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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

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 [X]

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 [X]

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 [X] 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 [X] 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 [ ]	Accelerated filer [X]
Non-accelerated filer [ ]	Smaller reporting company [X]

Emerging growth company [X]

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. [X]

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

As of June 30, 2019, 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 $78,984,578

As of March 4, 2020, the registrant had 178,257,199 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 2020 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, 2019

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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 infectious disease and immuno-oncology pipeline candidates;
- the potential benefits of strategic partnership agreements and our ability to enter into strategic partnership arrangements;
- our ability to maintain compliance with the NASDAQ Capital Market's listing standards;
- our ability to effectively execute and deliver our plans related to commercialization, marketing and 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 to the standards and requirements of regulatory agencies;
- the ability of our vendors 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 manufacturing facility where we manufacture all of our clinical and commercial supplies of Sci-B-Vac and clinical supplies of 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; and
- other factors discussed in this Form 10-K

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

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

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

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

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

PART I

ITEM 1. BUSINESS

Overview

We are a commercial-stage, biopharmaceutical company developing a next generation of vaccines to address unmet needs in infectious disease and immuno-oncology. We are advancing the prevention and treatment of hepatitis B, with the only trivalent hepatitis B vaccine, Sci-B-Vac, which is approved for use and commercially available in Israel, and recently completed a pivotal Phase III program in the United States, Europe and Canada, and with VBI-2601 (BRII-179), an immunotherapeutic candidate in development in collaboration with Brii Biosciences Limited ("Brii Bio") for a functional cure for chronic hepatitis B. Our enveloped virus-like particle ("eVLP") platform technology allows for the development of eVLP vaccines that closely mimic the target virus to elicit a potent immune response. Integrating our cytomegalovirus ("CMV") expertise with the eVLP platform technology, our lead eVLP program candidates include a glioblastoma ("GBM") vaccine immunotherapeutic candidate, VBI-1901, and a prophylactic CMV vaccine candidate, VBI-1501. We are headquartered in Cambridge, Massachusetts, with research operations in Ottawa, Canada, and manufacturing operations in Rehovot, Israel.

Product Pipeline – Lead Program Candidates

Program	Current Development Stage
Hepatitis B Portfolio:	
● Sci-B-Vac: Prophylactic hepatitis B	Phase III Complete
● VBI-2601: Therapeutic hepatitis B	Phase Ib/IIa
eVLP Platform Portfolio:	
● VBI-1901: Therapeutic CMV-Associated Cancers (GBM)	Phase I/IIa
● VBI-1501: Prophylactic CMV	Phase I Complete

A summary of these programs and recent developments follows.

Hepatitis B

Sci-B-Vac: Trivalent Prophylactic Hepatitis B Vaccine

Sci-B-Vac is a trivalent prophylactic hepatitis B vaccine, which is approved for use and commercially available in Israel, and recently completed its pivotal Phase III program in the United States, Europe, and Canada. In contrast to other commercially-available hepatitis B vaccines, which contain only one surface antigen (the S antigen) of hepatitis B, Sci-B-Vac contains all three of the hepatitis B surface antigens: the S antigen, the pre-S1 antigen, and the pre-S2 antigen. Moreover, Sci-B-Vac is distinguished from other commercially-approved hepatitis B vaccines because it is produced in mammalian cells (Chinese hamster ovary "CHO" cells) rather than in yeast. Published data demonstrate that T cell responses to the pre-S1 and pre-S2 antigens can further boost responses to the S antigen, resulting in a more immunogenic response.

Sci-B-Vac has not yet been approved for use by the United States Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") or Health Canada. The recently completed global Phase III clinical program was designed to achieve FDA, EMA, and Health Canada market approvals for commercial sale of Sci-B-Vac in the United States, Europe, and Canada, respectively. Our wholly-owned subsidiary, SciVac Ltd., in Rehovot, Israel, manufactures and sells Sci-B-Vac.

On June 17, 2019, we announced positive top-line results from the randomized, double-blind, controlled pivotal Phase III study, PROTECT, designed to evaluate the efficacy and safety of a 10µg dose of Sci-B-Vac compared with a 20µg dose of the standard of care vaccine, Engerix-B. The study, which enrolled a total of 1,607 adults, of which 81% were age ≥ 45 years, met both of its co-primary endpoints: (1) non-inferiority of seroprotection rate ("SPR") of Sci-B-Vac (91.4%) vs. Engerix-B (76.5%) in all subjects age ≥ 18 years, 4 weeks after 3rd vaccination (SPR difference: 14.9%; 95% confidence interval ("CI") [11.2%, 18.5%]); and (2) superiority of SPR of Sci-B-Vac (89.4%) vs. Engerix-B (73.1%) in subjects age ≥ 45 years, 4 weeks after 3rd vaccination (SPR difference: 16.4%; 95% CI [12.2%, 20.7%]). Moreover, the SPR of Sci-B-Vac compared to Engerix-B was higher in all key subgroup analyses of adults age ≥ 18 years, including by age, gender, body mass index ("BMI"), diabetic status, and smoking status, four weeks after 3rd vaccination.

On January 9, 2020 we reported positive top-line results from CONSTANT, the second pivotal Phase III study, designed to assess lot-to-lot manufacturing consistency of Sci-B-Vac, and compare the safety and immunogenicity of Sci-B-Vac to Engerix-B. The CONSTANT Phase III study, which enrolled 2,838 adults, age 18-45 years, met both the primary and secondary endpoints. The primary endpoint of CONSTANT study was directed to the manufacturing consistency of Sci-B-Vac. For this primary endpoint, the study evaluated the vaccine immune response, as measured by geometric mean concentration ("GMC") of antibodies across three independent, consecutively-manufactured lots of Sci-B-Vac, four weeks after the third vaccination. Together with the positive safety and immunogenicity results of the PROTECT Phase III study, we expect these data to comprise the basis for the regulatory submissions in the United States, Europe, and Canada.

A secondary endpoint of the CONSTANT study demonstrated non-inferiority of SPR of Sci-B-Vac (99.3%) vs. Engerix-B (94.8%), one month after completion of the full course of vaccination (SPR difference: 4.49%; 95% CI [2.90%, 6.63%] – up from 90.4% for Sci-B-Vac and 51.6% for Engerix-B at day 168, after only two vaccinations. In addition to demonstrating non-inferiority, the SPR achieved with Sci-B-Vac compared to Engerix-B was higher after both two and three vaccinations. An exploratory analysis in CONSTANT also compared the SPR after two doses of Sci-B-Vac (90.4%) to the SPR after three doses of Engerix-B (94.8%) (SPR difference: -4.3%; 95% CI [-6.48%, -1.90%]). As per the commonly-used statistical margin of non-inferiority for hepatitis B vaccines, defined as the lower limit of the 95% CI being above -10%, this analysis demonstrated non-inferiority after two doses of Sci-B-Vac (at day 168) compared with three doses of Engerix-B (at day 196). Similarly, at these time points, preliminary data from the integrated immunogenicity analysis of both the PROTECT and CONSTANT studies in subjects age 18-45 years demonstrate a difference in SPR of -4.2%; 95% CI [-6.38%, -1.99%]. The two versus three dose comparison is not part of the regulatory approval process and will not be included in the expected indication we will seek, but we believe it contributes to the robust immunogenicity profile of Sci-B-Vac.

The safety and tolerability seen in CONSTANT and PROTECT studies were consistent with the known safety profile of Sci-B-Vac. No new safety risks were identified, and no safety signals were observed in either study cohort. The integrated safety data analysis from both the PROTECT and CONSTANT studies is underway.

The completed Phase III studies are expected to support the Biologics License Application ("BLA") to the FDA, the Marketing Authorization Application ("MAA") to the EMA and the New Drug Submission ("NDS") to Health Canada. We plan to submit applications for regulatory approvals in the United States, Europe and Canada beginning in the fourth quarter of 2020.

VBI-2601: Hepatitis B Immunotherapeutic Candidate

VBI-2601 (BRII-179) is our novel, recombinant, protein-based immunotherapeutic candidate in development for the treatment of chronic hepatitis B infection, a disease that affects more than 250 million people worldwide. Chronic hepatitis B 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 the hepatitis B virus, including T-cell immunity which plays an important role in controlling hepatitis B infection.

On December 6, 2018, the Company announced that it had entered into a Collaboration and License Agreement ("License Agreement") with Brii Bio, pursuant to which, among other things, subject to terms and conditions set forth in the License Agreement, we and Brii Bio agreed to collaborate on the development of a hepatitis B recombinant protein-based immunotherapeutic candidate in China, Hong Kong, Taiwan and Macau (the "Licensed Territory"), and to conduct a Phase Ib/IIa collaboration clinical trial for the purpose of comparing VBI-2601 (BRII-179) with a novel composition developed jointly with Brii Bio.

On November 14, 2019 we announced initiation of enrollment in a Phase Ib/IIa Study of VBI-2601 (BRII-179) in patients with chronic hepatitis B infection. The Phase Ib/IIa clinical study of VBI-2601 (BRII-179) 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 is expected to enroll up to 65 patients. Initial human proof-of-concept data from the clinical study is anticipated in the second half of 2020. The study is sponsored by Brii Bio and will be conducted at multiple study sites in New Zealand, Australia, Thailand, South Korea, Hong Kong SAR, and China.

eVLP Platform

The eVLP technology enables the synthetic manufacture of an "enveloped" virus-like particle, or "eVLP". Many viruses are "enveloped" in that they are surrounded by a lipid bilayer membrane. Such viruses display antigenic proteins on the surface of their "envelope" which can be targets for vaccine development. The ability to synthetically manufacture an "enveloped" virus-like particle is different from previously developed VLP technologies, which did not include the lipid bilayer membrane, and thus these technologies were unable to express antigenic proteins within an "envelope" as they occur in nature.

VBI-1901: Cancer Vaccine Immunotherapeutic Candidate

Our GBM brain cancer vaccine immunotherapeutic program, VBI-1901, targets CMV proteins present in GBM tumor cells. CMV is associated with a number of other solid tumors in addition to GBM, including breast cancer and pediatric medulloblastoma. We initiated dosing in a multi-center Phase I/IIa clinical study evaluating VBI-1901, in combination with granulocyte-macrophage colony stimulating factor ("GM-CSF"), in patients with recurrent GBM in January 2018. Enrollment in Part A of the study was completed in December 2018. In April 2019, the independent data safety monitoring board completed reviews of all safety data from our fully-enrolled Part A portion of the Phase I/IIa trial in recurrent GBM subjects, which included 6 subjects in each of 3 different dose cohorts. The data safety monitoring board unanimously recommended the continuation of the study without modification and had no safety concerns about any of the 3 dose levels of VBI-1901. On April 23, 2019, we announced that, based on safety and immunogenicity data, the highest dose tested in Part A of the ongoing Phase I/IIa study in recurrent GBM patients, 10µg, was selected as the optimal dose level to test in Part B of the study. Where Part A was designed as a dose-escalation phase to assess safety, tolerability, and to define the optimal dose level of VBI-1901, Part B is a subsequent extension phase of the optimal dose level defined in Part A.

On September 10, 2019, we entered into a Clinical Collaboration Agreement ("Collaboration Agreement") with GlaxoSmithKline Biologicals S.A. ("GSK") 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 I/IIa clinical study. Part B is now a two-arm open-label study, enrolling 20 first recurrent GBM patients to receive VBI-1901 in combination with either granulocyte-macrophage colony-stimulating factor ("GM-CSF") or $AS01_B$ as immunomodulatory adjuvants. Enrollment of the 10 patients in the VBI-1901 with GM-CSF arm was initiated at the end of July 2019. Initiation of enrollment of the 10 patients in the VBI-1901 with $AS01_B$ was announced in March 2020.

Safety, immunologic responses, and clinical and tumor responses from the VBI-1901 with GM-CSF in Part A and in the GM-CSF arm of Part B of the study were announced throughout 2019 and early 2020, respectively. VBI-1901 continues to be well-tolerated, with no vaccine-related safety signals observed. In the high-dose cohort of Part A, vaccine response correlated with tumor response, with all three vaccine responders demonstrating stable disease ("SD") for greater than 12 weeks. Two patients in the high-dose cohort of Part A experienced a 60% reduction in the size of primary tumor. VBI-1901 also induced and expanded robust T cell responses in these two patients. For patients who were vaccines responders, the 12-month overall survival ("OS") rate was 83% (n = 5/6), compared to 33% (n = 3/9) for vaccine non-responders. Similarly, among patients evaluable for response and survival in Part A, vaccine responders saw a 6.25-month improvement in median OS (14.0 months) compared to vaccine non-responders (7.75 months). VBI-1901 continues to be safe and well tolerated at al doses tested, with no safety signals observed.

Based on the data announced in November 2019, the early tumor and immunologic responses seen in Part B appear similar to the responses observed in Part A of the study. Correlations between immunologic biomarkers and tumor/clinical responses will continue to be refined throughout the duration of Part B of the study.

We expect expanded immunologic data and tumor imaging data from the VBI-1901 with GM-CSF arm in Part B of the study in the first half of 2020.

VBI-1501: Prophylactic CMV Vaccine Candidate

Another of our eVLP programs is a vaccine candidate that aims to prevent CMV infections. 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.

In May 2018, we announced positive top-line results from the randomized, placebo-controlled Phase I study of VBI-1501. The final Phase I study results demonstrated that VBI-1501 was safe and well-tolerated at all doses, with and without the adjuvant alum. The highest dose of VBI-1501, 2.0µg, with alum, elicited CMV-neutralizing antibodies against fibroblast cell infection in 100% of subjects after the third vaccination, up from 81% of subjects after the second vaccination, inducing titers comparable to those observed in patients protected as a result of natural infection. Neutralizing antibodies against epithelial cell infection were also seen in 31% of subjects after the third vaccination of VBI-1501 2.0µg with alum. The data also showed the formulation of the vaccine with alum enhanced antibody titers. The highest dose of VBI-1501 tested, 2.0µg with alum, contains approximately 10-fold less antigen content than that used in several other VLP-based vaccines or in previous CMV vaccine candidates developed by other companies.

On December 20, 2018 we announced plans for a Phase II clinical study evaluating VBI-1501 following positive discussions with Health Canada. 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. The Company is currently evaluating the timing of next steps for the program.

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 vaccination efforts in immuno-oncology.

Recent Corporate Developments

Modernization and Capacity Increase 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 Good Manufacturing Practice ("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 Sci-B-Vac manufactured at the modernized facility. We increased the capacity of our manufacturing facility to be able to supply commercial quantities of Sci-B-Vac upon FDA, and/or EMA and/or Health Canada approval, as well as supply the clinical materials of VBI-2601 (BRII-179).

Equity Financing Activities

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.

NASDAQ Minimum Bid Price Requirement

As previously reported, on August 14, 2019, we received a letter from the Listing Qualifications Department of the Nasdaq Stock Market ("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). The letter also indicated that we would be provided with a compliance period of 180 calendar days, or until February 10, 2020 (the "Compliance Period"), in which to regain compliance pursuant to NASDAQ Listing Rule 5810(c)(3)(A). In order to regain compliance with NASDAQ's minimum bid price requirement, our common shares needed to maintain a minimum closing bid price of $1.00 for at least ten consecutive business days during the Compliance Period. 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.

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 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. SciVac currently manufactures and sells our lead product, Sci-B-Vac, a trivalent hepatitis B vaccine for adults, children and newborns.

SciVac USA, LLC, located in Miami, Florida, was a wholly-owned subsidiary of SciVac and was organized on November 26, 2014 in the State of Florida. SciVac USA, LLC was dissolved on December 18, 2017.

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 and is a research focused subsidiary.

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.

Contractual Arrangements

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

On December 4, 2018, we entered 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 hepatitis B recombinant protein-based immunotherapeutic in the Licensed Territory, 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 hepatitis B, 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 hepatitis B in the Licensed Territory and to commercialize and promote the Licensed Product for the diagnosis and treatment of chronic hepatitis B 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 hepatitis B 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 or Licensed Products pursuant to the License Agreement in such region to make and sell Licensed Products for the diagnosis and treatment of hepatitis B 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, Sci-B-Vac is a trivalent hepatitis B vaccine which is the subject of a license agreement with 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 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.

Royalty payments under the Ferring License Agreement of $38 and $42, were recorded in cost of revenues for the year ended December 31, 2019 and 2018, respectively.

Royalty payments under the SciGen Assignment Agreement of $27 and $30 were recorded in cost of revenues for the year ended December 31, 2019 and 2018, 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 prior to an amendment dated January 24, 2005); or (ii) the Berna Territory (as defined therein).

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 "enveloped Virus Like Particle" or "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 a 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 ("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 invalidation 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 us 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 would 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;

- €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.

Sublicensing Payments 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.

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. Payments made to UPMC were €0 during the year ended December 31, 2019 and €200 during the year ended December 31, 2018.

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 Sci-B-Vac. 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 Sci-B-Vac 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 Sci-B-Vac manufactured at the modernized facility. We increased the capacity of our manufacturing facility to be able to supply commercial quantities of Sci-B-Vac upon FDA, EMA and/or Health Canada approval as well as supply clinical materials of VBI-2601 (BRII-179).

The Canadian research site benefits from its location in Canada's National Capital Region, providing us with access to world-class research facilities at reasonable rates. This helps keep the unit cost of doing research lower compared to other locations in Canada or the United States. VBI Cda's active research collaboration with the Canadian federal government's National Research Council ("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.

Sales and Marketing

We maintain a business development function responsible for inbound and outbound licensing of our IP portfolio. We do not have a traditional sales and marketing function and distribute Sci-B-Vac through a network of distributors. We have an active named-patient program to supply Sci-B-Vac to patients in a few countries where Sci-B-Vac has not yet been approved via partnership with local distributors. Additionally, internal work is underway to prepare for the potential commercial launch of Sci-B-Vac in the United States, Europe, and Canada subject to receiving the applicable regulatory approvals.

Customers

Our customers for Sci-B-Vac vaccines 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 Innovations 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 Sci-B-Vac 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., GSK, Merck & Co ("Merck"), Janssen Pharmaceutical, Inc ("Janssen"), Mitsubishi Tanabe Pharma Corporation, Takeda Pharmaceutical Company Limited and Pfizer, Inc.; mid-size pharmaceutical companies and emerging biotechnology companies including Dynavax Technologies Corporation ("Dynavax"), Moderna, Inc., 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 hepatitis B vaccine space, we have several key competitors currently commercializing monovalent hepatitis B vaccines, including: GSK, the manufacturer of Engerix-B, Merck, the manufacturer of Recombivax HB, and Dynavax, the manufacturer of Heplisav-B. While Engerix-B and Recombivax HB are approved globally, Heplisav-B is currently only approved in the United States.

Within the therapeutic hepatitis B space, we face both competition from and potential collaboration with other developers of innovative hepatitis B therapeutics designed to achieve a hepatitis B functional cure either as a monotherapy or 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 hepatitis B, including: VIR Biotechnology Inc., Arbutus Biopharma Corp, Dicerna Pharmaceuticals Inc, and Assembly Biosciences, Inc. It is not yet known which mode of action, or combinations thereof, will lead to a hepatitis B 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 Phase II 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 CMV vaccine space, we have several key competitors, some of whom are further advanced with their CMV vaccine development. Among these, Merck's replication-defective CMV vaccine entered Phase II testing in 2019 and Moderna Inc's mRNA-based 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 currently rely on a single source for our supply of vials and certain raw materials required for the manufacturing of Sci-B-Vac. 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. Any interruption in the supply of these materials would disrupt our ability to manufacture Sci-B-Vac 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 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 the completed Sci-B-Vac Global Phase III clinical 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 rely on a number of contractors to provide services to characterize and release Sci-B-Vac for Israel and other markets. 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 Sci-B-Vac.

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 claims remain valid in a given jurisdiction. This patent portfolio has claims that are expected to remain valid 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 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. There can be no assurance that any such patent applications will be granted or, if granted, be enforceable, and they 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-funded industrial research grants. The NRC developed a proprietary cell line (HEK-293-NRC) that we are using for production of our eVLP-based CMV vaccine candidate. 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 the CMV vaccine candidate program. 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.

- 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. For example, Catalent Biologics, previous Paragon Bioservices, has manufactured clinical batches of our CMV vaccine candidate pursuant to the terms of a GMP-Manufacturing Services Agreement (the "Services Agreement") dated September 26, 2014. In addition, pursuant to the Services Agreement, Catalent Biologics, previous Paragon Bioservices, has manufactured clinical quantities of our GBM vaccine immunotherapeutic candidate. The term of the Services Agreement is indefinite, although either party may terminate the Services Agreement upon written notice to the other party. 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 preclinical 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 have agreed to collaborate on the development of a protein based immunotherapeutic candidate for treatment of hepatitis B 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 hepatitis B infection.

- On September 10, 2019, we entered into the Collaboration Agreement with GSK pursuant to which we will investigate the use of GSK's proprietary $AS01_B$ adjuvant in our ongoing Phase I/IIa study of VBI-1901. As a result of the Collaboration Agreement, we have 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".

Employees

As of December 31, 2019, we had a total of 123 full-time and 2 part-time employees. The SciVac manufacturing site in Israel had 85 full-time employees and 1 part-time employee and the VBI Cda research site employed 31 full-time and 1 part-time employee, as of December 31, 2019. The remaining 7 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 $1,128 during the fiscal year ended December 31, 2019.

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 $26 million and $38 million for the years ended December 31, 2019 and 2018, respectively. All R&D was funded by equity financings, term loan financings, collaboration agreements or government grants. Our most significant R&D expenses to date have been related to Sci-B-Vac, and the development of our CMV candidate, our GBM vaccine immunotherapeutic candidate, and the related eVLP platform. Our R&D expenses are expected to decrease as the Phase III Sci-B-Vac clinical program is complete, however we plan to continue to invest in the Phase I/IIa GBM clinical program, further development of our hepatitis B immunotherapeutic candidate and our CMV prophylactic vaccine candidate. 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 18 active patent families consisting of 142 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, 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 include a composition of matter patent describing the CMV vaccine candidate as well as a proprietary assays used to provide high-throughput screening of anti-CMV vaccine candidate responses.

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

- 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 2039.

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 confidentiality information.

Trademarks

We use the Sci-B-Vac trademarks in connection with our hepatitis B virus vaccine product. 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. New products must go through extensive preclinical and clinical development prior to product launch. This process can take more than ten years from candidate identification to licensure/marketing approval by health authorities worldwide. Despite efforts to harmonize regulatory requirements in different jurisdictions, there exists a divergence of legal and regulatory requirements in different countries and territories. Delays in regulatory approval to move from one stage of development to another can potentially cause us significant delays and can affect our market capitalization.

United States, Europe and Canada Regulatory Agencies

Before any of our products can be marketed and sold in the United States, Europe or Canada, they must receive approval from the relevant regulatory agencies, including the FDA, EMA or Health Canada, respectively. To receive regulatory approvals to market any drug or vaccine, including those we develop, the products in development must undergo rigorous preclinical 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:

- preclinical 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 BLA to the FDA, a MAA to the EMA; a NDS to Health Canada; and
- FDA approval of a BLA or a BLA supplement (for subsequent indications or other modifications, including a change in location of the manufacturing facility). EMA approval of the MAA. Health Canada approval of the NDS.

Preclinical Testing

In the United States, drug candidates are tested in animals until adequate proof of safety and efficacy is established. These preclinical 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 preclinical safety tests must be conducted in compliance with FDA and international regulations regarding good laboratory practices. The results of the preclinical 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 preclinical 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. Furthermore, an independent institutional review board for each medical center proposing to participate in the conduct of the clinical trial must review and approve the clinical protocol and patient informed consent form before commencement of the study at the respective medical center.

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 or BLA supplement 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 them 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 suppliers will be able to comply with the GMP regulations and other FDA regulatory requirements. If our present or future 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 preclinical 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.

Under the applicable EU regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all EU member states. This authorization is an MAA. The decentralized procedure provides for mutual recognition of national approval decisions.

Under this decentralized procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure.

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. For example, the procedure for obtaining marketing approval in the United Kingdom will be affected by Brexit, which took place on January 31, 2020. A transitional period is in place until December 31, 2020, during which time regulation of pharmaceuticals will be governed by EU law. However, it is not known at this time whether EU law will continue to be applied after this period, or whether a separate regulatory system will be established in the United Kingdom. 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.

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 our government relations and regulatory capabilities by leveraging consultants who have extensive experience with the regulatory 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.

Risks Related to Our Product Development

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:

- Sci-B-Vac may not be approved for sale in the United States, Europe or Canada;
- 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 Brii 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 facility 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 more clinical trials for our Sci-B-Vac than we currently expect or are conducting before granting regulatory approval, if regulatory approval is granted at all.

Our registration and commercial timelines for Sci-B-Vac depend on further discussions with the FDA and corresponding foreign regulatory agencies. They could have additional requirements and requests, beyond the ongoing Phase III studies, for additional data 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 Sci-B-Vac in the United States, Europe, Canada and other jurisdictions where Sci-B-Vac is not currently approved;
- result in significant additional costs;
- potentially diminish any competitive advantages for Sci-B-Vac;
- potentially limit the markets for Sci-B-Vac;
- 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 Sci-B-Vac 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 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, 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 biologic being studied in relation to other available therapies, including any new biologics 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 preclinical 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, including the Sci-B-Vac Phase III clinical studies. 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 Sci-B-Vac involve a relatively small patient population. Because of the small sample size, their results may not be indicative of future results.

International commercialization of Sci-B-Vac 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.

Sci-B-Vac is approved for sale in Israel. In countries where we do not currently have the required approvals (including the United States, many European countries and Canada), we will need to obtain separate approvals from the relevant regulatory, pricing and reimbursement authorities to market or sell Sci-B-Vac 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 for Sci-B-Vac or our pipeline candidates in another market, and the time required to obtain approval may differ in one market from that required to obtain approval for Sci-B-Vac or our pipeline candidates 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 currently market or sell Sci-B-Vac through collaborative relationships with foreign partners and entered into a collaborative relationship with Brii Bio for development of a hepatitis B 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 Sci-B-Vac and 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 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. Sci-B-Vac which is currently approved for sale in Israel; 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, 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 Ltd. as a defendant. In one claim, two minors, through their parents, allege among other things, defects in certain batches of Sci-B-Vac discovered in July 2015; that Sci-B-Vac was approved for use in children and infants in Israel without sufficient evidence establishing its safety; that SciVac Ltd failed to provide accurate information about Sci-B-Vac to consumers and that each child suffered side effects from the vaccine. The claim was filed together with a motion seeking approval of a class action on behalf of 428,000 children vaccinated with Sci-B-Vac in Israel since April 2011 and seeking damages in a total amount of NIS 1,879,500,000 (not in thousands) ($543.8 million). The second claim is a civil action brought by two minors and their parents against SciVac Ltd and IMoH alleging, among other things, that SciVac Ltd. marketed an experimental, defective, hazardous or harmful vaccine; that Sci-B-Vac was marketed in Israel without establishing its safety; and that Sci-B-Vac was produced and marketed in Israel without approval of a western regulatory body. The claim seeks damages for past and future losses and expenses as well as punitive damages. The motion seeking approval of a class action has been suspended until a ruling is given on the question of liability in the civil action. The preliminary hearings for the trial of the civil action began on January 15, 2020. 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-market 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, 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 Sci-B-Vac, which is currently manufactured by us, we are completely dependent on these third-party manufacturers for compliance with the requirements of United States and non-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 Sci-B-Vac 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 Sci-B-Vac 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 Sci-B-Vac for sale in the jurisdictions where it is approved for sale and for our ongoing and future clinical studies of VBI-2601 and for future clinical studies of Sci-B-Vac, if required, where we seek regulatory approval, 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 Sci-B-Vac 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 Sci-B-Vac manufactured at the modernized facility. If we are unable to promptly obtain IMoH approval, our ability to commercially sell Sci-B-Vac could be interrupted, the costs associated with our modernization project would increase, and our sales of Sci-B-Vac 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 Sci-B-Vac 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 Sci-B-Vac 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 Sci-B-Vac 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 Sci-B-Vac and VBI-2601 at our manufacturing facility. 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 drug 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, Sci-B-Vac will compete in the United States with approved hepatitis B virus vaccines marketed by GSK, Dynavax, and Merck and 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 vaccine 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.

In particular, there are significant challenges to obtaining regulatory approval for CMV vaccine candidates developed for a target market (i.e. pre-pregnant women) due to the relatively low tolerance for risk to these populations. The risk-benefit analysis undertaken by the FDA and other regulators in deciding whether or not to approve this product candidate will be high relative to other vaccines and biologic products that target less sensitive populations.

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 and commercial distribution.

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

The near and long-term viability of our pipeline candidates may depend, in part, on our ability to successfully establish new strategic collaborations with 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; 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 a sufficient number of collaborations or government relationships on acceptable terms, we may not be able to commercialize our pipeline candidates or generate sufficient revenue to fund further research and development efforts.

Even if we establish new collaborations or obtain government funding, these relationships, including our collaboration with Brii Bio, 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;
- 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 vaccine immunotherapeutic candidate VBI-1901 is administered in conjunction with two existing adjuvant therapies 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 $55 million and $64 million in 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $262 million. Our income generating activities have been from sales of our Sci-B-Vac product in 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 Sci-B-Vac regulatory submissions and pre-commercialization activities, expand our research and development, advance other pipeline candidates into and through clinical development, including our immunotherapeutic hepatitis B candidate, CMV candidate and GBM vaccine immunotherapeutic 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 Brii 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 5, 2020, 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, 2019, we had $44.2 million of cash. In order to have sufficient cash to fund our operations in the future, we will need to raise additional equity or debt capital and cannot provide any assurance that we will be successful in doing so.

Risks Related to Our Business

Adverse effects resulting from other immunotherapy drugs 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 immuno-oncology products for the treatment of cancer. If adverse effects were to result from any immunotherapy drugs or therapies being developed, manufactured and marketed by others it could be attributed to our products 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 and the future of immunotherapy for the treatment of cancer. 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 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.

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.

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.

Since taking office, President Trump has continued to support the repeal of all or portions of the Affordable Care Act. However, the current administration's relevant repeal and/or reform efforts have been 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. 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.

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. It is, thus, unlikely that these issues will be resolved before the next presidential election 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.

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 HIPAA. Among other things, 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. We could be subject to a wide range of penalties and sanctions under HIPAA, including criminal penalties if we, our affiliates, or our agents 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 applicable HIPAA requirements or other 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. If these information technology systems are subject to cybersecurity attacks, or are otherwise compromised, due to cyberattacks, human error or malfeasance, system errors or otherwise, it may adversely impact our business, disrupt our operations, or lead to the loss, theft, destruction, corruption, or compromise of our information or that of our collaborators, study subjects, or other third-party contractors, as applicable. Such information technology or security events could also lead to legal liability, regulatory investigations or enforcement actions, loss of business, negative media coverage, and reputational damage. 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).

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 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.

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.

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.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions and other public health safety measures in China and such other countries. We and Brii Bio are conducting a Phase Ib/IIa clinical study of VBI-2601 (BRII-179) at multiple study sites including South Korea, Thailand, Hong Kong SAR and China. The extent to which the coronavirus may impact our results will depend on future developments, which are highly uncertain and cannot be predicted, but enrollment of patients in our study may be delayed due to the outbreak of the coronavirus, as hospitals in South Korea, Thailand, Hong Kong SAR and China shift resources to patients affected by the disease. As a result, our expected development timeline for VBI-2601 (BRII-179) may be negatively impacted. Moreover, the coronavirus outbreak has begun to have indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that this coronavirus or any other epidemic harms the global economy generally.

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.

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, 2019, was US$1.00 = NIS 3.564 and US$1.00 = C$1.3267. 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 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 142 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.

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

Sci-B-Vac has no patent protection, and therefore, we will seek to rely on non-patent data exclusivity in the United States Biologics Price Competition and Innovation Act (the "BPCI Act") 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 BPCI Act or equivalent regulatory data exclusivity protection in other jurisdictions for our products*."

Sci-B-Vac is the only product we currently market. Failure to obtain and retain marketing exclusivity or expiration of the market exclusivity could seriously adversely affect the revenue potential for Sci-B-Vac 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 and patent applications 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 because we currently have one product manufactured, and we expect that one or more of our pipeline candidates will be manufactured, and used 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 and the countries in these regions 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 In Process Research and Development ("IPR&D") and goodwill, which may result in the need to record an impairment charge.

Our balance sheet contains approximately $60.8 million of intangible assets. For IPR&D assets, 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. 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. During the third quarter of 2019 to date, our market capitalization was below our net equity value for a substantial number of days, and we recorded an impairment charge for the year ended December 31, 2019 of $6,292 in the consolidated statement of operations and comprehensive loss.

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 BPCI Act or equivalent regulatory data exclusivity protection in other jurisdictions for our products.

The BPCI Act, 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 Sci-B-Vac 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 BPCI Act, 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.

Perceptive Credit Holdings, LP ("Perceptive Credit"), pursuant to the Amended and Restated Credit Agreement and, dated December 6, 2016 as amended (the "Amended Credit Facility"), has a security interest in all of our assets other than excluded and future projects. 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, 2019, was $15.0 million ($15.3 million including the exit fee).

In the event of a default in connection with our bankruptcy, insolvency, liquidation, or reorganization, 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 Amended Credit Facility or any of the other loan documents, a breach of covenants under the Amended Credit Facility, 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 Amended Credit Facility 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 cash 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 Amended Credit Facility also contains other customary covenants, including covenants that require us to meet specified financial ratios and financial tests and maintain a minimum cash balance of $2.5 million. 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 Amended Credit Facility, the lender made a term loan to us in aggregate amount of $15.0 million. In 2019, we made average monthly payments of interest in the amount of approximately $170. Commencing January 2020, our monthly payments include capital repayments of $200 until June 2020, when the entire amount is due. On July 17, 2018, the Amended Credit Facility was amended by the second amendment, pursuant to which we were required to make monthly interest payments plus monthly principal payments in the amount of approximately $200 per month from January 2019 until the loan matures and to extend the expiration date of certain warrants to purchase 363,771 common shares issued to Perceptive Credit with an original expiration date of July 25, 2019 to December 6, 2021. As amended by the second amendment, the term loan was set to mature on December 31, 2019. On January 31, 2019, we further amended the Amended Credit Facility by the third amendment to (i) extend the period we are 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 of certain warrants to purchase common shares issued to Perceptive Credit 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 principal amount of the term loan as of December 31, 2019, was $15.0 million ($15.3 million including the exit fee).

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. 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 December 31, 2019, our common shares traded as high as $2.20 per share and as low as $0.466 per share. The market prices of our common shares may continue to be volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- future announcements about us, our collaborators or competitors, including the results of testing, technological innovations, or new products and services;
- clinical trial results;
- depletion of cash reserves;
- additions or departures of key personnel;
- operating results that fall below expectations;
- announcements by us relating to any strategic relationship;
- sales of equity securities or issuance of additional debt;
- industry developments;
- changes in state, provincial or federal regulations affecting us and our industry;
- 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. Such broad market fluctuations may adversely affect 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, we and our shareholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common shares are a "penny stock" which will require brokers trading in our common shares to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our common shares;
- a limited amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

We have no immediate plans to pay dividends.

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

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

From time to time, certain of our shareholders may be eligible to sell all or some of their restricted common shares by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate shareholders may sell freely after six months, subject only to the current public information requirement (which disappears after one year). Of the 178,257,199 common shares outstanding as of December 31, 2019, approximately 117,781,686 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, 2019, we had outstanding options, awards, and warrants for the purchase of 9,248,529 common shares. Of this amount, options, awards and warrants for the purchase of 1,369,105 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 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 resources, 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 principal 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 are an "emerging growth company" and may elect to comply with reduced public company reporting requirements, which could make our common shares less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act. For as long as we continue to be an "emerging growth 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, 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 could be an "emerging growth company" up until December 31, 2021, although circumstances could cause us to lose that status earlier if our annual revenues exceed $1.07 billion, if we issue more than $1.0 billion in non-convertible debt in any three-year period or if the market value of our common shares held by non-affiliates exceeds $700.0 million as of any June 30th, in which case we would no longer be an "emerging growth company" as of the following December 31st. We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the price of our securities may be more volatile.

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

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

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

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

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.

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

As of December 31, 2019, approximately 33.9% of our outstanding common shares was controlled by our officers, directors, beneficial owners of 10% or more of our securities and their respective affiliates. As a result, these shareholders, if they acted together, may be able to determine or influence matters that require approval by our shareholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other shareholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a corporate transaction that other shareholders may view as beneficial.

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 sixth amendment we have extended the lease to April 30, 2020 with a base rent for the premises of $19 per month. 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 had an initial term ending on December 31, 2019 with the option to extend the term for two periods of three years each. On September 5, 2019, the sub-sublease was assigned by Iogen Corporation to 310 Hunt Club GP Inc. ("the Assignee") and the term of the sub-sub-lease was extended until December 31, 2022 with an option to extend the lease for one additional three year period. The base and additional rent for the premises is approximately $21 USD per square foot per year 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 $20.50 dollars CAD per square foot of rentable premises. VBI Cda was required to provide a security deposit in the amount of $18.80 CAD 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 $1,128 in 2019.

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, 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 actions were brought in the District Court of the central district in Israel naming our subsidiary SciVac as a defendant. In one claim, two minors, through their parents, allege among other things, defects in certain batches of Sci-B-Vac discovered in July 2015; that Sci-B-Vac was approved for use in children and infants in Israel without sufficient evidence establishing its safety; that SciVac failed to provide accurate information about Sci-B-Vac to consumers and that each child suffered side effects from the vaccine. The claim was filed together with a motion seeking approval of a class action on behalf of 428,000 children vaccinated with Sci-B-Vac in Israel from April, 2011 and seeking damages in a total amount of NIS 1,879,500,000 (not in thousands) ($543,837). The second claim is a civil action brought by two minors and their parents against SciVac and the IMoH alleging, among other things, that SciVac marketed an experimental, defective, hazardous or harmful vaccine; that Sci-B-Vac was marketed in Israel without sufficient evidence establishing its safety; and that Sci-B-Vac was produced and marketed in Israel without approval of a western regulatory body. The claim seeks damages for past and future losses and expenses as well as punitive damages.

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

The District Court 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.

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." Our common shares had traded on the Toronto Stock Exchange under the ticker symbol "VBV" from May 9, 2016, until March 23, 2018, on which date we voluntarily delisted our common shares from the Toronto Stock Exchange.

Holders

As of March 2, 2020, we had approximately 814 shareholders of record. This number does not include an indeterminate number of shareholders whose shares are held by brokers in street name.

Dividends

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

Recent Issuances of Unregistered Securities

None.

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.

Overview

We are a commercial-stage, biopharmaceutical company developing a next generation of vaccines to address unmet needs in infectious disease and immuno-oncology. We are advancing the prevention and treatment of hepatitis B, with the only trivalent hepatitis B vaccine, Sci-B-Vac®, which is approved for use and commercially available in Israel, and recently completed a pivotal Phase III program in the United States, Europe, and Canada, and with VBI-2601 (BRII-179), an immunotherapeutic candidate in development in collaboration with Brii Biosciences Limited ("Brii Bio") for a functional cure for chronic hepatitis B. Our enveloped virus-like particle ("eVLP") platform technology allows for the development of eVLP vaccines that closely mimic the target virus to elicit a potent immune response. Integrating our cytomegalovirus ("CMV") expertise with the eVLP platform technology, our lead eVLP program candidates include a glioblastoma ("GBM") vaccine immunotherapeutic candidate, VBI-1901, and a prophylactic CMV vaccine candidate, VBI-1501. We are headquartered in Cambridge, Massachusetts, with research operations in Ottawa, Canada, and manufacturing operations in Rehovot, Israel.

Product Pipeline – Lead Program Candidates

Program	Current Development Stage
Hepatitis B Portfolio:	
● Sci-B-Vac: Prophylactic hepatitis B	Phase III Complete
● VBI-2601: Therapeutic hepatitis B	Phase Ib/IIa
eVLP Platform Portfolio:	
● VBI-1901: Therapeutic CMV-Associated Cancers (GBM)	Phase I/IIa
● VBI-1501: Prophylactic CMV	Phase I Complete

A summary of these programs and recent developments follows.

Hepatitis B

Sci-B-Vac: Trivalent Prophylactic Hepatitis B Vaccine

Sci-B-Vac is a trivalent prophylactic hepatitis B vaccine, which is approved for use and commercially available in Israel, and recently completed its pivotal Phase III program in the United States, Europe, and Canada. In contrast to other commercially-available hepatitis B vaccines, which contain only one surface antigen (the S antigen) of hepatitis B, Sci-B-Vac contains all three of the hepatitis B surface antigens: the S antigen, the pre-S1 antigen, and the pre-S2 antigen. Moreover, Sci-B-Vac is distinguished from other commercially-approved hepatitis B vaccines because it is produced in mammalian cells (Chinese hamster ovary "CHO" cells) rather than in yeast. Published data demonstrate that T cell responses to the pre-S1 and pre-S2 antigens can further boost responses to the S antigen, resulting in a more immunogenic response.

Sci-B-Vac has not yet been approved for use by the United States Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") or Health Canada. The recently-completed global Phase III clinical program was designed to achieve FDA, EMA, and Health Canada market approvals for commercial sale of Sci-B-Vac in the United States, Europe, and Canada respectively. Our wholly-owned subsidiary, SciVac Ltd., in Rehovot, Israel, manufactures and sells Sci-B-Vac.

On June 17, 2019, we announced positive top-line results from the randomized, double-blind, controlled pivotal Phase III study, PROTECT, designed to evaluate the efficacy and safety of a 10µg dose of Sci-B-Vac compared with a 20µg dose of the standard-of-care vaccine, Engerix-B®. The study, which enrolled a total of 1,607 adults, of which 81% were age ≥ 45 years, met both of its co-primary endpoints: (1) non-inferiority of seroprotection rate ("SPR") of Sci-B-Vac (91.4%) vs. Engerix-B (76.5%) in all subjects age ≥ 18 years, 4 weeks after 3rd vaccination (SPR difference: 14.9%; 95% confidence interval ("CI") [11.2%, 18.5%]); and (2) superiority of SPR of Sci-B-Vac (89.4%) vs. Engerix-B (73.1%) in subjects age ≥ 45 years, 4 weeks after 3rd vaccination (SPR difference: 16.4%; 95% CI [12.2%, 20.7%]). Moreover, the SPR of Sci-B-Vac compared to Engerix-B was higher in all key subgroup analyses of adults age ≥ 18 years, including by age, gender, body mass index ("BMI"), diabetic status, and smoking status, four weeks after 3rd vaccination.

On January 9, 2020 we reported positive top-line results from CONSTANT, the second pivotal Phase III study, designed to assess lot-to-lot manufacturing consistency of Sci-B-Vac, and compare the safety and immunogenicity of Sci-B-Vac to Engerix-B. The CONSTANT Phase III study, which enrolled 2,838 adults, age 18-45 years, met both the primary and secondary endpoints. The primary endpoint of CONSTANT study was directed to the manufacturing consistency of Sci-B-Vac. For this primary endpoint, the study evaluated the vaccine immune response, as measured by geometric mean concentration ("GMC") of antibodies across three independent, consecutively-manufactured lots of Sci-B-Vac, four weeks after the third vaccination. Together with the positive safety and immunogenicity results of the PROTECT Phase III study, we expect these data to comprise the basis for the regulatory submissions in the United States, Europe, and Canada.

A secondary endpoint of the CONSTANT study demonstrated non-inferiority of SPR of Sci-B-Vac (99.3%) vs. Engerix-B (94.8%), one month after completion of the full course of vaccination (SPR difference: 4.49%; 95% CI [2.90%, 6.63%] – up from 90.4% for Sci-B-Vac and 51.6% for Engerix-B at day 168, after only two vaccinations. In addition to demonstrating non-inferiority, the SPR achieved with Sci-B-Vac compared to Engerix-B was higher after both two and three vaccinations. An exploratory analysis in CONSTANT also compared the SPR after two doses of Sci-B-Vac (90.4%) to the SPR after three doses of Engerix-B (94.8%) (SPR difference: -4.3%; 95% CI [-6.48%, -1.90%]). As per the commonly-used statistical margin of non-inferiority for hepatitis B vaccines, defined as the lower limit of the 95% CI being above -10%, this analysis demonstrated non-inferiority after two doses of Sci-B-Vac (at day 168) compared with three doses of Engerix-B (at day 196). Similarly, at these time points, preliminary data from the integrated immunogenicity analysis of both the PROTECT and CONSTANT studies in subjects age 18-45 years demonstrate a difference in SPR of -4.2%; 95% CI [-6.38%, -1.99%]. The two versus three dose comparison is not part of the regulatory approval process and will not be included in the expected indication we will seek, but we believe it contributes to the robust immunogenicity profile of Sci-B-Vac.

The safety and tolerability seen in CONSTANT and PROTECT studies were consistent with the known safety profile of Sci-B-Vac. No new safety risks were identified, and no safety signals were observed in either study cohort. The integrated safety data analysis from both the PROTECT and CONSTANT studies is underway.

The completed Phase III studies are expected to support the Biologics License Application ("BLA") to the FDA, the Marketing Authorization Application ("MAA") to the EMA and the New Drug Submission ("NDS") to Health Canada. We plan to submit applications for regulatory approvals in the United States, Europe and Canada beginning in the fourth quarter of 2020.

VBI-2601: Hepatitis B Immunotherapeutic Candidate

VBI-2601 (BRII-179) is our novel, recombinant, protein-based immunotherapeutic candidate in development for the treatment of chronic hepatitis B infection, a disease that affects more than 250 million people worldwide. Chronic hepatitis B 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 hepatitis B virus, including T-cell immunity which plays an important role in controlling hepatitis B infection.

On December 6, 2018, the Company announced that it had entered into a Collaboration and License Agreement ("License Agreement") with Brii Bio, pursuant to which, among other things, subject to terms and conditions set forth in the License Agreement, we and Brii Bio agreed to collaborate on the development of a hepatitis B recombinant protein-based immunotherapeutic candidate in China, Hong Kong, Taiwan and Macau (the "Licensed Territory"), and to conduct a Phase Ib/IIa collaboration clinical trial for the purpose of comparing VBI-2601 (BRII-179) with a novel composition developed jointly with Brii Bio.

On November 14, 2019, we announced initiation of enrollment in a Phase Ib/IIa Study of VBI-2601 (BRII-179) in patients with chronic hepatitis B infection. The Phase Ib/IIa clinical study of VBI-2601 (BRII-179) 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 is expected to enroll up to 65 patients. Initial human proof-of-concept data from the clinical study is anticipated in the second half of 2020. The study is sponsored by Brii Bio and will be conducted at multiple study sites in New Zealand, Australia, Thailand, South Korea, Hong Kong SAR, and China.

eVLP Platform

The eVLP technology enables the synthetic manufacture of an “enveloped” virus-like particle, or “eVLP”. Many viruses are “enveloped” in that they are surrounded by a lipid bilayer membrane. Such viruses display antigenic proteins on the surface of their “envelope” which can be targets for vaccine development. The ability to synthetically manufacture an “enveloped” virus-like particle is different from previously developed VLP technologies, which did not include the lipid bilayer membrane, and thus these technologies were unable to express antigenic proteins within an “envelope” as they occur in nature.

VBI-1901: Cancer Vaccine Immunotherapeutic Candidate

Our GBM brain cancer vaccine immunotherapeutic program, VBI-1901, targets CMV proteins present in GBM tumor cells. CMV is associated with a number of other solid tumors in addition to GBM, including breast cancer and pediatric medulloblastoma. We initiated dosing in a multi-center Phase I/IIa clinical study evaluating VBI-1901, in combination with granulocyte-macrophage colony stimulating factor (“GM-CSF”), in patients with recurrent GBM in January 2018. Enrollment in Part A of the study was completed in December 2018. In April 2019, the independent data safety monitoring board completed reviews of all safety data from our fully-enrolled Part A portion of the Phase I/IIa trial in recurrent GBM subjects, which included 6 subjects in each of 3 different dose cohorts. The data safety monitoring board unanimously recommended the continuation of the study without modification and had no safety concerns about any of the 3 dose levels of VBI-1901. On April 23, 2019, we announced that, based on safety and immunogenicity data, the highest dose tested in Part A of the ongoing Phase I/IIa study in recurrent GBM patients, 10µg, was selected as the optimal dose level to test in Part B of the study. Where Part A was designed as a dose-escalation phase to assess safety, tolerability, and to define the optimal dose level of VBI-1901, Part B is a subsequent extension phase of the optimal dose level defined in Part A.

On September 10, 2019, we entered into a Clinical Collaboration Agreement (“Collaboration Agreement”) with GlaxoSmithKline Biologicals S.A. (“GSK”) 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 I/IIa clinical study. Part B is now a two-arm open-label study, enrolling 20 first recurrent GBM patients to receive VBI-1901 in combination with either granulocyte-macrophage colony-stimulating factor (“GM-CSF”) or $AS01_B$ as immunomodulatory adjuvants. Enrollment of the 10 patients in the VBI-1901 with GM-CSF arm was initiated at the end of July 2019. Initiation of enrollment of the 10 patients in the VBI-1901 with $AS01_B$ was announced in March 2020.

Safety, immunologic responses, and clinical and tumor responses from the VBI-1901 with GM-CSF in Part A and in the GM-CSF arm of Part B of the study were announced throughout 2019 and early 2020, respectively. VBI-1901 continues to be well-tolerated, with no vaccine-related safety signals observed. In the high-dose cohort of Part A, vaccine response correlated with tumor response, with all three vaccine responders demonstrating stable disease (“SD”) for greater than 12 weeks. Two patients in the high-dose cohort of Part A experienced a 60% reduction in the size of primary tumor – VBI-1901 also induced and expanded robust T cell responses in these two patients. For patients who were vaccines responders, the 12-month overall survival (“OS”) rate was 83% (n = 5/6), compared to 33% (n = 3/9) for vaccine non-responders. Similarly, among patients evaluable for response and survival in Part A, vaccine responders saw a 6.25-month improvement in median OS (14.0 months) compared to vaccine non-responders (7.75 months). VBI-1901 continues to be safe and well tolerated at al doses tested, with no safety signals observed.

Based on the data announced in November 2019, the early the tumor and immunologic responses seen in Part B appear similar to the responses and observed in Part A of the study. Correlations between immunologic biomarkers and tumor/clinical responses will continue to be refined throughout the duration of Part B of the study.

We expect expanded immunologic data and tumor imaging data from the VBI-1901 with GM-CSF arm in Part B of the study in the first half of 2020.

VBI-1501: Prophylactic CMV Vaccine Candidate

Another of our eVLP programs is a vaccine candidate that aims to prevent CMV infections. 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.

In May 2018, we announced positive top-line results from the randomized, placebo-controlled Phase I study of VBI-1501. The final Phase I study results demonstrated that VBI-1501 was safe and well-tolerated at all doses, with and without the adjuvant alum. The highest dose of VBI-1501, 2.0µg, with alum, elicited CMV-neutralizing antibodies against fibroblast cell infection in 100% of subjects after the third vaccination, up from 81% of subjects after the second vaccination, inducing titers comparable to those observed in patients protected as a result of natural infection. Neutralizing antibodies against epithelial cell infection were also seen in 31% of subjects after the third vaccination of VBI-1501 2.0µg with alum. The data also showed the formulation of the vaccine with alum enhanced antibody titers. The highest dose of VBI-1501 tested, 2.0µg with alum, contains approximately 10-fold less antigen content than that used in several other VLP-based vaccines or in previous CMV vaccine candidates developed by other companies.

On December 20, 2018 we announced plans for a Phase II clinical study evaluating VBI-1501 following positive discussions with Health Canada. 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. The Company is currently evaluating the timing of next steps for the program.

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 vaccination efforts in immuno-oncology.

At present, our operations are focused on:

- preparing marketing authorization applications for Sci-B-Vac in the United States, Europe and Canada;
- preparing for commercialization of Sci-B-Vac in additional markets, including 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;
- developing VBI-2601 (BRII-179), our protein-based immunotherapeutic candidate for treatment of chronic hepatitis B, in collaboration with Brii Bio;
- preparation for further development of VBI-1501, our preventative CMV vaccine candidate, into the next phase of development;
- ensuring our recently modernized manufacturing facility in Rehovot, Israel obtains all required regulatory approvals;
- increasing sales of Sci-B-Vac in territories where it is currently registered or available on a named-patient basis;
- 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 Sci-B-Vac product in markets where it is approved or 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 our planned clinical, regulatory, R&D, sales and manufacturing activities with respect to the advancement of our Sci-B-Vac and new pipeline candidates. As of December 31, 2019, VBI had an accumulated deficit of approximately $262.4 million and stockholders' equity of approximately $88.3 million. Our ability to maintain our status as an operating company and to realize our investment in our In-Process Research and Development ("IPR&D") assets is dependent upon obtaining adequate cash to finance our clinical development, manufacturing, our administrative overhead and our research and development activities, and ultimately to profitably monetize our IPR&D. We plan to finance future operations with existing cash reserves. We expect that we will need to secure additional financing to finance our business plans, which may be a combination of proceeds from the issuance of equity securities, the issuance of additional debt, structured asset financings and revenues from potential business development transactions, if any. There is no assurance the Company will manage to obtain these sources of financing, if required. These factors raise substantial doubt about the Company's 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 $54.8 million for the year ended December 31, 2019 and we expect to continue to incur losses in future periods. We anticipate that we will continue to incur 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 marketing authorization applications for Sci-B-Vac in the United States, Europe and Canada;
- preparing for commercialization and commercialization of Sci-B-Vac in additional markets, including 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 hepatitis B immunotherapeutic candidate, and VBI-1501, our prophylactic CMV vaccine candidate;
- manufacturing, obtaining and maintaining required regulatory approvals at our recently modernized manufacturing facility in Rehovot, Israel;
- maintaining, expanding and protecting our intellectual property portfolio;
- hiring additional clinical, manufacturing, and scientific personnel or contractors; and
- 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 Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Sarbanes-Oxley Act and the rules and regulations of the NASDAQ Capital Market and the Canadian securities regulators.

Amended Credit Facility

In 2016, the Company through VBI DE assumed a term loan facility with Perceptive Credit Holdings, LP, a related party, (the "Lender") in the amount of $6,000 (the "Facility"). On December 6, 2016, the Company amended the Facility (the "Amended Credit Facility") and raised the Lender's commitment amount to $13,200, which was combined with the remaining balance from the Facility of $1,800. On July 17, 2018, the Company amended the Amended Credit Facility by the Second Amendment to extend the period the Company is required to pay only the interest on the loan from May 31, 2018 to December 31, 2018 and to extend the expiration date of certain warrants to purchase 363,771 common shares issued to the Lender with an original issue date of July 25, 2014, from 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 we further amended the Amended Credit Facility by the Third Amendment to i) extend the period we are required to pay only the interest on the loan from December 31, 2018 to January 31, 2020; ii) to extend the maturity date of the term loan from December 31, 2019 to June 30, 2020 and iii) reduce the exercise price of certain warrants to purchase common shares issued to the Lender 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.

Research and Development Services

Pursuant to an agreement with the Israel Innovation Authority (formerly the Office of the Chief Scientist of Israel), the Company is 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 GMP quality level suitable for toxicological studies in animals and clinical studies (Phase I & II) in humans. Service activities include analytics/bio analytics methods for development and process development of therapeutic proteins starting with a candidate clone through the upstream, purification, formulation and filling processes and manufacturing for Phase I & II clinical trials.

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, 2019, the Company provided services to biotechnology companies including analytical development, upstream development process, protein purification and formulation and filling for Phase I clinical studies.

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 Increase 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 IMoH occurred in December of 2019. We received our certificate of Good Manufacturing Practice ("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 Sci-B-Vac manufactured at the modernized facility. We increased the capacity of our manufacturing facility to be able to supply commercial quantities of Sci-B-Vac upon FDA, and/or EMA and/or Health Canada approval and to supply clinical materials 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 under the Ferring License Agreement and the license from the L'Universite Pierre et Marie Curie ("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.

NASDAQ Minimum Bid Price Requirement

As previously reported, on August 14, 2019, we received a letter from the Listing Qualifications Department of the Nasdaq Stock Market ("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). The letter also indicated that we would be provided with a compliance period of 180 calendar days, or until February 10, 2020 (the "Compliance Period"), in which to regain compliance pursuant to NASDAQ Listing Rule 5810(c)(3)(A). In order to regain compliance with NASDAQ's minimum bid price requirement, our common shares were required to maintain a minimum closing bid price of $1.00 for at least ten consecutive business days during the Compliance Period. 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.

Financial Overview

Overall Performance

The Company had net losses of approximately $54.8 million and $63.6 million for the years ended December 31, 2019, and 2018, respectively. The Company has an accumulated deficit of $262.4 million as December 31, 2019. The Company had $44.2 million of cash at December 31, 2019 and net working capital of approximately $17.2 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 the Sci-B-Vac 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 general and administrative expenses in the year ended December 31, 2019.

Research and Development Expenses

R&D expenses consist primarily of costs incurred for the development of Sci-B-Vac, VBI-1901, our GBM vaccine immunotherapeutic candidate, and VBI-1501, our CMV candidate 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 contract manufacturing organizations or CROs 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

General and administration expenses ("G&A") consist principally of salaries and related costs for executive and other administrative personnel and consultants, including stock-based compensation, and travel expenses. Other G&A expenses include professional fees for legal, patent protection, consulting and accounting services, travel and conference fees, including board, rent, maintenance of facilities, depreciation, office supplies and expenses, insurance and other general expenses. G&A expenses are expensed when incurred.

We expect that our G&A expenses will increase in the future as a result of adding employees and scaling our operations commensurate with advancing clinical candidates 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. See Note 6 of the Notes to the Consolidated Financial Statements.

Interest Income

Interest income consists principally of interest income earned on cash balances.

Interest Expense

Interest expense is associated with our credit facility as discussed in Note 9 of the Notes to the Consolidated Financial Statements.

Results of Operations

Year Ended December 31, 2019 Compared to the Year Ended December 31, 2018

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

	Years ended December 31			
	2019	**2018**	**Change $**	**Change %**
Revenues	**$ 2,221**	**$ 3,355**	**$ (1,134)**	**(34)%**
Expenses:				
Cost of revenues	7,904	4,509	3,395	75%
Research and development	26,332	38,467	(12,135)	(32)%
General and administration	14,092	20,509	(6,417)	(31)%
Impairment charges	6,292	278	6,014	2,163%
Total operating expenses	54,620	63,763	(9,143)	(14)%
Loss from operations	(52,399)	(60,408)	8,009	(13)%
Interest expenses, net of interest income	(2,196)	(2,632)	436	(17)%
Foreign exchange loss	(218)	(560)	342	(61)%
Loss before income taxes	(54,813)	(63,600)	8,787	(14)%
Income tax expense	-	-	-	-%
NET LOSS	$ (54,813)	$ (63,600)	$ 8,787	(14)%

Revenues

Revenue composition

	2019	2018
License revenue	$ -	$ 2,637
Product revenue	536	604
R&D Service revenue	1,685	114
	$ 2,221	$ 3,355

Revenue for the year ended December 31, 2019 was $2,221 as compared to $3,355 for the year ended December 31, 2018. The revenue decreased by $1,134 or 34%, as a result of the license revenue earned as part of the License Agreement with Brii Bio in the year ended December 31, 2018 with no similar transaction in the year ended December 31, 2019, offset by increased R&D services revenue as part of the License Agreement with Brii Bio for the year ended December 31, 2019. The decrease in revenue was also due to decreased product sales in Europe in the year ended December 31, 2019 due to reduced named-patient sales.

Revenue by Geographic Region

	Years ended December 31			
	2019	**2018**	**$ Change**	**% Change**
Revenue in Israel	$ 455	$ 435	$ 20	5%
Revenue in China/Hong Kong	1,635	2,667	(1,032)	(39)%
Revenue in Europe	131	253	(122)	(48)%
Total Revenue	**$ 2,221**	**$ 3,355**	**$ (1,134)**	**(34)%**

Cost of Revenues

Cost of revenues for the year ended December 31, 2019 was $7,904 as compared to $4,509 for the year ended December 31, 2018. The increase in the cost of revenues of $3,395, or 75%, was due to cost of revenue related to the License Agreement with Brii Bio during the year ended December 31, 2019 of $1,141, which did not occur during the year ended December 31, 2018; the net increase related to the reclassification of certain costs of revenues to G&A expenses during the year ended December 31, 2018, which were not as significant in the year ended December 31, 2019 of $372; and the re-commencement of manufacturing subsequent to the temporary closure of our manufacturing facility in Rehovot, Israel which occurred in the second quarter of 2019.

Research and Development Expenses

R&D expenses for the year ended December 31, 2019 were $26,332 as compared to $38,467 for the year ended December 31, 2018. The decrease in R&D expenses of $12,135, or 32%, was primarily due to a decrease in the costs related to the Sci-B-Vac Phase III clinical studies and our GBM vaccine immunotherapeutic candidate clinical study. With regard to the Sci-B-Vac clinical studies, we announced top-line results for the Sci-B-Vac CONSTANT study in January 2020 and completed the Sci-B-Vac PROTECT study during the second quarter of 2019, as compared to the year ended December 31, 2018, during which period both studies were ongoing. For the GBM vaccine immunotherapeutic, there were fewer patients on trial for the year ended December 31, 2019 compared to year ended December 31, 2018 as only the high dose cohort of Part A of the Phase I/IIa study was ongoing and Part B of the Phase I/IIa study

commenced in July 2019, as compared to year ended December 31, 2018 during which period both low and medium dose cohorts of Part A of the Phase I/IIa study were ongoing. This is offset by increased expenses related to increased manufacturing associated with our vaccine candidates during the year ended December 31, 2019 compared to the year ended December 31, 2018.

General and Administration

G&A expenses for the year ended December 31, 2019 were $14,092 as compared to $20,509 for the year ended December 31, 2018. The G&A expense decrease of $6,417, or 31%, was primarily due to a $6 million payment made to re-obtain distribution rights in Asia during the year ended December 31, 2018 with no similar payment made during the year ended December 31, 2019. Other variances include decreased administrative expenses and the allocation to G&A expenses of certain costs of revenues related to the temporary facility closure, as discussed above in “Cost of Revenues”.

Impairment Charges

Impairment charges for the year ended December 31, 2019 were $6,292 as compared to $278 for the year ended December 31, 2018. There was an impairment charge for the year ended December 31, 2019 related to goodwill of $6,292 as compared to the impairment charge on property and equipment of $278 for the year ended December 31, 2018.

Net Loss from Operations

Net loss from operations for the year ended December 31, 2019 was $52,399 as compared to $60,408 for the year ended December 31, 2018. The $8,009 decrease in the net loss from operations resulted from the increased cost of revenues and impairment charges offset by decreased R&D expenses and G&A expenses as discussed above.

Interest Expense, Net of Interest Income

Interest expense, net of interest income, decreased by $436 as a result of decreased amortization of the debt discount as a result of the debt extension from December 31, 2019 to June 30, 2020 offset by increased interest income earned on cash balances during the year ended December 31, 2019, compared to interest earned during the year ended December 31, 2018.

Foreign Exchange Loss

Foreign exchange loss for the year ended December 31, 2019 was $218 compared to a foreign exchange loss of $560 for the year ended December 31, 2018. 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, 2018 and for the year ended December 31, 2019.

Net Loss

The net loss decreased by $8,787, or 14%, from $63,600 for the year ended December 31, 2018 to $54,813 for the year ended December 31, 2019. 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			
	2019	2018	$ Change	% Change
Cash	$ 44,213	$ 59,270	$ (15,057)	(25)%
Current Assets	46,963	61,731	(14,768)	(24)%
Current Liabilities	29,757	23,377	6,380	27%
Working Capital	17,206	38,354	(21,148)	(55)%
Accumulated Deficit	(262,388)	(207,575)	(54,813)	26%

As of December 31, 2019, we had cash of $44,213 as compared to $59,270 as of December 31, 2018. As of December 31, 2019, the Company had working capital of $17,206 as compared to working capital of $38,354 at December 31, 2018. Working capital is calculated by subtracting current liabilities from current assets.

We expect that we will need to secure additional financing in the future to carry out all of our planned clinical, regulatory, R&D, sales and manufacturing activities with respect to the advancement of our Sci-B-Vac and new pipeline candidates. We base this belief on assumptions that are subject to change, and we may be required to use our available cash resources sooner than we currently expect. The Company expects to re-finance the current term loan obligations and secure additional funds in order to continue its ongoing development programs. The additional funds may be a combination of proceeds from the issuance of equity securities, the issuance of additional debt, structured asset financings or revenues from potential business development transactions, and may require that additional warrants be issued. To date, the Company has been able to obtain financing as and when it was needed; however, there is no assurance that financing will be available in the future, or if it is, that it will be available at acceptable terms.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern; however, the above conditions raise substantial doubt about the Company’s 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 the Company be unable to continue as a going concern. The Company’s 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 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.

On December 17, 2018, we closed an underwritten public offering of an aggregate of 30,665,304 common shares at a price of $1.40 per share for total gross proceeds of $42.9 million. The Company incurred $3.1 million of issuance costs related to the offering resulting in net cash proceeds of $39.8 million.

On December 4, 2018, we entered into the License Agreement with Brii Bio, whereby we received a total upfront payment of $11 million to collaborate on the development of a hepatitis B recombinant protein based immunotherapeutic in China, Hong Kong, Taiwan and Macau and to conduct a Phase II collaboration clinical trial. The License Agreement specified an allocation of $7 million of this amount as an equity investment in exchange for 2,295,082 common shares. The License Agreement set forth a price of $3.05 per share which was at a premium to the closing market price of $1.58 on the day of issuance, resulting in actual allocation of the fair value of the 2,295,082 shares being $3.6 million. The remaining $7.4 million of the $11 million consideration received was allocated to the sale of the license and research and development services.

Our actual future capital requirements will depend on many factors, including the progress and results of our clinical trials, the duration and cost of discovery and preclinical development, laboratory testing and clinical trials for our products, the timing and outcome of regulatory review of our products, product sales outside of Israel, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the number and development requirements of other pipeline candidates that we pursue and the costs of commercialization activities, including product marketing, sales and distribution.

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 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 expect to finance our future cash needs through public or private equity offerings, debt financings or structured asset financings, or business development transactions. Although we are pursuing different opportunities, other than as disclosed in this report, we currently do not have any signed commitments for future external funding. 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 or debt or structured asset financing, grants 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 unstable economic environment in Europe, and disruptions in the United States and 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, 2019 Compared to the Year Ended December 31, 2018

Net cash flows used in Operating Activities

The Company incurred net losses of $54,813 and $63,600 in the years ended December 31, 2019 and 2018, respectively. The Company used $48,712 and $45,533 in cash for operating activities during the years ended December 31, 2019 and 2018, respectively. The increase in cash outflows is largely as a result of an increase in net changes in working capital items, specifically accounts payable, other current liabilities 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, 2019 consisted primarily of the purchase of property and equipment in SciVac as part of the modernization and capacity increase of the manufacturing facility. Our net cash used in investing activities for the year ended December 31, 2019 consisted of purchases of equipment of $3,673 compared to purchases of equipment of $5,993 for the year ended December 31, 2018.

Net cash flows provided by Financing Activities

Cash flows provided by financing activities decreased by $6,202, from $43,617 for the year ended December 31, 2018 to $37,415 for the year ended December 31, 2019. In 2019, the Company closed an underwritten public offering for gross proceeds of $40,250 offset by $2,835 of share issuance costs. During the year ended December 31, 2018 the Company received $46,558 from the proceeds from the issuance of common shares for cash offset by $3,006 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, 2019, the Company had net operating loss carryovers ("NOL's") aggregating approximately $218.9 million. The NOL's are available to reduce taxable income of future years expire as follows:

	United States	Canada	Israel	**Total**
2024	$ -	$ 464	$ -	$ 464
2025	-	1,445	-	1,445
2026	10	3,644	-	3,654
2027	446	4,223	-	4,669
2028	718	1,635	-	2,353
2029	672	3,062	-	3,734
2030	2,556	991	-	3,547
2031	3,617	1,226	-	4,843
2032	2,962	-	-	2,962
2033	3,126	1,432	-	4,558
2034	5,626	5,364	-	10,990
2035	4,661	1,613	-	6,274
2036	5,323	8,557	-	13,880
2037	6,017	9,617	-	15,634
2038	-	2,389	-	2,389
2039	-	6,599	-	6,599
No expiration	14,101	-	116,840	130,941
Total losses	**$ 49,835**	**$ 52,261**	**$ 116,840**	**$ 218,936**

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, 2019, 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, 2019, 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

Our intangible assets determined to have indefinite useful lives including In-Process Research and Development ("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 Company's 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, 2019. The fair value of the IPR&D assets included in the impairment test was determined using the income approach method and is considered Level 3 in the fair value hierarchy. Some of the more significant estimates and assumptions inherent in the estimate of the fair value of IPR&D assets include the amount and timing of costs to develop the IPR&D into viable products, the amount and timing of future cash inflows, the discount rate and the probability of technical and regulatory success applied to the cash flows. The discount rate used was 12.5% 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. The Company recorded an impairment of goodwill of $4,549 as a result of its annual impairment test on August 31, 2019. The Company considered the decline in its stock price as of September 30, 2019 to be a triggering event for an interim goodwill impairment test, which resulted in an additional impairment of $1,743. The total impairment of goodwill recorded during the year ended December 31, 2019 was $6,292 and is included in impairment charges in the accompanying 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.

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.

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

SciVac entered into a services agreement with OPKO Biologics Ltd. (“OPKO Bio”), a wholly-owned subsidiary of OPKO Health, Inc., a related party shareholder of the Company, dated as of March 15, 2015 as amended on January 25, 2016, pursuant to which SciVac agreed to provide certain aseptic process filling services to OPKO Bio. For the years ended December 31, 2019 and 2018 revenue recognized amounted to $0 and $0, respectively. Effective October 17, 2018, OPKO Bio is no longer a related party.

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 $53, repayable over 3 years.

Our credit facility, pursuant to the Amended Credit Facility, as amended, with Perceptive Credit is from a lender that is affiliated with the Company’s largest shareholder and is a related party, see Note 9 of Notes to Consolidated Financial Statements.

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, 2019, and 2018, we had cash of $44.2 million and $59.3 million, respectively, which has been deposited in high interest rate bank accounts. Our cash holdings are in accordance with our investment policy approved by our board of directors, which specifies the categories, allocations and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash has significant risk of default or illiquidity.

As of December 31, 2019 and 2018 we had long-term debt outstanding of $15.3 million and $15.3 million, respectively. The debt bears interest at the greater of (a) one-month LIBOR (subject to a 5% cap) or (b) 1% plus the Applicable margin of 11%. The interest rate at December 31, 2019 and 2018 was 12.75% and 13.3125%, respectively. Our interest rate risk exposure is primarily due to LIBOR fluctuations when the rate is greater than 1%, capped to a maximum of 5%.

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, 2019, and December 31, 2018, 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, 2019, 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, 2019. 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, 2019, 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 2020 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, 2019 and 2018
- Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2019 and 2018
- Consolidated Statements of Stockholders' Equity - For the Years Ended December 31, 2019 and 2018
- Consolidated Statements of Cash Flows - For the Years Ended December 31, 2019 and 2018
- 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

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, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2019 and 2018, 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 incurred, and it anticipates it will continue to incur, significant losses and generate negative operating cash flows and as such will require significant additional funds to continue its development activities to ultimately achieve commercial launch of 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 United States 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.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
Iselin, New Jersey
March 5, 2020

VBI Vaccines Inc. and Subsidiaries

Consolidated Balance Sheets
(in thousands, except share amounts)

	December 31, 2019	December 31, 2018
CURRENT ASSETS		
Cash	**$ 44,213**	$ 59,270
Accounts receivable, net	**201**	56
Inventory, net	**1,075**	911
Prepaid expenses	**1,024**	982
Other current assets	**450**	512
Total current assets	**46,963**	61,731
NON-CURRENT ASSETS		
Other long-term assets	**620**	835
Property and equipment, net	**10,195**	8,525
Right of use assets	**1,459**	-
Intangible assets, net	**60,756**	58,249
Goodwill	**2,208**	8,265
Total non-current assets	**75,238**	75,874
TOTAL ASSETS	**$ 122,201**	$ 137,605
CURRENT LIABILITIES		
Accounts payable	**$ 1,127**	$ 6,055
Other current liabilities	**12,261**	13,847
Current portion of deferred revenues	**882**	2,375
Current portion of lease liability	**642**	-
Current portion of long-term debt, net of debt discount – related party	**14,845**	1,100
Total current liabilities	**29,757**	23,377
NON-CURRENT LIABILITIES		
Lease liability, net of current portion	**817**	-
Long-term debt, net of debt discount – related party	**-**	12,927
Liabilities for severance pay	**463**	371
Deferred revenues, net of current portion	**2,909**	2,797
Total non-current liabilities	**4,189**	16,095
COMMITMENTS AND CONTINGENCIES (NOTES 14 and 15)		
STOCKHOLDERS' EQUITY		
Common shares (unlimited authorized; no par value) (2019 issued – 178,257,199; 2018 - issued 97,343,777)	**284,965**	246,417
Additional paid-in capital	**66,430**	63,449
Accumulated other comprehensive loss	**(752)**	(4,158)
Accumulated deficit	**(262,388)**	(207,575)
Total stockholders' equity	**88,255**	98,133
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 122,201**	$ 137,605

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	
	2019	2018
Revenues	**$ 2,221**	$ 3,355
Operating expenses:		
Cost of revenues	**7,904**	4,509
Research and development	**26,332**	38,467
General and administration	**14,092**	20,509
Impairment charges	**6,292**	278
Total operating expenses	**54,620**	63,763
Loss from operations	**(52,399)**	(60,408)
Interest expense, net of interest income (including related party - see Note 9)	**(2,196)**	(2,632)
Foreign exchange loss	**(218)**	(560)
Loss before incomes taxes	**(54,813)**	(63,600)
Income tax expense	**-**	-
NET LOSS	**$ (54,813)**	$ (63,600)
Other comprehensive income (loss) - Currency translation adjustments	**3,406**	(5,223)
COMPREHENSIVE LOSS	**$ (51,407)**	$ (68,823)
Net loss per share of common shares, basic and diluted	**$ (0.46)**	$ (0.97)
Weighted-average number of common shares outstanding, basic and diluted	**119,446,377**	65,647,781

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) - Currency Translation Adjustments	Accumulated Deficit	Total Stockholders' Equity
BALANCE AS OF DECEMBER 31, 2017	**64,078,781**	**$ 201,806**	**$ 60,891**	**$ 1,065**	**$ (143,975)**	**$ 119,787**
Common shares issued in financing transaction	**30,665,304**	**39,780**	-	-	-	**39,780**
Fair value of common shares issued as part of Brii Bio License Agreement	**2,295,082**	**3,626**	-	-	-	**3,626**
Warrant modification in connection with debt amendment	-	-	**386**	-	-	**386**
Stock-based compensation	**264,782**	**1,140**	**2,172**	-	-	**3,312**
Common shares issued on exercise of stock options	**39,828**	**65**	-	-	-	**65**
Net loss	-	-	-	-	**(63,600)**	**(63,600)**
Currency translation adjustments	-	-	-	**(5,223)**	-	**(5,223)**
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**

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	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	**$ (54,813)**	**$ (63,600)**
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	**1,204**	**542**
Impairment charges	**6,292**	**278**
Stock-based compensation	**3,935**	**3,312**
Amortization of debt discount	**998**	**1,274**
Inventory reserve	**300**	**189**
Net change in operating working capital items:		
Change in accounts receivable	**(136)**	**79**
Change in inventory	**(385)**	**(378)**
Change in prepaid expenses	**326**	**(285)**
Change in other current assets	**57**	**213**
Change in other long-term assets	**6**	**(31)**
Change in operating right of use assets	**982**	**-**
Change in accounts payable	**(5,175)**	**3,804**
Change in deferred revenues	**(1,694)**	**4,924**
Change in other current liabilities	**374**	**4,146**
Payments made on operating lease liabilities	**(983)**	**-**
Net cash flows used in operating activities	**(48,712)**	**(45,533)**
INVESTING ACTIVITIES		
Purchase of property and equipment	**(3,673)**	**(5,993)**
Net cash flows used in investing activities	**(3,673)**	**(5,993)**
FINANCING ACTIVITIES		
Proceeds from issuance of common shares for cash	**40,250**	**46,558**
Share issuance costs	**(2,835)**	**(3,006)**
Proceeds from issuance of common shares for cash, upon exercise of stock options	**-**	**65**
Net cash flows provided by financing activities	**37,415**	**43,617**
Effect of exchange rates on cash	**(87)**	**(515)**
CHANGE IN CASH FOR THE YEAR	**$ (15,057)**	**$ (8,424)**
CASH, BEGINNING OF YEAR	**$ 59,270**	**$ 67,694**
CASH, END OF YEAR	**$ 44,213**	**$ 59,270**
Supplementary information:		
Interest paid	**$ 2,033**	**$ 1,980**
Non-cash investing and financing:		
Warrant modification in connection with debt amendment	**$ 179**	**$ 386**
Capital expenditures included in accounts payable and other current liabilities	**33**	**1,552**
Share issuance costs included in accounts payable and other current liabilities	**-**	**(146)**

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") and SciVac Hong Kong Limited ("SciVac HK") 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 is a commercial-stage, biopharmaceutical company developing a next generation of vaccines to address unmet needs in infectious disease and immuno-oncology. We are advancing the prevention and treatment of hepatitis B, with the only trivalent hepatitis B vaccine, Sci-B-Vac®, which is approved for use and commercially available in Israel, and recently completed a pivotal Phase III program in the United States, Europe, and Canada, and with VBI-2601 (BRII-179), an immunotherapeutic candidate in development in collaboration with Brii Biosciences Limited ("Brii Bio") for a functional cure for chronic hepatitis B. Our enveloped virus-like particle ("eVLP") platform technology allows for the development of eVLP vaccines that closely mimic the target virus to elicit a potent immune response. Integrating our cytomegalovirus ("CMV") expertise with the eVLP platform technology, our lead eVLP program candidates include a glioblastoma ("GBM") vaccine immunotherapeutic candidate, VBI-1901, and a prophylactic CMV vaccine candidate, VBI-1501.

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 $262,388 as of December 31, 2019 and cash outflows from operating activities of $48,712, for the year-ended December 31, 2019.

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 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.

On May 15, 2017, the Company entered into an equity distribution agreement (the "Distribution Agreement") with a registered broker-dealer, as sales agent (the "Sales Agent"), pursuant to which the Company may offer and sell, from time to time, through the Sales Agent its common shares having an aggregate offering price of up to $30 million. The Company is not obligated to sell any common shares under the Distribution Agreement. Subject to the terms and conditions of the Distribution Agreement, the Sales Agent will use commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations, and the rules of the NASDAQ Capital Market to sell shares from time to time based upon the Company's instructions, including any price, time or size limits specified by the Company. The Company will pay the Sales Agent a commission of 3.0% of the aggregate gross proceeds from each sale of common shares occurring pursuant to the Distribution Agreement, if any. The Distribution Agreement may be terminated by the Sales Agent or the Company at any time upon ten days' notice to the other party, or by the Sales Agent at any time in certain circumstances. To-date, no amounts have been raised under the Distribution Agreement and there are no assurances as to how much, if any, funds will be raised under the Distribution Agreement.

On December 4, 2018, the Company entered into a license and collaboration agreement ("License Agreement") with Brii Bio, whereby we received a total upfront payment of $11,000 to collaborate on the development of a hepatitis B recombinant protein based immunotherapeutic in China, Hong Kong, Taiwan and Macau and to conduct a Phase II collaboration clinical trial. In connection with the License Agreement, we entered into a stock purchase agreement through which we issued to Brii Bio 2,295,082 common shares. See Note 11 and 12 for further discussion.

On December 17, 2018, the Company closed an underwritten public offering of 30,665,304 common shares at a price of $1.40 per share for total gross proceeds of $42,932. The Company incurred $3,152 of share issuance costs related to the offering resulting in net cash proceeds of $39,780.

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 related to the offering resulting in net cash proceeds of $37,415.

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 and VBI Cda.

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

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 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, 2019 and 2018, 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 an quarterly basis, the Company evaluates the condition and age of inventories and makes provisions for slow moving inventories accordingly.

Deferred financing costs

Offering costs related to debt and equity financing consist of direct incremental external expenses. The Company presents debt issuance costs related to a recognized long-term debt in the consolidated balance sheet as a direct reduction of the carrying value of the long-term debt, consistent with the accounting treatment of debt discounts. The amortization of debt issuance costs follows the effective interest rate method (see Note 9). Offering costs related to registration statements and the initiation of the Distribution Agreement are recorded as an asset and are reclassified to equity upon the successful selling of common shares. The costs are reviewed for impairment and will be recorded to expense if and when the Company determines that future equity offerings are not probable of occurring. At December 31, 2019 and 2018, the Company had $169 and $154 of deferred offering costs, respectively, recorded as an other current asset.

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 recorded an impairment of $278 during the year ended December 31, 2018 related to certain leasehold improvements and manufacturing equipment no longer being utilized in the business as a result of the modernization and capacity increase of our manufacturing facility. The amount represented the remaining net book value of these assets. The impairment is included in impairment charges in the accompanying consolidated statements of operations and comprehensive loss. The Company did not record an impairment for long-lived assets during the year ended December 31, 2019.

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, 2019. The fair value of the IPR&D assets included in the impairment test was determined using the income approach method and is considered Level 3 in the fair value hierarchy. Some of the more significant estimates and assumptions inherent in the estimate of the fair value of IPR&D assets include the amount and timing of costs to develop the IPR&D into viable products, the amount and timing of future cash inflows, the discount rate and the probability of technical and regulatory success applied to the cash flows. The discount rate used was 12.5% 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. The Company recorded an impairment of goodwill of $4,549 as a result of its annual impairment test on August 31, 2019. The Company considered the decline in its stock price as of September 30, 2019 to be a triggering event for an interim goodwill impairment test, which resulted in an additional impairment of $1,743. The total impairment of goodwill recorded during the year ended December 31, 2019 was $6,292 and is included in impairment charges in the accompanying 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 amendments to long-term debt as a substantial modification if the present value of the cash flows under the terms of the new debt instrument is at least 10 percent different from the present value of the remaining cash flows under the terms of the original instrument. A substantial modification shall be accounted for like an extinguishment. If the cash flow effect on a present value basis is less than 10%, the debt instruments are accounted for as a debt modification.

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.

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 operates a defined contribution retirement benefit plan for all qualifying employees with corresponding federal, and state/provincial law. 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 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 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, 2019 and 2018. If such matters were to arise, the Company would recognize interest and penalties related to income tax matters in income tax expense.

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

Fair value measurements of financial instruments

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

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

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

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

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

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

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

The fair value of our outstanding debt, including the current portion, is estimated to be approximately $15,272 and $14,975 at December 31, 2019 and 2018, 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. See also Note 3.

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. Options subject to vesting are required to be periodically remeasured over their service performance period until the measurement date, when service is completed.

3. NEW ACCOUNTING PRONOUNCEMENTS

Recently Adopted Accounting Pronouncements

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. On January 1, 2019, the Company adopted the new lease standard using the optional transition method under which comparative financial information will not be restated and continue to apply the provisions of the previous lease standard in its annual disclosures for the comparative periods. In addition, the new lease standard provides a number of optional practical expedients in transition. The Company elected the package of practical expedients. As such, the Company did not have to reassess whether expired or existing contracts are or contain a lease and did not have to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases.

The new lease standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption under which the Company will not recognize ROU assets or lease liabilities for short term leases. The Company elected the practical expedient to not separate lease and non-lease components.

On January 1, 2019, the Company recognized ROU assets and lease liabilities of $1,653 on its consolidated balance sheet.

Compensation – Stock Compensation

In June 2018, the FASB issued ASU 2018-07: Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. Our adoption of this ASU, effective January 1, 2019, did not have a material impact on our consolidated financial statements and the related footnote disclosures.

Recently Issued Accounting Standards, Not Yet Adopted

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 ("ASU 2018-15"). ASU 2018-15 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. ASU 2018-15 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. This ASU can be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company will apply this ASU prospectively and we do not anticipate that this new guidance will have a material impact on its consolidated financial statements and related disclosures going forward.

4. PROPERTY AND EQUIPMENT

	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**

	December 31, 2018		
	Cost	Accumulated Depreciation	Net Book Value
Machinery and equipment	$ 3,603	$ (1,046)	$ 2,557
Furniture and office equipment	132	(41)	91
Computer equipment and software	384	(227)	157
Leasehold improvements	6,817	(1,097)	5,720
	$ 10,936	$ (2,411)	$ 8,525

Depreciation expense for the years ended December 31, 2019, and 2018 was $1,142 and $481, respectively.

5. INVENTORY, NET

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

	2019	2018
Finished goods	**$ 58**	$ 81
Work-in-process	**237**	64
Raw materials	**780**	766
	$ 1,075	$ 911

The Company recorded a provision of approximately $300 and $189 as of December 31, 2019 and 2018, 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.

6. INTANGIBLE ASSETS AND GOODWILL

	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**

	December 31, 2018				
	Gross Carrying amount	Accumulated Amortization	Impairment Charge	Cumulative Currency Translation	Net Book Value
License	$ 669	$ (457)	$ -	$ 11	$ 223
IPR&D assets	61,500	-	(300)	(3,174)	58,026
	$ 62,169	$ (457)	$ (300)	$ (3,163)	$ 58,249

The license is held in Israel at SciVac. Amortization expenses for the years ended December 31, 2019 and 2018 amounted to $62 and $61, respectively. Amortization is expected to be approximately $63 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 from December 31, 2018 relates to currency translation adjustments which increased IPR&D assets by $2,552 for the year ended December 31, 2019. The change in carrying value from December 31, 2017 to December 31, 2018 relates to currency translation adjustments which decreased IPR&D assets by $4,976.

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

	December 31, 2018			
	Gross Carrying Amount	Cumulative Impairment Charge	Cumulative Currency Translation	Net Book Value
Goodwill	$ 8,714	$ -	$ (449)	$ 8,265

The goodwill is in VBI Cda and the change in carrying value from December 31, 2018 relates to currency translation adjustments which increased goodwill by $235 for the year ended December 31, 2019, excluding the effect of the impairment charge of $6,292. The change in carrying value from December 31, 2017 to December 31, 2018 relates to currency translation adjustments which decreased goodwill by $709.

7. OTHER CURRENT LIABILITIES

Other current liabilities consisted of the following:

	2019	2018
Accrued research and development expenses (including clinical trial expenses)	**$ 9,247**	$ 9,763
Payroll and employee-related costs	**2,184**	2,294
Other current liabilities	**830**	1,790
	$ 12,261	$ 13,847

8. 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 11, Stockholders' Equity and Additional Paid-in Capital.

The following potentially dilutive securities outstanding at December 31, 2019 and 2018 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	2019	2018
Warrants	**2,618,824**	2,618,824
Stock options and unvested stock awards	**6,629,705**	3,748,246
	9,248,529	6,367,070

9. LONG-TERM DEBT – RELATED PARTY

	2019	2018
Long-term debt, net of debt discount of $455 ($1,274 at December 31 2018)	**$ 14,845**	$ 14,027
Less: current portion, net of debt discount of $455 ($100 at December 31, 2018)	**14,845**	1,100
	$ -	$ 12,927

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

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

On January 31, 2019, the Company further amended the Amended Credit Facility (the "Third Amendment") to i) extend the period the Company is required to pay only the interest on the loan from December 31, 2018 to January 31, 2020, ii) extend the maturity of the term loan to June 30, 2020 and iii) reduce the exercise price of certain warrants to purchase common shares issued to the Lender 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 principal amount of the loan under the Amended Credit Facility, as subsequently amended, outstanding at December 31, 2019, including the $300 exit fee discussed below, is $15,300. The principal amount of the loan made under the Amended Credit Facility accrues interest at an annual rate equal to the greater of (a) one-month LIBOR (subject to a 5.00% cap) or (b) 1.00%, plus the applicable margin. The applicable margin will be 11.00%. The Company was required to only pay interest initially until May 31, 2018, which date was extended to December 31, 2018, pursuant to the Second Amendment and further extended to January 31, 2020, pursuant to the Third Amendment. The interest rate as of December 31, 2019 was 12.75%. Upon the occurrence of an Event of Default (as defined in the Amended Credit Facility), and during the continuance of an Event of Default, the applicable margin, described above, will be increased by 4.00% per annum. This term loan facility maturity date has been extended from December 6, 2019 to June 30, 2020 and includes both financial and non-financial covenants, including a minimum cash balance requirement. The Company was in compliance with these covenants as of December 31, 2019. Pursuant to the Amended Credit Facility, the Company agreed that the Lender shall designate an individual who would be appointed to the Company's board of directors (the "Board"). The Lender's designee was also a portfolio manager of the Company's largest shareholder. Effective January 2018, the Lender's designee resigned from our Board.

The Company's obligations under the Amended Credit Facility are secured on a senior basis by a lien on substantially all of the assets of the Company and its subsidiaries and are guaranteed by the Company and its subsidiaries. The Amended Credit Facility also contains customary events of default.

The total debt discount of $4,018 is being charged to interest expense using the effective interest method over the term of the debt. As of December 31, 2019, and December 31, 2018, the unamortized debt discount was $455 and $1,274, respectively.

Interest expense, net of interest income recorded for the year ended December 31, 2019 and 2018 was as follows:

	December 31	
	2019	2018
Interest expense – related party	**$ 2,033**	$ 1,980
Amortization of debt discount – related party	**998**	1,274
Interest income	**(835)**	(622)
Total interest expense, net of interest income	**$ 2,196**	$ 2,632

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

Year ending December 31,	
2020	15,300
	$ 15,300

10. 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 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, 2019 and 2018 was $263 and $218, respectively, and represents contributions payable to these plans by the Company at rates specified in the rules of the plan.

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.

Liability for severance pay

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

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

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

Included in research and development expenses for the year ended December 31, 2018 is $24 of severance payments pursuant to the aforementioned statutory or contractual obligations.

11. STOCKHOLDERS' EQUITY AND ADDITIONAL PAID-IN CAPITAL

Authorized

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

Common shares issuances

2018 common share issuances were as follows:

i. During the first half of 2018 the Company issued 39,828 common shares related to stock options that were exercised during the year.

ii. On March 7, 2018, the Company issued 135,000 stock awards pursuant to the 2016 VBI Equity Incentive Plan ("2016 Plan"). Pursuant to Israeli tax requirements, the common shares were issued to a Trustee on behalf of SciVac employees.

iii. On June 18, 2018, 25% of the stock awards granted on June 24, 2016 vested and the Company issued 129,782 shares of the Company's common shares.

iv. On December 4, 2018, the Company issued 2,295,082 common shares of the Company to Brii Bio as part of the License Agreement (see Note 1). The transaction was measured using the fair value of the Company's common shares at December 4, 2018 at a price of $1.58 for a total net proceeds of $3,626.

v. On December 17, 2018, the Company closed an underwritten public offering of 30,665,304 common shares at a price of $1.40 per share for total gross proceeds of $42,932. The Company incurred $3,152 of share issuance costs of which $3,006 were paid in cash during the year ended December 31, 2018 and $146 are included in other current liabilities as of December 31, 2018.

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.

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, 2019, there were 994,716 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, 2019, 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, 2019, 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, 2019, there were 4,955,750 options outstanding and 157,997 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 10,001,505 at December 31, 2019.

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, 2019 and 2018.

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, 2019 and 2018. All RSUs issued under the plan at December 31, 2019 and 2018 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, 2019.

Stock-based compensation expense

The table below provides information, as of December 31, 2019, 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	994,716	$ 4.00
2013 Plan	-	$ -
2014 Plan	521,242	$ 5.07
2016 Plan	5,113,747	$ 2.32
Total	6,629,705	$ 2.79

Activity related to stock options is as follows:

	Number of Stock Options	Weighted Average Exercise Price
Balance outstanding at December 31, 2017	2,351,395	$ 4.44
Granted	1,515,000	$ 3.82
Exercised	(39,828)	$ 2.50
Forfeited	(346,891)	$ 4.47
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**
Exercisable at December 31, 2019	**3,459,745**	**$ 3.45**

	Outstanding		Exercisable	
Exercise Price	Number Of Options	Weighted Average Remaining Contractual Life (Years)	Number Of Options	Weighted Average Exercise Price
$ 0.00- $ 3.49	3,964,743	8.78	1,322,364	$ 1.90
$ 3.50 - $ 4.49	1,813,366	6.63	1,443,782	$ 4.14
$ 4.50 - $ 5.49	670,711	5.31	670,711	$ 4.85
$ 5.50+	22,888	4.57	22,888	$ 8.17
	6,471,708	7.80	3,459,745	$ 3.45

The weighted average remaining contractual life of exercisable options was 6.81 years and 6.12 years at December 31, 2019 and 2018, 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, 2017 and December 31, 2017	424,379	3.99
Granted	150,000	$ 4.26
Vested	(237,669)	$ 4.01
Forfeited	(68,140)	$ 3.89
Unvested shares outstanding at 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**

The intrinsic value of outstanding options at December 31, 2019 was $0 (the intrinsic value of vested options was $0 and the intrinsic value of those expected to vest was $0). The fair value of the vested RSU's was $1,153 for the year ended December 31, 2019. There were no options exercised for the year ended December 31, 2019 and the intrinsic value of exercised options was not significant for the year ended December 31, 2018.

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:

	2019	2018
Volatility	**118.62%**	114.68%
Risk free interest rate	**2.46%**	2.57%
Expected term in years	**5.78**	5.84
Expected dividend yield	**0.00%**	0.00%
Weighted average fair value per option	**$ 1.45**	$ 3.21

The volatility was based on an average of volatility rates of a pool of public pharmaceutical or biotechnology companies that are at a comparable stage of development and the Company's recent historic volatility, all calculated taking into account the expected term of the option.

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:

	2019	2018
Research and development	**$ 796**	$ 696
General and administration	**3,080**	2,556
Cost of revenue	**59**	60
Total stock-based compensation expense	**$ 3,935**	$ 3,312

There is $5,414 of unrecognized compensation from all equity awards as of December 31, 2019. This expense will be recognized over a weighted average period of 1.88 years.

The number of restricted stock awards vested during the year ended December 31, 2019 and 2018 includes no shares and 9,281 shares withheld or repurchased, respectively, by the Company on behalf of employees to satisfy $0 and $35 of tax obligations relating to the vesting of such shares, respectively.

Warrants

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 9.

During the year ended December 31, 2018, the Company extended the expiration date of certain warrants issued on July 25, 2014, as described in Note 9.

Activity related to the warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance outstanding at December 31, 2017 and 2018	2,618,824	$ 3.57
Issued	-	$ -
Balance outstanding at December 31, 2019	**2,618,824**	**$ 2.87**

12. REVENUE AND DEFERRED REVENUE

Revenue is comprised of the following:

	2019	2018
License revenue	**$ -**	$ 2,637
Product revenue	**536**	604
R&D Service revenue	**1,685**	114
	$ 2,221	$ 3,355

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. Cost of revenues for the year ended December 31, 2018 related solely to product revenue.

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, 2019:

	Total	2020	2021 and thereafter
Product revenue	$ **469**	$ -	$ 469
R&D Service revenue	**3,322**	882	2,440
Total	**$ 3,791**	**$** 882	**$** 2,909

The following table presents changes in the deferred revenue balance for the year ended December 31, 2019:

Balance at December 31, 2018	**$ 5,172**
Amounts received in 2019	-
Recognition of deferred revenue	**(1,649)**
Currency translation	**268**
Balance at December 31, 2019	**$ 3,791**
Short Term	**$ 882**
Long Term	**$ 2,909**

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 hepatitis B 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 hepatitis B, 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 hepatitis B in the Licensed Territory and to commercialize and the Licensed Product for the diagnosis and treatment of chronic hepatitis B 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 a $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). See Note 11. 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 transferred and Brii Bio is able to use and benefit from the license, as it was determined to be distinct. 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, 2019 R&D services related Brii Bio that remain unsatisfied are $3.1 million, out of the $3.8 million total deferred revenue.

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

Prior to us entering into the License Agreement, the Company paid $6 million to terminate a distribution agreement with a third party who previously held certain distribution rights to certain Asian markets. This amount is included in general and administrative expenses for the year ended December 31, 2018.

13. COLLABORATIVE ARRANGEMENTS

GlaxoSmithKline Biologicals S.A. ("GSK")

On September 10, 2019, we 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; year to date costs have been de minimis.

Brii Biosciences Limited

On December 4, 2018, we entered into a License Agreement with Brii Bio, as described in Note 12.

14. INCOME TAXES

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

	2019	2018
United States	**$ (9,079)**	$ (4,757)
Canada	**(15,537)**	(8,177)
Israel	**(30,197)**	(50,666)
Total	**$ (54,813)**	$ (63,600)

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:

	2019	2018
Loss before income taxes	**$ (54,813)**	$ (63,600)
Canadian statutory tax rate	**26.50%**	26.50%
Expected benefit of income tax	**14,525**	16,854
Research and development tax credits	**300**	256
Change in valuation allowance	**(10,873)**	(14,685)
Difference between Canadian and foreign tax rates	**(982)**	(1,708)
Impairment of Goodwill	**(1,667)**	-
Non – deductible portion of capital losses	**(217)**	-
Other	**(44)**	(125)
Change in tax rates	**-**	59
Stock based compensation	**(1,042)**	(651)
Income tax expense	**$ -**	$ -

For 2019 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 statuary income rate is approximately 23%.

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

	2019	2018
Deferred tax assets (liabilities):		
Net operating losses	**$ 54,337**	$ 41,556
Research and development tax credits	**12,605**	13,350
Property and equipment	**431**	435
Reserves and other	**1,859**	1,457
Interest	**-**	858
Intangible assets	**(16,249)**	(15,546)
Net deferred tax assets	**52,983**	42,110
Less: valuation allowance	**(52,983)**	(42,110)
Net deferred tax assets (liabilities)	**$ -**	$ -

As of December 31, 2019, and 2018, the Company had United States federal net operating loss carryovers ("NOLs") of approximately $49.8 million and $39.0 million, respectively, 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, 2019. 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, 2019, and 2018, the Company also had Canadian net operating loss carryovers of approximately $52.3 million and $47.0 million, respectively available to offset future taxable income which expire beginning in 2024. As of December 31, 2019, and 2018, the Company also had Israel net operating loss carryovers of approximately $116.8 million and $80.3 million, respectively, which can be carried forward indefinitely.

At December 31, 2019 and 2018, the Company had $5.5 million and $4.9 million, respectively, of investment tax credits available to carry forward and reduce future years' Canadian income taxes which expire beginning in 2026.

As of December 31, 2019, and 2018, the Company had unclaimed research and development expenses in Canada of approximately $19.9 million and $17.2 million, respectively, which are available to offset future taxable income indefinitely.

At December 31, 2019, the Company had NOLs aggregating approximately $218.9 million. The NOLs are available to reduce taxable income of future years and expire as follows:

	United States	Canada	Israel	**Total**
2024	$ -	$ 464	$ -	$ 464
2025	-	1,445	-	1,445
2026	10	3,644	-	3,654
2027	446	4,223	-	4,669
2028	718	1,635	-	2,353
2029	672	3,062	-	3,734
2030	2,556	991	-	3,547
2031	3,617	1,226	-	4,843
2032	2,962	-	-	2,962
2033	3,126	1,432	-	4,558
2034	5,626	5,364	-	10,990
2035	4,661	1,613	-	6,274
2036	5,323	8,557	-	13,880
2037	6,017	9,617	-	15,634
2038	-	2,389	-	2,389
2039	-	6,599	-	6,599
No expiration	14,101	-	116,840	130,941
Total losses	**$ 49,835**	**$ 52,261**	**$ 116,840**	**$ 218,936**

15. 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.

Except for the Transfer Payment, which became due upon successful technology transfer to a contract manufacturing organization, the events obliging the Company to make these payments to the Sellers have not yet occurred and are not probable of occurring; consequently, no amounts are accrued in respect of these contingencies.

(b) The Company's manufactured and marketed product, Sci-B-Vac is a recombinant trivalent hepatitis B 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 $38 and $42, were recorded in cost of revenues for the year ended December 31, 2019 and 2018, respectively.

Royalty payments under the SciGen Assignment Agreement of $27 and $30 were recorded in cost of revenues for the year ended December 31, 2019 and 2018, 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 actions were brought in the District Court of the central district in Israel naming our subsidiary SciVac as a defendant. In one claim, two minors, through their parents, allege among other things, defects in certain batches of Sci-B-Vac discovered in July 2015; that Sci-B-Vac was approved for use in children and infants in Israel without sufficient evidence establishing its safety; that SciVac failed to provide accurate information about Sci-B-Vac to consumers and that each child suffered side effects from the vaccine. The claim was filed together with a motion seeking approval of a class action on behalf of 428,000 children vaccinated with Sci-B-Vac in Israel from April, 2011 and seeking damages in a total amount of NIS 1,879,500,000 (not in thousands) ($543,837). The second claim is a civil action brought by two minors and their parents against SciVac and the Israel Ministry of Health alleging, among other things, that SciVac marketed an experimental, defective, hazardous or harmful vaccine; that Sci-B-Vac was marketed in Israel without sufficient evidence establishing its safety; and that Sci-B-Vac was produced and marketed in Israel without approval of a western regulatory body. The claim seeks damages for past and future losses and expenses as well as punitive damages.

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

The District Court has accepted SciVac's motion to suspend reaching a decision on the approval of the class action pending the determination of liability under the civil action. Preliminary hearings for the trial of the civil action began on January 15, 2020.

16. 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 expires on April 30, 2020, with no option to extend. 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.

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:		
Operating lease costs:	$	1,128
Other information:		
Weighted average remaining lease term		2.4 years
Weighted average discount rate		12%

Rent expense for the year ended December 31, 2018 was $992. 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, 2019:

On January 1, 2019, initial right of use (“ROU”) assets of $1,653 was recognized as a non-cash asset addition with the adoption of the new lease standard. During the year ended December 31, 2019, the Company entered into new lease agreements and recognized a ROU asset of $504.

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

Year ending December 31

2020	**$**	**774**
2021		**699**
2022		**165**
Total	**$**	**1,638**
Effect of discounting		**(179)**
Total lease liability	**$**	**1,459**
Less: current portion		**(642)**
Long term lease liability	**$**	**817**

17. 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.

	2019	2018
Revenue in Israel	**$ 455**	$ 435
Revenue in China/Hong Kong	**1,635**	2,667
Revenue in Europe	**131**	253
Total	**$ 2,221**	$ 3,355

There was no revenue attributed to our country of domicile, Canada, for years ended December 31, 2019 and 2018.

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

For the year ended December 31, 2018, the Company had 1 customer that individually accounted for 79% of revenues.

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

	2019	2018
Property and equipment in Israel	**$ 11,062**	$ 8,396
Property and equipment in United States	**112**	52
Property and equipment Canada (country of domicile)	**480**	77
Total	**$ 11,654**	$ 8,525

18. RELATED PARTY TRANSACTIONS

SciVac entered into a services agreement with OPKO Biologics Ltd. ("OPKO Bio"), a wholly-owned subsidiary of OPKO Health, Inc., a related party shareholder of the Company, dated as of March 15, 2015 as amended on January 25, 2016, pursuant to which SciVac agreed to provide certain aseptic process filling services to OPKO Bio. For the years ended December 31, 2019 and 2018 there was no revenue recognized pursuant to such services agreement. Effective October 17, 2018, OPKO Bio is no longer a related party.

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 $53, repayable over 3 years.

See Note 9 for the Company's long-term debt with a lender that is affiliated with the Company's largest shareholder and is a related party.

19. SUBSEQUENT EVENTS

On January 22, 2020, the Company approved to grant 4,060,000 stock options and awards to existing employees and directors pursuant to the 2016 Plan. All of the granted options and awards vest on a monthly basis over 36 months and automatically expire on January 22, 2030.

EXHIBIT INDEX

Exhibit No.	Description
2.4	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+	Employment Agreement with Adam Buckley, dated July 25, 2014 (incorporated by reference to Exhibit 10.8 to VBI DE's current report on Form 8-K (SEC File No. 000-18188), filed with the SEC on July 28, 2014).
10.8	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).
10.9	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).

10.10	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).
10.11	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).
10.12	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).
10.13	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).
10.14	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).
10.15	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).
10.16+	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).
10.17+	Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, dated March 29, 2017 (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 March 30, 2017).
10.18+	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).
10.19	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).

10.20	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).
10.21	Waiver Agreement, dated as of March 14, 2017, by and among Variation Biotechnologies (US), Inc., the Guarantors party thereto, and Perceptive Credit Holdings, LP (incorporated by reference to Exhibit 10.47 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).
10.22	Waiver Agreement, dated as of May 12, 2017, by and between VBI Vaccines Inc. and Perceptive Credit Holdings, LP (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 15, 2017).
10.23	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).
10.24	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).
10.25	Equity Distribution Agreement, dated May 15, 2017, by and between the Company and Canaccord Genuity Inc. (incorporated by reference to Exhibit 1.2 to the Registration Statement on Form S-3 (SEC File No. 333-217995), filed with the SEC on May 15, 2017).
10.26	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).
10.27	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).
10.28	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).
10.29+	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).
10.30+	Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, dated February 19, 2018 (incorporated by reference to Exhibit 10.57 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on February 26, 2018).
10.31	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).
10.32	Waiver Agreement, dated February 21, 2018, by and among Variation Biotechnologies (US), Inc., the Guarantors party thereto, and Perceptive Credit Holdings, LP (incorporated by reference to Exhibit 10.59 to the current report on Form 10-K (SEC File No. 001-37769), filed with the SEC on February 26, 2018).

10.33	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)
10.34+	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)
10.35(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).
10.36	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).
10.37	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).
10.38+	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).
10.39	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).
10.40	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)
10.41	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)
10.42*+	Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective January 1, 2020
10.43*	Waiver Agreement, dated February 25, 2020, by and among Variation Biotechnologies (US), Inc., the Guarantors party thereto, and Perceptive Credit Holdings, LP
21.1	VBI Vaccines Inc. – List of Subsidiaries (Incorporated by reference to Exhibit 21.1 to the Annual Report on Form 10-K for the year ended December 31, 2018).
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.

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 5th day of March, 2020.

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 5, 2020 */s/ Jeffrey Baxter*
Jeffrey Baxter, President, Chief Executive Officer and Director (Principal Executive Officer)

Date: March 5, 2020 */s/ Christopher McNulty*
Christopher McNulty, Chief Financial Officer and Head of Business Development (Principal Financial and Accounting Officer)

Date: March 5, 2020 */s/ Steven Gillis,*
Steven Gillis,
Director

Date: March 5, 2020 */s/ Michel De Wilde*
Michel De Wilde
Director

Date: March 5, 2020 */s/ Blaine McKee*
Blaine McKee
Director

Date: March 5, 2020 */s/ Joanne Cordeiro*
Joanne Cordeiro
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.

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.

Registration Rights

Pursuant to the warrants issued to Perceptive Credit Holdings, LP (the "Lender") in accordance with that certain Amended and Restated Credit Agreement and Guaranty, as may be amended from time to time in accordance with its terms, at any time after the one hundred eightieth day following the original issue date of the warrant, which was December 6, 2016, the Lender, or its assignees, may request that we register all or any portion of the common shares underlying the warrants for sale on a registration statement under the Securities Act of 1933, as amended (the "Securities Act").

In addition, if at any time we propose to register any of our common shares under the Securities Act for public sale either for our own account or for the account of other shareholders, the holder of the warrants are entitled to notice of the registration and may request that we include all or a portion of the common shares in the registration. These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under specified circumstances.

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, the holders of not less than 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 not less 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.

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.

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 10.42

AMENDMENT TO CONSULTING AGREEMENT

This Amendment to Consulting Agreement (the "**Amendment**"), effective as of **January 1st, 2020** (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, and further amended as of January 1, 2019 (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, 2020 (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 **$44,250.00 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 Parties 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.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed by their respective authorized officers as of the Effective Date.

VARIATION BIOTECHNOLOGIES INC.

/s/ Jeffrey Baxter

Name: Jeffrey Baxter
Title: Chief Executive Officer

F. DIAZ-MITOMA PROFESSIONAL CORPORATION

/s/ Francisco Diaz-Mitoma

Name: Francisco Diaz-Mitoma
Title: President

Schedule A

Appendix C – Performance Incentives

1. Bonus payable as of January 31, 2020 – CAD **$127,449**

2. The Company shall cause VBI Vaccines Inc., a British Columbia corporation (the "**Parent**") to grant to Francisco Diaz-Mitoma, as designee of Consultant, **350,000** stock options (the "**Options**"), each Option exercisable for one common share of Parent, to be granted effective as of **January 22, 2020**, which was the date on which the board of directors of Parent approved such grant, and to be subject to the provisions of the Plan. Conditions regarding the Options and their exercise, including the exercise price, the term of the Options and the timing of vesting shall be set out in an Option Agreement between the Parent and Francisco Diaz-Mitoma. The common shares issuable upon exercise of the Options shall bear the appropriate legend to indicate such shares are "control securities" as defined in General Instruction C.1(a) of Form S-8.

Exhibit 10.43

WAIVER AGREEMENT

THIS WAIVER AGREEMENT (this "Agreement"), dated as of February 25, 2020, is entered into by and among VARIATION BIOTECHNOLOGIES (US), INC., a Delaware corporation (the "Borrower"); the Guarantors identified under the caption "GUARANTORS" on the signature pages hereto, and Perceptive Credit Holdings, LP, a Delaware limited partnership (the "Lender"). Terms used herein without definition shall have the meanings ascribed to them in the Credit Agreement defined below.

RECITALS

WHEREAS, the Lender, the Borrower and the Guarantors entered into that certain Amended and Restated Credit Agreement and Guaranty dated as of December 6, 2016 (as subsequently amended or otherwise modified, the "Credit Agreement"), pursuant to which the Lender has made certain loans and financial accommodations available to the Borrower;

WHEREAS, pursuant to Section 7.1(c) of the Credit Agreement the Borrower is required, among other things, to deliver to the Lender consolidated financial statements of Parent for each Fiscal Year, which financial statements are to be audited without any Impermissible Qualification;

WHEREAS, EISNERAMPER LLP, the independent public accounting firm (the "Auditor") retained to audit Parent's consolidated financial statements for the Fiscal Year ended December 31, 2019 (the "2019 Audited Financial Statements"), has informed Parent and the Borrower that its audit opinion letter with respect to the 2019 Audited Financial Statements will contain an Impermissible Qualification;

WHEREAS, a true and correct copy of the Auditor's draft audit opinion for the 2019 Audited Financial Statements containing the Impermissible Qualification is attached hereto as Annex A (the "Proposed Audit Opinion"); and

WHEREAS, the Borrower and the Guarantors have requested that the Lender waive the Default that will occur as a result of the Borrower's delivery of the 2019 Audited Financial Statements being subject to the Impermissible Qualification contained in the Proposed Audit Opinion (the "Impermissible Qualification Default"), which the Lender has agreed to do subject to the terms and provisions hereof.

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Lender, the Borrower and the Guarantors hereby agree as follows.

1. **Waiver**. Subject to the terms and conditions set forth herein, and so long as (i) the 2019 Audited Financial Statements are delivered to the Lender on a timely basis as required pursuant to Section 7.1(b) of the Credit Agreement, (ii) the Proposed Audit Opinion, in substantially the form as attached as Annex A, is delivered along with the 2019 Audited Financial Statements (without any material change or modification thereto) and (iii) at the time of delivery of such 2019 Audited Financial Statements and Proposed Audit Opinion, no other Event of Default shall have occurred and be continuing or, with passage of time, the giving of notice or both, would occur, the Lender will be deemed to have waived, for all purposes of Sections 9.1.4 and 11.1 of the Credit Agreement, the Impermissible Qualification Default, all without need of further action or notice of any kind.

2. **Effect of this Agreement.**

a. Except as otherwise expressly provided herein, nothing contained herein shall prejudice, waive or alter, or be deemed to prejudice, waive or alter, any of the Lender's rights and remedies under the Credit Agreement or any of the other Loan Documents against the Borrower or the Guarantors or any assets of the Guarantors.

b. No changes or modifications to the Credit Agreement or the other Loan Documents are intended or implied, and, in all respects, the Credit Agreement and the other Loan Documents shall continue to remain in full force and effect in accordance with their terms as of the date hereof. Except as specifically set forth herein, nothing contained herein shall evidence (nor is there any intent to evidence) a waiver by the Lender of any other provision of the Credit Agreement (including, without limitation, with respect to any other or future financial statements to be delivered pursuant to Section 7.1 of the Credit Agreement) or any of the other Loan Documents nor shall anything contained herein be construed as a consent by the Lender to any transaction other than those specifically consented to herein.

3. **Successors and Assigns**. The terms and provisions of this Agreement shall be for the benefit of the parties hereto and their respective successors and assigns; no other person, firm, entity or corporation shall have any right, benefit or interest under this Agreement.

4. **Counterparts; Effectiveness.** This Agreement may be signed in counterparts, each of which shall be an original and all of which taken together constitute one and the same document. In making proof of this Agreement, it shall not be necessary to produce or account for more than one counterpart signed by the party to be charged. This Agreement may be executed and delivered via facsimile or other means of electronic communication with the same force and effect as if it were a manually executed and delivered counterpart. This Agreement shall not become effective until and unless counterparts, duly executed and delivered by all parties hereto, have been received by Lender and written notice thereof (via email) shall have been sent to the Borrower by the Lender.

5. **Choice of Law.** The rights and obligations hereunder of each of the parties hereto shall be governed by and interpreted and determined in accordance with the internal laws of the State of New York (without giving effect to principles of conflicts of laws).

6. **Entire Agreement.** This Agreement sets forth the entire agreement and understanding of the parties with respect to the matters set forth herein. This Agreement cannot be changed, modified, amended or terminated except in a writing executed by the party to be charged.

[Signature page follows]

IN WTINESS WHEREOF, THE PARTIES HAVE ENTERED INTO THIS AGREEMENT AS OF THE DATE FIRST ABOVE WRITTEN.

PERCEPTIVE CREDIT HOLDINGS, LP,
as the Lender

By: Perceptive Credit Opportunities GP, LLC
its general partner

By: */s/ Sandeep Dixit*
Name: Sandeep Dixit
Title: Chief Credit Officer

By: */s/ Sam Chawla*
Name: Sam Chawla
Title: Portfolio Manager

ACKNOWLEDGED AND ACCEPTED:

BORROWER:

VARIATION BIOTECHNOLOGIES (US), INC., as the Borrower

By: */s/ Jeff Baxter*
Name: Jeff Baxter
Title: Chief Executive Officer

GUARANTORS:

VARIATION BIOTECHNOLOGIES, INC.,
as Guarantor

By: */s/ Jeff Baxter*
Name: Jeff Baxter
Title: Chief Executive Officer

VBI VACCINES INC.,
as Guarantor

By: */s/ Jeff Baxter*
Name: Jeff Baxter
Title: Chief Executive Officer

VBI VACCINES (DELAWARE) INC.,

By: */s/ Jeff Baxter*
Name: Jeff Baxter
Title: Chief Executive Officer

SCIVAC LTD,
as Guarantor

By: */s/ Jeff Baxter*
Name: Jeff Baxter
Title: Chief Executive Officer

ANNEX A
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2019 and 2018, 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 incurred, and it anticipates it will continue to incur, significant losses and generate negative operating cash flows and as such will require significant additional funds to continue its development activities to ultimately achieve commercial launch of 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 United States 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.

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

EISNERAMPER LLP
Iselin, New Jersey
February XX, 2020

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 on Form S-3 (Nos. 333-226271 and 333-217995) and Form S-8 (Nos. 333-226261 and 333-212160) of our report dated March 5, 2020 on our audits of the consolidated financial statements as of December 31, 2019 and 2018 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 5, 2020. 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

Iselin, New Jersey
March 5, 2020

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, 2019 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 5, 2020

/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, 2019 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 5, 2020

/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, 2019 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 5, 2020

/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, 2019 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 5, 2020

/s/ Christopher McNulty

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