS Pharma purchased all of Scigen's holdings in the Company and on the same date, Scigen assigned all of its rights, obligations and liabilities under the License Agreement to FDS Pharma pursuant to an Assignment Agreement between FDS Pharma and Scigen dated February 14, 2012 (the "**Assignment Agreement**");

WHEREAS, FDS Pharma wishes to sell fifty percent (50%) of its holdings in the Company to Opko Israel Holdings, Ltd., and such transaction (the "**Opko Transaction**") is subject to the fulfillment of certain conditions, including, *inter alia*, the execution of this Agreement.

NOW, THEREFORE, in consideration of the mutual promises herein set forth, the Parties agree as follows:

1. **General**

   1.1. The preamble to this Agreement and the Exhibits attached hereto constitute an integral part hereof.

   1.2. "**Triggering Date**" shall mean the date upon which the following cumulative conditions have been met: (i) Ferring consents in writing to the assignment of the License Agreement from FDS Pharma to the Company; and (ii) the Opko Transaction is consummated.

   1.3. Section headings are for convenience of reference only and are not to be considered in interpreting this Agreement.

2. **Assignment**

2.1. As from and subject to the Triggering Date, FDS Pharma does hereby absolutely, unconditionally and irrevocably assign, transfer, convey and grant to the Company all of its rights, liabilities, obligations and interest in and under the License Agreement and the Assignment Agreement and the Company hereby absolutely, unconditionally and irrevocably undertakes to be bound by all of the obligations of FDS Pharma under the License Agreement and the Assignment Agreement.

2.2. As from and subject to the Triggering Date, Scigen hereby consents to the assignment by FDS Pharma of all of its rights, liabilities and interests in and under the Assignment Agreement, to the Company.

3. **Pledges**

3.1. In case the Triggering Date occurs any time prior to October 31, 2012, then Pledge Agreement 1 and Pledge Agreement 2 referred to in Section 2.4 of the Assignment Agreement (the "**FDS Pharma Pledges**") shall be terminated as of and subject to the Triggering Date and any pledges registered thereunder shall be discharged. Should the Triggering Date not take place by October 31, 2012, the FDS Pharma Pledges shall remain in full force and effect, and shall govern all security interests contemplated hereunder or thereunder.

3.2. The Company and Scigen shall execute the Pledge Agreement in the form of Exhibit A attached hereto and Debenture-Floating Charge document in the form of Exhibit B attached hereto (the "**Company Pledges**") which shall replace the FDS Pharma Pledges as of and subject to the Triggering Date.

4. **Clarifications**

Scigen hereby confirms that the FDS Pharma Pledges, and the Company Pledges, once they replace the FDS Pharma Pledges, are meant to secure the payment of USD 1,500,000 (one million five hundred thousand US Dollars), which is the balance of the lump sum payment pursuant to Section 2.1 of the Assignment Agreement, which will be due and payable to Scigen pursuant to Sections 2.3.2 and 2.3.3 of the Assignment Agreement, and not to secure any other obligations under the Assignment Agreement or this Agreement.

5. **Term**

This Agreement shall go into force on the Triggering Date. Should Scigen not receive written notice from the Company by October 31, 2012, confirming that (i) Ferring has consented in writing to the assignment of the License Agreement from FDS Pharma to the Company; and (ii) the Opko Transaction has been consummated, this Agreement shall automatically terminate and be of no further force and effect.

6. **Notices**

All notices or other communications hereunder shall be in writing and shall be given in person, by registered mail (registered international air mail if mailed internationally), by an overnight courier service which obtains a receipt to evidence delivery, or by facsimile transmission (provided that written confirmation of receipt is provided) with a copy by mail, addressed as set forth below:

If to FDS Pharma:

FDS Pharma LLP
Hillbrow House, Hillbrow Road, Esher,
Surrey KT10 9NW,
United Kingdom
Fax: +78123298080
Attn: Dmitry Genkin

If to the Company to:

Scigen (I.L.) Ltd.
Derech Gad Feinstein
Rehovot Park
Rehovot 76100
Israel
Fax: + 972-8-9480660
Attn: CEO

With a copy to:

Opko Israel Holdings Ltd.
c/o Opko Health, Inc.
4400 Biscayne Boulevard
Miami, Florida 33137
Fax: +1-305-5754140
Attn: Deputy General Counsel

If to Scigen:
152 Beach Road
Suite 26-07/08
Gateway East, Singapore 189721
Fax: +65-6779-3784
Attn: Mr. Slawomir Ziegert
With a copy to: Adam Polonek
Fax: +48-22721-4004

or such other address as any party may designate to the other in accordance with the aforesaid procedure. All communications delivered in person or by courier service shall be deemed to have been given upon delivery, those given by facsimile transmission shall be deemed given on the business day following transmission with confirmed answer back, and all notices and other communications sent by registered mail (or air mail if the posting is international) shall be deemed given ten (10) days after posting.

7. **Miscellaneous**

7.1. No modification or waiver of any provision of this Agreement shall be effective unless the same shall be in writing and signed by the Parties.

7.2. Each Party agrees and covenants that at any time and from time to time it will promptly execute and deliver to the other Parties such further instruments and documents and take such further action as the other Parties may reasonably require in order to carry out the full intent and purpose of this Agreement.

7.3. This Agreement shall be governed by and construed in accordance with the laws of the State of Israel, without regard to the conflicts of laws provisions stipulated therein.

7.4. The competent courts in Tel Aviv-Jaffa shall have exclusive jurisdiction over any and all disputes arising out of or relating to this Agreement, including any disputes concerning validity and interpretation, which the Parties are not able to solve in an amicable way, and each of the Parties hereby consents to and submits to the jurisdiction of such court.

7.5. This Agreement constitutes the complete and entire agreement of the Parties hereto and supersedes all previous communications, oral or written and all other communications between them relating to the subject hereof. No representations or statements of any kind made by either Party, which are not expressly stated herein, shall be binding on such Party.

7.6. This Agreement may be executed in any number of counterparts and executed signature pages sent by facsimile transmission or e-mail as a PDF document shall be binding as evidence of such Party's agreement hereto and acceptance hereof.

[Intentionally left blank]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first above written.

FDS Pharma LLP

By: _____

Name: Murray D Gennoy

Title: Director of General Partner

Office of Director of General Partner Angport Limited

SciGen Ltd.

By: _____

Name: _____

Title: _____

SciGen (I.L.) Ltd.

By: _____

Name: Mehamed Dobrislav

Title: President

Exhibit A - Form of Pledge Agreement

Exhibit B - Form of Debenture - Floating Charge

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first above written.

FDS Pharma LLP

By: _____

Name: _____

Title: _____

SciGen Ltd.

By: _____

Name: _____

Title: _____

SciGen (I.L.) Ltd.

By: _____

Name: _____

Title: _____

Exhibit A - Form of Pledge Agreement

Exhibit B - Form of Debenture - Floating Charge

AGREEMENT

This Agreement ("**Agreement**") is made and entered into as of February 14, 2013, by and between **SciGen Ltd.**, a public company incorporated under the laws of Singapore, with its registered seat at 152 Beach Road, Suite 26-07/08, Gateway East, Singapore 189721 ("**Scigen**") and **SciGen (I.L.) Ltd.**, a private company incorporated under the laws of Israel, with company registration no. 51- 367955-5, with its registered office at Gad Feinstein Rd., Rehovot 76100, Israel (the "**Company**").

Scigen and the Company may sometimes be referred to individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS, on October 16, 2012, FDS Pharma LLP ("**FDS Pharma**"), Scigen and the Company entered into an Assignment and Assumption Agreement (the "**Assignment and Assumption Agreement**") under which the Company assumed all of the rights and obligations of FDS Pharma under the Assignment Agreement dated February 14, 2012 by and between FDS Pharma and the Company (the "**Assignment Agreement**");

WHEREAS, the Parties have agreed to amend the Company's payment obligations under the Assignment Agreement, as assumed by the Company under the Assignment and Assumption Agreement, solely as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises herein set forth, the Parties agree as follows:

1. **Financial Understandings**

1.1. Notwithstanding anything to the contrary set forth in Section 2.3.2 of the Assignment Agreement, the Parties hereby agree that the second payment of US$ 500,000.00 (five hundred thousand) described in Section 2.3.2 of the Assignment Agreement shall be due and payable in 3 (three) installments paid to SciGen's bank account as follows:

1.1.1. US$ 300,000 (three hundred thousand US Dollars) - by not later than February 28, 2013;

1.1.2. US$ 100,000 (one hundred thousand US Dollars - by no later than April 30, 2013; and

1.1.3. US$ 100,000 (one hundred thousand US Dollars) - by no later than May 30, 2013.

1.2. Tthe Parties hereby agree that royalties in the amount of US$ 25,000 (twenty five thousand US Dollars) which are currently due and owing to Scigen pursuant to Section 2.5 of the Assignment Agreement shall be paid by no later than March 30, 2013.

1.3. In addition the Parties agree that the amounts mentioned in Article 1.1 above shall not be decreased by, in particular through set off, any Company's receivables against Scigen, in particular by any receivables which may arise in connection with the SPA (as defined in the Assignment Agreement), including claims relating to Warranties (as defined in the SPA).

2. **Miscellaneous**

2.1. This Agreement contains all of the modifications to the payment obligations assumed by the Company under the Assignment and Assumption Agreement and except as expressly amended hereby, such obligations shall continue in full force and effect. The Assignment and Assumption Agreement, as modified pursuant to this Agreement shall be read and construed as one and the same instrument. In any case of a contradiction between the provisions of this Agreement and the provisions of the Assignment and Assumption Agreement, the provisions of this Agreement will prevail.

2.2. This Agreement may be executed in any number of counterparts and executed signature pages sent by facsimile transmission or e-mail as a PDF document shall be binding as evidence of such Party's agreement hereto and acceptance hereof.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first above written.

SciGen IL Ltd

~~SciGen Ltd.~~

By: _____

Name: Michal Ben-Attar

Title: CEO

SciGen IL Ltd.
513679555

SciGen (I.L.) Ltd.

By: Mohamed Dobroslav

Name: Mohamed Dobroslav

Title: President

SciGen Ltd.
513679555

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2. **Miscellaneous**

2.1. This Agreement contains all of the modifications to the payment obligations assumed by the Company under the Assignment and Assumption Agreement and except as expressly amended hereby, such obligations shall continue in full force and effect. The Assignment and Assumption Agreement, as modified pursuant to this Agreement shall be read and construed as one and the same instrument. In any case of a contradiction between the provisions of this Agreement and the provisions of the Assignment and Assumption Agreement, the provisions of this Agreement will prevail.

2.2. This Agreement may be executed in any number of counterparts and executed signature pages sent by facsimile transmission or e-mail as a PDF document shall be binding as evidence of such Party's agreement hereto and acceptance hereof.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first above written.

SciGen Ltd.	**SciGen (I.L.) Ltd.**
By: _____	By: _____
Name: STAWOMIR ZIEGERT	Name: _____
Title: CEO	Title: _____

SCIGEN LTD.

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Exhibit 10.51

PLEASE NOTE: CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

MASTER COMMERCIAL SERVICES AGREEMENT

This **MASTER COMMERCIAL SERVICES AGREEMENT** effectively dated as of the 17th day of December, 2019 ("**Effective Date**"), made by and between inVentiv Commercial Services, LLC, a New Jersey limited liability company and a Syneos Health™ group company, with an office located at 500 Atrium Drive, Somerset, NJ 08873 ("**Syneos Health**") and VBI Vaccines Inc., a company organized under the laws of the Province of British Columbia, Canada with principal offices located at 222 Third St., Suite 2241, Cambridge, MA, 02139 ("**Client**"). Client and Syneos Health may each be referred to herein as a "**Party**" and collectively, the "**Parties**".

WITNESSETH:

WHEREAS, Client is engaged in the business of developing, manufacturing, distributing, and/or selling pharmaceutical products, biotechnological products, and/or medical devices;

WHEREAS, Syneos Health is a contract commercial organization that offers a wide range of commercial services to clients in the pharmaceutical and biotechnology industry; and

WHEREAS, Client and Syneos Health desire to agree on terms which will be applied to govern Syneos Health's provision of various commercial services to Client.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and adequacy of which hereby are mutually acknowledged, the Parties intending to be legally bound do hereby agree as follows:

AGREEMENT

1. DEFINITIONS

1.1. "**Affiliate**" means, with respect to a Party to this Agreement, any entity that directly or indirectly controls, is controlled by, or is under common control with such Party. "Control", "controls", or "controlled" means the possession, directly or indirectly, of at least 50% of the share capital or voting rights or of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, by contract or otherwise.

1.2. "**Agreement**" means this Master Commercial Services Agreement together with any amendments entered into between the Parties from time to time.

1.3. "**Applicable Law**" means any applicable international, national, federal, state, and local laws and regulations, including, without limitation, EU Directive 2001/83/EC, the Federal Food, Drug and Cosmetic Act ("**FDCA**"), and the Medicare/Medicaid anti-kickback statute, the Prescription Drug Marketing Act ("**PDMA**").

1.4. "**Change Order**" means an amendment to a Work Order that captures a change in the scope of Services or other parameters, which may include an increase or decrease in Fees and/or any timeline adjustments required due to the change in assumptions. Each Change Order shall be agreed in writing between the Parties and expressly approved by an authorized individual on behalf of each Party.

1.5. "**Commercially Reasonable Efforts**" means the efforts and resources which would be used (including the promptness in which such efforts and resources would be applied) by a Party, consistent with generally accepted industry standards with regard to the activity to be undertaken.

1.6. "**Confidential Information**" has the meaning given thereto in Section 8.3.

1.7 "**FDA**" means the United States Food and Drug Administration.

1.7. "**Fees**" means the price charged for labor in the performance of Services as set forth in the applicable Work Order.

1.8. "**Pass Through Costs**" means any costs identified in a Work Order to be incurred by Syneos Health in the performance of Services that are not Fees, including, without limitation, for Service-related travel, Subcontractor and Third Party Vendor fees for items such as printing, shipping, and facsimile costs, language translation, telephone charges, advertising, and/or other expenses associated with the Services or as may be otherwise described in any Work Order. Travel costs may include, but are not limited to, those associated with reasonable transportation, lodging, internet connection, fuel, and meals.

1.9. "**Regulatory Authority**" means the FDA, the European Medicines Agency (EMA), Health Canada, or any other local, state, national or multinational regulatory authority or government agency that is equivalent to or has any similar regulatory functions or responsibilities as the FDA.

1.10. "**Sanctioned Entity**" means an entity that

1.10.1. Is currently under indictment or prosecution for, or has been convicted (as defined in 42 C.F.R. § 1001.2) of: (i) any offense related to the delivery of an item or service under the Medicare or Medicaid programs or any program funded under Title V or Title XX of the Social Security Act (the Maternal and Child Health Services Program or the Block grants to States for Social Services programs, respectively); (ii) a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service; (iii) fraud, theft, embezzlement or other financial misconduct in connection with the delivery of a health care item or service; (iv) obstructing an investigation of any crime referred to in (i) through (iii) above; or (v) unlawful manufacture, distribution, prescription or dispensing of a controlled substance; or

1.10.2. Has been required to pay any civil monetary penalty regarding false, fraudulent, or impermissible claims under, or payments to induce a reduction or limitation of health care services to beneficiaries of, any state or federal health care program, or is currently the subject of any investigation or proceeding which may result in such payment; or

1.10.3. Has been excluded from participation in the Medicare, Medicaid or Maternal and Child Health Services (Title V) program, or any program funded under the Block Grants to States for Social Services (Title II) program.

1.11. **"Subcontractor"** means any entity or individual other than Syneos Health, Syneos Health Affiliates, or Syneos Health Personnel that performs Services under the direction of Syneos Health, which Syneos Health agreed to directly perform for Client in a Work Order. For purposes of clarification, Subcontractors shall not include Third Party Vendors.

1.12. "**Syneos Health Personnel**" mean employees of Syneos Health or of any Syneos Health Affiliate performing the Services in connection with a given Work Order. For clarification, "Syneos Health Personnel" shall not include Subcontractors or Third Party Vendors or employees thereof.

1.13. "**Third Party Vendor**" means any entity that performs ancillary services for the Services pursuant to a contract entered into by Client or an Affiliate thereof or, if expressly so authorized in a Work Order, by Syneos Health or an Affiliate thereof. Third Party Vendors may include, but are not limited to, drug depots, transportation companies, translation vendors, scale providers, equipment providers, electronic data capture (EDC) providers, or any other vendor performing services not within those provided by Syneos Health to Client. For purposes of clarification, Third Party Vendors shall not include Subcontractors.

1.14. "**Work Order**" means an individual statement of work executed between Client and Syneos Health that: (i) is expressly governed by the terms and conditions of this Agreement; (ii) is signed by both Parties; (iii) specifies the parameters and sets forth the details of the Services to be performed by Syneos Health, including, without limitation, the scope of work, specific assumptions, estimated time period for completing Services, milestones and target dates, estimated budget, payment and currency schedules, and/or resource allocation to the extent applicable to the Services; and (iv) is generally in the form attached hereto as Exhibit A.

2. SERVICES

2.1. **Use of Affiliates**.

2.1.1. Use of Affiliates. The Parties acknowledge that in addition to Syneos Health and Client, certain of either Party's Affiliates may directly enter into a Work Order setting forth the particular project or scope of Services to be provided, provided however, that such Work Order expressly provides that it is intended to be governed by the terms of this Agreement.

2.1.2. Responsibility. If an Affiliate of a Party enters into or performs Services in association with Work Orders under this Agreement with the other Party or the other Party's Affiliate, such Affiliates are bound by the terms and conditions contained herein; *provided, however,* Syneos Health and Client agree that each Party acts solely on its own behalf and shall not be liable, or otherwise responsible, for the acts and/or omissions of any Party Affiliate under any circumstances in connection with any Work Order that is not signed by Syneos Health or Client, as applicable. Further, each Party Affiliate acts solely on its own behalf and shall not be liable, or otherwise responsible, for the acts and/or omissions of Syneos Health, Client or any other Party Affiliate under any circumstances in connection with this Agreement or any Work Order that is not signed by that particular Party Affiliate.

2.2. **Work Orders**. Each Work Order shall be governed by and will be incorporated into and made an integral part of this Agreement, and shall be subject to mutually agreed Change Orders. The Parties acknowledge and agree that variation may exist in the form of Work Order depending on the Affiliate and/or the nature and type of services provided. Subject to the terms of the Work Order, the Parties agree that the Work Order shall set forth a reasonable schedule for the Services to be performed, and each Party will use Commercially Reasonable Efforts to comply with the timelines stated therein.

2.3. **Order of Documents**. To the extent that terms and/or provisions of a Work Order conflict with the terms and/or provisions of this Agreement, the terms and/or provisions of this Agreement shall control unless the Work Order expressly states otherwise.

2.4. **Start-Up Services**. Upon written approval from Client (email is acceptable), Syneos Health may proceed with providing Services prior to the execution of a Work Order ("**Work Ahead E-mail**"). Each Work Ahead Email shall provide a description of the Services to be performed by Syneos Health and shall also include the Fees and Pass Through Costs associated with said Services and attach the then current Work Order in process. Upon finalization of the Work Order, the Services set forth in the Work Ahead E-mail shall be integrated into, and superseded by, the full Work Order.

2.5. **Change Orders**. Once a Work Order is executed, if either Party requests a change in the scope of Services, or the assumptions upon which the Work Order is based change, then the Parties shall execute a Change Order prior to implementing such changes. Should any requirements of Applicable Law change, each Party will use Commercially Reasonable Efforts to satisfy the new requirements. In the event that compliance with such new regulatory requirements necessitates a change in the Services, the Parties will evaluate the need for a Change Order.

2.6. **Anti-Corruption**. The Parties represent and warrant that they are, and will remain, in compliance with the Foreign Corrupt Practices Act ("**FCPA**") and/or all other applicable anti-bribery laws or regulations.

2.7. **HIPAA**. For Services provided by [***] only, Client recognizes that [***] may have access to and/or be utilizing Protected Health Information ("**PHI**") (as such term is defined under the Health Insurance Portability and Accountability Act of 1996, as amended ("**HIPAA**") and the HITECH Act) to provide the Services. Such PHI is provided and owned by third party retail pharmacy providers ("**Third Party PHI**"). Client and Syneos Health agree that at no time and under no circumstances will Syneos Health or [***] make available to Client, or any agent of Client, any Third Party PHI, nor any individual patient names or addresses derived from Third Party PHI. Client and Syneos Health also agree, that at no time, and under no circumstances, will Client request that Syneos Health or [***] make available to Client, or any agent of Client, any Third Party PHI, nor any individual patient names or addresses derived from Third Party PHI. Further, Client agrees that it will make no attempt to use any data provided by [***], either alone or joined with other data, in any attempt to identify individuals who may be represented in the Third Party PHI data. [***] agrees to comply with the requirements set forth in HIPAA with regard to access to, handling of and use of Third Party PHI as such requirements may be amended from time to time.

3. SYNEOS HEALTH PERSONNEL, SUBCONTRACTORS, AND THIRD PARTY VENDORS

3.1. **Responsibility and Management**.

3.1.1. **Subcontractors**. To the extent permitted by the terms of a Work Order, Syneos may retain Subcontractors to perform Services. If Syneos Health uses Subcontractors in the performance of Services, Syneos Health shall remain responsible for the actions of its Subcontractors as if Syneos Health had taken such actions itself. Notwithstanding the foregoing, if Client requests that Syneos Health use a particular provider of materials or services in connection with the Services (a "**Client Preferred Subcontractor**") then Syneos Health will make Commercially Reasonable Efforts to deliver the Services in cooperation with the Client Preferred Subcontractor provided, however, that Syneos Health will have no responsibility for the selection of such Client Preferred Subcontractor. In such case, the Client may contract directly with such Client Preferred Subcontractor. Syneos Health shall not have any responsibility for the performance of any Client Preferred Subcontractor, including the quality and timing of work performed by such Client Preferred Subcontractor. Any delay caused by a Client Preferred Subcontractor shall cause an equal extension to any affected timeline or deadline for Syneos Health's Services.

3.1.2. **Syneos Health Personnel**. Syneos Health is, and at all times shall remain, solely responsible for the human resource and performance management functions of all Syneos Health Personnel assigned to perform the Services. Syneos Health shall be solely responsible and liable for all disciplinary, probationary, and termination actions taken by it, and for the formulation, content, and dissemination of all employment policies and rules (including written disciplinary, probationary, and termination policies) applicable to the Syneos Health Personnel. Client shall have no responsibility to Syneos Health or any Syneos Health Personnel for any compensation, expense reimbursements, or benefits (including, without limitation, vacation and holiday remuneration, healthcare coverage or insurance, life insurance, pension or profit-sharing benefits, and disability benefits), payroll- related or withholding taxes, or any governmental charges or benefits that may be imposed upon or be related to the performance by Syneos Health or Syneos Health Personnel of the obligations under this Agreement or any Work Order, all of which shall be the sole responsibility of Syneos Health. To clarify, Client will not withhold any income tax or payroll tax of any kind on behalf of Syneos Health.

3.1.3. **Third Party Vendors**. Any Third Party Vendors shall be approved by Client in a Work Order or otherwise in writing. Subject to the terms of a Work Order, Syneos Health shall not be liable for any Third Party Vendor errors, omissions, delays, or consequences therefrom which are not the result of Syneos Health's failure to manage the Third Party Vendor. Syneos Health shall keep Client reasonably informed regarding the performance of the Third Party Vendors. If the Third Party Vendor is non-compliant with any instruction provided by Syneos Health or provides non-conforming services or goods, Syneos Health will [***] to such Third Party Vendor and promptly inform the Client of [***]. [***], Syneos Health and Client will [***] which may include [***].

3.2. **Debarment/Exclusions**.

3.2.1. **Syneos Health and Client**. Each Party hereby represents that neither it, nor to the best of its knowledge and belief, any of its employees or contractors nor any of its Affiliates or employees or contractors thereof have been debarred or convicted of a crime which could lead to debarment or disqualification under the Generic Drug Enforcement Act of 1992 or is a Sanctioned Entity.

3.2.2. **Subcontractors and Third Party Vendors**. To the best of its knowledge, Syneos Health does not and shall not use the services of any Subcontractors or Third Party Vendors that are or have been debarred or disqualified under the Generic Drug Enforcement Act of 1992 or are a Sanctioned Entity or that have engaged any employees or contractors who have been so debarred or disqualified.

3.2.3. **Notification**. In the event that Syneos Health becomes aware that any of its officers, directors, Syneos Health Personnel, Subcontractors (or employees or contractors thereof) or any Third Party Vendors (or employees or contractors thereof), used in connection with the Services has become debarred, Syneos Health will promptly notify Client. In the event that Client becomes aware that any of its officers, directors, or employees has become debarred, Client will promptly notify Syneos Health.

3.3. **Relationship of the Parties**. Syneos Health is at all times an independent contractor with respect to Client. The Parties are not agents of each other unless otherwise explicitly agreed to in writing. Nothing in this Agreement or any Work Order is intended or shall be deemed to constitute a partnership, principal/agent, employer/employee, or joint venture relationship. Neither Party shall have the power or right to bind or obligate the other Party, nor shall it hold itself out as having such authority, except to the extent, if at all, specifically provided for in this Agreement, Work Order or as authorized in writing.

3.4. **Media Buys**. Notwithstanding anything to the contrary set forth herein, to the extent the Services include advertising and/or public relations services in any Work Order, Syneos Health may at times, in a Work Order, be authorized to act as Client's agent in the purchase of media and as such may be given the authority to bind Client to certain terms and conditions which may include but not be limited to indemnification and financial liability, provided however, that Client shall provide its prior written approval of any such purchases and the terms and conditions governing such purchases are within the scope of the authority provided in the Work Order. Syneos Health will be solely liable for payment to the extent that payments from Client for the subject invoices have cleared from Client to Syneos Health for promotional and other materials. No media will be purchased by Syneos Health on behalf of Client if funds have not successfully been received and cleared by Syneos Health. Should these funds not be received and cleared by Syneos Health, all purchases of media shall be made solely in the name of Client.

3.5 **Specialized Services**. Unless, otherwise provided in a Work Order, the Parties acknowledge and agree that this Agreement shall not cover certain specialized services which would entail Syneos Health acting as a legal representative, agent or qualified person on behalf of Client and the Parties agree that any such specialized services shall require and be subject to the terms of a separate services agreement between the Parties with respect to such specialized services.

4. REPRESENTATIONS, WARRANTIES, AND OBLIGATIONS OF THE PARTIES

4.1. **By Client**. Client represents and warrants that:

4.1.1. Client's products in connection with which the Services are being provided are fit for the intended uses and purposes.

4.1.2. Client shall apply the degree of skill and care necessary, and will act in good faith to provide Syneos Health with the necessary materials, information, and assistance required to enable Syneos Health to perform the Services in compliance with Applicable Law. Certain Client obligations and responsibilities unique to a specific Work Order, if applicable, shall be specified within that Work Order. Subject to, and as set out in, the terms of a Work Order, Client shall provide any and all necessary training regarding the Client product(s) and may be responsible for all costs and expenses of such training, including Syneos Health personnel travel, lodging and meals.

4.1.3. Client shall ensure all content (product or otherwise), materials, documentation and information provided by it to Syneos Health for use in provision of the Services are in compliance with Applicable Law and shall be solely responsible for reviewing and approving all product related materials to ensure that any assertions regarding the safety or efficacy of Client's products in such materials comply with Applicable Law, such materials including, but not limited to, promotional materials and literature created pursuant to this Agreement .

4.1.4. Any trademarks used in association with Client's products shall be owned by or licensed to Client. Client represents and warrants that, to the best of its knowledge, use of its trademarks, trade names, and trade dress in association with those of its products which are used by Syneos Health in performance of the Services does not infringe any trademark rights of any other person or entity in the countries where the Services are provided. Client further represents and warrants that, to the best of its knowledge, the promotion of any Client product by Syneos Health does not infringe any patent of any other person or entity in any countries where the Services are provided.

4.1.5. Client shall notify Syneos Health in the event it is party to, or becomes party to, a Corporate Integrity Agreement (CIA) with the Office of the Inspector General or if Client otherwise become subject to compliance obligations pursuant to Applicable Law which require Syneos Health to provide Client with data, training, analysis, oversight or certifications that are not contemplated by the Services described herein. In such event, the Parties shall mutually agree in writing on an appropriate allocation of costs and expenses associated with Syneos Health's provision of such CIA related data, training, analysis, oversight, or certifications not included in the scope of Services provided under this Agreement or any related Work Order.

4.1.6. Client is solely responsible for obtaining registrability searches and trademark registration for any trademarks, taglines, logos, graphics, or designs (collectively, "**Marks**") that may be developed by Syneos Health for Client under a Work Order to the extent development of Marks are part of the Services. Syneos Health will not be liable for any intellectual property infringement claims relating to any Marks provided to Client in connection with this Agreement. Syneos Health disclaims all warranties and representations, express or implied, including but not limited to any warranties of fitness for a particular purpose, merchantability, or otherwise regarding trademarks developed by Syneos Health for Client pursuant to a Work Order.

4.1.7. In carrying out its obligations under this Agreement and any Work Order, Client shall comply with Applicable Law.

4.2. **By Syneos Health**. Syneos Health represents and warrants that:

4.2.1. Syneos Health shall perform the Services in a professional, workmanlike manner and in accordance with the terms of this Agreement, each Work Order and those specifications and timelines which Syneos Health and Client agree to in writing;

4.2.2. Syneos Health shall maintain in full force and effect all necessary licenses, permits, approvals (or waivers), and authorizations required by Applicable Law to carry out its obligations under this Agreement and any Work Order;

4.2.3. the execution, delivery, and performance of this Agreement by Syneos Health and the consummation of the transaction(s) contemplated hereby has been duly authorized by all requisite corporate action; the Agreement constitutes the legal, valid, and binding obligation of Syneos Health, enforceable in accordance with its terms (except to the extent enforcement is limited by bankruptcy, insolvency, reorganization or other laws affecting creditors' rights generally and by general principles of equity); and this Agreement and performance hereunder does not violate or constitute a breach under any organizational document of Syneos Health or any contract, other form of agreement, or judgment or order to which Syneos Health is a party or by which it is bound;

4.2.4. Syneos Health is not a party to any agreement which would prevent it from fulfilling its obligations under this Agreement or any Work Order and that during the term of this Agreement, it will not enter into any agreement to provide services which would, in any way, prevent it from performing the Services under this Agreement;

4.2.5. unless otherwise provided in a specific Work Order, during such time as there is any Work Order in effect for [***], Syneos Health shall not assign any personnel whom are members of dedicated client service, strategic and creative teams (excluding experts and advisors) and perform market research, medical and scientific communications, marketing, medical affairs, sales or market access services ("Commercialization Services") under such Work Order ("Project Personnel") to perform any Commercialization Services for the following products: [***] (each a "Competitive Product"). This restriction shall not apply to Syneos Health's shared services personnel, including but not limited to, personnel performing tasks related to operations, editing, traffic, production, development, administration, finance and other "back office" support functions. The Parties acknowledge and agree that Syneos Health employs parameters and standards to preserve the confidentiality of client information and to avoid conflicts of interest, which include segregating personnel, data, and assets through physical barriers and electronic firewalls and prohibiting the use of client confidential information for any purpose other than as necessary for the performance of the Services. To the extent legally permissible, Syneos Health will notify Client if it becomes aware of any conflict of interest involving a Competitive Product, [***]. This provision shall not apply to Syneos Health's Affiliates unless the Work Order between Client and the Affiliate expressly provides otherwise; and

4.2.6. In carrying out its obligations under this Agreement and any Work Order, Syneos Health shall comply with Applicable Law.

5. INVOICING AND PAYMENT

5.1. **Fees and Pass Through Costs**. In consideration for the Services, Client shall pay Syneos Health the Fees as set forth in each specific Work Order. In addition, Pass Through Costs will be billed to Client based on the actual cost incurred by Syneos Health. Pass Through Costs specific to a particular Service shall be set forth in the Work Order.

5.2. **Invoicing**. Syneos Health shall invoice Client as set forth in each Work Order for the Fees, Pass Through Costs, authorized expenses, and Applicable Taxes as set out in Section 5.7. All Pass Through Costs and expenses invoiced to Clients shall be supported by provision of copies of supporting invoices from Subcontractors, Third Party Vendors or other suppliers. Payments are due within [***] of Client's receipt of each applicable invoice from Syneos Health. In the event that a Subcontractor or Third Party Vendor of Syneos Health requires expedited payment from Syneos Health for a Pass Through Cost, and with Client's prior written approval, Client will pay Syneos Health for such expenses on the same terms that Syneos Health is required to pay such Subcontractor or Third Party Vendor. If a purchase order number is required for Syneos Health to invoice for the Services performed, Client agrees to provide such purchase order number within [***] after the execution of the applicable Work Order. If the purchase order number is not provided within that time period, Client agrees to timely pay any invoices issued without a purchase order number. Should Client require that Syneos Health use a third party invoicing service/system, any costs associated with such use shall be invoiced to Client as incurred, without mark-up. The Parties understand and agree that all terms and conditions set forth in a purchase order are null and void, it being understood and agreed that this Agreement and the applicable Work Order provides the terms and conditions governing the relationship between the Parties.

5.3. **Late Payments**. If any undisputed invoice amount is not paid within [***] of Client's receipt, Syneos Health reserves the right, following [***] prior written notice, to charge late payment interest in the amount of [***] for any undisputed payment not timely received. In the event that any non-disputed amounts remain unpaid after the invoice due date, Syneos Health may stop work on the Services until it receives such past due payment. Prior to any such work stoppage, Syneos Health shall give [***] notice of its intent to cease Services. Other than as may be required under Applicable Law, Syneos Health shall have no liability to Client for any costs or damages as a result of suspension caused by Client's failure to pay non-disputed amounts in accordance with the terms herein.

5.4. **Disputed Charges.** If Client, in good faith, disputes one or more items in an invoice, Client shall notify Syneos Health in writing, noting its objection with specificity within [***] of receipt of the invoice. Syneos Health shall respond to Client within [***] of receipt of the notification of dispute. This written communication pattern shall continue until the Parties agree to a resolution of the disputed amount. Client shall pay the undisputed portion of an invoice according to Section 5.2 and shall pay the disputed amount within [***] upon resolution of the dispute. Any dispute that cannot be resolved by good faith negotiation shall be resolved in accordance with Section 12.6. Client shall not withhold payment of any non-disputed amounts due and payable under this Agreement by reason of any setoff, claim or dispute with Syneos Health.

5.5. **RESERVED**.

5.6. **Financial Records**. Syneos Health shall keep and maintain complete and accurate books and records in sufficient detail to determine amounts owed to Syneos Health hereunder. Such books and records shall be maintained for at least [***] following completion or termination of a Work Order and shall be made available for inspection, copying, and audit by Client in accordance with Section 7 and for the purpose of determining the accuracy of amounts invoiced.

5.7. **Taxes**. As and when required by local law, VAT, GST or similar sales taxes or duties actually incurred by Syneos Health and imposed by any governmental agency as a result of this Agreement ("**Applicable Taxes**") will be invoiced at current statutory rates and paid to Syneos Health by Client in addition to contracted Fees and Pass Through Costs**.** Any invoices issued by Syneos Health to Client which include charges for value added taxes shall include Syneos Health's registration numbers with the applicable taxing authorities. Excluding taxes based on Syneos Health's income, Syneos Health shall invoice Client, and Client shall pay Syneos Health in accordance with Section 5.2 for such Applicable Taxes. If requested by Client, Syneos Health shall provide official documentation for such Applicable Taxes paid. If any payments made by the Parties become subject to withholding taxes under Applicable Law, each Party shall be authorized to withhold such taxes as required under Applicable Law, pay such taxes, and remit the balance due to the other Party net of such taxes. The Parties will cooperate to qualify the transactions for any exemptions or reductions in the amount of otherwise applicable withholding tax provided under Applicable Law (including the provisions of any relevant income tax treaty) and to complete such forms as necessary for such purpose.

5.8. **Currency**. Unless otherwise agreed in the applicable Work Order, Client shall make all payments to Syneos Health in U.S. Dollars, and accordingly, Syneos Health shall invoice Client for all Fees and Pass Through Costs in U.S. Dollars. If Pass Through Costs are incurred in a currency other than U.S. Dollars, then Syneos Health and Client shall define the mechanism for currency exchange adjustment in the applicable Work Order, or if not specified therein, then Syneos Health shall invoice Client using the exchange rate published in oanda.com at the average bid rate on the day the invoice is generated by Syneos Health.

5.9. **Special Expenses**. Client shall reimburse Syneos Health for all reasonable and pre-approved actual out-of-pocket expenses, fees and costs (including, but not limited to attorneys' fees and costs) ("**Special Expenses**") incurred by Syneos Health in connection with subpoenas, civil investigative demands, government investigations and other similar legal orders and legal and regulatory processes issued to Syneos Health (collectively referred to herein as a "**Subpoena**") regarding Client, Client's product, or the Services performed by Syneos Health pursuant to this Agreement (as may be amended from time to time). Special Expenses shall include, but are not limited to, attorneys' fees and other professional fees incurred by Syneos Health in response to the Subpoena, travel costs related to witness interviews and depositions related to the Subpoena, all e-discovery costs (including, but not limited to third party vendor costs), and internal Syneos Health costs related to the production of documents, testimony, or other information and material requested pursuant to the Subpoena. Client shall have no obligation to reimburse Syneos Health for such expenses, fees, and costs which are proximately caused by Syneos Health's actions or omissions that violate this Agreement or Applicable Law. The additional expenses referred to in this Section 5.9 shall be paid by Client to Syneos Health on a monthly basis, as incurred by Syneos Health, upon the presentation by Syneos Health to Client of an invoice in accordance with Section 5.2.

6. TERM AND TERMINATION

6.1. **Term**. This Agreement shall commence as of the Effective Date and shall continue for a period of five (5) years, or until earlier terminated as provided below. Any Work Orders in existence as of the date of expiration or termination of this Agreement shall continue to be governed by the terms and conditions of this Agreement unless such Work Order is specifically terminated in accordance with the terms therein, or as otherwise mutually agreed in writing by the Parties.

6.2. **Termination**. Except as otherwise provided in any Work Order, this Agreement or any Work Order may be terminated as follows:

6.2.1. [***] after a Party delivers written notice of termination to the other Party;

6.2.2. without further notice by Syneos Health, if any undisputed payment to Syneos Health by Client is not made when due and such payment is not made within [***] from the date of written notice from Syneos Health to Client of such nonpayment;

6.2.3. by the non-breaching Party, in the event that the other Party has committed a material breach of this Agreement (other than failure to make timely payment of any undisputed amount due to Syneos Health), and such breach has not been cured within [***] of receipt of written notice from the non-breaching Party of such breach;

6.2.4. by either Party, in the event the other Party is either debarred from federal contracting or becomes a Sanctioned Entity;

6.2.5. immediately without notice if the other Party (i) ceases, or threatens to cease, to carry on business or maintain itself as a going concern; or (ii) becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, files or has filed against it, a petition in bankruptcy, or (iii) has a receiver appointed for a substantial part of its assets and is not discharged within [***] after the date of such appointment.

6.2.6. A Party may terminate this Agreement and any Work Order [***] as a result of the other Party's breach of the FCPA warranty in Section 2.6.

6.3. **Duties Upon Termination**.

6.3.1. **Cooperation**. Upon termination of this Agreement or any Work Order, the Parties shall promptly meet and/or agree upon wind down activities and associated costs prior to the performance of any additional tasks not otherwise addressed in such Work Order. The Parties shall reasonably cooperate with each other to provide for an orderly cessation of Services. In the event Client terminates only part of the Services described in a Work Order, the Parties will cooperate in good faith to enter into a Change Order. Additionally, upon termination, to the extent applicable and as mutually agreed to by the Parties, Syneos Health will give or otherwise transfer to Client, at Client's expense, all property in Syneos Health's possession that belongs to and was paid for by Client (excluding archival copies thereof), provided that all outstanding undisputed invoices have been paid in full.

6.3.2. **Payment**. Client shall pay or reimburse Syneos Health for the following upon termination in accordance with the terms set forth in Section 5 or the applicable Work Order:

6.3.2.1. [***].

6.3.3. **Excess Payments**. In the event of excess payment to Syneos Health by Client,[***].

7. INSPECTIONS AND AUDITS

7.1. **Conducted by Regulatory Authority**. Each Party shall promptly notify the other Party of any Regulatory Authority's inspections, investigations, or inquiries pertaining to any Services ("**Inspections**"). If a Regulatory Authority requests Syneos Health not provide notification to Client of an Inspection, Syneos Health will comply with such request, and its failure to notify Client will not be a breach of this Agreement. Client may not direct the manner in which Syneos Health fulfills its obligations to permit Inspections by Regulatory Authorities. Syneos Health will prepare responses for Inspections occurring on Syneos Health's premises so long as Client timely provides Syneos Health information required for adequately responding to Inspection findings. To the extent legally permissible, Syneos Health shall provide Client with copies of any communications from Regulatory Authorities relating to the Services or Client's products, and any responses to such communications submitted by Syneos Health. Prior to submission of any communications to any Regulatory Authorities regarding the Services or Client's products, Syneos Health shall, to the extent legally permissible, provide a draft of such submission to Client for comment and shall make Commercially Reasonable Efforts to address comments received from Client in its communication prior to submission. Commercially reasonable costs associated with hosting and responding to any Inspection (including any preparation, participation, follow-up and resolution of findings), shall be invoiced to Client on a time and materials basis.

7.2. **Conducted by Client**. Records and any other materials related to this Agreement shall be maintained in accordance with Syneos Health's record retention schedule. Syneos Health agrees that Client may, at Client's sole cost and expense, upon [***] advance written notice to Syneos Health and [***]conduct an audit of Syneos Health's facilities used to perform the Services, its documentation (including Standard Operating Procedures) and financial records for the prior [***] relating directly to Syneos Health's purchases and expenditures (including Pass Through Expenses) on Client's behalf under this Agreement and the Work Orders, for the purpose of determining Syneos Health's compliance with this Agreement and the applicable Work Order(s). using a mutually agreed upon third party accounting firm (i.e., Deloitte, KPMG, Ernst & Young, or PWC) ("**Auditor**"), provided such Auditor generally adheres to and utilizes professional standards of its industry and agrees in writing to continue to do so in the audit permitted hereunder, and further provided that the Auditor is not (i) compensated on a contingency basis and (ii) providing cost consulting services to Client. It is understood that no audit shall take longer than [***] and the audit shall not include, and in no event shall Client have access to, individual payroll and personnel files; any information relating to Syneos Health's other clients; any of Syneos Health's internal costs or non-billable expenses; or any information that is subject to legal restrictions regarding confidentiality. Any such audit shall take place in Syneos Health's primary office or such location as Services are provided. Each audit shall be conducted during regular business hours and in such a manner as to not unduly interfere with Syneos Health operations. The Auditor shall execute a confidentiality agreement provided by Syneos Health prior to conducting the examination. The scope of the audit shall be reviewed for appropriateness and subject to Syneos Health agreement prior to the commencement of the audit. Syneos Health shall be provided with a copy of the audit report within [***] of its receipt by Client from the auditor and Syneos Health shall be permitted to review and comment upon the audit report. Subject to the terms of a Work Order, all audit rights shall cease upon expiration of this Agreement.

8. CONFIDENTIALITY

8.1. **Obligations**. Either Party may become the recipient of Confidential Information of the other during the term of this Agreement. The Receiving Party shall (i) treat the Disclosing Party's Confidential Information as confidential and proprietary and protect it with the same level of prudence and care as it would protect its Confidential Information, but in no event less than reasonable care; and (ii) use the Disclosing Party's Confidential Information only as necessary to perform its obligations or exercise its rights hereunder or under a Work Order. These confidentiality and non-use obligations shall remain in effect for [***] after the expiration or termination of this Agreement.

8.2. **Disclosure**. Without the prior written consent of the Disclosing Party, the Receiving Party shall not disclose Confidential Information to any third party; provided, however, that Syneos Health may disclose Client's Confidential Information to Syneos Health's Subcontractors, Third Party Vendors, agents, representatives, or Affiliates of Syneos Health and the Affiliates' respective employees that have a need to know such information in connection with the Services where such parties are bound to obligations of confidentiality and non-use substantially similar to those set forth herein.

8.3. **Confidential Information**. Confidential Information means all non-public, protected and/or proprietary information in the broadest sense, including, but not limited to, personal information (e.g., phone number, address and e-mail address) of employees, Subcontractors, consultants and agents; customers; clients; unpublished research results; development plans; processes; protocols; data; undisclosed financial statements; marketing plans or techniques; contacts; pricing and/or business activities including organization and operations; product information; unpublished intellectual property, undisclosed contractual rights or interests; and procedures and business practices involving trade secrets or know-how disclosed by a Party or a Party's Affiliate (the "Disclosing Party") to the other Party or its Affiliate (the "Receiving Party") and includes any materials, reports or documents produced therefrom or therewith by the Receiving Party or one of its Affiliates. Confidential Information shall include any Confidential Information disclosed previously by a Disclosing Party to a Receiving Party in connection with the discussions between the Parties with respect to the subject matter of this Agreement. The Parties further agree that Confidential Information shall include information discovered during an audit of either Party's or its Affiliates' facilities. Notwithstanding the foregoing, Confidential Information shall not include, and these confidentiality obligations shall not operate as a restriction on, each Party's right to use, disclose, or deal with information which:

8.3.1. was in the Receiving Party's possession prior to the time it was acquired from the Disclosing Party and was not directly or indirectly acquired from the Disclosing Party;

8.3.2. is or lawfully becomes generally available to the public through no fault of Receiving Party;

8.3.3. is lawfully and independently made available to the Receiving Party by a third party;

8.3.4. is released from its confidential status by the Disclosing Party; or

8.3.5. is independently developed by or for the Receiving Party without the use of the Disclosing Party's Confidential Information as evidenced by written records.

Nothing in this Agreement shall restrict the Parties from disclosing Confidential Information as required by Applicable Law or court order or other governmental order or request, provided in each case the Party requested to make such disclosure shall, to the extent permitted by law, timely inform the other Party and use Commercially Reasonable Efforts to limit the disclosure and maintain the confidentiality of such Confidential Information. The Party required to make such disclosure shall cooperate with the other Party if it acts to attempt to limit such disclosure by appropriate legal means.

8.4. **Return of Confidential Information**. Upon the expiration or termination of this Agreement and receipt of Disclosing Party's written request, Receiving Party, at its option, shall promptly either (a) return to the Disclosing Party all tangible forms of the other Party's Confidential Information in its possession, including any and all copies and/or derivatives of such Confidential Information made by either Party or their employees as well as any writings, drawings, specifications, manuals, or other printed or electronically stored material based on or derived from such Confidential Information, or (b) destroy the Confidential Information of the other Party in its possession and deliver to Disclosing Party a certification that such destruction has occurred; provided, however, that Receiving Party may retain a copy of any information, including such Confidential Information, that the Receiving Party reasonably believes is required to comply with Applicable Law or to effectuate the purposes of this Agreement, or is held as a backup in electronic form in backup servers or other sources as a result of the Receiving Party's normal backup procedures for electronic data provided, however, that any such retained Confidential Information shall continue to be governed by the terms of this Agreement.

9. INTELLECTUAL PROPERTY

9.1. **Deliverables**. Except as set forth in Sections 9.2 and 9.3, all designs, documents, materials, reports, and deliverables provided by Syneos Health to Client pursuant hereto or pursuant to any Work Order whether or not patentable, copyrightable, or susceptible to any other form of legal protection which are made, conceived, reduced to practice, or authored by Syneos Health or Syneos Health Personnel as a result of the performance of Services, or to the extent derived from use or possession of Client's Confidential Information (collectively, the "**Deliverables**") shall be the sole and exclusive property of Client upon full payment of all sums due to Syneos Health for each such Deliverable under this Agreement. Subject to Sections 9.2 and 9.3, each Deliverable constituting an original work shall be considered a work made for hire under applicable copyright laws. Subject to Sections 9.2 and 9.3, Syneos Health hereby assigns, and agrees to assign, to Client all right, title, and interest in all worldwide intellectual property rights in the Deliverables, including without limitation, inventions, patents, copyrights, and trade secrets and shall take such further actions and execute such further documents as may be required to evidence such assignment.

9.2. **Syneos Health Works**. Notwithstanding anything to the contrary set forth herein, to the extent any Deliverable or work made for hire includes Syneos Health's intellectual property (which shall include, models, know-how, software, source or object code, methodologies, technology, techniques, procedures, management tools, workshops, manuals, data files and inventions) that Syneos Health has developed, created, or acquired independent of performing the Services or independent of any Client Confidential Information or Client intellectual property ("**Syneos Health Works**"), Syneos Health shall retain exclusive ownership in such Syneos Health Works. Any improvements, alterations, or enhancements to Syneos Health Works made without the use of Client's Confidential Information or Client's intellectual property and which are not specific to the Services or Client's products shall be the sole property of Syneos Health. Upon full payment of all sums due to Syneos Health for each Deliverable, Syneos Health hereby grants Client a royalty- free, fully paid-up, perpetual, irrevocable, sublicensable, worldwide, non-exclusive right and license to use any Syneos Health Works in connection with Client's use of the Deliverable. For the avoidance of doubt, the Parties agree that, subject to the terms of any Work Order, any source or object code previously owned or licensed by Syneos Health or created hereunder are not a part of the rights provided to Client and may be used by Syneos Health on behalf of itself or any of its other clients.

9.3. **Third Party IP**. Without limiting the general rights of Client as provided in this Section 9, it is understood and agreed that a Work Order may provide that certain Deliverables may contain the intellectual property of third parties ("**Third Party IP**") pursuant to a license or other arrangement which permits Client to use such Third Party IP only in connection with a specific project or campaign, and which would require additional payments for a different or extended use by Client. Syneos Health shall provide written notification to Client of any material conditions, costs, or limitations relating to such Third Party IP, and Client shall be solely responsible for any costs or other charges associated with any use of such Third Party IP outside the scope of the use contemplated by the applicable Work Order.

9.4. **Third Party Sources**. Pursuant to this Agreement, Syneos Health may obtain and deliver to Client information that has been derived from a variety of sources, including but not limited to proprietary data services, government information, industry publications, Client press releases and other Client content, web sites, marketing materials, and other generally available public sources. To the extent that Syneos Health selects the third party sources of information, Syneos Health will exercise the standard of care provided for in Section 4.2.1 in selecting such sources; however, all such information, statements, facts, analyses, interpretations and opinions contained in Syneos Health's Deliverables and based upon the foregoing are provided without representation or warranty by Syneos Health, its Affiliates, officers, employees, contractors or business partners as to accuracy, completeness, usefulness, or otherwise. Client agrees that the Services are not intended to support the purchase or sale of securities and acknowledges and agrees that Syneos Health does not, and shall not be deemed to, give investment advice or advocate the purchase or sale of any security or investment. Nothing herein is intended to negate Syneos Health's obligations under Section 4.2.1.

9.5. **Software Rights**. If applicable to the Services provided under this Agreement or a particular Work Order, Syneos Health may facilitate the use or distribution of software and associated software documentation in accordance with this Agreement. Subject to the terms of any applicable Work Order, Syneos Health accordingly grants Client a non-exclusive right to use, store, or disseminate such software and associated documentation for the sole purpose for which Syneos Health is providing Services.

9.6. **Data Use; De-Identification**. Provided that Syneos Health de-identifies all personal data, Client and Client product identifying information, Syneos Health may use all project data, excluding Client Confidential Information, for the purpose of evaluating its performance under this Agreement and for business development and analytics purposes.

10. INDEMNIFICATION, LIABILITY, INSURANCE

10.1. **Indemnification by Client**. Client shall promptly, indemnify, defend, and hold harmless Syneos Health and its Affiliates and its and their respective directors, officers, employees, and agents ("**Syneos Health Parties**") from and against any and all losses, liabilities, damages, expenses, costs and fees (including reasonable attorneys' fees) (collectively, the "**Losses**") arising from third party claims, causes of action or suits ("Claims") relating to, arising from, or in connection with this Agreement or the Services contemplated herein, including without limitation, any product liability claims, whether arising out of warranty, negligence, strict liability (including manufacturing, design, warning or instruction claims), or any other product based statutory claim, any failure by Client to comply with any applicable federal, state, or local laws, regulations, or codes, including but not limited to, the United States Federal Anti-Kickback Statute (42 U.S.C. 1320a-7b) and the related safe harbor regulations, the Federal False Claims Act, the Federal Food, Drug, and Cosmetic Act and the Prescription Drug Marketing Act, in the performance of its obligations under this Agreement or any material breach by Client of its warranties, representations, covenants, agreements and obligations set forth in this Agreement or any Work Order. Client's indemnity obligations shall not apply to the extent that such Losses result or arise from (y) the negligent acts or omissions by or the willful misconduct of Syneos Health Parties; or (z) any material breach of this Agreement or any Work Order by Syneos Health Parties.

10.2. **Indemnification by Syneos Health**. Syneos Health shall promptly indemnify, defend, and hold harmless Client and its Affiliates and its and their respective directors, officers, employees, and agents ("**Client Parties**") from and against [***].

10.3. Indemnification Procedures.

10.3.1. **Notice.** Each Party and any person seeking indemnification and/or defense pursuant to this Section 10 shall give the indemnifying party prompt and timely written notice and reasonable cooperation and assistance in the defense of any claim; provided however, that failure of the indemnified party to give timely notice shall not limit the indemnified party's right to indemnification except in such case where such failure materially and adversely affects the indemnifying party's ability to defend against such claim.

10.3.2. **Counsel.** The indemnifying party shall defend the Claim using counsel of its own choosing. The indemnified party shall have the right to participate jointly with the indemnifying party, at its own expense, in the defense, settlement or other disposition of any indemnification claim. If the indemnified party exercises such right, all costs and expenses incurred by the indemnified party for separate counsel shall be borne by the indemnified party.

10.3.3. **Settlement.** Neither Party will enter into any settlement agreement regarding a Claim which is the subject of this Article 10 that attributes fault or negligence to, requires any payment by, or restricts the future actions or activities of the other Party, without such Party's prior written consent, which shall not be unreasonably withheld or delayed.

10.4. **Limitation of Liability**. IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY, PUNITIVE, OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH OR RELATED TO THIS AGREEMENT (INCLUDING LOSS OF PROFITS, USE, DATA, OR OTHER ECONOMIC ADVANTAGE), HOWSOEVER ARISING, EITHER OUT OF BREACH OF THIS AGREEMENT (INCLUDING BREACH OF EXPRESS OR IMPLIED WARRANTY), NEGLIGENCE, STRICT LIABILITY, TORT, OR ANY OTHER THEORY, EVEN IF THE OTHER PARTY HAS BEEN PREVIOUSLY ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN ADDITION, SYNEOS HEALTH'S LIABILITY FOR DIRECT DAMAGES ARISING UNDER A WORK ORDER SHALL BE LIMITED TO THE TOTAL FEES (EXCLUDING PASS THROUGH COSTS AND EXPENSES) ACTUALLY PAID BY CLIENT TO SYNEOS HEALTH UNDER THE SPECIFIC WORK ORDER FOR THE SERVICES EXCEPT TO THE EXTENT THAT SUCH DAMAGES WERE THE RESULT OF GROSS NEGLIGENCE OR WILFUL MISCONDUCT ON THE PART OF SYNEOS HEALTH.

10.5. **Insurance**. Upon written request, each Party shall provide the other with a copy of its effective certificate of insurance or such other document evidencing compliance with this Section 10.5. Without limiting the generality of and in addition to the foregoing, during the term of this Agreement and for claims made insurance policies [***], each Party undertakes to maintain, as applicable, [***]. Limits may be provided with Umbrella/Excess insurance. Insurance companies must have an AM Best Rating of "A-/VII" or better, or an analogous rating by a similar organization if the insurance company is not a United States company. Neither Party's liability shall be capped by its insurance limits. The Parties agree that additional project-specific insurance requirements may be set forth in a Work Order.

11. NON-SOLICITATION

11.1. **Non-Solicitation**. Except as may otherwise be provided in a Work Order, during the term of this Agreement and for a period of [***] following the date of expiration or termination of (i) the Agreement or (ii) the Services under the applicable Work Order for any reason whatsoever (whichever is later), Client agrees not to solicit or attempt to solicit, directly or indirectly, for its own benefit or for that of others, any director, officer, or Syneos Health Personnel, or to induce any of them to quit his/her employment with Syneos Health and thereafter to employ them, or to induce the representatives, agents, consultants, or suppliers of Syneos Health to cease to do business with Syneos Health; provided, however, that the foregoing shall not prevent Client from interviewing or hiring any such employee of Syneos Health who contacts Client on his/her own initiative without any solicitation by Client. The term "solicit" shall not include general solicitations (i.e., advertisements, websites, etc.) for employment not specifically directed towards Syneos Health employees. For avoidance of doubt, this clause would not apply to any Syneos Health Personnel who is hired by Syneos Health with a view to potentially becoming an employee of the Client pursuant to a Work Order.

11.2. **Contact**. Except as may otherwise be provided in a Work Order, Client agrees during the term of this Agreement, and for [***] thereafter, that Client shall not assist actively in any way a third party competitor of Syneos Health to induce Syneos Health Personnel to leave their employment with Syneos Health.

11.3. **Violation**. Client shall pay to Syneos Health a fee equal to [***] of the hired person's annual compensation (or in the case of hourly paid employees, the amount equal to [***] of such employee's annual compensation based on a forty (40) hour work week), which the Parties agree is a reasonable estimate of actual damages in lost revenues, recruiting fees, and productivity costs associated with securing a replacement for each Syneos Health Personnel so employed or retained as liquidated damages for breach of either Sections 11.1 or 11.2.

12. GENERAL TERMS

12.1. **Data Processing**. Syneos Health shall process personal data in accordance with all applicable privacy and personal data protection laws and regulations. To the extent the Services involve the processing of personal data within the European Economic Area (EEA), the Parties agree that such processing will be governed by the terms set forth in Exhibit B to this Agreement.

12.2. **Public Announcement**. Neither Party shall make a public announcement regarding this Agreement or any Work Order, if applicable, or the subject matter contained herein or therein, without the prior written consent of the other Party (which consent may not be unreasonably withheld), except as may be, in the reasonable opinion of the disclosing Party's legal counsel, required by Applicable Law, including Regulatory Authorities, the U.S. Securities and Exchange Commission or any stock exchange upon which such Party's securities are listed or to which application for listing has been submitted, in which event the disclosing Party shall provide the other Party reasonable advance notice, review, and comment of any such disclosure, including a copy of the proposed redacted filings, if any. Notwithstanding the above, either Party may list the name of the other Party in a non-descriptive fashion: (i) in connection with its general marketing materials; (ii) in its regular filings with Regulatory Authorities and securities commissions; and (iii) in internal business communications, including communications to Affiliates. In addition, Syneos Health may use any final Deliverables in its marketing materials and/or press releases once Client releases the Deliverable to the public upon written approval of the Client of such use.

12.3. **Non-Exclusivity.** Subject to Section 4.2.4, neither Party shall have any obligation of exclusivity of any nature to the other, nor any obligation to provide any particular services unless specified in a Work Order. Each Party shall be free to provide services to other parties, so long as a Party's agreement with any such third party does not prevent it from performing its material obligations under this Agreement or any Work Order.

12.4. **Force Majeure**. In the event either Party is delayed, hindered, or prevented from performing any act required hereunder by reasons beyond its ability to reasonably anticipate and prevent, control, or mitigate, including, but not limited to, (i) acts of God; (ii) flood, fire, earthquake or explosion; (iii) war, invasion, hostilities (whether war is declared or not), terrorist threats or acts, riot or other civil unrest; (iv) government order of general application; (v) actions, embargoes, or blockades in effect on or after the date of this Agreement; (vi) action by any governmental authority of general application; (vii) national or regional emergency; (viii) strikes, labor stoppages, or slowdowns or other industrial disturbances (except where such strike, lockout, or labor trouble involves a Party's own employees); or (ix) shortage of adequate power or transportation facilities (a "**Force Majeure Event**"), then performance of such act (except for payment of money owed) shall be extended for the reasonable period of such delay, and either Party shall be granted a reasonable period of time to perform after the cessation of the reason for the delay. Notwithstanding the foregoing, Client shall not be relieved from payment of non-cancellable expenses authorized in a Work Order incurred by Syneos Health by reason of a Force Majeure Event.

12.5. **Governing Law**. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York, excluding that body of law known as choice of law, and shall be binding upon the Parties hereto in the United States and worldwide.

12.6. **Dispute Resolution**. In the event any dispute arises between the Parties concerning this Agreement, the interpretation of this Agreement, the application of this Agreement, or the Services performed pursuant to this Agreement, the Parties shall first settle such a dispute by good faith negotiation and consultation between themselves, including senior representatives with authority to resolve the dispute ("**Senior Representatives**"). This Section 12.6 shall apply regardless of whether the nature of the dispute originates in contract, tort, statute, or other legal basis. The Parties agree to attorn to the jurisdiction of the courts of the State of New York.

12.7. **Notices**. All formal or legal notices, requests, demands or other communications hereunder, other than communications reasonably deemed to be day-to-day within the duties of project management shall be in writing and shall be deemed given if personally delivered or disseminated by nationally recognized courier or registered mail with return receipt within [***] after prior mailing to the address set forth below:

If to Syneos Health:
inVentiv Commercial Services, LLC
500 Atrium Drive
Somerset, NJ 08873
Attention: [***]

With copy to:
Syneos Health
1030 Sync Street
Morrisville, NC 27560
Attention: [***]

If to Client:
VBI Vaccines Inc.
310 Hunt Club Rd East, Suite 201 Ottawa, ON, Canada
K1V1C1
Attn: [***]

With copy to:

VBI Vaccines Inc.
222 Third St., Suite 2241
Cambridge, MA 02139

12.8. **Assignment**. Neither Party shall have the right to assign this Agreement or any Work Order or any of the rights or obligations hereunder without the prior written consent of the other Party, except that (i) either Party may assign this Agreement to an Affiliate or to a successor to that part of its business to which this Agreement is related, upon prior written notice, where such Affiliate or successor has the financial and operational capacity and ability to perform the assigning Party's obligations hereunder, and in the case of Client as the assignor, all outstanding balances owing to Syneos Health at the time of assignment are paid in full prior to the effective date of the assignment, and (ii) either Party may assign or transfer this Agreement and any Work Order and/or the rights and obligations thereunder in connection with a merger, consolidation or sale of substantially all assets of its business.

12.9. **Survival**. The terms, provisions, representations, and warranties contained in this Agreement that, by their context are intended to survive the expiration or termination of this Agreement, shall so survive the expiration or termination of this Agreement and include, for greater certainty, Articles 8 and 9.

12.10. **Entire Agreement**. This Agreement, in conjunction with its attachments, embodies the entire and integrated understanding between the Parties and supersedes all prior agreements or understandings, negotiations, or representations, either written or oral, regarding its subject matter. The Parties have not relied on any statement, representation, warranty, or agreement of the other Party, or of any other person on such Party's behalf, except for the representations, warranties, or agreements expressly contained in this Agreement. No modification of this Agreement shall be deemed effective unless in writing and executed by both Parties.

12.11. **Binding Agreement**. This Agreement shall be binding upon the Parties and shall inure to the successors and permitted assigns of the Parties.

12.12. **Waiver**. Any waiver granted shall not be deemed effective unless in writing and executed by the Party against whom enforcement of the waiver is sought. Waiver or forbearance by either Party or the failure to claim a breach of any provision of this Agreement or to exercise any right or remedy provided by hereunder, or under Applicable Law, shall not constitute a waiver with respect to any subsequent breach of this Agreement.

12.13. **Severability**. If any term or provision of this Agreement shall be held to be invalid, illegal, unenforceable or in conflict with Applicable Law, the validity, legality, and enforceability of the remaining terms shall not be affected or impaired, except if the principal intent of this Agreement is negated by such reformation or deletion, in which case this Agreement shall terminate.

12.14. **Headings Not Controlling**. Headings used in this Agreement are for reference purposes only and shall not be used to modify the meaning of the terms and conditions of this Agreement.

12.15. **Counterparts**. This Agreement and any Work Order may be executed in two counterparts by duly authorized individuals on behalf the Parties, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Executed signature pages may be delivered electronically and copies thereof shall have the same force and effect as signed original documents.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the undersigned have caused this Agreement to be executed by a duly authorized individual on behalf of each requisite Party as of the Effective Date.

INVENTIV COMMERCIAL SERVICES, LLC

By: */s/ Philip P Moussally*
Name: Philip P Moussally
Title: CFO Deployment Solutions
Date: Dec 19, 2019

VBI VACCINES INC.

By: */s/ Jeff Baxter*
Name: Jeff Baxter
Title: CEO
Date: 19th December 2019

Exhibit 21.1

VBI Vaccines Inc. – List of Subsidiaries

Name of Subsidiary	Country of Incorporation	Ownership Interest (direct or indirect)
VBI Vaccines (Delaware) Inc.	Delaware (U.S.A)	100%
SciVac Ltd.	Rehovot (Israel)	100%
Variation Biotechnologies (US), Inc.	Delaware (U.S.A)	100%
Variation Biotechnologies Inc.	Ottawa, Ontario (Canada)	100%
SciVac Hong Kong Limited	Hong Kong	100%
VBI Vaccines B.V	Netheralands	100%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of VBI Vaccines, Inc. and Subsidiaries (the "Company") on Form S-3 (Nos. 333-240266, 333-226271, and 333-217995) and Form S-8 (Nos. 333-226261 and 333-212160) of our report dated March 2, 2021, on our audits of the consolidated financial statements as of December 31, 2020 and 2019 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 2, 2021. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
March 2, 2021

Exhibit 31.1

CERTIFICATION

I, Jeffrey Baxter, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2020 of VBI Vaccines Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2021

/s/ Jeffrey Baxter

Jeffrey Baxter
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Christopher McNulty, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2020 of VBI Vaccines Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2021

/s/ Christopher McNulty

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

Exhibit 32.1

CERTIFICATION

In connection with the annual report of VBI Vaccines Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, Jeff Baxter, Chief Executive Officer (Principal Executive Officer) of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: March 2, 2021

/s/ Jeffrey Baxter
Jeffrey Baxter
Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

CERTIFICATION

In connection with the annual report of VBI Vaccines Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, Chris McNulty, Chief Financial Officer and Head of Business Development (Principal Financial and Accounting Officer) of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: March 2, 2021

/s/ Christopher McNulty

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