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, 2018

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	**Name of each exchange on which each is registered**
Common Shares, no par value per share	**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 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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ].

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

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]
(Do not check if a smaller reporting company)	

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, 2018, 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 $107,583,032.

As of February 25, 2019, the registrant had 97,661,887 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 2019 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, 2018

TABLE OF CONTENTS

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

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

- the timing of, and our ability to, obtain and maintain regulatory approvals for our clinical trials, products and product candidates;
- the timing and results of our ongoing and planned clinical trials for products and product candidates;
- the amount of funds we require for our immuno-oncology and infectious disease product candidate pipeline;
- the potential benefits of strategic partnership agreements and our ability to enter into strategic partnership arrangements;
- our ability to effectively execute and deliver our plans related to commercialization, marketing and manufacturing capabilities and strategy;
- our ability to license our intellectual property;
- 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 future clinical supplies of VBI-2601;
- the ability to complete the modernization and capacity increase of our manufacturing facility and resume manufacturing in a timely manner;
- 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 product 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 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 next generation vaccines to address unmet needs in infectious disease and immuno-oncology. Our lead product, Sci-B-Vac, is a prophylactic hepatitis B vaccine ("HBV") for adults, children and newborns, which is approved for use in Israel and 10 other countries. Sci-B-Vac has not yet been approved by the United States Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA") or Health Canada. We are currently conducting a global Phase III clinical program for Sci-B-Vac 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.

We are also developing VBI-2601, a recombinant, protein-based immunotherapeutic for treatment of Hepatitis B, which affects more that 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 is uniquely 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 License Agreement with Brii Bio for development of a functional cure for treatment of Hepatitis B using VBI-2601.

We are also advancing a pipeline of "enveloped" virus-like particle ("eVLP") vaccines, developed with our eVLP platform technology, that allows for the design of vaccines that closely mimic the structure of the target viruses. We have programs in both infectious diseases, with our prophylactic cytomegalovirus ("CMV") vaccine candidate, and in immuno-oncology, with our glioblastoma multiforme ("GBM") vaccine immunotherapeutic candidate. CMV is an infection that, while common, can lead to serious complications in newborns and people with weakened immune systems, and GBM is an aggressive form of adult brain cancer.

Recent Developments

License and Collaboration Agreement with Brii Biosciences - VBI-2601

On December 4, 2018, we entered into a license and collaboration agreement (the "License Agreement") with Brii Biosciences Limited ("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 in the licensed territory, which consists of China, Hong Kong, Taiwan and Macau (collectively, the "Licensed Territory"), and to conduct a Phase II collaboration clinical trial for the purpose of comparing VBI-2601, which is a recombinant protein-based immunotherapeutic developed by us for use in treating chronic hepatitis B, with a novel composition developed jointly with Brii Bio (either being the "Licensed Product"). We also granted Brii Bio an exclusive, royalty bearing license to develop and commercialize the Licensed Product in the Licensed Territory. As part of the consideration for the collaboration and license, 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. See "—Contractual Arrangements—License and Collaboration Agreement with Brii Biosciences-VBI-2061."

Sci-B-Vac

On October 16, 2018, we announced the last subject has received the last vaccination in our previously announced PROTECT Phase III study of Sci-B-Vac. Additionally, the independent Data and Safety Monitoring Board ("DSMB") has reviewed all safety data from the global Phase III program available to-date and has not identified any safety signals or vaccine-related severe adverse events. Top-line data from the PROTECT study is expected mid-2019. On November 9, 2018, we announced that we had completed enrollment in our previously announced CONSTANT Phase III study of Sci-B-Vac. Top-line data from the CONSTANT study are expected around year-end 2019.

CMV Vaccine Candidate (eVLP) - VBI-1501

Our first eVLP program is a prophylactic vaccine that aims to prevent cytomegalovirus ("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. This vaccine candidate uses the eVLP platform and it is adjuvanted with alum, a safe adjuvant widely used in many FDA-approved human vaccines.

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, 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.

On December 20, 2018 we announced plans for a Phase II clinical study evaluating VBI-1501 following positive discussions with Health Canada. The Phase II study is expected to be a formal dose-ranging study designed to assess the safety and immunogenicity of three different dosages of VBI-1501: 5µg, 10µg, and 20µg. The program will be an observer-blind, four-arm, placebo-controlled study in both men and women, aged 18 – 40, and is expected to enroll approximately 110 subjects. Following discussions with Health Canada, toxicology studies are underway, the results of which are required prior to the start of the clinical study. This enables a potential clinical trial application ("CTA") submission to Health Canada in the fourth quarter of 2019.

GBM Vaccine Immunotherapeutic Candidate (eVLP)- VBI-1901

Our VBI-1901, GBM brain cancer vaccine immunotherapeutic program was developed using our eVLP technology, and we initiated dosing in a multi-center Phase I/IIa clinical study evaluating VBI-1901 in patients with recurrent GBM in January 2018. The DSMB has 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 DSMB unanimously recommended the continuation of the study without modification and had no safety concerns about any of the 3 dose levels of VBI-1901. The final subject in the high dose cohort was enrolled in mid-December 2018. On November 16, 2018, initial immunologic and biomarker data was presented in a poster presentation at the Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology.

Modernization and Capacity Increase of our Manufacturing Facility

On April 22, 2018, we temporarily closed our manufacturing facility in Rehovot, Israel, where we manufacture all clinical and commercial supplies of Sci-B-Vac and future clinical supplies of VBI-2601, for modernization and capacity increase. We intend to increase 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. The construction related to the modernization and the capacity increase is ongoing and validation activities are in progress. During this time, we ceased and will continue to cease manufacturing operations at our manufacturing facility. We will recommence manufacturing operations upon receiving approval from the Israeli Ministry of Health ("IMoH") following its review of the modernization and the capacity increase, which is expected in the second half of 2019.

Equity Financing Activities

On December 17, 2018, we received aggregate gross proceeds of $42.9 million from an underwritten public offering of an aggregate of 30,665,304 common shares at a price of $1.40 per share. After deducting the underwriting discounts and commissions and offering expenses, net proceeds from the offering were $39.8 million. Net proceeds from the offering will be used to support our vaccine development programs, to continue the advancement of our clinical development and research programs and for other general corporate purposes.

In addition, we received a gross contractual allocation of $7 million, which had a fair value of $3.6 million on the date of issuance, through the issuance of 2,295,082 shares to Brii Bio as part of the consideration under the License Agreement.

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 third generation 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.

On January 29, 2019, we established a wholly owned subsidiary, SciVac Hong Kong Limited incorporated pursuant to the Companies Ordinance (Chapter 622 of the Laws of Hong Kong).

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.

Principal Products

Our principal products include our Sci-B-Vac vaccine, CMV vaccine candidate, GBM vaccine immunotherapeutic candidate, Hepatitis B immunotherapeutic candidate and the eVLP Platform.

Sci-B-Vac Vaccine

Our Sci-B-Vac product is a third-generation hepatitis B virus vaccine for adults, children and newborns, approved for use in Israel and 10 other countries. Sci-B-Vac has not yet been approved by the FDA, Health Canada or the EMA. The Sci-B-Vac vaccine has demonstrated safety and efficacy in over 500,000 patients in currently licensed markets. Several clinical trials have shown more rapid and high rates of seroprotection with Sci-B-Vac.

The Phase IV clinical study, conducted in Israel in order to qualify a new in-house reference standard for regulatory and quality control purposes, was successfully completed in June 2017.

A pivotal Phase III clinical program is ongoing, the results of which are intended to support regulatory and marketing authorization application submissions to obtain FDA, EMA, and Health Canada market approvals for commercial sale of Sci-B-Vac in the United States, Europe, and Canada respectively.

Sci-B-Vac is a "third generation" hepatitis B virus vaccine, distinguished from previous generations in that Sci-B-Vac (i) is produced in mammalian cells (CHO cells) rather than in yeast, and (ii) contains all three surface antigens, naturally occurring on the surface of the hepatitis B virus – preS1, preS2, and the S proteins. The composition of Sci-B-Vac therefore provides more opportunities for the immune system to respond with antibodies, or neutralizing antibodies, which can recognize one of these components of the hepatitis B particle. Because the Sci-B-Vac active component displays proteins substantially similar to those found on the outer surface of the naturally occurring hepatitis B virus, we believe that Sci-B-Vac could be highly potent and immunogenic (capable of conferring immunity) and provide patients with an alternative to existing yeast-derived hepatitis B virus vaccines. We will be investigating in our clinical trials whether Sci-B-Vac has the potential to fill a significant gap in an unmet medical need to protect against hepatitis B virus, especially in older individuals who may not be adequately protected with other licensed hepatitis B vaccines.

Several clinical studies conducted have demonstrated that Sci-B-Vac possesses the following benefits relating to the prevention of the hepatitis B virus:

- Sci-B-Vac has been demonstrated to be highly immunogenic in adults, children and newborn infants;
- Several clinical trials have shown rapid and high rates of seroprotection with Sci-B-Vac in a high percentage of vaccinated individuals. In addition, seroprotection (the attainment of immunologically protective levels of anti-hepatitis B virus antibodies) was induced with lower dosages of Sci-B-Vac than with other licensed hepatitis B virus vaccines; and
- Sci-B-Vac generated an adequate immune memory for long-term protection against hepatitis B.

Sci-B-Vac is generally well-tolerated by patients; during the clinical development and trials of Sci-B-Vac less than half of the patients experienced local reactions at the injection site (as commonly observed with the use of most vaccines). These reactions were generally mild and were resolved within two days after vaccination. Additionally, fatigue, weakness, headache, fever, malaise, nausea, diarrhea, pharyngitis, which is inflammation of the pharynx, and upper respiratory infection were observed.

Phase III Clinical Studies

On February 7, 2017, we announced that we received positive scientific advice from the Committee for Medicinal Products for Human Use ("CHMP") of the EMA regarding our development path for our Sci-B-Vac vaccine in Europe. In its letter, the CHMP expressed its support of our proposed plan to proceed to the Phase III clinical studies of Sci-B-Vac. The CHMP also agreed that the product information, as well as data from ongoing studies, supports the Phase III clinical studies and our planned filing of a Marketing Authorization Application ("MAA") for Sci-B-Vac.

On February 22, 2017, we announced that the Biologics and Genetic Therapies Directorate ("BGTD") of Health Canada expressed its general support and acceptance of our development path for our Sci-B-Vac vaccine in a pre-Clinical Trial Application ("CTA") meeting. Considering the manufacturing data, licensed clinical efficacy and safety experience of Sci-B-Vac, the BGTD agreed in principle with our overall development strategy. In addition, the BGTD agreed that the proposed Phase III program would satisfy the regulatory requirements, for marketing authorization in Canada, supporting the indication for active immunization against hepatitis B in adults. On June 14, 2017, Health Canada provided us with a No Objection Letter for both PROTECT and CONSTANT studies, which authorized us to proceed with the Sci-B-Vac Phase III clinical studies as described in our CTA.

On August 25, 2017, the FDA accepted our IND for the Sci-B-Vac Phase III clinical program. Acceptance of the IND enabled us to initiate the Sci-B-Vac Phase III clinical program in the United States. Based on the clinical data collected to date, and the discussions held with the FDA, EMA and Health Canada, we initiated enrollment in the Phase III clinical program of Sci-B-Vac for prevention of the hepatitis B virus in December 2017 and commenced patient dosing.

The Phase III program consists of two concurrent studies – PROTECT and CONSTANT.

ABOUT PROTECT – Safety and Immunogenicity Study

PROTECT is a double-blind, two-arm, randomized, controlled study. Approximately 1,600 adult subjects, age 18 years and older, have been randomized in a 1:1 ratio to receive either a three-dose course of Sci-B-Vac 10µg or a three-dose course of the control vaccines, Engerix-B® 20µg. Enrollment was stratified by age group.

The co-primary objectives of the study are:

- To demonstrate non-inferiority of the seroprotection rate induced by Sci-B-Vac as compared to Engerix-B four weeks after the third vaccination in adults age 18 and older; and

- To demonstrate superiority of the seroprotection rate induced by Sci-B-Vac as compared to Engerix-B four weeks after the third vaccination in adults older than 45 years of age

The study also includes multiple secondary objectives, including demonstrated non-inferiority of the seroprotection rate after two doses of Sci-B-Vac 10µg compared to after three doses of Engerix-B 20µg, and the overall safety and tolerability of Sci-B-Vac as compared to Engerix-B.

ABOUT CONSTANT - Lot-to-Lot Consistency Study

CONSTANT is a double-blind, four-arm, randomized, controlled study. Approximately 2,850 adult subjects, age 18-45 years, were randomized in a 1:1:1:1 ratio to receive one of four three-dose courses: Lot A of Sci-B-Vac 10µg, Lot B of Sci-B-Vac 10µg, Lot C of Sci-B-Vac 10µg, or the control vaccine Engerix-B 20µg.

The primary objective of this study is to demonstrate lot-to-lot consistency for immune response as measured by geometric mean concentration of antibodies across three independent, consecutive lots of Sci-B-Vac four weeks after the third vaccination.

The secondary objective is to evaluate safety and efficacy of Sci-B-Vac as compared to Engerix-B.

On October 16, 2018, we announced the last subject has received the last vaccination in our PROTECT Phase III study of Sci-B-Vac. Additionally, the independent Data and Safety Monitoring Board ("DSMB") has reviewed all safety data from the global Phase III program available to-date and has not identified any safety signals or vaccine-related adverse events. Top-line data from the PROTECT study is expected mid-2019. On November 9, 2018, we announced that we had completed enrollment in our CONSTANT Phase III study of Sci-B-Vac. Top-line data from the CONSTANT study are expected around year-end 2019.

CMV Vaccine Candidate (eVLP)

Our first eVLP program 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.

Clinical Development

In June 2016, patient enrollment was initiated in a Phase I clinical study for our congenital CMV vaccine candidate. In July 2017, we announced interim Phase I safety data, through day 84 of the study, and initial immunogenicity signals in participant samples collected one month after the second of three planned vaccine doses.

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, 2.0 µg, 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, has approximately 10-fold less antigen content than that used in several other VLP-based vaccines or in past non-VBI CMV vaccine candidates.

On December 20, 2018 we announced plans for a Phase II clinical study evaluating VBI-1501 following positive discussions with Health Canada. The Phase II study is expected to be a formal dose-ranging study designed to assess the safety and immunogenicity of three different dosages of VBI-1501: 5µg, 10µg, and 20µg. The program will be an observer-blind, four-arm, placebo-controlled study in both men and women, aged 18 – 40, and is expected to enroll approximately 110 subjects. Following discussions with Health Canada, a toxicology study to support the new dose levels is underway, the results of which are required prior to the start of the clinical study. This enables a potential CTA submission to Health Canada in the fourth quarter of 2019.

GBM Vaccine Immunotherapeutic Candidate (eVLP)

Our GBM brain cancer vaccine immunotherapeutic program, VBI-1901, targets CMV in tumor cells; CMV is an infection that is associated with a number of solid tumors, including GBM, which is an aggressive form of adult brain cancer. VBI submitted an IND for VBI-1901, which was accepted by the FDA on August 11, 2017. We initiated dosing in a multi-center Phase I/IIa clinical study evaluating VBI-1901 in patients with recurrent GBM in January 2018. The DSMB has 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 the 3 different dose cohorts. The DSMB unanimously recommended the continuation of the study without modification and with no safety concerns about any of the 3 dose levels of VBI-1901. The final subject in the high dose cohort was enrolled in mid-December 2018. On November 16, 2018, initial immunologic and biomarker data was presented in a poster presentation at the Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology. We expect to announce data regarding more extensive immunologic data and 6-month survival data from all three dose cohorts in Phase I of the study (low, intermediate, and high), mid 2019.

On October 3, 2017, the United States Patent and Trademark Office granted a patent on VBI-1901.

Hepatitis B Immunotherapeutic Candidate

Our VBI-2601 candidate is a recombinant, protein-based immunotherapeutic for treatment of chronic Hepatitis B, which affects more that 250 million people, making it the world's most prevalent infectious disease. 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 is uniquely formulated to induce stronger T-cell immunity against the Hepatitis B preS1, preS2 and HBsAg antigens, which are believed to play an important role in controlling Hepatitis B infection and disease. On December 6, 2018, the Company announced that it had entered into a License Agreement with Brii Bio for development of a functional cure for treatment of Hepatitis B using VBI-2601.

eVLP Vaccine Platform

On August 11, 2011, VBI Cda acquired the eVLP vaccine technology through the acquisition of ePixis. The eVLP vaccine technology allows for the expression of envelope glycoproteins within a lipid-bilayer membrane of a virus-like particle ("VLP"). The 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 in 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. In addition to the $450 initial payment for the technology and $75 in related transaction costs, we paid approximately $236 and $0 in milestone payments under the e-Pixis Licensing Agreement in the years ended December 31, 2018 and 2017, respectively.

We expect to develop additional vaccine targets based on this platform, either through a partnership, or internally. In October 2017, we disclosed new data on a Zika vaccine candidate, VBI-2501, which employs the eVLP platform. The vaccine candidate contains a proprietary modified version of glycoprotein E and NS1 of Zika in a bivalent construct. Preclinical data in mice demonstrated that the bivalent produced a surprisingly superior neutralization of Zika, relative to monovalent versions. We believe that such data supports the flexibility of eVLP platform. VBI has filed for, and been granted, a patent protecting its Zika candidate which was issued on December 5, 2017.

In the normal course of our business, we assess and consider potential acquisition, or collaboration opportunities to gain access to, technologies or assets that are adjacent to our core competencies.

Contractual Arrangements

License and Collaboration Agreement with Brii Biosciences - VBI-2601

On December 4, 2018, we entered into a 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 II collaboration clinical trial for the purpose of comparing VBI-2601, which is a recombinant protein-based immunotherapeutic developed by VBI for use in treating chronic 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. Outside of the field of the diagnosis and treatment of chronic hepatitis B, we will not have any right to practice the joint technology in the countries outside of the Licensed Territory unless and until the parties have negotiated a separate 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 a 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 License Agreement

Our manufactured and marketed product, Sci-B-Vac is a recombinant third generation hepatitis B vaccine which is the subject of a license agreement ("Ferring License Agreement") with Ferring International Center S.A. ("Ferring"). Under the Ferring License Agreement, we are committed to pay Ferring royalties equal to 7% of net sales (as defined therein). Royalty payments of $42 and $35, were recorded in cost of revenues for the year ended December 31, 2018 and 2017, 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).

We are to pay Ferring the above-mentioned royalties on a country-by-country basis until the date which is 10 years after the date of commencement of the first royalty year in respect of such country. Until the 30th day prior to the expiration of the first license period, we have the 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 paying Ferring $100. Royalties will continue to be payable for the duration of the extended license periods. When the license has been in effect for, and elapsed after, a 17 year license period with respect to a country in the territory, we will thereafter have a royalty-free license to market in such country and when all the license periods have expired in each country in the territory.

SciGen Singapore Assignment Agreement

Under an assignment and assumption agreement, we are required to pay royalties to SciGen Ltd. ("SciGen Singapore") equal to 5% of Net Sales of Sci-B-Vac product sales (as defined in such agreement). Royalty payments of $30 and $25 were recorded in cost of revenues for the year ended December 31, 2018 and 2017, respectively.

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 €200 during the year ended December 31, 2018 and €0 during the year ended December 31, 2017.

Kevelt AS

Prior to VBI-SciVac Merger completed on May 6, 2016, one of the directors of SciVac was also the chairman of the board of Kevelt AS (“Kevelt”), a wholly-owned subsidiary of OAO Pharmsynthez (“Pharmsynthez”), and was also the chairman of the board of Pharmsynthez. Following the Levon Merger, in accordance with the merger agreement, this director resigned. On April 26, 2013, prior to May 6, 2016, SciVac entered into a Development and Manufacturing Agreement (“DMA”) with Kevelt, pursuant to which SciVac agreed to develop the manufacturing process for the production of clinical and commercial quantities of certain materials in drug substance form for an aggregate amount of $4.3 million. The original term of the DMA was for a period of one year commencing April 26, 2013, but pursuant to the terms of the DMA, the term automatically renewed thereafter for successive additional one-year periods, unless the parties failed to agree on the terms applicable to any renewal term and either party provided at least 30 days prior written notice of non-renewal to the other. On November 8, 2017, SciVac entered into a settlement agreement with Kevelt, pursuant to which SciVac paid Kevelt $1 million in cash on November 9, 2017, and issued 274,000 common shares of VBI Vaccines Inc. with a value of $1,142 on December 18, 2017. As part of the settlement, the DMA was terminated and each of SciVac and Kevelt released the other from all claims and liabilities arising under the DMA.

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, which we are in the process of modernizing and increasing capacity. The facility was built in December 2006 and was Good Manufacturing Practice (“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 without the need for re-testing at import and official-control-authority batch release; however, our facility will have to pass FDA inspection as part of the BLA application process for Sci-B-Vac in the United States. During the modernization and capacity increase, we ceased and will continue to cease manufacturing operations at our manufacturing facility. The construction related to the modernization and the capacity increase is ongoing and validation activities are in progress. We will recommence manufacturing operations upon receiving approval from IMoH following its review of the modernization and the capacity increase which is expected in the second half of 2019.

We believe that the production capabilities of our manufacturing facility prior to the modernization would satisfy our current manufacturing requirements for Israel and export markets. However, in the event we receive FDA and/or EMA approval for Sci-B-Vac, our production requirements may increase beyond our pre-modernization production capabilities, and we may enter into agreements with various third parties for the manufacture of Sci-B-Vac. We are in the process of increasing 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.

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 product 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 in approved countries 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.

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 its vaccine platforms and products which may be licensed to major pharmaceutical companies and larger biotechnology companies.

Competitors

Our products and product 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 product candidates and technologies and may develop and commercialize additional products and technologies that will compete with our product 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, GlaxoSmithKline ("GSK"), Merck, Mitsubishi Tanabe Pharma Corporation, Takeda Pharmaceutical Company Limited and Pfizer, Inc.; mid-size pharmaceutical companies and emerging biotechnology companies including, Dynavax Technologies Corporation ("Dynavax"), and Hookipa Biotech AG; and academic and not-for-profit vaccine researchers and developers including the National Institutes of Health and Butantan Institute. 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, including: GSK, the manufacturer of Engerix-B, Merck, the manufacturer of Recombivax HB, and Dynavax, the manufacturer of Heplisav-B. Engerix-B was first approved in the United States in 1989 and is considered a global standard of care for immunization against infection caused by all known subtypes of the hepatitis B virus in all age groups. Recombivax HB was first approved in the United States in 1983 and has a similar label and positioning as Engerix-B. Dynavax received FDA approval for Heplisav-B in November 2017 as a 2 dose regimen for adults age 18 years and older, and based on data in head-to-head clinical studies, demonstrated statistically significantly higher rates of seroprotection compared with Engerix-B. Dynavax has committed to a 60,000 subject Phase IV post-marketing study. 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: Janssen Pharmaceutica Products, L.P. (“Janssen”), Gilead Sciences, Inc, and F. Hoffmann-La Roche Ltd (“Roche”). These large companies are each developing their own Hepatitis B therapies as well as acquiring ownership or licenses to others’ innovative drug candidates. There are a number of innovative companies developing alternative approaches to treat Hepatitis B, including: siRNA approaches (VIR Biotechnology Inc., Arbutus Biopharma Corp, Dicerna Pharmaceuticals Inc), and Core assembly inhibitors (Janssen, Roche, Assembly Biosciences, Inc) and numerous other approaches. It is not yet known which mode of action, or combinations thereof, will lead to a Hepatitis B functional cure.

Within the CMV vaccine space, we have several key competitors, some of whom are further advanced with their CMV vaccine development, as compared to us. Among these, Merck has a highly potent vaccine based on a replication defective CMV virus with an adjuvant and entered Phase II testing in 2018. Additionally, Hookipa Biotech AG is engaged in clinical development of HB - 101 a prophylactic CMV vaccine based on its Vaxwave™ technology.

Suppliers, Contractors and Collaborations

Suppliers

We currently rely on a single source for our supply of vials and certain reagents required for the manufacture of Sci-B-Vac. Currently, we do not have supply agreements with these vendors and all orders are handled through individual purchase orders on an order-by-order basis. Alternative sources from which we can obtain our supply of these materials exist. However, 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.

Currently, we engage CRO's to conduct our clinical programs including the ongoing GBM Phase I/IIa clinical program and the ongoing 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 22.

We rely on a number of key contractors 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 product 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 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 22.

- We, through our wholly-owned subsidiaries, depend on subcontractor arrangements to facilitate the completion of our research programs. For example, 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, 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 April 2, 2015, VBI Cda entered into a Collaboration and Option License Agreement (the "Sanofi Agreement") with Sanofi., a company organized under the laws of France ("Sanofi"). Certain provisions of the Sanofi Agreement have not been publicly disclosed in accordance with an Order Granting Confidential Treatment issued by the United States Securities and Exchange Commission (the "SEC") on June 23, 2015. The purpose of the Sanofi Agreement is to allow Sanofi to evaluate the feasibility of using VBI Cda's LPV technology and expertise to reformulate a Sanofi vaccine candidate (the "Sanofi Project Vaccine") to provide improved stability (the "Sanofi Project"). VBI has completed the research as per the Sanofi Agreement and data has been shared with Sanofi. The research confirmed stabilizing properties of the LPV technology and Sanofi will continue to evaluate its fit for future programs, but has not exercised its option to apply LPV technology to the Sanofi Project Vaccine. We have no further obligations under the Sanofi Agreement and no further work is anticipated at this time.

- On October 8, 2015, we announced that we had applied our eVLP Platform in the development of a novel immunotherapeutic vaccine candidate for GBM with Columbia University's Brain Tumor Center. We have not made any payments under this collaboration and the related materials transfer agreement. Our GBM vaccine immunotherapeutic candidate is currently in a Phase I/IIa clinical study in recurrent GBM patients.

- On February 8, 2016, VBI Cda entered into an Evaluation and Option Agreement (the "GSK Agreement") with GSK, a company registered in Belgium ("GSK"). Certain provisions of the GSK Agreement have not been publicly disclosed in accordance with an Order Granting Confidential Treatment issued by the SEC on March 14, 2016. The purpose of the GSK Agreement is to allow GSK to evaluate the feasibility of using VBI Cda's LPV technology and expertise to formulate a vaccine candidate using GSK's technology. We have completed its research obligations and data has been shared with GSK as per the terms of the previously disclosed agreements. No further work is anticipated at this time.

- On December 4, 2018, we entered into a 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 for treatment of Hepatitis B subject to terms and conditions set forth in the License Agreement as described in" Part I— Item I—Business—Recent Developments".

Employees

As of December 31, 2018, we have a total of 108 full-time and 4 part-time employees. The SciVac manufacturing site in Israel had 77 full-time employees and 1 part-time employee and the VBI Cda research site employed 24 full-time and 3 part-time employees, as of December 31, 2018. 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 $992 in 2018.

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 $38 million and $21 million for the years ended December 31, 2018 and 2017, respectively. All R&D was funded by equity financings, term loan financings, collaboration agreements or government grants. Our most significant R&D expense to date has been related mainly to Sci-B-Vac, the development of our CMV candidate, GBM vaccine immunotherapeutic candidate, and the related eVLP platform. Our R&D expenses are expected to remain at current levels as we complete the Phase III Sci-B-Vac clinical program, the Phase I/IIa GBM clinical program, begin to conduct the CMV Phase II clinical program and develop the hepatitis B immunotherapeutic candidate. In addition, we may bring other product candidates through the clinical development stage and explore other vaccine opportunities and/or collaborations.

Intellectual Property

Patents

Our IP portfolio includes 16 active patent families consisting of 126 fully owned or co-owned or exclusively licensed patents and patent applications. The highlights of our patent portfolio include:

- 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 assay used to provide high-throughput screening of anti-CMV vaccine candidate responses.

- 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.

- 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.

- Hepatitis B Immunotherapeutic: VBI has filed on a novel formulation developed for use as a Hepatitis B Immunotherapeutic. The patent claims a unique immunogenic formulation which offers enhanced T-cell responses against hepatitis B. The formulation is subject of further study in our collaboration with Brii Biosciences.

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 the CMV project. 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 US and 2021 in other countries. Our most recently filed patent family will have a patent term that extends to 2038.

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;
- In the United States, submission of an investigational new drug application (an "IND"), which must be reviewed by the FDA before human clinical trials may begin; submission of a Scientific Advice application to EMA 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 Biologics License Application ("BLA") to the FDA, New Drug Submission ("NDS") to Health Canada; or submission of an MAA to the EMA; 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.

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, or PPACA, 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 PPACA 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 MMA. 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. 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 Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our website at *www.vbivaccines.com*, as soon as reasonably practicable after such reports are available on the Securities and Exchange Commission website at *www.sec.gov*.

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

Our vaccine 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 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 and requirements and requests they may make for additional data or completion of additional clinical trials. Any such requirements or requests could:

- adversely affect our ability to timely and successfully commercialize or market Sci-B-Vac in the United States 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 the affected product candidate 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 product 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 product candidates, and the projected timelines for continued development of the technologies and related product 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 (“IRB”), or us;

- delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites;
- delays in obtaining required IRB 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 IRB 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 IRBs 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 IRB 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 IRB approval. Any delay or failure to obtain IRB 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 product 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 product 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 product candidates are safe and effective for indicated uses. Such failure could cause us to abandon a product candidate and could delay development of other product 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 IRBs. 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 a product candidate.

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 IRB for a clinical trial. An IRB 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 product candidate 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 product candidate 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 product 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 product 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 product candidate 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 product 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 other than the Sci-B-Vac clinical trials 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 product 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 and 10 other countries. 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 product candidates. Pursuing regulatory approvals will be time-consuming and expensive, and we may not obtain foreign regulatory approvals on a timely basis, if at all. The regulations vary among countries, and regulatory authorities in one market may require different or additional clinical trials than those required to obtain approval for our product candidates in another market, and the time required to obtain approval may differ in one market from that required to obtain approval for our product candidates in another market. Obtaining approval in one country does not ensure approval by regulatory authorities in other countries.

In addition, we have limited foreign 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 product candidates in the future, and, as such, current and future partners are critical to our international success. We may not be able to maintain current, or enter into future, collaboration agreements with appropriate partners for important foreign markets on acceptable terms, if at all. Current and future collaborations with foreign partners may not be effective or profitable.

Future legislation, or regulations and policies adopted by the FDA or other regulatory authorities may increase the time and costs required for us to conduct and complete clinical trials for our product 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 product 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 product 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 11 countries; our current product 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 product candidates during clinical trials were to cause adverse side effects, we may be exposed to substantial liabilities. In September 2018, two 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 from April, 2011 and seeking damages in a total amount of NIS 1,879,500,000 (not in thousands) ($501.5 million). The second claim is a civil action brought by two minors and their parents against SciVac Ltd. and the 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. Regardless of the merits or eventual outcome, product liability claims or other claims related to our products or product 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 product 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 product 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 product 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 product candidates in the United States, which we cannot guarantee, the FDA 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 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 product 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 product 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 product 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. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. License 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 product candidates may also include restrictions on use. Such regulatory agencies may impose further requirements or restrictions on the distribution or use of our product 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 product 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 product 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 product 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 product 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 product 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 product candidate 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 ("cGMP") 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 future 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 proposed clinical studies of VBI-2601 and for future clinical studies of Sci-B-Vac where we seek regulatory approval, which would result in increased costs and losses and adversely affect our business and results of operations.

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

We are investing substantial funds to modernize and increasing the capacity of our manufacturing facility in Rehovot, Israel, where we manufacture all clinical and commercial supplies of Sci-B-Vac and future clinical supplies of VBI-2601. During the modernization and capacity increase, which started in April 2018, we ceased manufacturing operations at our manufacturing facility. Following completion of the modernization and capacity increase of our manufacturing facility, IMoH will need to perform a full facility and process validation audit in order to provide its approval for us to recommence manufacturing operations. If we are unable to successfully complete this modernization and capacity increase in a timely manner or promptly obtain IMoH approval our ability to manufacture Sci-B-Vac for commercial sale could be interrupted, the costs associated with our modernization project would increase, and our sales of Sci-B-Vac and the timing of our proposed 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 product 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 & Co. and compete outside the United States with vaccines from GSK, Merck & Co., 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 product 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 product candidates may never achieve market acceptance, even if we obtain regulatory approvals.

Even if we receive regulatory approvals for the commercial sale of our product candidates, the commercial success of these product 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 product 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 the target market (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 product 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 vaccines 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 product candidates require access to, or development of, facilities to manufacture our eVLP product candidates at sufficient yields and at commercial-scale. We have limited experience manufacturing any of our eVLP product 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 product 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 product candidates. Our vaccines 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 product 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 product candidates.

The near and long-term viability of our product 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 product 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 product 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 product candidates, in a timely manner or at all;
- such partners may not devote sufficient resources to our product 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 product 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 product 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 FDCA, 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 vaccine candidates and/or in connection with the commercial use of any such candidates approved by the FDA for marketing in the U.S. in the future.

One or more existing FDA-approved therapies may be involved in the clinical testing of a given vaccine candidate, as such vaccine 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 candidate VBI-1901 is administered in conjunction with an existing adjuvant therapy 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 vaccine 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 product 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 $64 million and $39 million in 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $208 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 and increasing operating losses for the next several years as we complete the Phase III clinical program for Sci-B-Vac and support regulatory submissions, expand our research and development, advance other product candidates into and through clinical development, including 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 Sci-B-Vac Phase III clinical program and our License Agreement with Brii Bio, 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 February 25, 2019, 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, 2018, we had $59.3 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 product candidates.

There are many other companies that have developed or are currently trying to develop immunology vaccines 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 product 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 match 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 the United States.

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 are subject to federal, provincial and state laws and regulations relating to our business and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

We are subject to healthcare regulation and enforcement by the United States federal government and the states and other jurisdictions in which we conduct our business. The laws that may affect our ability to operate include 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 PPACA, 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, or CMS, 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 federal Health Insurance Portability and Accountability Act of 1996 ("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;

- other federal and state laws, and state law equivalents of each of the federal laws, including fraud and abuse laws, prohibitions on self-referral, kickbacks, false claims, fee-splitting, the provision of products at no or discounted cost to induce physician or patient adoption, and transparency, reporting and disclosure requirements and laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers, and laws that prohibit other specified practices related to billing, such as billing physicians for orders, waiving coinsurance, co-payments, deductibles, and other amounts owed by patients, and billing a state Medicaid program at a price that is higher than what is charged to other payers; and

- state law equivalents of HIPAA related to the privacy and security of patient information.

Further, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now 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. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs and forfeiture of amounts collected in violation of such prohibitions. 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. 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. As such, patients may choose to use other low-cost, established drugs or therapies.

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.

In addition, we expect that the current presidential administration and United States Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Since taking office, President Trump has continued to support the repeal of all or portions of the Affordable Care Act. In January 2017, the House and Senate 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. There is still uncertainty with respect to the impact President Trump's administration and the United States Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In the context of securing and protecting any patient information that our clinical sites may obtain which may be subject to HIPAA or state law protections, we intend to and do include in the written agreements we will enter into with such clinical sites provisions requiring such clinical sites to have appropriate policies, procedures and systems in place to satisfy the privacy and security requirements. Our efforts, however, cannot protect against every potential threat to such patient information. For example, cyber attacks or improper actions of an employee could result in a breach of our systems, resulting in immediate costs to address and correct the breach and notify any impacted parties, as well as potential litigation or governmental proceedings which could result in monetary fines and/or criminal sanctions. A breach of protected information could result in material adverse effects on our reputation, business operations and financial condition.

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 US 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 product candidates that could disrupt our business and harm our financial condition.

We may expand our product offerings, and we may seek acquisitions of product 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 product 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 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.

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 and July-August 2014 - 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. Since February 2011, Egypt has experienced political turbulence and an increase in terrorist activity in the Sinai Peninsula following the resignation of Hosni Mubarak as president. This included protests throughout Egypt, and the appointment of a military regime in his stead, followed by the elections to parliament which brought groups affiliated with the Muslim Brotherhood (which had been previously outlawed by Egypt), and the subsequent overthrow of this elected government by a military regime instead. Such political turbulence and violence could affect the region as a whole. Similar 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 has been ongoing in Syria has escalated, and evidence indicates that chemical weapons have been used in the region. Syria is now widely viewed as a failed state on the verge of disintegration into tribal fiefdoms. 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 Unites 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, 2018, was US$1.00 = NIS 3.597 and US$1.00 = Canadian Dollar $1.2953. 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 product 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 126 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 product 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 product 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 product 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 product 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 product 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 product candidates.

We currently are dependent on licenses from third parties for certain of our key technologies relating to the Sci-B-Vac and eVLP technology, including the license from the L'Universite Pierre et Marie Curie ("UPMC") and the Ferring License Agreement. Under our license agreement with UPMC and other licensors, we are granted 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 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 product candidates. Furthermore, such loss of these licenses may enable development of new products based on the eVLP platform that may compete with our product 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.

Under the Ferring License Agreement, under which we license key components for our Si-B-Vac product, we pay Ferring royalties on a country-by-country basis until the date which is 10 years after the date of commencement of the first royalty year in respect of such country. Until the 30th day prior to the expiration of the first license period, we have the 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 payment to Ferring of $100. Royalties will continue to be payable for the duration of the extended license periods. Should Ferring fail to honor the terms of this license agreement, including our extension right, our ability to continue to sell Sci-B-Vac in certain countries could be interrupted, which could result in a material adverse effect on our business.

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 product 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 product 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, 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") which may result in the need to record an impairment charge.

Our balance sheet contains significant amounts 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 while we currently expect to be able to monetize our intangible assets, these IPR&D 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. For IPR&D projects, this could result from, among other things, a change in outlook based on clinical trial data, a delay in the projected launch date or additional expenditures to commercialize the product.

While all intangible assets other than goodwill can face events and circumstances that can lead to impairment, in general, intangible assets other than goodwill 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 our Sci-B-Vac product and our other product candidate products 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 Heath 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"), the lender under our credit facility, pursuant to the Amended and Restated Credit Agreement and Guaranty, dated December 6, 2016 ("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, 2018, 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 2018, we have made average monthly payments of interest in the amount of approximately $165. On July 17, 2018 the Amended Credit Facility was amended (the "Second Amendment") where 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. The principal amount of the term loan as of December 31, 2018, was $15.0 million ($15.3 million including the exit fee). The term loan under the Second Amendment was set to mature on December 31, 2019. On January 31, 2019 we further amended the Amended Credit Facility (the "Third Amendment") to i) extend the period we are required to pay only the interest on the loan from December 31, 2018 to the Amortization Commencement Date (which is defined as the later of July 31, 2019 and, if Sci-B-Vac Phase III clinical trial endpoints are achieved on or before June 30, 2019, January 31, 2020) ii) extend the maturity of the term loan to June 30, 2020 and iii) reduce the exercise price on certain warrants to purchase common shares issued to Perceptive 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 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, 2018, our common shares traded as high as $4.60 per share and as low as $1.14 per share. Due to the volatility of the market for our common shares, the market price for our shares may be significantly affected by factors such as variations in quarterly and yearly operating results or changes in state, provincial or federal regulations affecting us and our industry. Furthermore, in recent years the stock market has 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 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, 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 97,343,777 common shares outstanding as of December 31, 2018, approximately 63,093,273 common shares are held by "non-affiliates," all of which, other than 2,295,082 for which the holding period has not yet passed, 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, 2018, we had outstanding options, awards, and warrants for the purchase of 6,367,070 common shares. Of this amount, options, awards and warrants for the purchase of 800,458 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 share trades. 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 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, 2018, approximately 35.2% of our outstanding common shares was controlled by our officers, directors, beneficial owners of 10% or more of our securities and their respective affiliates. As a result, these shareholders, if they acted together, may be able to determine or influence matters that require approval by our shareholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other shareholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a corporate transaction that other shareholders may view as beneficial.

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. Although we currently have research coverage by securities and industry analysts, you should not invest in our common shares in anticipation that we will increase such coverage. If one or more of the analysts who covers us at any given time downgrades our common shares or publishes inaccurate or unfavorable research about our business, the price of our common shares would likely decline. If one or more of these analysts ceases coverage of us or fails 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 ("ATLP") for 2,359 square feet. The lease has been amended six times since it was entered into for the purpose of revising the length, providing for a new base rent and adding additional office space. Pursuant to the fifth amendment, which was entered into on May 9, 2017, the lease term was extended to April 30, 2018 with a base rent for the premises of $12 per month. We are also responsible for the payment of additional rent, including our pro rata share of real estate taxes, operating expenses, as defined in the lease, and betterment assessments, as defined in the lease. On March 23, 2018 we entered into the sixth amendment with ATLP to extend the lease to April 30, 2020 and increase the square feet by 1,116 with a base rent for the entire premises of $19 per month.

b) our manufacturing facility is comprised of approximately of 3,096 square meter 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. The lease has been amended four times since it was entered into for the purpose of revising the length of the term and providing for a new base rent. Pursuant to the fourth amendment, which was entered into on February 24, 2016, the lease term was extended to January 31, 2022. The amount of the lease is approximately $29 per month and linked to the CPI. We entered into an agreement on September 5, 2016 for additional office space of 490 square meters (fifth amendment to the lease agreement) under which we are obligated to pay an additional $5 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 Sub lease agreement for additional office space of 200 square meters with Green Power YE. The term of the sub-sublease extends to January 22, 2018 with an option to extend for one year. The lease term was extended until January 22, 2019. The amount of the sub lease was a fixed price including all rental utilities of $7 per month. 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 and extend the initial term to December 31, 2019. VBI Cda has the right to extend the term for two periods of three years. The base and additional rent for the premises is currently nineteen dollars USD per square foot per year through December 31, 2019. 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 eighteen dollars CAD per square foot of rentable premises. VBI Cda was required to provide a security deposit in the amount of $18.8 CAD which Iogen Corporation 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 $992 in 2018.

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 claims were filed in the District Court of the central district in Israel which named our subsidiary SciVac Ltd. as a defendant. In the first 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 from April, 2011 and seeking damages in a total amount of NIS 1,879,500,000 (not in thousands) ($501.5 million). The second claim is a civil action brought by two minors and their parents against SciVac Ltd. and the 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 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 Ltd. believes these matters to be without merit and intends to oppose the motion and otherwise defend the claims vigorously.

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. Prior to May 9, 2016, our common shares had traded in Canada on the Toronto Stock Exchange under the symbol "VAC" and quoted in the United States on the OTC Markets QX Tier (OTCQX) under the symbol "SVACF."

Holders

As of February 20, 2019, we had approximately 820 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

On December 4, 2018, in connection with the equity investment as part of the consideration for the collaboration with Brii Bio pursuant to 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 $7 million, or $3.05 per share, which had a fair value of $3.6 million on the date of issuance. The issuance of the Brii Bio shares was not registered under the Securities Act or the securities laws of any state, and was issued in reliance on the exemption from registration under the Securities Act provided by Section 4(a)(2) and Regulation D (Rule 506) under the Securities Act. Brii Bio represented that it was an accredited investor (as defined by Rule 501 under the Securities Act).

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 next generation vaccines to address unmet needs in infectious disease and immuno-oncology. Our lead product, Sci-B-Vac, is a prophylactic Hepatitis B vaccine for use in adults, children and newborns, which is approved for use in Israel and 10 other countries. Sci-B-Vac has not yet been approved for use by the FDA, EMA or Health Canada. We are currently conducting a global Phase III clinical program for Sci-B-Vac 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. The program consists of two concurrent Phase III studies - a safety and immunogenicity study ("PROTECT") and a lot-to-lot consistency study ("CONSTANT"). Top-line data from PROTECT are expected mid-year 2019, and top-line data from CONSTANT are expected around year-end 2019. Our wholly-owned subsidiary in Rehovot, Israel, SciVac Ltd., manufactures and sells Sci-B-Vac.

We are also developing VBI-2601, a recombinant, protein-based immunotherapeutic for treatment of Hepatitis B, which affects more that 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 is uniquely 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 License Agreement with Brii Bio for development of a functional cure for treatment of Hepatitis B using VBI-2601.

We are also advancing a pipeline of "enveloped" virus-like particle ("eVLP") vaccines, developed with our eVLP platform technology that allows for the design of vaccines that closely mimic the structure of the target viruses. We have programs in both infectious disease, with our prophylactic cytomegalovirus ("CMV") vaccine candidate, and in immuno-oncology, with our glioblastoma multiforme ("GBM") vaccine immunotherapeutic candidate.

CMV may cause severe infections in newborn children (congenital CMV) and may also cause serious infections in people with weakened immune systems, such as solid organ or bone marrow transplant recipients. 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, 2.0 µg, 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, has approximately 10-fold less antigen content than that used in several other VLP-based vaccines or in past non-VBI CMV vaccine candidates. On December 20, 2018 we announced plans for a Phase II clinical study evaluating VBI-1501 following positive discussions with Health Canada. The Phase II study is expected to be a formal dose-ranging study designed to assess the safety and immunogenicity of three different dosages of VBI-1501: 5µg, 10µg, and 20µg. The program will be an observer-blind, four-arm, placebo-controlled study in both men and women, aged 18 – 40, and is expected to enroll approximately 110 subjects. Following discussions with Health Canada, a toxicology study to support the new dose levels is underway, the results of which are required prior to the start of the clinical study. This enables a potential CTA submission to Health Canada in the fourth quarter of 2019.

Our GBM brain cancer vaccine immunotherapeutic program, VBI-1901, targets CMV in tumor cells. CMV is an infection that is associated with a number of solid tumors, including GBM. We initiated dosing in a multi-center Phase I/IIa clinical study evaluating VBI-1901 in patients with recurrent GBM in January 2018. The DSMB has 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 the 3 different dose cohorts. The DSMB unanimously recommended the continuation of the study without modification and had no safety concerns about any of the 3 dose levels of VBI-1901. The final subject in the high dose cohort was enrolled in mid-December 2018. On November 16, 2018, initial immunologic and biomarker data was presented in a poster presentation at the Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology. We expect to announce data regarding more extensive immunologic data and 6-month survival data from all three dose cohorts in Phase I of the study (low, intermediate, and high), mid 2019.

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:

- conducting the Sci-B-Vac Phase III clinical program to support various marketing authorization applications in the United States, Europe, Canada;
- conducting the Phase I/IIa clinical study of our GBM vaccine immunotherapeutic candidate, VBI-1901;
- further developing the clinical program for VBI-1501, our preventative CMV vaccine candidate into the next phase of development;
- developing VBI-2601, our protein-based immunotherapeutic for treatment of Hepatitis B, in collaboration with Brii Bio;
- modernizing and increasing capacity of our Sci-B-Vac manufacturing facility in Rehovot, Israel;
- increasing sales of Sci-B-Vac in territories where it is currently registered or available on a named-patient basis, and further preparing for commercialization of Sci-B-Vac in additional markets where we may obtain regulatory approval;
- continuing the research and development of our product candidates, including the exploration and development of new product candidates, including a Zika vaccine candidate;
- implementing operational, financial and management information systems and adding human resources support, including additional personnel to support our product development and commercialization activities; and
- maintaining, expanding and protecting our intellectual property portfolio.
- 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 collaboration agreements, 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 product candidates. As of December 31, 2018, VBI had an accumulated deficit of approximately $208 million and stockholders' equity of approximately $98 million. Our ability to maintain our status as an operating company is dependent upon obtaining adequate cash to finance our clinical development, manufacturing, our administrative overhead and our research and development activities. 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, if required, 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 collaborations, 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 $64 million for the year ended December 31, 2018 and we expect to continue to incur substantial losses in future periods. We anticipate that our operating expenses will increase as we continue our clinical studies. These include expenses related to:

- continuing the Phase III clinical program for Sci-B-Vac and the Phase I/IIa clinical study of our GBM vaccine immunotherapeutic candidate;
- continuing the research and development of our product candidates, including further developing the clinical program for VBI-1501 our preventative CMV vaccine candidate and VBI-2601 our Hepatitis B immunotherapeutic candidate;
- modernizing and increasing capacity of our manufacturing facility at Rehovot, Israel;
- commercializing products and dose forms for which we may obtain regulatory approval, including through the use of sub-contractors;
- 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 vaccine development
- developing our internal systems and processes for regulatory affairs and compliance.

In addition, we have incurred and will continue to incur significant expenses as a public company, which subjects us to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the NASDAQ Capital Market and the Canadian securities regulators. Effective as of March 23, 2018, we voluntarily delisted our common shares from the Toronto Stock Exchange.

Equity Financing Activities

On December 17, 2018, we received aggregate gross proceeds of $42.9 million from an underwritten public offering of an aggregate of 30,665,304 common shares at a price of $1.40 per share. After deducting the underwriting discounts and commissions and offering expenses, net proceeds from the offering were of $39.8 million. Net proceeds from the offering will be used to support our vaccine development programs, to continue the advancement of our clinical development and research programs and for other general corporate purposes.

On December 4, 2018, we entered into a 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.

Based upon our current cash position and by monitoring our discretionary expenditures as well as the management of our clinical trial commitments and operating costs, we believe these proceeds will be sufficient to fund our activities, including our approved capital expenditure requirements throughout 2019. We expect, however, that additional financing will be needed in the future to further support clinical, regulatory, research and development, sales and manufacturing, and general business operations.

Amended Credit Facility

On May 6, 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 Perceptive Credit’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 Amended Facility, 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 (the "Third Amendment") to i) extend the period we are required to pay only the interest on the loan from December 31, 2018 to the Amortization Commencement Date (which is defined as the later of July 31, 2019 and, if Sci-B-Vac Phase III clinical trial endpoints are achieved by June 30, 2019, 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 on 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.

Research and Development ("R&D") Services

Pursuant to an agreement with the Israel Innovations 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. In 2018, the Company provided services to biotechnology companies including analytical development, upstream development process, protein purification and formulation and filling for Phase I clinical studies.

Modernization and Capacity Increase of Our Manufacturing Facility

On April 22, 2018, we temporarily closed our manufacturing facility in Rehovot, Israel, for modernization and capacity increase. We intend to increase 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 future clinical supplies of VBI-2601. The construction related to the modernization and the capacity increase is ongoing and validation activities are in progress. We will recommence manufacturing operations upon receiving approval from the IMoH following its review of the modernization and the capacity increase, which is expected in the second half of 2019.

Financial Overview

Overall Performance

The Company had net losses of approximately $64 million and $39 million for the years ended December 31, 2018, and 2017, respectively. The Company has an accumulated deficit of $208 million as December 31, 2018. The Company had $59.3 million of cash at December 31, 2018 and net working capital of approximately $38.4 million.

Revenues

Revenues consist primarily of license 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 $720 was allocated to General and Administrative Expenses in the year ended December 31, 2018.

Research and Development Expenses

R&D expenses consist primarily of costs incurred for the development of Sci-B-Vac, our CMV candidate and GBM vaccine immunotherapeutic 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 Contract Research Organizations to advance the vaccines into and through completion of clinical studies; and
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense.

We expense research and development costs when we incur them.

General and Administration Expenses

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

We expect that our general and administration 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.

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, 2018 Compared to the Year Ended December 31, 2017

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

	Years ended December 31			
	2018	**2017**	**Change $**	**Change %**
Revenues	**$ 3,355**	**$ 865**	**$ 2,490**	**288%**
Expenses:				
Cost of revenues	4,509	5,193	(684)	(13)%
Research and development	38,467	20,918	17,549	84%
General and administration	20,787	12,034	8,753	73%
Total operating expenses	**63,763**	**38,145**	**25,618**	**67%**
Net loss from operations	**(60,408)**	**(37,280)**	**(23,128)**	**62%**
Interest expenses, net	(2,632)	(2,882)	250	(9)%
Foreign exchange gain	(560)	736	(1,296)	(176)%
Loss before income taxes	**(63,600)**	**(39,426)**	**(24,174)**	**61%**
Income tax benefit	-	431	(431)	(100)%
NET LOSS	**$ (63,600)**	**$ (38,995)**	**$ (24,605)**	**63%**

Revenues

Revenue for the year ended December 31, 2018 was $3,355 as compared to $865 for the year ended December 31, 2017. The revenue increased by $2,490 or 288%, as a result of the license revenue earned as part of the License Agreement with Brii Bio (revenue in China of $2,637). Product sales increased in Europe due to named patients sales offset by a decrease in R&D service revenues as a result of the modernization of the manufacturing facility.

Revenue by Geographic Region

	Years ended December 31			
	2018	**2017**	**$ Change**	**% Change**
Revenue in Israel	$ 435	$ 520	$ (85)	(16)%
Revenue in China/Hong Kong	2,667	151	2,516	1,666%
Revenue in Europe	253	194	59	30%
Total Revenue	**$ 3,355**	**$ 865**	**$ 2,490**	**288%**

Cost of Revenues

Cost of revenues for the year ended December 31, 2018 was $4,509 as compared to $5,193 for the year ended December 31, 2018. The decrease in the cost of revenues of $684, or 13% was due to the temporary manufacturing facility closure resulting in the allocation of certain costs of revenues to general and administrative expenses.

Research and Development

Research and development (“R&D”) expenses for the year ended December 31, 2018 were $38,467 as compared to $20,918 for the year ended December 31, 2017. The increase in R&D of $17,549 or 84% is a result of the increase in the costs related to the ongoing Phase III clinical studies of Sci-B-Vac, which commenced patient dosing in December 2017 and our the ongoing Phase I/IIa clinical study for our GBM vaccine immunotherapeutic candidate, which commenced patient dosing in January 2018. This is compared to the year ended December 31, 2017 during which time only the CMV clinical study has been ongoing for most of the year, with the last patient visit in August 2017, and we had a ramp up in R&D expenses leading up to the Phase III Sci-B-Vac clinical studies.

General and Administration

General and administration ("G&A") expenses for the year ended December 31, 2018 were $20,787 as compared to $12,034 for the year ended December 31, 2017. The G&A expense increase of $8,753 or 73% is a result of (1) the increased human resource expenses, including stock-based compensation expenses, and the allocation of certain costs of revenues related to the temporary closure of our manufacturing facility, to G&A expenses, (2) $6 million paid to re-obtain distribution rights in Asia, (3) certain marketing expenses and (4) the impairment loss on property and equipment that were incurred in the first half of 2018.

Net Loss from Operations

The net loss from operations for the year ended December 31, 2018 was $60,408 as compared to $37,280 for the year ended December 31, 2017. The $23,128 increase in the net loss from operations resulted from the increased cost of revenues and R&D and G&A expenses as discussed above.

Interest Expense, net

The interest expense, net of interest income decrease of $250 is largely as a result of increased interest as the interest rates increased compared to the year ended December 31, 2017, offset by interest income earned on cash balances during the year ended December 31, 2018, compared to minimal interest earned during the year ended December 31, 2017.

Foreign Exchange Loss

The foreign exchange loss for the year ended December 31, 2018 was $560 compared to a foreign exchange gain of $736 for the year ended December 31, 2017. 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 benefit

The income tax benefit for the year ended December 31, 2018 was $0 as compared to $431 for the year ended December 31, 2017. The tax benefit recognized in 2017 was related to the deferred taxes recorded for the increase in net operating loss carry forwards in the Company.

Net Loss

The net loss increased by $24,605 or 63%, from $38,995 for the year ended December 31, 2017 to $63,600 for the year ended December 31, 2018. The increase in our net loss is mainly attributable to the increase in our loss from operations, discussed above.

Liquidity and Capital Resources

	Year ended December 31			
	2018	2017	$ Change	% Change
Cash	$ 59,270	$ 67,694	$ (8,424)	(12)%
Current Assets	61,731	70,426	(8,695)	(12)%
Current Liabilities	23,377	13,236	10,141	77%
Working Capital	38,354	57,190	(18,836)	(33)%
Accumulated Deficit	(207,575)	(143,975)	(63,600)	44%

As of December 31, 2018, we had cash of $59,270 as compared to $67,694 as at December 31, 2017. As at December 31, 2018, the Company had working capital of $38,354 as compared to working capital of $57,190 at December 31, 2017. 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 product 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 a need to raise additional funds in order to continue its ongoing development programs. The additional funds may be obtained through the issuance of equity securities, the issuance of additional debt, structured asset financings or revenues from potential collaborations, 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 the research and development of its products, to bring about their successful commercial release, to generate revenue and, ultimately, to attain profitable operations or, alternatively, to advance its products and technology to such a point that they would be attractive candidates for acquisition by others in the industry.

On December 4, 2018, we entered into a 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.

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 $42,932. The Company incurred $3,152 of issuance costs related to the offering resulting in net cash proceeds of $39,780.

On October 30, 2017, we closed an underwritten public offering and a concurrent registered direct offering of an aggregate of 23,575,410 common shares at a price of $3.05 per share for total gross proceeds of $71,905. In addition, in connection with the registered direct offering, the Company issued four-year warrants to purchase 550,000 common shares at an exercise price of $3.34 per share. The Company incurred $4,683 of cash issuance costs related to the offering resulting in net cash proceeds of $67,222. We have and will continue to use the proceeds of the underwritten public offering to support our Sci-B-Vac, CMV and GBM vaccine immunotherapeutic program, to continue the advancement of our research programs and for other general corporate purposes.

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 product 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.

We expect to finance our future cash needs through public or private equity offerings, debt financings or structured asset financings, or corporate collaboration and licensing arrangements. 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 corporate collaboration and licensing arrangements 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 product 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, 2018 Compared to the Year Ended December 31, 2017

Net cash used by Operating Activities

The Company incurred net losses of $63,600 and $38,995 in the years ended December 31, 2018 and 2017, respectively. The Company used $45,533 and $31,381 in cash for operating activities during the years ended December 31, 2018 and 2017, respectively. The increase in cash outflows is largely as a result of increased professional fees and increased R&D expenses from our ongoing Phase III clinical studies of Sci-B-Vac, which commenced patient dosing in December 2017 and the ongoing Phase I/IIa clinical study for our GBM vaccine immunotherapeutic candidate, which commenced patient dosing in January 2018 offset by an increase in net changes in working capital items, specifically accounts payable, other current liabilities and deferred revenue.

Net cash used in/ provided by Investing Activities

The Company's net cash used in investing activities for the year ended December 31, 2018 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 provided by investing activities for the year ended December 31, 2017 consisted of purchases of equipment of $640 and $61 provided by long term deposits.

Net cash received from Financing Activities

Cash flows provided by financing activities decreased by $23,621, from $67,238 for the year ended December 31, 2017 to $43,617 for the year ended December 31, 2018. In 2018, the Company closed an underwritten public offering for gross proceeds of $42,932 offset by $3,006 of cash issuance costs and the issuance of shares to Brii Bio, accounted for at fair value of $3,626. During the year ended December 31, 2017 the Company completed an underwritten public offering for gross proceeds of $71,905 offset by $4,683 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, 2018, the Company had NOL's aggregating approximately $166.1 million. The NOL's are available to reduce taxable income of future years expire as follows:

	United States	Canada	Israel	**Total**
2024	$ -	$ 444	$ -	$ **444**
2025	-	1,382	-	**1,382**
2026	10	3,486	-	**3,496**
2027	446	4,040	-	**4,486**
2028	718	1,564	-	**2,282**
2029	672	2,929	-	**3,601**
2030	2,556	948	-	**3,504**
2031	3,617	1,173	-	**4,790**
2032	2,962	-	-	**2,962**
2033	3,126	1,370	-	**4,496**
2034	5,626	5,131	-	**10,757**
2035	4,661	1,543	-	**6,204**
2036	5,323	8,191	-	**13,514**
2037	6,017	9,204	-	**15,221**
2038	-	5,432		**5,432**
No expiration	3,312	-	80,265	**83,577**
Total losses	$ **39,046**	**$ 46,837**	**$ 80,265**	**$ 166,148**

Net operating loss 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, 2018, we recorded a 100% valuation allowance against our net operating loss carryforwards, 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, 2018, 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 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

Effective January 1, 2018, we adopted Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606) ("Topic 606") using the modified retrospective method which consisted of applying and recognizing the cumulative effect of Topic 606 at the date of initial application. Topic 606 supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC") Topic 605, Revenue Recognition ("Topic 605"). There was no material impact on adoption to our consolidated financial statements related to the adoption of ASC 606.

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 with the transfer of control of the goods to the customers.

Collaborative Arrangements

We enter into collaborative arrangements, which are within the scope of ASC 606, with partners that typically include payment to us of one of 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. 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 ASC Topic 808, Collaborative Arrangements, based on the risks and rewards and activities of the parties pursuant to the contractual arrangement. The Company accounts for collaborative arrangements (or elements within the contract that are deemed part of a collaborative arrangement), which represent a collaborative relationship and not a customer relationship, outside the scope of ASC 606. The Company's collaborations primarily represent revenue arrangements.

License fees

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

R&D Services

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

Royalties

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

Income taxes

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

Impairment of Goodwill and IPR&D Assets

Our intangible assets determined to have indefinite useful lives including IPR&D and goodwill, are tested for impairment annually, or more frequently if events or circumstances indicate that the assets might be impaired. Such circumstances could include but are not limited to: (1) a significant adverse change in legal factors or in business climate, (2) unanticipated competition, or (3) an adverse action or assessment by a regulator.

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 has established August 31st as the date for its annual impairment test of goodwill. There was no goodwill impairment determined as a result of the Company's annual testing on August 31, 2018. The fair value of the Company, which consists of a single reporting unit, included in the impairment test was determined using the closing market stock price of VBI as of August 31, 2018.

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

IPR&D acquired in a business combination is capitalized as an intangible asset and 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, 2018. The fair value of the IPR&D assets, which consist of our CMV and GBM programs, included in the impairment test on August 31, 2018 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 13.5% and the cumulative probability of technical and regulatory success to achieve approval to market the products ranged from approximately 6% to 25%.

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, 2018 and 2017 revenue recognized amounted to $0 and $4, respectively. Effective October 17, 2018, OPKO Bio is no longer a related party.

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 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, 2018, and 2017, we had cash of $59.3 million and $67.7 million, respectively, which is 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 at December 31, 2018 and 2017 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, 2018 and 2017 was 13.3125% and 12.56%, 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, 2018, and December 31, 2017, 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, 2018, 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, 2018. 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, 2018, 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 2019 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, 2018 and 2017
- Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2018 and 2017
- Consolidated Statements of Stockholders' Equity - For the Years Ended December 31, 2018 and 2017
- Consolidated Statements of Cash Flows - For the Years Ended December 31, 2018 and 2017
- Notes to Consolidated Financial Statements

2. **Exhibits**

See Index to Exhibits

VBI Vaccines Inc.

Table of Contents

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, 2018 and 2017, 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, 2018 and 2017, 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
February 25, 2019

VBI Vaccines Inc. and Subsidiaries

Consolidated Balance Sheets
(in thousands, except share amounts)

	December 31, 2018	December 31, 2017
CURRENT ASSETS		
Cash	**$ 59,270**	$ 67,694
Accounts receivable, net	**56**	143
Inventory, net	**911**	788
Prepaid expenses	**982**	951
Other current assets	**512**	850
Total current assets	**61,731**	70,426
NON-CURRENT ASSETS		
Other long-term assets	**835**	675
Property and equipment, net	**8,525**	2,245
Intangible assets, net	**58,249**	63,336
Goodwill	**8,265**	8,974
Total non-current assets	**75,874**	75,230
TOTAL ASSETS	**$ 137,605**	$ 145,656
CURRENT LIABILITIES		
Accounts payable	**$ 6,055**	$ 1,810
Other current liabilities	**13,847**	9,826
Deferred revenues	**2,375**	-
Current portion of long-term debt, net of debt discount – related party	**1,100**	1,600
Total current liabilities	**23,377**	13,236
NON-CURRENT LIABILITIES		
Long-term debt, net of debt discount – related party	**12,927**	11,538
Liabilities for severance pay	**371**	426
Deferred revenues, net of current portion	**2,797**	669
Total non-current liabilities	**16,095**	12,633
COMMITMENTS AND CONTINGENCIES (NOTES 14 and 15)		
STOCKHOLDERS' EQUITY		
Common shares (unlimited authorized; no par value) (2018 issued – 97,343,777; 2017 - issued 64,078,781)	**246,417**	201,806
Additional paid-in capital	**63,449**	60,891
Accumulated other comprehensive (loss) income	**(4,158)**	1,065
Accumulated deficit	**(207,575)**	(143,975)
Total stockholders' equity	**98,133**	119,787
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 137,605**	$ 145,656

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	
	2018	2017
Revenues	**$ 3,355**	$ 865
Operating expenses:		
Cost of revenues	**4,509**	5,193
Research and development	**38,467**	20,918
General and administration	**20,787**	12,034
Total operating expenses	**63,763**	38,145
Net loss from operations	**(60,408)**	(37,280)
Interest expense, net (including related party - see Note 9)	**(2,632)**	(2,882)
Foreign exchange (loss) gain	**(560)**	736
Loss before incomes taxes	**(63,600)**	(39,426)
Income tax benefit	**-**	431
NET LOSS	**$ (63,600)**	$ (38,995)
Other comprehensive (loss) income - Currency translation adjustment	**(5,223)**	4,261
COMPREHENSIVE LOSS	**$ (68,823)**	$ (34,734)
Net loss per share of common shares, basic and diluted	**$ (0.97)**	$ (0.88)
Weighted-average number of common shares outstanding, basic and diluted	**65,647,781**	44,158,692

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 Stockholder's Equity
BALANCE AS OF JANUARY 1, 2017	40,018,495	$ 133,312	$ 58,595	$ (3,196)	$ (104,980)	$ **83,731**
Common shares issued in financing transaction	23,575,410	67,222	-	-	-	**67,222**
Warrants issued in connection with financing transaction	-	(611)	611	-	-	-
Common shares issued on settlement agreement with Kevelt	274,000	1,142	-	-	-	**1,142**
Stock-based compensation	179,499	640	1,685			**2,325**
Common shares issued for services	25,000	85	-	-	-	**85**
Common shares issued on exercise of stock options	6,377	16	-	-	-	**16**
Net loss					(38,995)	**(38,995)**
Currency translation adjustments	-	-	-	4,261	-	**4,261**
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**

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	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ **(63,600)**	$ (38,995)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	**542**	730
Impairment of property and equipment	**278**	-
Impairment of intangible assets	**-**	300
Stock-based compensation	**3,312**	2,410
Amortization of debt discount	**1,274**	1,181
Deferred taxes	**-**	(431)
Inventory reserve	**189**	217
Net change in operating working capital items:		
Decrease (increase) in accounts receivable	**79**	(127)
Increase in inventory	**(378)**	(89)
Increase in prepaid expenses	**(285)**	(265)
Decrease (increase) in other current assets	**213**	(230)
Increase in other long-term assets	**(31)**	(14)
Increase (decrease) in accounts payable	**3,804**	(675)
Increase (decrease) in deferred revenues	**4,924**	(107)
Increase in other current liabilities	**4,146**	4,714
Net cash flows used in operating activities	**(45,533)**	(31,381)
INVESTING ACTIVITIES		
Changes in other long-term assets	**-**	61
Purchase of property and equipment	**(5,993)**	(640)
Net cash flows used in investing activities	**(5,993)**	(579)
FINANCING ACTIVITIES		
Proceeds from issuance of common shares for cash	**46,558**	71,905
Share issuance costs	**(3,006)**	(4,683)
Proceeds from issuance of common shares for cash, upon exercise of stock options	**65**	16
Net cash flows provided by financing activities	**43,617**	67,238
Effect of exchange rates on cash	**(515)**	134
CHANGE IN CASH FOR THE YEAR	$ **(8,424)**	$ 35,412
CASH, BEGINNING OF YEAR	$ **67,694**	$ 32,282
CASH, END OF YEAR	$ **59,270**	$ 67,694
Supplementary information:		
Interest paid	$ **1,980**	$ 1,850
Non-cash investing and financing:		
Warrant modification in connection with debt amendment	**386**	-
Capital expenditures included in accounts payable and other current liabilities	**1,552**	145
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") 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 next generation vaccines to address unmet needs in infectious disease and immuno-oncology. We currently manufacture our product, Sci-B-Vac a third generation prophylactic Hepatitis B ("HBV") vaccine for adults, children and newborns, which is approved for use in Israel and 10 other countries. Sci-B-Vac has not yet been approved by the United States Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA") or Health Canada. VBI is currently conducting a global Phase III clinical program to obtain FDA, EMA and Health Canada market approvals for commercial sale of Sci-B-Vac in the United States, the European Union (the "EU"), and Canada, respectively. Our wholly-owned subsidiary in Rehovot, Israel, currently manufactures and sells Sci-B-Vac. We are also developing a protein-based immunotherapeutic for treatment of Hepatitis B in collaboration with Brii Biosciences Limited ("Brii Bio").

We are also developing technologies that seek to enhance vaccine protection in large, underserved markets. These include an enveloped "Virus Like Particle" or "eVLP" vaccine platform that allows for the design of enveloped virus-like particle vaccines that closely mimic the target viruses. VBI is advancing a pipeline of eVLP vaccines, with programs in human cytomegalovirus ("CMV"), an infection that, while common, can lead to serious complications in newborns and people with weakened immune systems, and glioblastoma multiforme ("GBM"), which is an aggressive form of adult brain cancer.

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 $207,575 as of December 31, 2018 and cash outflows from operating activities of $45,533, for the year-ended December 31, 2018.

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, if required, will be a combination of proceeds from the issuance of equity securities, the issuance of additional debt, structured asset financings, and revenues from potential collaborations, 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 has a term of three years and expires on May 15, 2020; however 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 this Distribution Agreement and there are no assurances as to how much, if any, funds will be raised under the Distribution Agreement.

On October 30, 2017, the Company closed an underwritten public offering and a concurrent registered direct offering of an aggregate of 23,575,410 common shares at a price of $3.05 per share for total gross proceeds of $71,905. In addition, in connection with the registered direct offering, the Company issued four-year warrants to purchase 550,000 common shares at an exercise price of $3.34 per share. The Company incurred $4,683 of cash issuance costs related to the offering resulting in net cash proceeds of $67,222.

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.

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Consolidation

The consolidated financial statements include the accounts of VBI and its wholly owned subsidiaries, SciVac, 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, 2018 and 2017, respectively.

Inventory

Inventory components include all raw materials, work-in-progress and finished goods. Cost is determined on a first-in, first-out basis. Inventory is valued at the lower of cost or net realizable value. The cost of inventories comprises costs to purchase and costs incurred in bringing the inventories to their present location and condition. 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 annual 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 deduction 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. 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, 2018 and 2017, the Company had $154 and $240 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 general and administrative on the consolidated statements of operations and comprehensive loss.

Goodwill and In-Process Research and Development (“IPR&D”) Assets

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

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 has established August 31st as the date for its annual impairment test of goodwill. There was no goodwill impairment determined as a result of the Company’s annual testing on August 31, 2018. The fair value of the Company, which consists of a single reporting unit, included in the impairment test was determined using the closing market stock price of VBI as of August 31, 2018.

The goodwill is in VBI Cda and the change in carrying value from December 31, 2017 relates to currency translation adjustments which decreased goodwill by $709 for the year ended December 31, 2018. The change in carrying value from December 31, 2016 to December 31, 2017 relates to currency translation adjustments which increased goodwill by $589.

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

IPR&D acquired in a business combination is capitalized as an intangible asset and 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, 2018. The fair value of the IPR&D assets included in the impairment test on August 31, 2018 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 13.5% and the cumulative probability of technical and regulatory success to achieve approval to market the products ranged from approximately 6% to 25%.

The IPR&D assets are in VBI Cda and the change in carrying value from December 31, 2017 relates to currency translation adjustments which decreased IPR&D assets by $4,976 for the year ended December 31, 2018. The change in carrying value from December 31, 2016 to December 31, 2017 relates to currency translation adjustments which increased IPR&D assets by $4,131.

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

Effective January 1, 2018, we adopted Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606) ("Topic 606") using the modified retrospective method which consisted of applying and recognizing the cumulative effect of Topic 606 at the date of initial application. Topic 606 supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC") Topic 605, Revenue Recognition ("Topic 605"). There was no material impact on adoption to our consolidated financial statements related to the adoption of ASC 606.

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 with the transfer of control of the goods to the customers.

Collaborative Arrangements

We enter into collaborative arrangements, which are within the scope of ASC 606, with partners that typically include payment to us of one of 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. 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 ASC Topic 808, Collaborative Arrangements, based on the risks and rewards and activities of the parties pursuant to the contractual arrangement. The Company accounts for collaborative arrangements (or elements within the contract that are deemed part of a collaborative arrangement), which represent a collaborative relationship and not a customer relationship, outside the scope of ASC 606. The Company's collaborations primarily represent revenue arrangements.

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 in accordance with 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 at December 31, 2018 and 2017. 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 $14,975 and $15,157 at December 31, 2018 and 2017, 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 and the impact of all dilutive potential shares. There is no dilutive effect on the earnings per share for all periods presented.

Operating leases

Operating lease payments are recognized as an expense on a straight-line basis over the lease term. Contingent rentals arising under operating leases are recognized as an expense in the period in which they are incurred.

Stock-based compensation

The Company accounts for share-based awards to employees and directors in accordance with the provisions of ASC 718, Compensation—Stock Compensation. 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

Revenue from Contracts with Customers

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"). ASU 2014-09 outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. ASU 2014-09 also requires entities to disclose sufficient information, both quantitative and qualitative, to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Our adoption of this ASU, effective as of January 1, 2018, did not have a material impact on our condensed consolidated financial statements and footnote disclosures. See also Note 2.

Recognition and Measurement of Financial Assets and Financial Liabilities

In January 2016, the FASB issued ASU 2016-01, "Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities". This update will change the income statement impact of equity investments held by an entity; disclosures related to fair value of financial instruments and presentation of financial assets and liabilities. ASU 2016-01 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Entities must apply the standard using a cumulative-effect adjustment as of the beginning of the fiscal year of adoption. Except for certain early application guidance, early adoption is not permitted. We adopted this ASU effective January 1, 2018 and are no longer required to disclose the fair value assumptions in determining the fair value of the long-term debt in the footnote disclosures.

Collaborative Arrangements

In November 2018, the FASB issued ASU 2018-18: Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. This ASU provides guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. Accordingly, this amendment added unit of account guidance in Topic 606 when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606. In addition, the amendment provides certain guidance on presenting the collaborative arrangement transaction together with Topic 606. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. This ASU is to be applied retrospectively to the date of initial application of Topic 606. The Company has early adopted this ASU effective in the fourth quarter of 2018 with no impact on our consolidated financial statements and related footnote disclosures.

Recently Issued Accounting Standards, not yet Adopted

Leases

In February 2016 the FASB issued ASU 2016-02: Leases. The ASU introduces a lessee model that results in most leases impacting the balance sheet. The ASU addresses other concerns related to the current lease model. Under ASU 2016-02, lessees will be required to recognize for all leases with terms longer than 12 months, at the commencement date of the lease, a lease liability, which is a lessee's obligation to make lease payments arising from a lease measured on a discounted basis, and a right-to-use asset, which is an asset that represents the lessee's right to use or control the use of a specified asset for the lease term. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition. The update is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years.

In July 2018, the FASB issued ASU 2018-10 "Codification Improvements to Topic 842, Leases". This ASU affects narrow aspects of the guidance issued in the amendments in ASU 2016-02 including those regarding residual value guarantees, rate implicit in the lease, lessee reassessment of lease classification, lessor reassessment of lease term and purchase option, variable lease payments that depend on an index or a rate, investment tax credits, lease term and purchase option, transition guidance for amounts previously recognized in business combinations, certain transition adjustments, transition guidance for leases previously classified as capital leases under Topic 840, transition guidance for modifications to leases previously classified as direct financing or sales-type leases under Topic 840, transition guidance for sale and leaseback transactions, impairment of net investment in the lease, unguaranteed residual asset, effect of initial direct costs on rate implicit in the lease, and failed sale and leaseback transactions.

The Company will implement ASC 842 retrospectively with an application date of January 1, 2019 through a cumulative-effect adjustment to opening retained earnings while the comparative period presented in the financial statements and footnote disclosures will continue to be in accordance with Topic 840 – Leases. The Company will use the package of practical expedients relating to: 1) the need to re-assess expired or existing contracts that are or contain leases; 2) the need to reassess lease classification for any expired or existing leases; and 3) the need the reassess initial direct costs for existing leases.

The Company expects to recognize right-of use assets and operating lease liabilities of approximately $1,620 on its consolidated balance sheet upon adoption on January 1, 2019. There will be no impact on opening retained earnings.

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. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, early adoption is permitted but no earlier than an entity's adoption date of Topic 606. The Company does not believe there will be a material impact from the adoption of this new accounting guidance on our consolidated financial statements and related footnote disclosures.

Intangibles – Goodwill and Other, Internal-Use Software

In August 2018, the FASB issued ASU 2018-15: Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customers' accounting for implementation costs incurred in a cloud computing arrangement that is a service contract. This ASU aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. Accordingly, the amendments require an entity (customer) in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. 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 is currently evaluating the impact this new guidance will have on its financial statements and related disclosures.

4. PROPERTY AND EQUIPMENT

	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**

	December 31, 2017		
	Cost	Accumulated Depreciation	Net Book Value
Machinery and equipment	$ 1,748	$ (698)	$ 1,050
Furniture and office equipment	92	(26)	66
Computer equipment and software	315	(140)	175
Leasehold improvements	2,453	(1,499)	954
	$ 4,608	$ (2,363)	$ 2,245

Depreciation expense for the years ended December 31, 2018, and 2017 was $481 and $667, respectively.

5. INVENTORY, NET

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

	2018	2017
Finished goods	**$ 81**	$ 99
Work-in-process	**64**	119
Raw materials	**766**	570
	$ 911	$ 788

The Company recorded a provision of approximately $189 and $217 as of December 31, 2018 and 2017, 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. INTANGIBLES

	December 31, 2018				
	Gross Carrying amount	**Accumulated Amortization**	**Cumulative 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**

	December 31, 2017				
	Gross Carrying amount	Accumulated Amortization	Impairment Charge	Cumulative Currency Translation	Net Book Value
License	$ 669	$ (397)	$ -	$ 33	$ 305
IPR&D assets	61,500	-	(300)	1,831	63,031
	$ 62,169	$ (397)	$ (300)	$ 1,864	$ 63,336

The license is held in Israel at SciVac. Amortization expenses for the years ended December 31, 2018 and 2017 amounted to $61 and $63, respectively. Amortization is expected to be approximately $58 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.

7. OTHER CURRENT LIABILITIES

Other current liabilities consisted of the following:

	2018	2017
Accrued research and development expenses (including clinical trial expenses)	**$ 9,763**	$ 7,008
Payroll and employee-related costs	**2,294**	1,699
Other current liabilities	**1,790**	1,119
	$ 13,847	$ 9,826

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, 2018 and 2017 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	2018	2017
Warrants	**2,618,824**	2,618,824
Stock options and unvested stock awards	**3,748,246**	2,775,774
	6,367,070	5,394,598

9. LONG-TERM DEBT – RELATED PARTY

	2018	2017
Long-term debt, net of debt discount of $1,274	**$ 14,027**	$ 13,138
Less: current portion, net of debt discount of $100	**1,100**	1,600
	$ 12,927	$ 11,538

On May 6, 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 (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 Amended Facility, 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 the Amortization Commencement Date (which is defined as the later of July 31, 2019 and, if Sci-B-Vac Phase III clinical trial endpoints are achieved by June 30, 2019, January 31, 2020), ii) extend the maturity of the term loan to June 30, 2020 and iii) reduce the exercise price on certain warrants to purchase common shares issued to Perceptive 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 Company will account for this as a debt modification, and as result of the amendment to the exercise price in connection with the Third Amended Facility, the debt discount will be 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 outstanding at December 31, 2018, including the $300 exit fee discussed below, is $15,300. The principal amount of the loan made under the Second Amendment 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 the Amortization Commencement Date pursuant to the Third Amendment. The interest rate as of December 31, 2018 was 13.3125%. Upon the occurrence of an event of default, and during the continuance of an event of default, the Applicable Margin, defined 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, 2018. Pursuant to the Amended Credit Facility, the Company agreed to appoint a representative of the lender on the Company's board of directors (the "Board") who was also a portfolio manager of the Company's largest shareholder. Effective January 2018, the Lender's representative 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 $3,839 is being charged to interest expense using the effective interest method over the term of the debt. As of December 31, 2018, and December 31, 2017, the unamortized debt discount is $1,274 and $2,163.

Interest expense, net of interest income recorded for the year ended December 31, 2018 and 2017 was as follows after giving effect to the Third Amendment dated January 31, 2019 as discussed above:

	December 31	
	2018	2017
Interest expense – related party	**$ 1,980**	$ 1,850
Amortization of debt discount – related party	**1,274**	1,181
Interest income	**(622)**	(149)
Total interest expense, net of interest income	**$ 2,632**	$ 2,882

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

Year ending December 31,	
2019	$ 1,200
2020	14,100

	$ 15,300

10. EMPLOYEE BENEFITS

Defined contribution plan

The Company operates a defined contribution retirement benefit plan for all qualifying employees in accordance with 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, 2018 and 2017 was $218 and $190, 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 now stands at 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 research and development expenses for the year ended December 31, 2018 is $24 of severance payments pursuant to the aforementioned statutory or contractual obligations.

Included in research and development expenses and cost of revenues for the year ended December 31, 2017 is $187 and $50, respectively of severance payments pursuant to the aforementioned statutory or contractual obligations.

11. STOCKHOLDERS' EQUITY AND ADDITIONAL PAID-IN CAPITAL

Authorized

Unlimited number of common shares without par value.

Common shares issuances
2017 common share issuances

i. On January 17, 2017 the Company issued 6,377 common shares related to stock options that were exercised during the year.

ii. On March 22, 2017, the Company issued 23,250 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.

iii. On June 22, 2017, 25% of the stock awards granted on June 24, 2016 (see 2016 common share issuances ii above) vested and the Company issued 156,249 shares of the Company's common shares.

iv. During the first half of 2017, the Company issued 25,000 common shares of the Company to one consultant for services provided to the Company's shareholders in connection with their respective consulting agreements. The fair value of the common shares of $85 was recognized as an expense.

v. On October 30, 2017, the Company closed an underwritten public offering and a concurrent registered direct offering of an aggregate of 23,575,410 common shares at a price of $3.05 per share for total gross proceeds of $71,905. In addition, in connection with the registered direct offering, the Company issued four-year warrants to purchase 550,000 common shares to an investor as a finder's fee, at an exercise price of $3.34 per share. The Company incurred $4,683 of cash share issuance costs.

vi. On December 18, 2017, the Company issued 274,000 common shares of the Company to Kevelt as part of a settlement agreement related to a Development and Manufacturing Agreement. The transaction was measured using the fair value of the Company's common shares at November 8, 2017 at a price of $4.17 for a total of $1,142.

2018 common share issuances

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 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 a 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 at December 31, 2018.

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 at December 31, 2018, there were 1,140,053 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 at December 31, 2018, there were 3,460 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 at December 31, 2018, there were 613,577 options outstanding under the 2014 Plan.

2016 VBI Equity Incentive Plan

The 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 at December 31, 2018, there were 1,722,586 options outstanding and 268,570 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 VBI Equity Incentive 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 VBI Equity Incentive 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 this plan total 5,213,166 at December 31, 2018.

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 VBI Equity Incentive 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 Tandem Stock Appreciation Rights 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 VBI Equity Incentive 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 this plan at December 31, 2018 and 2017.

Under the 2016 VBI Equity Incentive 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 Equity Incentive 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 VBI Equity Incentive 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 at 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, 2018 and 2017. All RSUs issued under the plan at December 31, 2018 and 2017 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 VBI Equity Incentive 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 of Directors. 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, 2018.

Stock-based compensation expense

The table below provides information, as of December 31, 2018, 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 of outstanding awards	Weighted average exercise price
2006 Plan	1,140,053	$ 4.09
2013 Plan	3,460	$ 7.31
2014 Plan	613,577	$ 5.23
2016 Plan	1,991,156	$ 3.82
Total	**3,748,246**	**$ 4.14**

Activity related to stock options is as follows:

	Number of Stock Options	Weighted Average Exercise Price
Balance outstanding at December 31, 2016	2,167,903	**$** 4.45
Granted	303,500	$ 3.72
Exercised	(6,377)	$ 2.50
Forfeited	(113,631)	$ 4.37
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**
Exercisable at December 31, 2018	**2,292,112**	**$ 4.34**

	Outstanding			Exercisable	
Exercise Price	Number Of Options	Weighted Average Remaining Contractual Life (Years)		Number Of Options	Weighted Average Exercise Price
$ 0.00 - $ 3.49	508,493	7.47		212,651	$ 2.87
$ 3.50 - $ 4.49	2,211,920	7.60		1,380,852	$ 4.15
$ 4.50 - $ 5.50	691,299	5.37		630,645	$ 4.91
$ 5.50+	67,964	5.51		67,964	$ 8.13
	3,479,676	7.10		2,292,112	$ 4.34

The weighted average remaining contractual life of exercisable options was 6.12 years and 5.57 years at December 31, 2018 and 2017, 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, 2016 and December 31, 2016	639,374	3.88
Granted	57,000	$ 4.72
Vested	(213,870)	$ 3.93
Forfeited	(58,125)	$ 3.89
Unvested shares outstanding at 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**

The intrinsic value of outstanding options at December 31, 2018 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 $954 for the year ended December 31, 2018. The intrinsic value of exercised options was not significant for the years ended December 31, 2018 and 2017.

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:

	2018	2017
Volatility	**114.68%**	87.22%
Risk free interest rate	**2.57%**	2.31%
Expected term in years	**5.84**	6.3
Expected dividend yield	**0.00%**	0.00%
Weighted average fair value per option	**$ 3.21**	$ 3.12

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:

	2018	2017
Research and development	**$ 696**	$ 702
General and administration	**2,556**	1,648
Cost of revenue	**60**	60
Total stock-based compensation expense	**$ 3,312**	$ 2,410

There is $3,935 of unrecognized compensation from all equity awards as at December 31, 2018. This expense will be recognized over a weighted average period of 1.96 years.

The number of restricted stock awards vested during the year ended December 31, 2018 includes 9,281 shares withheld or repurchased by the Company on behalf of employees to satisfy $35 of tax obligations relating to the vesting of such shares.

Warrants

The Company amended a portion of the warrants issued on December 6, 2016, as described in Note 9.

The warrants issued on October 30, 2017, as a finder’s fee in connection with the registered direct offering described earlier in Note 11, entitle the holder to purchase 550,000 common shares at an exercise price of $3.34 per share. The warrants are exercisable at any time on or prior to the fourth anniversary of their issue date. The fair value of the warrants issued on October 30, 2017 in the amount of $611 was based on the Black-Scholes option pricing model.

Activity related to the warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance outstanding at December 31, 2016	2,068,824	$ 3.63
Issued	550,000	$ 3.34
Balance outstanding at December 31, 2017 and 2018	**2,618,824**	$ **3.57**

12. REVENUE AND DEFERRED REVENUE

Revenue is comprised of the following:

	2018	2017
License revenue	**$ 2,637**	$ -
Product revenue	**604**	502
R&D Service revenue	**114**	363
	$ 3,355	$ 865

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, 2018:

	Total	**2019**	**2020 and thereafter**
Product revenue	**469**	-	469
R&D Service revenue	**4,703**	2,375	2,328
Total	**$ 5,172**	$ 2,375	$ 2,797

The following table presents changes in the deferred revenue balance for the year ended December 31, 2018:

Balance at December 31, 2017	$ 669
Amounts received in 2018	4,815
Recognition of deferred revenue	(74)
Currency translation	(238)
Balance at December 31, 2018	**5,172**
Short Term	**2,375**
Long Term	**2,797**

Collaboration and License Agreement – Brii Bio

On December 4, 2018, we entered into a 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, 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 Collaboration and 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 Collaboration and License Agreement consisted of a $11 million non-refundable upfront payment. As part of Collaboration and Licences 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 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 a expected cost plus a margin approach and the remaining transaction price of $2.6 million was allocated to the VBI-2601 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 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.

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. INCOME TAXES

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

	2018	2017
United States	**$ (4,757)**	$ (7,220)
Canada	**(8,177)**	(10,568)
Israel	**(50,666)**	(21,638)
Total	**$ (63,600)**	$ (39,426)

The components of the income tax (provision) benefits are as follows:

	2018	2017
Current Tax		
Canada	**$ -**	$ 3
	-	3
Deferred Tax		
Canada	-	428
	-	428
Total		
Canada	-	431
	$ -	$ 431

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 provisions are as follows:

	2018	2017
Loss before income taxes	**$ (63,600)**	$ (39,425)
Canadian statutory tax rate	**26.50%**	26%
Expected recovery of income tax	**16,854**	10,251
Research and development tax credits	**256**	227
Change in valuation allowance	**(14,685)**	(5,496)
Difference between Canadian and foreign tax rates	**(1,708)**	1,011
Other	**(125)**	706
Change in tax rates	**59**	(5,749
Stock based compensation	**(651)**	(519)
Income tax benefit	**$ -**	$ 431

The income tax benefit for the year ended December 31, 2017 related to the deferred tax assets recorded for the increase in net operating loss carry forwards.

For 2018 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%.

For 2017, the Canadian statutory income tax rate of approximately 26% is comprised of federal income tax at approximately 15% and provincial income tax at approximately 11%. The Israel statuary income rate is approximately 25%. On December 22, 2017, the United States enacted tax reform legislation through the Tax Cuts and Jobs Act, which significantly changes the existing U.S. tax laws, including a reduction in the corporate tax rate from 35% to 21%, a move from a worldwide tax system to a semi-territorial system, a change in the treatment of operating loss carryforwards generated subsequent to 2017 fiscal year as well as other changes. As a result of enactment of the legislation, the Company recorded a one-time change to its deferred tax assets and related valuation allowance. As the Company has a full valuation allowance such change did not impact the Company's results of operations or financial position.

The deferred tax asset (liability) consists of the following:

	2018	2017
Deferred tax assets (liabilities):		
Net operating losses	**$ 41,556**	$ 31,858
Research and development tax credits	**13,350**	10,550
Property and equipment	**435**	581
Reserves and other	**1,457**	1,250
Interest	**858**	-
Intangible assets	**(15,546)**	(16,814)
Net deferred tax assets	**42,110**	27,425
Less: valuation allowance	**(42,110)**	(27,425)
Net deferred tax assets (liabilities)	**$ -**	$ -

As of December 31, 2018, and 2017, the Company has United States federal net operating loss carryovers ("NOLs") of approximately $39 million and $35.3 million, respectively, including $29 million related to the acquisition of VBI DE, available to offset taxable income which expire beginning in 2026. The NOL's related to the acquisition of VBI DE may be subject to limitations under Internal Revenue Code Section 382 and similar state income tax provisions should there be a greater than 50% ownership change as determined under the regulations. 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, 2018, and 2017, the Company also has Canadian net operating loss carryovers of approximately $47 million and $44.9 million, respectively available to offset future taxable income which expire beginning in 2024. As at December 31, 2018 the Company also has Israel net operating loss carryovers of approximately $80.3 million (2017 - $44.9 million) respectively, which can be carried forward indefinitely.

At December 31, 2018 and 2017, the Company has $4.9 million and $5.0 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, 2018, and 2017, the Company has unclaimed research and development expenses in Canada of approximately $17.2 million and $17.0 million, respectively, which are available to offset future taxable income indefinitely.

At December 31, 2018, the Company had NOL's aggregating approximately $166.1 million. The NOL's are available to reduce taxable income of future years expire as follows:

	United States	Canada	Israel	**Total**
2024	$ -	$ 444	$ -	$ **444**
2025	-	1,382	-	**1,382**
2026	10	3,486	-	**3,496**
2027	446	4,040	-	**4,486**
2028	718	1,564	-	**2,282**
2029	672	2,929	-	**3,601**
2030	2,556	948	-	**3,504**
2031	3,617	1,173	-	**4,790**
2032	2,962	-	-	**2,962**
2033	3,126	1,370	-	**4,496**
2034	5,626	5,131	-	**10,757**
2035	4,661	1,543	-	**6,204**
2036	5,323	8,191	-	**13,514**
2037	6,017	9,204	-	**15,221**
2038	-	5,432		**5,432**
No expiration	3,312	-	80,265	**83,577**
Total losses	$ **39,046**	**$ 46,837**	**$ 80,265**	**$ 166,148**

14. 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 third generation hepatitis B vaccine whose sales and territories are governed by the Ferring License Agreement ("License Agreement"). Under the License Agreement the Company is committed to pay Ferring royalties equal to 7% of net sales (as defined therein). Royalty payments of $42 and $35 were recorded in cost of revenues for the years ended December 31, 2018 and 2017, 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 License Agreement), provided that the payment of 30% shall not apply to a grant of rights in or relating to: (i) the territory "(Territory")as such term was defined prior to an amendment dated January 24, 2005; or (ii) the Berna Territory (as defined in therein).

We are to pay Ferring the above-mentioned royalties on a country-by-country basis until the date which is 10 years after the date of commencement of the first royalty year in respect of such country Until the 30th day prior to the expiration of the first license period, we have the 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 paying Ferring $100. Royalties will continue to be payable for the duration of the extended license periods. When the license has been in effect for, and elapsed after, a 17 year license period with respect to a country in the territory, we will thereafter have a royalty-free license to market in such country and when all the license periods have expired in each country in the territory.

(c) Under an Assignment and Assumption Agreement, the Company is required to pay royalties to SciGen Singapore equal to 5% of Net Sales of Sci-B-Vac. Royalty payments of $30 and $25 were recorded in cost of revenues for the years ended December 31, 2018 and 2017 respectively.

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) ($501,467). 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 oppose the motion and otherwise defend these claims vigorously.

15. OPERATING LEASES

The Company has entered into various non-cancellable lease agreements for its office, lab and manufacturing facilities. These arrangements expire at various times through 2022. Rent expense for the years ended December 31, 2018 and 2017 was $992 and $919, respectively, and is included in general and administration in the statement of operations and comprehensive loss.

The future annual minimum payments under these leases is as follows:

Year ending December 31	
2019	$ 902
2020	503
2021	427
2022	36
Total	$ 1,868

On January 15, 2019, the Company entered into a 3 year non-cancelable lease agreement for its office at SciVac for $85 a year.

16. 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.

	2018	2017
Revenue in Israel	**$ 435**	$ 520
Revenue in China/Hong Kong	**2,667**	151
Revenue in Europe	**253**	194
Total	**$ 3,355**	$ 865

There was no revenue attributed to our country of domicile, Canada, for years ended December 31, 2018 and 2017.

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

For the year ended December 2017, the Company had 5 customers that individually accounted for 25%, 17%, 17%, 12% and 11% of revenues, respectively.

Tangible Long Lived Assets (Property and equipment) attributed to geographic areas are as follows:

	2018	2017
Property and equipment in Israel	**$ 8,396**	$ 2,116
Property and equipment in United States	**52**	-
Property and equipment Canada (country of domicile)	**77**	129
Total	**$ 8,525**	$ 2,245

17. 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, 2018 and 2017 revenue recognized amounted to $0 and $4, respectively. Effective October 17, 2018, OPKO Bio is no longer a related party.

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.

18. SUBSEQUENT EVENTS

On January 31, 2019, the Company approved to grant 3,900,000 stock options and awards to existing employees, directors and an eligible service provider pursuant to the 2016 Plan. 3,710,000 of the granted options and awards vest on a monthly basis over 36 months and automatically expire on January 31, 2029 while 190,000 awards vest immediately.

On January 31, 2019, the Company entered into the Third Amendment to the Amended Credit Facility, see Note 9 for more further discussion.

On January 15, 2019, the Company entered into a 3 year non-cancelable lease agreement for its office at SciVac, see Note 15 for further discussion.

On January 29, 2019 we incorporated SciVac Hong Kong Limited.

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).
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).
10.7+	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).
10.8+	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).
10.9+	Employment Agreement with Egidio Nascimento, dated May 8, 2014 (incorporated by reference to Exhibit 10.7 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+	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).
10.12	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).
10.13	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).

10.23[(1)]	Collaboration and Option License Agreement, dated April 2, 2015, by and between Variation Biotechnologies, Inc. and Sanofi Vaccines Technologies S.A.S (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to VBI DE's current report on Form 8-K SEC File No. 000-18188), filed with the SEC on April 29, 2015).
10.24	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).
10.26	License Agreement, dated Mary 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).
10.27	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).
10.28	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).
10.29	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).

10.30[(1)]	Evaluation and Option Agreement, dated February 8, 2016, by and between Variation Biotechnologies Inc. and GlaxoSmithKline Biologicals SA (incorporated by reference to Exhibit 10.28 to VBI DE's annual report on Form 10-K (SEC File No. 000-18188), filed with the SEC on February 26, 2016).
10.31	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).
10.36+	Separation and Release Agreement with Jim Martin, dated September 1, 2016 (incorporated by reference to Exhibit 10.36 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).
10.42+	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).
10.43+	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).
10.44+	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).
10.45	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).

10.46	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).
10.47+	Separation and Release Agreement with Curt Lockshin, dated as of December 22, 2016 (incorporated by reference to Exhibit 10.46 to the annual report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).
10.48	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).
10.49	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).
10.50	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).
10.51	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).
10.52	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).
10.53	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).
10.54	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).
10.55	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).
10.56+	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).
10.57+	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).
10.58	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).
10.59	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).

10.60	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)
10.61+	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)
10.62*(2)	Collaboration and License Agreement, dated December 4, 2018, between VBI Vaccines, Inc. and Brii Biosciences Limited
10.63*	Stock Purchase Agreement, dated December 4, 2018, between VBI Vaccines, Inc. and Brii Biosciences Limited
10.64*	Amendment to Sublease Lease, dated January 15, 2019, by and between Green Power YE and SciVac Ltd.
10.65+*	Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, effective January 1, 2019
10.66*	Waiver Agreement, dated February 14, 2019, by and among Variation Biotechnologies (US), Inc., the Guarantors party thereto, and Perceptive Credit Holdings, LP
10.67	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)
10.68	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)
21.1*	Subsidiary List of VBI Vaccines Inc. (Incorporated by reference to Exhibit 21.1 to the Annual Report on Form 10-K
23.1*	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.
24.1*	Powers of Attorney (attached to the signature page hereto).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of Chief Financial Officer and Head of Business Development pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934.

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

* Filed herewith.

** Furnished herewith.

+ Indicates a management contract or compensatory plan.

(1) Certain material has been omitted from this document pursuant to a request for confidential treatment. The omitted material has been filed separately with the SEC.

(2) Certain portions of this exhibit have been omitted and filed separately with the SEC under a confidential treatment request pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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 25th day of February, 2019.

VBI VACCINES INC.

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

By: */s/ Chris McNulty*
Chris 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 Jeff R. 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: February 25, 2019 */s/ Jeff R. Baxter*
Jeff Baxter, President, Chief Executive Officer and Director (Principal Executive Officer)

Date: February 25, 2019 */s/ Chris McNulty*
Chris McNulty, Chief Financial Officer and Head of Business Development (Principal Financial and Accounting Officer)

Date: February 25, 2019 */s/ Steven Gillis,*
Steven Gillis,
Director

Date: February 25, 2019 */s/ Michel De Wilde*
Michel De Wilde
Director

Date: February 25, 2019 */s/ Scott Requadt*
Scott Requadt
Director

Date: February 25, 2019 */s/ Blaine McKee*
Blaine McKee
Director

Date: February 25, 2019 */s/ Tomer Kariv*
Tomer Kariv
Director

Exhibit 10.62

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE "COMMISSION") PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "*****"

COLLABORATION AND LICENSE AGREEMENT

This **COLLABORATION AND LICENSE AGREEMENT** ("**Agreement**") is entered into as of December 4, 2018 (the "**Effective Date**") between **VBI VACCINES INC.**, a company organized under the laws of the Province of British Columbia, Canada ("**VBI**"), and having a principal place of business at 310 Hunt Club Road, Suite 201, Ottawa ON K1V 1C1, and **Brii Biosciences Limited**, an exempted company organized under the laws of the Cayman Islands ("**Brii Bio**"), having its registered office at Vistra (Cayman) Limited, PO Box 3119, Grand Pavilion Hibiscus Way, 802 West Bay Road Grand Cayman KYI-1205.

WHEREAS

A. VBI has developed a new recombinant protein based immunotherapeutic for use in treatment of Hepatitis B; and

B. Brii Bio and VBI wish to collaborate on further development of VBI's Hepatitis B recombinant protein based immunotherapeutic; and

C. Brii Bio desires to obtain from VBI certain exclusive rights and licenses to make, have made, use, sell, offer for sale and import VBI's Hepatitis B recombinant protein based immunotherapeutic in the Field (as defined below) in the Licensed Territory (as defined below), and VBI is willing to grant to Brii Bio such rights and licenses on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, VBI and Brii Bio hereby agree as follows:

ARTICLE 1

DEFINITIONS

As used in this Agreement, the following terms shall have the meanings set out in this Article 1 unless the context clearly and unambiguously dictates otherwise.

1.1 "**Additional Pre-Clinical Trials**" has the meaning set forth in Section 5.2(d).

1.2 "**Adjuvant**" shall mean [*****].

1.3 "Affiliate" of a Party shall mean any company, partnership or other entity that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by, or is under common control with such Party, as the case may be, but for only so long as such control exists. For the purposes of this definition, "control" shall mean (i) direct or indirect beneficial ownership of at least fifty percent (50%) of the voting share capital or other equity interest in such Person or (ii) the power to direct the management of such Person by contract or otherwise.

1.4 "**Agreement**" has the meaning set forth in the Preamble.

1.5 "**Alliance Manager**" has the meaning set forth in Section 4.5.

1.6 "Applicable Laws" shall mean the applicable provisions of any and all national, state and local laws, statutes, rules, regulations, administrative codes, ordinances, judgments, decrees, directives, injunctions, orders, permits (including Marketing Approvals) of or from any court, Regulatory Authority or Governmental Authority having jurisdiction over or related to the subject matter.

1.7 "**Anti-Corruption Laws**" shall mean (a) the U.S. Foreign Corrupt Practices Act of 1977, (b) the U.K. Bribery Act 2010, (c) the Peoples Republic of China (PRC) Anti-Unfair Competition Law, and (d) the criminal code of each Region in the Licensed Territory.

1.8 "**BLA**" shall mean a Biologics License Application filed pursuant to the requirements of the FDA under Section 351(k) of the Public Health Services Act (Title 42, U.S.C., Chapter 6A) and 12 C.F.R., Section 601.2, to obtain Marketing Approval for a biological product in the United States, or the equivalent application or filing in another country (as applicable).

1.9 "**Brii Bio**" shall have the meaning set forth in the Preamble.

1.10 "Brii Bio Adjuvant" shall mean an Adjuvant [*****], which Brii Bio Adjuvant shall be designated by Brii Bio in its sole discretion, subject to Section 4.4.

1.11 "**Brii Bio Know-How**" shall mean Know-How owned or Controlled by Brii Bio as of the Effective Date or developed during the Term independent of activities under this Agreement excluding any Joint Know-How.

1.12 "**Brii Bio Patents**" shall mean Patents owned or Controlled by Brii Bio as of the Effective Date or during the Term that cover or claim the Brii Bio Know-How.

1.13 "Brii Bio Technology" shall mean the Brii Bio Know-How and the Brii Bio Patents.

1.14 "**Business Day**" shall mean a day other than a Saturday or Sunday or any public holiday in the United States or China. For the avoidance of doubt, references in this Agreement to "days" shall mean calendar days.

1.15 "Chairperson" shall mean the chairperson of the Joint Steering Committee.

1.16 "**Clinical Trial**" shall mean a study in which human subjects or patients are dosed with a drug, whether approved or investigational, including any Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial or any study required to be conducted following Marketing Approval as a condition to maintaining such approval.

1.17 "CMC" shall mean chemistry, manufacturing and controls.

1.18 "**Collaboration Clinical Trial**" shall mean the Phase II Clinical Trial, to be conducted in accordance with the Development Plan in the Licensed Territory for the purpose of comparing VBI-2601 and a Novel Composition across multiple cohorts and dosing regimens.

1.19 "**Commercial Supply Agreement**" shall have the meaning set forth in Section 7.3.

1.20 "**Commercially Reasonable Efforts**" shall mean, with respect to a Party and an obligation to conduct a particular activity pertaining to the research, development, manufacturing or commercialization obligations hereunder, that level of efforts and resources reasonably required to carry out such obligation consistent with the efforts commonly used by such Party with respect to a biopharmaceutical product which is of similar market potential and at a similar stage in its development or product life, and all other relevant factors. Notwithstanding the foregoing, to the extent that the performance of a Party's obligations hereunder is impaired by the other Party's failure to perform its obligations hereunder, the determination of whether such first Party has used Commercially Reasonable Efforts in performing a given obligation will be determined in the context of such other Party's failure.

1.21 "**Competing Product**" shall mean [*****].

1.22 "**Confidential Information**" shall have the meaning set forth in Section 11.1.

1.23 "Confidentiality Agreement" shall mean that certain letter agreement dated July 9, 2018 between VBI and Brii Bio.

1.24 "**Control**" or "**Controlled**" shall mean, with respect to any Know-How, Patent or other intellectual property right, the legal authority or right (whether by ownership, license or otherwise but without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) of a Party or its Affiliates to grant access, a license or a sublicense of or under such Know-How, Patent or other intellectual property rights to another Party hereto, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party, in each case in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, license or sublicense.

1.25 "**Development Costs**" shall mean, with respect to a Party, such Party's Internal Costs and External Costs incurred in the conduct of activities assigned to such Party under the Development Plan, to the extent incurred in accordance with the budget set forth in the Development Plan.

1.26 "Development Plan" shall mean the research and development plan to be conducted by the Parties covering research and development activities through the completion of the Collaboration Clinical Trial for the purpose of developing improved therapeutic Hepatitis B recombinant protein based immunotherapeutics comprising the Licensed Compound, as may be amended in accordance with Section 5.1(b). The initial Development Plan is attached hereto as Schedule C.

1.27 "Disclosing Party" shall have the meaning set forth in Section 11.1.

1.28 "Distributor" shall mean a Third Party to whom Brii Bio has granted the right to market, detail, promote, advertise, sell and distribute Product in the Licensed Territory.

1.29 "**Dollar**" or "**$**" shall mean the legal tender of the United States.

1.30 "**Effective Date**" shall have the meaning set forth in the Preamble hereto.

1.31 "**External Costs**" shall mean amounts paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP) by a Party (or its Affiliate) and incurred in the performance of activities under the Development Plan, excluding (a) pre-paid amounts, capital expenditures, and financing costs, (b) any items included in the FTE Rate, and (c) any mark-up on any amounts paid to Third Parties imposed by a Party.

1.32 "**FDA**" shall mean the United States Food and Drug Administration or its successor.

1.33 "[*****]" shall have the meaning set forth in Section 1.34.

1.34 "[*****]**"** means that certain [*****].

1.35 "Field" means the diagnosis and treatment of Hepatitis B.

1.36 "**First Commercial Sale**" shall mean with respect to a Licensed Product in any Region in the Licensed Territory, the first sale for monetary value for use or consumption of such Licensed Product in such Region after Marketing Authorization for such Licensed Product has been obtained in such Region.

1.37 "**Force Majeure Event**" shall have the meaning set forth in Section 17.1.

1.38 "**FTE**" shall mean the equivalent of the work of one duly qualified employee of a Party full time for one year (consisting of a total of one thousand eight hundred (1,800) hours per year) carrying out development, manufacturing, commercialization, or other regulatory, distribution, scientific, or technical work under the Development Plan. Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution, and no individual may be charged at greater than one FTE, regardless of that individual's hours worked during that year. The portion of an FTE billable by a Party for one employee during a given accounting period will be determined by dividing the number of hours worked directly by such employee on the work to be conducted under this Agreement during such accounting period by the number of FTE hours applicable for such accounting period based on one thousand eight hundred (1,800) working hours per calendar year.

1.39 "**FTE Rate**" shall mean the rate of three hundred thousand Dollars (300,000) per FTE per calendar year which rate will be prorated on a daily basis as necessary, and which rate is subject to one annual adjustment in each calendar year during the Term by the percentage increase or decrease in the consumer price index (CPI) as of December 31 of each calendar year, over the level of the CPI as of December 31 of the prior calendar year, with the first such increase to be effective on January 1, 2020. Notwithstanding the foregoing, for any calendar year during the Term that is less than a full year, the above referenced rate will be proportionately reduced to reflect such portion of such full calendar year.

1.40 "GAAP" shall mean generally accepted accounting principles in the United States, or internationally, as appropriate, consistently applied and shall mean the international financial reporting standards ("**IFRS**") at such time as IFRS becomes the generally accepted accounting standard and applicable laws require that a Party use IFRS.

1.41 "**Global Clinical Trial**" shall mean a Clinical Trial conducted by VBI or Brii Bio in the Licensed Territory and the VBI Territory in accordance with the Global Development Plan with the intent of generating data to support an application for Marketing Approval in each of the Licensed Territory and the VBI Territory.

1.42 "**Global Development Plan**" shall mean, for a Licensed Product, the plan setting forth (a) the global development activities for Licensed Product, including the proposed pre-clinical studies and Clinical Trials and regulatory plans, (b) the timelines for such activities, (c) an outline of the key elements involved in obtaining Marketing Approval of such Licensed Product, and (d) the allocation of responsibilities between the Parties of the development activities set forth under such Global Development Plan, as the same may be amended from time-to-time in accordance with Section 4.1(b).

1.43 "Good Clinical Practices" or "**GCP**" shall mean all applicable then-current standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Studies, including, as applicable, as set forth in the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) or any other guidelines for good clinical practice for trials on medicinal products as required by the equivalent Applicable Laws in any relevant country.

1.44 "Good Laboratory Practices" or "**GLP**" shall mean all applicable then-current standards for laboratory activities for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58, the PRC Good Laboratory Practice effective as of September 1, 2003, the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development (OECD), and any such standards of good laboratory practice as are required by the equivalent Applicable Laws in any relevant country, or in countries in which the Licensed Product is intended to be sold by the Party that is subject to such standards.

1.45 "Good Manufacturing Practices" or "**GMP**" shall mean the then-current good manufacturing practices required by the FDA, as set forth in the United States Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable laws or regulations applicable to the manufacture and testing of pharmaceutical materials in jurisdictions outside the United States, as they may be updated from time to time. Good Manufacturing Practices shall include applicable quality guidelines promulgated under the ICH.

1.46 "**Governmental Authority**" shall mean any multinational, federal, national, state, provincial or local entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature over any of the activities contemplated by this Agreement.

1.47 "ICH" shall mean the International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use).

1.48 "**IFRS**" shall have the meaning set forth in Section 1.40.

1.49 "IND" shall mean an Investigational New Drug Application (including any amendments thereto) filed with the FDA pursuant to 21 C.F.R. §312 before commencement of clinical trials of a pharmaceutical product, or any comparable filings with Regulatory Authorities in the Licensed Territory, including clinical trial applications.

1.50 "**Internal Costs**" shall mean, for any period and any activity under the Development Plan, (a) the product obtained by *multiplying* (i) the actual total FTEs (or portion thereof) devoted to the performance of such activity during such period, *by* (ii) the applicable FTE Rate, and (b) a Party's reasonably allocated other internal costs with respect to such activity to the extent not included in the FTE Rate.

1.51 "**Interruption Event**" shall mean, with respect to a Party and a Licensed Product, any event caused by facts or circumstances beyond the reasonable control of such Party including, without limitation, (a) a Force Majeure Event, (b) a delay caused by the other Party, (c) a delay related to the formulation, manufacturing or release testing of a Brii Bio Adjuvant, (d) a delay by a Regulatory Authority in providing necessary Marketing Approvals for a Licensed Product, (e) a requirement for such Party to seek pricing or reimbursement approval in a Region in the Licensed Territory, (f) a withdrawal or recall of such Licensed Product from the market (to the extent due to circumstances outside of such Party's reasonable control), or (g) a suspension of the Marketing Approval of such Licensed Product.

1.52 "Inventions" shall mean any and all inventions, discoveries, improvements, processes and techniques discovered, conceived or first reduced to practice in the course of activities conducted pursuant to the Development Plan, whether or not patentable or included in any claim of patents and patent applications.

1.53 "Joint Inventions" shall mean (a) any and all Inventions discovered, conceived or first reduced to practice jointly by the Parties (or their Affiliates) during course of carrying out the Development Plan, and (b) any Novel Composition. For the avoidance of doubt, "Joint Inventions" shall exclude any Inventions to the extent such Inventions comprise improvements to the VBI Technology or the Brii Bio Technology.

1.54 "Joint Know-How" shall mean (a) Know-How developed jointly by the Parties or by Third Parties acting on their behalf during the conduct of activities under the Development Plan or the Global Development Plan (as applicable) that is necessary or useful to research, develop, make, have made, distribute, use, sell, offer for sale, have sold, import, export and otherwise commercialize the Licensed Products, and (b) any Know-How developed by either Party or jointly by the Parties or by Third Parties acting on their behalf during the conduct of activities under the Development Plan or the Global Development Plan (as applicable) to the extent specifically related to the Brii Bio Adjuvant or any Novel Composition.

1.55 "Joint Patents" shall mean all Patents claiming any Joint Inventions.

1.56 "Joint Steering Committee" or "**JSC**" shall have the meaning set forth in Section 4.1(a).

1.57 "**Joint Technology**" shall mean the Joint Know-How and the Joint Patents.

1.58 "Know-How" shall mean information including unpatented Inventions, methods, technologies, data, processes, procedures, techniques, designs, plans, research tools, reagents, formulations, assay techniques, clinical test design, protocols, product life cycle management strategies and operating conditions except to the extent that such information is publicly available or is otherwise protect by patent or trade secret law.

1.59 "Licensed Compound" shall mean the [*****] owned or Controlled by VBI or an Affiliate of VBI.

1.60 "Licensed Product" shall mean VBI-2601 or a Novel Composition (as applicable).

1.61 "Licensed Territory" shall mean mainland China, Hong Kong, Taiwan and Macau (each, a "**Region**").

1.62 "Manufacturing Technology" shall mean any process, technology, information, data or documentation that is necessary or useful in the manufacture, formulation, vialing or release of the Licensed Compound and Licensed Product, including any assays or testing required to comply with GMP including process validation, product identity assays, in-process-control assays and any relevant standard operating procedures.

1.63 "Marketing Approval" shall mean, with respect to any particular country or Region, all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Product in such country or Region, including, where applicable, (a) pricing or reimbursement approval in such country or Region, (b) pre- and post-approval marketing authorizations (including any prerequisite manufacturing approval or authorization related thereto), (c) labeling approval, and (d) technical, medical and scientific licenses.

1.64 "Net Sales" shall mean, with respect to a Licensed Product, [*****].

1.65 "**NMPA**" means the National Medical Products Administration of the People's Republic of China (formerly the China Food and Drug Administration) and any successor agency(ies) or authority thereto having substantially the same function.

1.66 "**Novel Composition**" shall mean a new recombinant protein based immunotherapeutic formulation which includes the Licensed Compound and a Brii Bio Adjuvant.

1.67 "Party" shall mean VBI or Brii Bio individually, and "**Parties**" shall mean VBI and Brii Bio collectively.

1.68 "**Patent(s)**" shall mean, with respect to any jurisdiction, (a) any and all issued patents and patent applications, including all provisional applications, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (b) patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, and (c) other forms of government-issued rights substantially similar to any of the foregoing.

1.69 "Person" shall mean any individual, corporation, partnership, limited liability company, trust, Governmental Authority, or other legal entity of any nature whatsoever.

1.70 "**Phase I Clinical Trial**" means a clinical study of a Licensed Product in humans the purpose of which is preliminary determination of pharmacokinetics, safety and tolerability of a dosing regime and for which there may or may not be primary endpoints (as understood by the applicable Regulatory Authorities) in the protocol relating to efficacy.

1.71 "**Phase II Clinical Trial**" means a clinical study of a Licensed Product in humans to assess the safety, dose ranging and efficacy or therapeutic benefit of such Licensed Product.

1.72 "**Phase III Clinical Trial**" means a controlled clinical study, or a portion of a controlled study, in humans of the efficacy and safety of a Licensed Product, which study (in its entirety or portion, as applicable), is prospectively designed to demonstrate statistically whether such Licensed Product is effective and safe for use in a particular indication in a manner sufficient to file an application for Marketing Approval.

1.73 "Pre-clinical Studies" shall mean studies of a Licensed Product in animals for the purpose of assessing preliminary efficacy, toxicity, pharmacokinetic and safety information.

1.74 "Receiving Party" shall have the meaning set forth in Section 11.1

1.75 "**Region**" shall have the meaning set forth in Section 1.61.

1.76 "Regulatory Authority" shall mean any national, regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority whose review and/or approval is necessary for the clinical research, development, manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale, selling, pricing or reimbursement (as applicable) of Licensed Products, including, for the avoidance of doubt, the NMPA and the FDA.

1.77 "Regulatory Documentation" shall mean (a) submissions to any Regulatory Authority, including INDs, BLAs, Drug Master Files, correspondence with regulatory agencies (registrations and licenses, regulatory drug lists, advertising and promotion documents), period safety update reports, adverse event files, complaint files and manufacturing records and, if applicable, any updates or supplements to any of the foregoing and (b) any minutes or contact logs with respect to any telephone conferences conducted with any Regulatory Authority relating to the subject matter described in clause (a) of this sentence.

1.78 "**Relevant Factors**" shall mean all relevant factors that may affect the development, Marketing Approval or commercialization of a Licensed Product, including (as applicable): actual and potential issues of safety, efficacy or stability; product profile (including product modality, category and mechanism of action); stage of development or life cycle status; actual and projected development, Marketing Approval, manufacturing, and commercialization costs; any issues regarding the ability to manufacture or have manufactured the Licensed Compound or a Licensed Product; the likelihood of obtaining Marketing Approvals (including satisfactory price approvals); the timing of such approvals; the current guidance and requirements for Marketing Approval for a Licensed Product and similar products and the current and projected regulatory status; labeling or anticipated labeling; the then-current competitive environment and the likely competitive environment at the time of projected entry into the market; past performance of the Licensed Product or similar products; present and future market potential; existing or projected pricing, sales, reimbursement and profitability; pricing or reimbursement changes in relevant countries; proprietary position, strength and duration of patent protection and anticipated exclusivity; and other relevant scientific, technical, operational and commercial factors.

1.79 "Royalty Report" shall have the meaning set forth in Section 9.8.

1.80 "Royalty Term" shall have the meaning set forth in Section 9.5(a).

1.81 "[*****]**"** means that certain [*****].

1.82 "**Senior Executives"** shall have the meaning set for in Section 4.4.

1.83 "**SEC**" shall mean the US Securities Exchange Commission.

1.84 "Stock Purchase Agreement" means that certain Stock Purchase Agreement, dated as of the Effective Date, between the Parties, pursuant to which Brii Bio will purchase certain shares of VBI Common Stock in accordance with the terms and conditions set forth therein.

1.85 "Sublicensee" shall mean a Third Party or an Affiliate of Brii Bio, to whom Brii Bio or an Affiliate of Brii Bio has granted a sublicense under the VBI Technology to, offer for sale and sell Licensed Product in the Field in any country in the Licensed Territory as contemplated by Section 2.3(a) of this Agreement. For clarity, the term "Sublicensee" shall not include any wholesellers that are not granted any sublicense under the VBI Technology to offer for sale and sell Licensed Product in the Field in the Licensed Territory.

1.86 "**Term**" shall have the meaning set forth in Section 15.1.

1.87 "**Third Party**" shall mean any Person other than VBI, Brii Bio and their respective Affiliates.

1.88 "Third Party Claims" shall have the meaning set forth in Section 14.1.

1.89 "Third Party Manufacturer" shall have the meaning set forth in Section 7.2(a).

1.90 "Third Party Royalties" shall mean royalties payable by VBI under [*****].

1.91 "**VBI**" shall have the meaning set forth in the Preamble.

1.92 "**VBI-2601**" shall mean a recombinant protein based immunotherapeutic for use in treating Hepatitis B developed by VBI.

1.93 "**VBI Know-How**" shall mean all Know-How owned or Controlled by VBI as of the Effective Date or during the Term that is necessary or useful to research, develop, make, have made, distribute, use, sell, offer for sale, have sold, import, export and otherwise commercialize the Licensed Compounds or Licensed Products. For the avoidance of doubt, the "VBI Know-How" shall not include Joint Know-How.

1.94 "VBI Patents" shall mean all Patents owned or Controlled by VBI as of the Effective Date or during the Term that (a) claim the composition of matter of, or the method of making or using Licensed Compounds or Licensed Products, or (b) are otherwise necessary or useful to research, develop, make, have made, distribute, use, sell, offer for sale, have sold, import, export or otherwise commercialize the Licensed Compounds or Licensed Products. For the avoidance of doubt, the "VBI Patents" shall not include Joint Patents. The VBI Patents existing as of the Effective Date are set forth on Schedule A hereto; provided that, any Patent not included on Schedule A that otherwise meets the definition of a VBI Patent shall still be considered a VBI Patent notwithstanding its omission from Schedule A.

1.95 "VBI Technology" shall mean all VBI Know-How, VBI Patents and VBI's interest in Joint Patents and Joint Inventions.

1.96 "**VBI Territory**" means all countries outside of the Licensed Territory.

ARTICLE 2

DESCRIPTION OF THE COLLABORATION

2.1 VBI and Brii Bio wish to collaborate on the development of a Hepatitis B recombinant protein based immunotherapeutic in the Licensed Territory. This collaboration will initially focus on the execution of a Development Plan by the Parties with the objective of developing a Novel Composition and comparing such Novel Composition to VBI-2601 in the Collaboration Clinical Trial. Brii Bio will select the Brii Bio Adjuvant [*****] within five (5) days of the Effective Date. Based on the results of such Pre-clinical Studies, Brii Bio will select the Novel Compositions to be included in the Collaboration Clinical Trial subject to Section 4.4. Once selected, INDs for the Novel Composition and the VBI-2601 candidate will be filed in the Licensed Territory and, if approved, the Novel Composition and the VBI-2601 candidate will be tested in the Collaboration Clinical Trial, after which, Brii Bio will have the right to select either the Novel Composition or VBI-2601 for further clinical development in support of an application for Marketing Approval in the Licensed Territory.

ARTICLE 3

GRANT OF LICENSES

3.1 VBI License to Brii Bio. Subject to the terms and conditions of this Agreement, VBI hereby grants to Brii Bio an exclusive royalty-bearing license, with the right to grant sublicenses through multiple tiers in accordance with Section 3.3, under the VBI Technology for Brii Bio, its Affiliates and Sublicensees to:

(a) carry out its obligations pursuant to the Development Plan and the Global Development Plan (as applicable);

(b) perform, or have performed, studies (including Clinical Trials) and regulatory and other activities as may be required to obtain and maintain Marketing Approval of the Licensed Products in the Licensed Territory; and

(c) use, sell and offer for sale the Licensed Products in the Field in the Licensed Territory.

3.2 Brii Bio License to VBI. Subject to the terms and conditions of this Agreement, Brii Bio hereby grants to VBI an exclusive, royalty-free license, with the right to sublicense in accordance with Section 3.3, under (i) the Brii Bio Technology, solely to the extent that such Brii Bio Technology covers or claims the Brii Bio Adjuvant or the Novel Composition, and (ii) Brii Bio's interest in the Joint Technology solely to:

(a) perform, or have performed, activities pursuant to the Development Plan and the Global Development Plan (as applicable) anywhere in the world for the purpose of the exploitation of Licensed Products in the Field in the Licensed Territory by Brii Bio; and

(b) make, have made, use, sell, and offer for sale the Licensed Products in the Field in the VBI Territory.

3.3 Sublicenses.

(a) Brii Bio Right to Sublicense. Brii Bio shall have the right to sublicense any or all rights granted to it under Section 3.1 in any Region in the Licensed Territory to any of its Affiliates or Third Parties through multiple tiers.

(b) VBI Right to Sublicense. VBI shall have the right to sublicense any or all rights granted to it under Section 3.2 to any of its Affiliates or Third Parties, provided that, with respect to any sublicense of VBI's obligations set forth in Section 3.2(a), VBI shall be required to obtain Brii Bio's consent prior to entering into any such sublicense except to the extent that such sublicense is to an Affiliate.

3.4 Rights Reserved. Except for the rights and licenses expressly granted in this Agreement, VBI retains all rights under its intellectual property, including the VBI Technology, and Brii Bio retains all rights under its intellectual property.

3.5 Option for License Outside the Field. For the duration of the Term, VBI shall have an option to negotiate with Brii Bio an exclusive license under (a) the Brii Bio Technology that covers or claims the Brii Bio Adjuvant or the Novel Composition and (b) Brii Bio's interest in the Joint Technology for use outside the Field in the VBI Territory. In the event that VBI wishes to exercise its option pursuant to this Section 3.5, VBI shall provide written notice to Brii Bio thereof, and within thirty (30) days of Brii Bio's receipt of such notice, the Parties shall commence negotiating in good faith the terms of such license agreement, which agreement shall include adjuvant licensing terms consistent with market terms and conditions. If the Parties fail to reach agreement on the terms of such exclusive license agreement within one hundred and eighty (180) days after such discussions commence, then, provided that the Parties have negotiated in good faith during such one hundred and eighty (180) day period, Brii Bio shall have no further obligation to negotiate with VBI the terms of such exclusive license.

ARTICLE 4

GOVERNANCE

4.1 Joint Steering Committee.

(a) Establishment. Within thirty (30) days following the Effective Date, VBI and Brii Bio shall establish a joint development committee ("**Joint Steering Committee**" or "**JSC**") to oversee, review and coordinate the activities of the Parties under this Agreement with regard to development and regulatory approval of Licensed Products in the Field in the Licensed Territory.

(b) Duties. The Joint Steering Committee shall:

(i) promote and facilitate ongoing communication and exchange of information between the Parties regarding conduct of the Development Plan and the Global Development Plan (as applicable), progress toward obtaining Marketing Approval of the Licensed Product in the Licensed Territory and manufacture of the Licensed Product for distribution in the Licensed Territory;

(ii) establish the strategic direction for the conduct of the Development Plan and the Global Development Plan (as applicable);

(iii) review and approve any additions or amendments to the Development Plan and the Global Development Plan (as applicable), including the budget (subject to Section 4.9);

(iv) review and approve the initial Global Development Plan, including the budget (as applicable);

(v) oversee implementation or the Development Plan and the Global Development Plan (as applicable) including assigning roles, responsibilities, timelines and budgets for activities based upon the Development Plan and the Global Development Plan;

(vi) review and discuss the results obtained during conduct of the Development Plan and the Global Development Plan, including the Collaboration Clinical Trial;

(vii) discuss disputes that may arise between the Parties in the course of carrying out the terms of this Agreement with a view of facilitating a mutually satisfactory resolution;

(viii) serve as a forum for information sharing regarding the progress of VBI's [*****] in accordance with Section 9.7;

(ix) discuss the overall regulatory strategies for obtaining Marketing Approval of the Licensed Product in the Licensed Territory; and

(x) perform such other duties as are specifically assigned by the Parties to the Joint Steering Committee pursuant to this Agreement.

4.2 Joint Steering Committee Membership. The JSC shall be composed of six (6) members, three (3) of whom shall be nominated by VBI and three (3) of whom shall be nominated by Brii Bio. The JSC shall have two Chairpersons, one appointed by each Party to serve for a period of twelve (12) months. The meetings of the Joint Steering Committee shall be led, alternately by one Chairperson. Any member of the Joint Steering Committee may designate a substitute to attend and perform the functions of that member at any meeting of the Joint Steering Committee. Each Party may, with the consent of the other Party, such consent not to be unreasonably withheld or delayed, invite non-member, non-voting representatives of such Party to attend meetings of the Joint Steering Committee, provided that such attendees are subject to non-disclosure agreements and obligations of confidentiality at least as restrictive as those set forth in Article 11. The Alliance Manager of each Party will attend each meeting of the JSC as a non-voting participant.

4.3 Meetings. All Joint Steering Committee meetings shall be held as often as the members may determine, but in any event Joint Steering Committee meetings shall occur not less than four (4) times per calendar year. Such meetings may be held in person, or by any means of telecommunications or video conference, as the members deem necessary or appropriate; *provided, however,* that at least one Joint Steering Committee meeting per year shall be held in person and the location of such in-person meeting shall alternate between VBI's office in Boston Massachusetts and Brii Bio's office in either Durham North Carolina or Beijing, China (at Brii Bio's election) provided, however, that no more than one (1) JSC meeting per calendar year will be held in China. The first meeting shall be held at Brii Bio's offices in Durham. A quorum for Joint Steering Committee meetings shall be four (4) members, with at least two (2) members from each Party.

4.4 Decision-making of Joint Steering Committee. The Joint Steering Committee may make decisions with respect to any subject matter that is within the purview of the Joint Steering Committee's duties. Except as expressly provided in this Agreement, all decisions of the Joint Steering Committee shall be made by unanimous vote or written consent, with VBI and Brii Bio each having, respectively, one vote in all decisions. The Joint Steering Committee shall use reasonable efforts to resolve any disputes concerning the matters within its duties. If, with respect to a matter that is subject to the Joint Steering Committee's duties the Joint Steering Committee cannot reach consensus, then the Chairperson of the Joint Steering Committee shall escalate the dispute for resolution to on behalf of VBI, the Chief Executive Officer of VBI and to, on behalf of Brii Bio, the President of Brii Bio (collectively, the "**Senior Executives**"). The Senior Executives shall use good faith efforts to resolve the matter referred to them within fifteen (15) days of such referral (which shall become the decision of the Joint Steering Committee). If the Senior Executives fail to resolve such matter within ten (10) Business Days after the date on which the matter is referred to such Senior Executives (unless a longer period is agreed to by the Parties), then:

(a) Brii Bio shall have final decision-making authority with respect to matters in dispute relating solely to the development, Marketing Approval and commercialization of Licensed Products in the Licensed Territory, including (i) selection of the Novel Composition(s) to be included in the Collaboration Clinical Trial; provided that, [*****], (ii) any modification or amendment to, or issue arising under, the Development Plan, and (iii) the selection of the Third Party Manufacturer pursuant to Section 7.2(a), but excluding decisions that would reasonably be expected to have a material adverse impact on the development, Marketing Approval or commercialization of Licensed Products in the VBI Territory or would increase the costs allocated to VBI pursuant to the Development Plan in contravention of Section 4.9;

(b) VBI shall have final decision-making authority with respect to the development, Marketing Approval and commercialization of Licensed Products in the VBI Territory, including any modification or amendment to, or issue arising under, the Global Development Plan (as applicable), except for those decisions that would reasonably be expected to have a material adverse impact on the development, Marketing Approval or commercialization of Licensed Products in the Licensed Territory or would increase the costs allocated to Brii Bio pursuant to the Development Plan in contravention of Section 4.9; and

(c) with respect to all other matters in dispute, such matters shall be settled by expert determination pursuant to Section 16.3.

4.5 Alliance Manager. Each of the Parties will appoint a single individual to manage Development and Commercialization obligations between the Parties (each, an "**Alliance Manager**"). The role of the Alliance Manager will be to act as a single point of contact between the Parties to ensure a successful relationship under this Agreement. The Alliance Managers will attend all JSC meetings as non-voting participants; provided that, an Alliance Manager may bring any matter to the attention of the JSC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will designate its initial Alliance Manager promptly after the Effective Date and each Party may change its designated Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Alliance Manager will also: (a) be the point of first referral in all matters of conflict resolution; (b) provide a single point of communication for seeking consensus between the Parties regarding key strategy and plan issues; (c) identify and bring disputes to the attention of the JSC in a timely manner; and (d) take responsibility for ensuring that governance activities, such as the conduct of required JSC meetings and production of meeting minutes, occur as set forth in this Agreement, and that the relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

4.6 Minutes. Minutes for each of the Joint Steering Committee meetings shall be prepared by a VBI member or a Brii Bio member of the Joint Steering Committee alternately, with Brii Bio's member preparing the minutes for the first meeting of the Joint Steering Committee. The draft minutes shall be sent to all members of the Joint Steering Committee for comment promptly after each such meeting (but in no event more than fifteen (15) days after each such meeting). All actions noted in the minutes shall be reviewed and approved at subsequent meetings of the Joint Steering Committee; *provided* that if the Parties cannot agree as to the content of the minutes by the time the Joint Steering Committee next meets, such minutes shall be finalized to reflect any areas of disagreement.

4.7 Expenses. Each Party shall bear its own costs, including expenses incurred by the members nominated by it in connection with their activities as members of the Joint Steering Committee or as Chairperson.

4.8 Subcommittees. From time to time, the Joint Steering Committee may establish subcommittees to oversee particular projects or activities within the scope of authority of the Joint Steering Committee, as it deems necessary or advisable. Each subcommittee shall consist of such number of representatives of each Party as the Joint Steering Committee determines is appropriate from time to time and shall meet with such frequency as the Joint Steering Committee shall determine. All decisions of each subcommittee shall be made by unanimous vote or written consent, with VBI and Brii Bio each having, collectively, one vote in all decisions. If, with respect to a matter that is subject to a subcommittee's decision-making authority, the subcommittee cannot reach unanimity, the matter shall be referred to the Joint Steering Committee, which shall resolve such matter in accordance with Section 4.4.

4.9 Scope of Governance; Limitation of Authority. Notwithstanding the creation of the Joint Steering Committee or any subcommittee, each Party shall retain the rights, powers and discretion granted to it hereunder, and neither the Joint Steering Committee nor any subcommittee shall be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. Neither the Joint Steering Committee nor any subcommittee shall have the power to (a) amend or modify this Agreement, (b) waive either Party's obligation to comply with the terms and conditions of this Agreement, or (c) materially increase costs under the Development Plan, unless such increased costs are a result of a requirement by a Regulatory Authority in the Licensed Territory, and no decision of the Joint Steering Committee or any subcommittee shall be in contravention of any terms and conditions of this Agreement. It is understood and agreed that issues to be decided by the Joint Steering Committee or any subcommittee, as applicable, are only those specific issues within the Joint Steering Committee's duties.

4.10 Dissolution. The Joint Steering Committee shall dissolve and cease to exist upon the completion of activities under the Development Plan; provided that, if the Parties elect to enter into a Global Development Plan in accordance with Section 5.5, then the Joint Steering Committee shall dissolve and cease to exist upon the completion of all activities under the Global Development Plan.

ARTICLE 5

DEVELOPMENT ACTIVITIES

5.1 Development Plans.

(a) Initial Development Plan. Within sixty (60) days following the Effective Date, the Parties shall, notwithstanding Section 4.4, meet to review the initial Development Plan (including a budget for activities thereunder) attached hereto as Schedule C. For the avoidance of doubt, Brii Bio shall have the sole right to select the Brii Bio Adjuvant for use in the [*****] and the Novel Composition(s) to be included in the Collaboration Clinical Trial, subject to Section 4.4. The initial Development Plan shall include (but not be limited to) and assign responsibility between the Parties for the following:

(i) formulations of Novel Compositions which shall be evaluated during the conduct of the Development Plan;

(ii) Pre-clinical Studies of recombinant protein based immunotherapeutic candidates to evaluate immunogenicity;

(iii) in vitro assessment of recombinant protein based immunotherapeutic candidates for stability;

(iv) preparation of an IND;

(v) technology transfer of immune-monitoring assays to support clinical development in the Licensed Territory;

(vi) design of the Collaboration Clinical Trial to support an application for Marketing Approval in the Licensed Territory; and

(vii) development of Manufacturing Technologies for Licensed Products.

(b) Review and Amendment of the Development Plan. From time to time, and no less than once per calendar year, the Joint Steering Committee shall review the Development Plan and determine if any amendments or additions are required in order to advance the objective of obtaining Marketing Approval for a Licensed Product in the Licensed Territory. Any modifications or amendments to the Development Plan shall become effective when reduced to writing and signed by both Parties.

5.2 Conduct of Development Plan.

(a) Diligence. Each Party shall use Commercially Reasonable Efforts to conduct and complete the activities assigned to such Party in the Development Plan in accordance with the timelines and budget specified therein. Without limiting the foregoing, each Party shall use good faith efforts to allocate sufficient time, effort, equipment and facilities to such activities and to use personnel with sufficient skills and experience as are required to accomplish such activities in accordance with the Development Plan and the terms of this Agreement. In addition, Brii Bio shall use Commercially Reasonable Efforts to initiate the Collaboration Clinical Trial within [*****] following the Effective Date. Following the completion of the Collaboration Clinical Trial, subject to the terms of this Agreement, Brii Bio shall have sole responsibility for, and sole discretion with respect to all development activities regarding the Licensed Product in the Field in the Licensed Territory.

(b) Compliance with Applicable Laws. Each Party shall conduct the activities assigned to it, including with respect to documentation and records requirements, in the Development Plan in compliance in all material respects with all Applicable Laws.

(c) Records; Reports. Each Party shall maintain records regarding its activities under the Development Plan in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of such Party, including with respect to Clinical Trials relating to the Licensed Compound, drafting formal clinical study reports in compliance with Applicable Laws and ICH guidelines. Each Party shall keep the Joint Steering Committee appropriately informed of the status of such activities. Upon request by the Joint Steering Committee, without limiting the foregoing, each Party shall provide the Joint Steering Committee with reasonably detailed summaries of data and results generated or obtained in the course of such Party's performance of activities under the Development Plan. With respect to Clinical Trials relating to the Licensed Compound (including Global Clinical Trials, as applicable), the Party responsible for the conduct of such Clinical Trial shall present to the Joint Steering Committee at each meeting thereof a summary of the progress of such ongoing Clinical Trial including, when available, a summary of the resulting data. Following completion of a Clinical Trial relating to the Licensed Compound, the Party that conducted such Clinical Trial (or Global Clinical Trial, as applicable) shall provide the other Party with a copy of the clinical study reports and access to data underlying any such study report.

(d) Conduct of Clinical Trials. Brii Bio shall be the sponsor for, and shall use Commercially Reasonable Efforts to, conduct any and all Clinical Trials (excluding Pre-Clinical Studies) set out in the Development Plan as are required to support Marketing Approval in the Licensed Territory. In the event that, following submission of a IND for a Licensed Product in a Region in the Licensed Territory, the applicable Regulatory Authority does not approve such IND and requests that additional Pre-clinical Studies of such Licensed Product be conducted (the "**Additional Pre-clinical Studies**"), then Brii Bio shall conduct such Additional Pre-clinical Studies, and the Parties shall amend the Development Plan to include such Additional Pre-Clinical Studies.

5.3 Development Funding.

(a) Development Plan Costs. Each Party shall be responsible for costs and expenses associated with activities assigned to such Party under the Development Plan, provided that VBI shall be responsible for clinical supply costs and expenses to the extent set forth in Schedule 7.1(a).

(b) Post-Development Plan Costs. With the exception of costs related to Global Clinical Trials (as applicable), all Clinical Trials conducted in the Licensed Territory following the conclusion of the Development Plan shall be borne by Brii Bio.

5.4 Post- Development Plan. Following the completion of the Development Plan, Brii Bio shall use Commercially Reasonable Efforts to develop a Licensed Product in the Licensed Territory in the Field, and in the event that the Parties do not enter into a Global Development Plan pursuant to Section 5.5, then Brii Bio shall provide annual high-level development reports to VBI describing ongoing and planned development activities until such time as a first Marketing Approval is obtained in mainland China.

5.5 Global Development. Following the completion of the Collaboration Clinical Study and within ninety (90) days following the provision of a clinical study report to the JSC pursuant to Section 5.2(c), each Party shall determine, in its sole discretion, whether it intends to pursue subsequent development activities in its territory for VBI-2601 or the Novel Composition evaluated in such Collaboration Clinical Study. In the event that the Parties both elect to proceed with further development of VBI-2601 or the Novel Composition, then the Parties shall decide, through the JSC, whether to enter into a Global Development Plan to govern the conduct of Global Clinical Trials with the objective of obtaining clinical trial data to support applications for Marketing Approval in the Field for the applicable product in both the Licensed Territory and countries within the VBI Territory. If the Parties so decide to enter into such Global Development Plan, then the Parties shall mutually agree upon such plan through the JSC, including the allocation of costs between the Parties for such Global Clinical Trials. Notwithstanding the foregoing, the Parties may elect not to jointly conduct a Global Clinical Trial under the Global Development Plan, which election must be made prior to the commencement of any activities relating to such Global Clinical Trial, in which event, neither Party shall thereafter have a right to use any efficacy data resulting from such Clinical Trial to support Marketing Approval in its respective territory.

ARTICLE 6

REGULATORY ACTIVITIES

6.1 Marketing Approval.

(a) Regulatory Plan. Brii Bio shall develop, in its sole discretion, a regulatory plan for each Licensed Product that describes the regulatory actions to be taken by Brii Bio to obtain Marketing Approval in the Field in the Licensed Territory with respect to such Licensed Product. The regulatory plan shall be submitted to the Joint Steering Committee for review and comment, and Brii Bio shall consider such comments in good faith. Such regulatory plan shall be updated to reflect regulatory activities and changes agreed upon by the JSC at least once per year, until such time as the applicable Licensed Product receives Marketing Approval.

(b) Diligence. Brii Bio shall use Commercially Reasonable Efforts to obtain and maintain Marketing Approval for at least one Licensed Product in the Licensed Territory.

(c) Regulatory Submissions.

(i) **Licensed Territory**. Brii Bio, or its designated Affiliate, shall have the sole right to prepare and submit all Regulatory Documentation in the Licensed Territory, including applications for Marketing Approval in the Licensed Territory; provided that in mainland China, Brii Bio shall conduct such regulatory activities (and any and all regulatory activities delegated to Brii Bio hereunder) (i) as the express and authorized regulatory agent of record for VBI , with VBI retaining ownership of such Marketing Approvals, and the applicable product importation licenses, (ii) on behalf of VBI and for the benefit of VBI, and (iii) in accordance with the applicable regulatory plan set forth in Section 6.1(a). Promptly after the Effective Date, the Parties shall execute such documents as are required for Brii Bio to act as VBI's express and authorized regulatory agent of record in mainland China, including powers of attorney. For the avoidance of doubt, as soon as practicable in accordance with Applicable Law, VBI shall transfer the Marketing Authorization(s) for the Licensed Product in mainland China to Brii Bio. In the Regions in the Licensed Territory other than mainland China, Brii Bio or its designated local Affiliate will own all Marketing Approvals relating to the Licensed Product in the Field.

(ii) **VBI Territory.** VBI shall have sole responsibility and authority for the preparation and submission of all Regulatory Documentation in the VBI Territory with respect to (a) INDs, permission to conduct Clinical Trials and ongoing correspondence with the relevant Regulatory Authorities relating thereto; (b) applications for Marketing Approval and ongoing correspondence relating thereto. For the avoidance of doubt, Brii Bio shall have no rights to any Marketing Approvals for Licensed Products in the VBI Territory.

(d) Communications with Regulatory Authorities. Brii Bio shall have sole responsibility and authority to communicate with Regulatory Authorities in the Licensed Territory regarding the Clinical Trials and the Marketing Approvals. VBI shall have sole responsibility and authority to communicate with Regulatory Authorities in the VBI Territory regarding the Clinical Trials and the Marketing Approvals.

(e) VBI Assistance. VBI shall, and shall cause its Affiliates to, provide all reasonable assistance, facilitation and support including providing all documents and data reasonably requested by Brii Bio in a timely manner and at Brii Bio's cost to obtain and maintain Marketing Approvals in the Licensed Territory and the applicable product importation licenses. Such documents shall include copies of any clinical study reports or clinical data regarding the Licensed Products in its possession and by providing comments on Regulatory Documentation to be filed by Brii Bio at Brii Bio's request. For the avoidance of doubt, VBI shall not be obligated as a result of this Section 6.1(e) to develop or prepare additional information or materials beyond those that it has otherwise developed or prepared for its own purposes.

6.2 Exchange of Information. Each of Brii Bio and VBI shall promptly provide to the other copies of any communications received from, or sent to any Regulatory Authority in the Licensed Territory or the VBI Territory, as applicable, with respect to the Clinical Trials, the Marketing Approval or the Licensed Products.

6.3 Coordination of Regulatory Activities. Each Party shall permit the other Party to review and comment, in a timely manner, on Regulatory Documentation for submission in the Licensed Territory or VBI Territory, as applicable, and the Parties shall use reasonable efforts to ensure that such Regulatory Documentation are consistent as between the Licensed Territory and VBI Territory.

6.4 Rights of Reference. Each Party shall have the right to cross reference, file or incorporate by reference any regulatory submission for any Licensed Product, or any component thereof (including all Approvals), in order to support regulatory submissions that such Party may make for a Licensed Product in its respective territory. For the avoidance of doubt, no Party shall be obligated as a result of this Section 6.4 to develop or prepare additional information or materials beyond those that it has otherwise developed or prepared for its own purposes. For the avoidance of doubt, in the event that the Parties decide not to jointly develop and implement a Global Development Plan pursuant to Section 5.5, then neither Party shall have the right to reference any data obtained by the other Party pursuant to independent Clinical Trials conducted by such other Party, except that the Parties shall provide to each other any information or data generated in any Clinical Trials regarding the safety of the Licensed Products.

6.5 Pharmacovigilance. VBI shall be responsible, at its own expenses, for the creation and maintenance of the global safety database for Licensed Product. VBI shall be the sole owner of this global safety database. Brii Bio shall (at its sole cost and expense), and shall cause its Affiliates, Sublicensees and Distributors to submit to VBI all data relating to adverse events relating to Licensed Products in the Licensed Territory. Within six (6) months after the Effective Date, the Parties shall enter into a pharmacovigilance agreement on terms no less stringent than those required by ICH guidelines, including: (i) providing detailed procedures regarding the maintenance of core safety information and the exchange of safety data relating to Licensed Product within appropriate timeframes and in an appropriate format to enable each Party to meet both expedited and periodic regulatory reporting requirements; and (ii) ensuring compliance with the reporting requirements of all applicable Regulatory Authorities for the reporting of safety data in accordance with standards stipulated in the ICH guidelines, and all applicable regulatory and legal requirements regarding the management of safety data.

6.6 Funding Obligation. Brii Bio shall bear one hundred percent (100%) of all costs and expenses relating to requesting and maintaining Marketing Approval for the Licensed Product in the Licensed Territory.

ARTICLE 7

SUPPLY OBLIGATIONS

7.1 Clinical Supply Obligations.

(a) VBI shall supply quantities of Licensed Product for use by Brii Bio in the conduct of Clinical Trials in the Licensed Territory, either itself or through a Third Party Manufacturer, subject to Section 7.2, in accordance with the terms and conditions set forth on Schedule 7.1(a) hereto, including the deliverables, cost allocation and timeframes set forth therein. For the avoidance of doubt, VBI shall not be required to develop formulation processes for the manufacture of any Licensed Product other than VBI-2601 pursuant to this Section 7.1(a) and any such formulation processes shall be developed by the Parties pursuant to the terms of the Development Plan.

(b) In the event that VBI fails to meet any of its final deliverable obligations set forth in Table I on Schedule 7.1(a) hereto in accordance with the timeframes set forth therein, then Brii Bio shall have the right to reduce the milestone payment that is next owed by Brii Bio to VBI under Section 9.3 or Section 9.4 (as applicable) by [*****] Dollars ($[*****]) for each month beyond the first month that VBI is so delayed in meeting such obligation, with the first such reduction being triggered on the thirty-first (31st) day following the date on which such obligation is required to be completed pursuant to Schedule 7.1(a). For example, if VBI is delayed in meeting a final deliverable obligation set forth in Table I of Schedule 7.1(a) by seventy-five (75) days, then Brii Bio would have the right to deduct [*****] Dollars ($[*****]) from the next milestone payment owed by Brii Bio to VBI under Section 9.3 or Section 9.4 (as applicable). Notwithstanding the foregoing, the total reduction in milestone payments pursuant to this Section 7.1(b) shall not exceed [*****] ($[*****]) in the aggregate. Notwithstanding the foregoing, the timeframes set forth in Table I of Schedule 7.1(a) shall be tolled during the pendency of any Interruption Event that directly causes a delay in VBI's ability to meet such timeframes.

(c) With respect to the supply of the Brii Bio Adjuvant for use in Clinical Trials, Brii Bio shall provide such Brii Bio Adjuvant to VBI at [*****].

7.2 Technology Transfer.

(a) At any time prior to the initiation of the first Phase III Clinical Trial (subject to Brii Bio's ability to initiate an earlier transfer of Manufacturing Technology as set forth in Schedule 7.1(a) in the event that VBI is delayed by more than six (6) months in meeting its final deliverable obligations set forth therein) for the Licensed Product in the Licensed Territory, Brii Bio may elect to have VBI transfer manufacturing responsibility for clinical supply and commercial supply to a Third Party manufacturer either in the VBI Territory or the Licensed Territory (to the extent permitted by Applicable Law) (the "**Third Party Manufacturer**"); provided that, VBI shall have no obligation to commence such transfer until after the Collaboration Clinical Trial has been initiated. Once Brii Bio has elected to have VBI initiate such transfer, then VBI will use Commercially Reasonable Efforts to effect a transfer of the Manufacturing Technology in accordance with the requirements set forth in this Section 7.2(a), including the timeframes set forth in the foregoing sentence. The Parties shall mutually agree upon such Third Party Manufacturer through the JSC, provided that the selection of such Third Party Manufacturer shall be subject to Brii Bio's final-decision making authority in accordance with Section 4.4(a). Once such selection has been made, the Parties shall enter into a three (3)-party Supply Agreement with such Third Party Manufacturer for commercial supply of Licensed Products solely to Brii Bio; provided that, VBI's rights under such Third Party Manufacturer supply agreement shall be limited to ensuring that such Third Party Manufacturer (i) maintains the confidentiality of VBI's Confidential Information, including any information related to the VBI Technology, (ii) complies with VBI's obligations under the [*****], and (iii) complies with applicable Licensed Product specifications and Applicable Laws. VBI shall use Commercially Reasonable Efforts to fully enable such Third Party Manufacturer to manufacture Licensed Products, including through the technology transfer requirements set forth in Section 7.2(b) below.

(b) VBI shall promptly, but in any event within thirty (30) days after the execution of such Third Party Manufacturer supply agreement, commence a transfer of the Manufacturing Technology for the Licensed Product to the Third Party Manufacturer. VBI's contribution to the costs relating to transfer of Manufacturing Technology shall be limited to the provision of the services of VBI staff members. Any additional obligations or costs required to effect transfer of Manufacturing Technology to the Third Party Manufacturer shall be borne by Brii Bio. For the avoidance of doubt, nothing in this Section 7.2(b) shall require VBI to develop any new Manufacturing Technology applicable to the Novel Composition for use by the Third Party Manufacturer and any such development will be conducted pursuant to a separate agreement between the Parties, provided that, on a calendar year basis, VBI shall provide to the Third Party Manufacturer any updates or improvements to the Manufacturing Technology relating to the Licensed Product that have been developed in the prior calendar year. Brii Bio acknowledges that, as between the Parties, all right, title and interest to such Manufacturing Technology belongs to VBI and that the Third Party Manufacturer will be permitted to use such Manufacturing Technology solely for the purpose of manufacturing the Licensed Product for commercial supply to Brii Bio.

7.3 Commercial Supply. In the event that VBI is unable to transfer the Manufacturing Technology to a Third Party Manufacturer despite using Commercially Reasonable Efforts to do so, then VBI shall manufacture and supply Licensed Products to Brii Bio for commercial use in the Licensed Territory. Promptly following a determination that such transfer will not be feasible, the Parties shall execute a supply agreement for such commercial supply containing supply and quality terms and conditions consistent with the principles set forth on Schedule 7.3 hereto (the "**Commercial Supply Agreement**") and typical for such agreements.

ARTICLE 8

COMMERCIALIZATION AND PROMOTION

8.1 Commercialization of Product.

(a) Brii Bio Responsibilities. Brii Bio shall have the exclusive right and responsibility for commercializing Licensed Products in the Field in the Licensed Territory in accordance with the terms and conditions of this Agreement. Commercialization of Licensed Products shall include, but not be limited to:

(i) establishing the commercialization and marketing strategy and tactics;

(ii) establishing pricing and reimbursement policies;

(iii) receiving, accepting and filling orders;

(iv) bidding and listing;

(v) labeling;

(vi) advertising and detailing;

(vii) storage and distribution to customers;

(viii) controlling invoicing, processing orders and collecting accounts receivable for sales; and

(ix) recording sales in its books of account for sales.

(b) Commercialization Plan; Commercialization Reports. Within a reasonable time prior to anticipated launch of a Licensed Product, Brii Bio shall prepare a high-level summary setting forth the material commercialization activities, including revenue targets, pricing and unit forecasts, planned for such Licensed Product in the Field in the Licensed Territory. For each calendar year following the First Commercial Sale of such Licensed Product, Brii Bio shall, within forty-five (45) days after the end of such calendar year, provide to VBI a high-level report summarizing the commercialization activities performed by or on behalf of Brii Bio in such calendar year to enable VBI to assess Brii Bio's commercialization obligations set forth in this Section 8.1, including the minimum sales obligation set forth in Section 8.1(d).

(c) Diligence. Brii Bio shall use Commercially Reasonable Efforts to commercialize at least one (1) Licensed Product in the Field in the Licensed Territory in accordance with the provisions of this Agreement and shall not, at any time during the Term of this Agreement, commercialize a Competing Product.

(d) Minimum Sales. Following receipt of Marketing Approval of a Licensed Product in a Region, Brii Bio shall commence commercialization of such Licensed Product and, with respect to mainland China, shall sell or invoice at least [*****] ([*****]) doses of such Licensed Product in mainland China within [*****] months of commercial launch of such Licensed Product, and thereafter, shall sell at least [*****] ([*****]) doses annually. For the avoidance of doubt, if at any time during the Term VBI [*****]. Notwithstanding the foregoing, the minimum sales obligation set forth in this Section 8.1(d) shall be tolled during the pendency of any Interruption Event, and any failure of Brii Bio to meet such minimum sales requirement during the occurrence of a Interruption Event shall not be deemed to be a breach of this Agreement by Brii Bio.

(e) VBI Rights. Nothing in this Agreement shall limit VBI's exclusive rights to commercialize the Licensed Product in the VBI Territory.

8.2 Territory Compliance. VBI and its Affiliates (i) shall not, directly or indirectly, commercialize any Licensed Product in the Licensed Territory, whether inside or outside of the Field, and (ii) shall promptly cease selling or distributing any Licensed Product to any Third Party, or otherwise assisting any Third Party, who is commercializing or attempting to commercialize or distribute any Licensed Product in the Licensed Territory. Brii Bio and its Affiliates, Distributors and Sublicensees (A) shall not, directly or indirectly, commercialize the Licensed Product in the VBI Territory or outside the Field in the Licensed Territory, and (B) shall promptly cease selling or distributing the Licensed Product to any Third Party, or otherwise assisting any Third Party, who is commercializing or attempting to commercialize or distribute the Licensed Product in the VBI Territory or outside the Field in the Licensed Territory.

8.3 Compliance with Laws. Each Party hereby agrees that it will comply in all material respects with all Anti-Corruption Laws in the commercialization of Licensed Products in its respective territory.

8.4 Sci-B-Vac® Product. During the Term, VBI shall not sell or offer to sell, nor shall it authorize any Third Party to sell or offer to sell, any Sci-B-Vac® Product for prophylactic use in any Region of the Licensed Territory except Hong Kong.

ARTICLE 9

FINANCIAL TERMS

9.1 Equity Investment. In partial consideration of the rights granted by VBI to Brii Bio hereunder, Brii Bio shall purchase two million, two hundred and ninety-five thousand, and eighty two (2,295,082) shares of VBI Common Stock at a purchase price of three dollars and five cents ($3.05) per share, for an aggregate purchase price of seven million Dollars ($7,000,000), pursuant to the Stock Purchase Agreement.

9.2 Up-Front Payment. In partial consideration of the rights granted by VBI to Brii Bio hereunder, subject to the terms and conditions set forth in this Agreement, Brii Bio shall pay a one-time fee in the amount of four million Dollars ($4,000,000) (the "**Up-Front Payment**") on or before ten (10) days after the Effective Date.

9.3 Regulatory Milestones.

(a) In partial consideration of the rights granted by VBI to Brii Bio hereunder and subject to the terms and conditions set forth in this Agreement, Brii Bio shall pay to VBI the regulatory milestone payments set forth below:

(b)

Regulatory Milestone	Milestone Payment if Licensed Product is VBI-2601	Milestone Payment if Licensed Product is a Novel Composition
[*****]	$ [*****]	$ [*****]
[*****]	$ [*****]	$ [*****]

For the purposes of this Section 9.3, "initiation" means the date the first patient is dosed with a Licensed Product in the [*****]. Each milestone payment in this Section 9.3 shall be payable only upon the first achievement of such milestone and no amounts shall be due for subsequent or repeated achievements of such milestone, whether for the same or a different Licensed Product.

(c) Brii Bio shall promptly, but in any event no later than ten (10) days following achievement of a regulatory milestone by Brii Bio or any of its Affiliates, inform VBI of such achievement. Thereafter, VBI shall promptly invoice Brii Bio for the payment set forth above with respect to such regulatory milestone, and Brii Bio shall pay such invoice within thirty (30) days of receipt.

9.4 Sales Milestones.

(a) In partial consideration of the rights granted by VBI to Brii Bio hereunder and subject to the terms and conditions set forth in this Agreement, Brii Bio shall pay to VBI the following sales milestones:

Annual Net Sales in the Licensed Territory		Milestone Payment	
$	[*****]	$	[*****]
$	[*****]	$	[*****]
$	[*****]	$	[*****]

Each milestone payment in this Section 9.4 shall be payable only once upon the first achievement of such milestone and no amounts shall be due for subsequent or repeated achievements of such milestone.

(a) Brii Bio shall promptly, but in any event no later than ten (10) days following achievement of a sales milestone by Brii Bio or any of its Affiliates, inform VBI of such achievement. Thereafter, VBI shall promptly invoice Brii Bio for the payment set forth above with respect to such sales milestone, and Brii Bio shall pay such invoice within thirty (30) days of receipt.

9.5 Royalty Payments.

(a) In partial consideration of the rights granted by VBI to Brii Bio hereunder and subject to the terms and conditions set forth in this Agreement, Brii Bio shall pay to VBI a royalty of [*****] percent ([*****]%) of Net Sales of each Licensed Product in each Region from the date of the First Commercial Sale of such Licensed Product in each Region until the later of:

(i) expiration, invalidation or lapse of the last VBI Patent claiming such Licensed Product,

(ii) ten (10) years from the date of First Commercial Sale of such Licensed Product in the applicable Region, or

(iii) termination or expiration of VBI's obligation to pay Third Party Royalties with respect to sales of such Licensed Product (the "**Royalty Term**").

9.6 Royalty Reduction. The amount of royalties payable by Brii Bio pursuant to Section 9.5 shall be reduced in the following circumstances:

(a) [*****]; and

(b) [*****].

9.7 Third Party Licenses.

(a) [*****].

(b) [*****].

9.8 Royalty Payments and Reports. Within forty-five (45) days after the end of each calendar quarter (or, for the last quarter in a calendar year, sixty (60) days after the end of such quarter), Brii Bio shall make all royalty payments payable to VBI under this Agreement with respect to such quarter. Along with such payments, Brii Bio shall also provide a report containing reasonably detailed information regarding the calculation of royalties due pursuant to Article 9 including allowable deductions in the calculation of Net Sales of each Licensed Product on which royalties are paid (the "**Royalty Report**").

ARTICLE 10

PAYMENTS, BOOKS AND RECORDS

10.1 Payment Method. All payments to VBI under this Agreement shall be made by bank wire transfer in immediately available funds to an account in the name of VBI designated in writing by VBI. Payments hereunder shall be considered to be made as of the day on which they are received by VBI's designated bank.

10.2 Payment Currency: Currency Conversion.

(a) United States Dollars. Unless otherwise expressly stated in this Agreement, all amounts specified to be payable under this Agreement are in Dollars and shall be paid in Dollars.

(b) Currency Conversion. For the purpose of computing the Net Sales for any Licensed Product sold in a currency other than Dollars and for purposes of determining Net Sales and Development Costs, or other shared expenses under this Agreement incurred by a Party in a currency other than Dollars, such Net Sales or costs amounts shall be converted into Dollars each quarter using an exchange rate that is the arithmetic average of the daily exchange rates (obtained as described below) during such quarter. Each daily exchange rate shall be obtained from *The Wall Street Journal*, Eastern United States Edition, or, if not so available, as otherwise agreed by the Parties.

(c) Blocked Currency. Notwithstanding the provisions of Section 10.2, if by Applicable Law or fiscal policy of a Region, conversion into Dollars or transfer of funds of a convertible currency to the United States is restricted, forbidden or substantially delayed, then amounts accrued in such Region shall be paid to VBI in such Region in local currency by deposit in a local bank designated by VBI for a period no longer than one hundred and twenty (120) days, after which any payments due to VBI shall be paid in Dollars, unless the Parties otherwise agree.

10.3 Taxes.

(a) Cooperation and Coordination. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible, income and other taxes payable with respect to their collaborative efforts under this Agreement and that they shall use their reasonable efforts to cooperate and coordinate with each other to achieve such objective.

(b) Payment of Tax. A Party receiving a payment shall pay any and all taxes levied on such payment. If the taxing authorities of any relevant jurisdiction assert that amounts are required to be withheld from the payments due to a Party hereunder, or the tax laws in one (1) or more jurisdictions have changed so as to explicitly require such treatment, the Party made aware of such assertion or change in law shall inform the other Party within thirty (30) days and shall consult with the other Party regarding the consequences of such assertion or change. If applicable laws require that taxes be deducted and withheld from a payment, the remitting Party shall (i) deduct those taxes from the payment; (ii) pay the taxes to the proper taxing authority; (iii) send evidence of the obligation together with proof of payment to the other Party within sixty (60) days following that payment; and (iv) shall provide such assistance as the other Party may reasonably require in obtaining any refund of such amounts to which the other Party may be entitled, to the extent that such assistance does not cause the remitting Party to incur any liability in respect of the taxes asserted to be due.

10.4 Records. Brii Bio shall keep, and cause its Affiliates and Sublicensees to keep, complete, true and accurate books of accounts and records for the purpose of determining, in a manner consistent with GAAP, the amounts payable to VBI pursuant to this Agreement. Such books and records shall be kept for such period of time required by law, but no less than at least three (3) years following the end of the calendar quarter to which they pertain. Such records shall be subject to inspection in accordance with Section 10.5.

10.5 Audits. Upon not less than sixty (60) days' prior written notice, Brii Bio shall permit an independent, certified public accountant selected by VBI and reasonably acceptable to Brii Bio, which acceptance will not be unreasonably withheld or delayed (for the purposes of this Section 10.5, the "**Auditor**"), to audit or inspect those books or records of Brii Bio, its Affiliates, or Sublicensees that relate to Net Sales and Royalty Reports for the sole purpose of verifying the: (a) royalties payable hereunder in respect of Net Sales; (b) withholding taxes, if any, required by Applicable Law to be deducted as a payment by Brii Bio in respect of such Net Sales; (c) exchange rates used in determining the amount of Dollars. Such Auditor shall be under reasonable written obligations of confidentiality to the audited party and shall disclose to VBI only the amount and accuracy of payments reported and actually paid or otherwise payable under this Agreement. Notwithstanding the foregoing, provided that Brii Bio obtains an audit right for itself with respect to a Sublicensee's records that is consistent with the terms of this Section 10.5, as well as the right to share the results of such audit with VBI, Brii Bio shall not be required to obtain from such Sublicensee a direct audit right for VBI. The Auditor shall send a copy of the report to Brii Bio at the same time it is sent to VBI. Such inspections may be made no more than once each calendar year and during normal business hours. VBI shall be responsible for the cost of any such audit, provided that if the Auditor determines that Brii Bio has underpaid any amounts payable to VBI hereunder by ten percent (10%) or more, Brii Bio shall pay the costs and expenses of such audit.

10.6 Late Payments. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at a rate per annum equal to three percent (3%) above the U.S. Prime Rate (as set forth in the Wall Street Journal, Eastern Edition) for the date on which payment was due, calculated daily on the basis of a three hundred and sixty-five (365)-day year, or similar reputable data source; provided that, in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the Party entitled to receive such payment from exercising any other rights it may have as a consequence of the lateness of any payment.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that the receiving Party (the "**Receiving Party**") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential or proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed to it by the other Party (the "**Disclosing Party**") including, but not limited to, all Know How, Inventions and any other technical, regulatory or business information of whatever nature (collectively, "**Confidential Information**"). For purposes of this Agreement, (a) all VBI Know-How shall be Confidential Information of VBI and (b) all Brii Bio Know-How shall be Confidential Information of Brii Bio.

11.2 Exceptions. Notwithstanding Section 11.1 above, the obligations of confidentiality and non-use shall not apply to Confidential Information that, in each case as demonstrated by competent evidence:

(a) was already known to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality, at the time of disclosure;

(b) was generally available to the public or was otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates in breach of this Agreement;

(d) was subsequently lawfully disclosed to the Receiving Party or any of its Affiliates by a Person other than the Disclosing Party, and who, to the best knowledge of the Receiving Party, did not directly or indirectly receive such information directly or indirectly from the Disclosing Party under an obligation of confidence; or

(e) was independently developed by the Receiving Party or its Affiliate without use of or reference to any information or materials disclosed by the Disclosing Party.

11.3 Permitted Disclosures. Notwithstanding the provisions of Section 11.1, each Party may disclose Confidential Information belonging to the other Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patents as permitted by this Agreement;

(b) prosecuting or defending litigation as permitted by this Agreement;

(c) submission to a Regulatory Authority in connection with a Marketing Approval of a Licensed Product;

(d) complying with applicable court orders, Applicable Law or governmental regulations including the requirements of any securities exchange;

(e) to those of its employees, Affiliates, contractors or agents who have a need to know such Confidential Information in order to enable the Receiving Party to carry out its obligations pursuant to this Agreement provided that such persons are subject to obligations of confidentiality and non-use at least equivalent in scope to the obligations set forth in this Article 11;

(f) to existing or potential acquirers or merger candidates; investment bankers; existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 11; and advisors; provided, however, that neither Party shall make such disclosure to a competitor of the other Party, without obtaining the Disclosing Party's prior consent in writing; and provided further, that each Party will remain responsible for any failure by any of the foregoing individuals to treat such Confidential Information as required under Section 11.1 as if such individuals were parties directly bound to the requirements of this Article 11.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information, it shall, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts; *provided*, that any Confidential Information so disclosed shall still be subject to the restrictions on use set forth in this Article 11. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

11.4 Confidentiality of this Agreement and its Terms. Except as otherwise provided in this Article 11, each Party agrees not to disclose to any Third Party the existence of this Agreement or the terms of this Agreement without the prior written consent of the other Party hereto, which Agreement and terms shall be deemed the Confidential Information of both Parties.

11.5 Public Announcements and Filings. As soon as practicable following the Effective Date hereof, the Parties shall each issue a press release announcing the existence of this Agreement which is approved in writing by both Parties. For greater certainty, neither Party (nor its Affiliates) shall be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC, the NASDAQ stock exchange or any other stock exchange or Governmental Authority; provided that a disclosing Party shall give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as such Party would use to protect its own confidential information.

11.6 Prior Non-Disclosure Agreements. As of the Effective Date, the terms of this Article 11 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement, including without limitation the Confidentiality Agreement effective July 9, 2018. Any information disclosed under such prior agreements shall be deemed disclosed under this Agreement.

11.7 Use of Name. Each Party may use the name, insignia, symbol, trademark, trade name or logotype of the other Party only (a) in connection with permitted disclosures relating to this Agreement and the activities contemplated hereby, (b) as required by Applicable Law, or (c) as otherwise expressly permitted by this Agreement or agreed in writing by such other Party.

11.8 Publication. At least thirty (30) days prior to publishing, publicly presenting, and/or submitting for written or oral publication a manuscript, abstract or the like that includes information relating to any Development Plan, or Joint Invention that has not been previously published, each Party shall provide to the other Party a draft copy thereof for its review. The publishing Party shall consider in good faith any comments provided by the other Party during such thirty (30) day period. In addition, the publishing Party shall, at the other Party's reasonable request, remove therefrom any Confidential Information of such other Party. If requested in writing by the non-publishing Party, the publishing Party shall withhold material from submission for publication or presentation for an additional thirty (30) days to allow for the filing of a Patent application or the taking of such other measures as may be required to establish and preserve proprietary rights in the information in the material being submitted for publication or presentation. The contribution of each Party shall be noted in all publications or presentations by acknowledgment or co-authorship, whichever is appropriate.

ARTICLE 12

INTELLECTUAL PROPERTY

12.1 Ownership of Intellectual Property.

(a) Inventions. Except as otherwise expressly set forth in this Agreement, ownership of Inventions, and any and all intellectual property rights therein, will be determined based on the principles of inventorship in accordance with United States patent laws.

(b) VBI Technology and Brii Bio Technology. Notwithstanding Section 12.1(a), (i) VBI and its Affiliates have, and shall retain all right, title and interest in and to, the VBI Technology, and (ii) Brii Bio and its Affiliates have, and shall retain all right, title and interest in and to, the Brii Bio Technology. Each Party shall execute such documents, including assignments, as may be required to vest title in the owning Party in accordance with the foregoing.

(c) Joint Technology. The Parties shall jointly own all right, title and interest in all Joint Technology and hereby agree that each Party may only use such Joint Technology to the extent permitted by this Agreement. For the avoidance of doubt, VBI shall have no right to practice the Joint Technology in the VBI Territory outside of the Field unless and until the Parties have negotiated a license pursuant to Section 3.5. Each Party shall execute such documents, including assignments, as may be required to vest title to all Joint Inventions and Joint Patents in both Parties.

(d) Assignment Obligation. Each Party will cause all employees of such Party who perform activities for such Party under this Agreement to be under an obligation to assign their rights in any Inventions and Know-How, whether or not patentable, resulting therefrom to such Party. With respect to any activities of a Party under this Agreement that are contracted to a Person that is not an employee, the Party retaining such contractor will include in the applicable contract an assignment to such Party of all rights in Inventions and Know-How made by such contractor resulting from such activities.

12.2 Patent Prosecution and Maintenance.

(a) VBI Patents.

(i) **Initial Right.** VBI shall have the first right to prepare, file, prosecute and maintain all VBI Patents in mainland China and shall bear the costs associated therewith. VBI shall retain patent counsel registered to practice before the Chinese patent and trademark office and shall keep Brii Bio fully informed of progress with regard to the preparation, filing, prosecution and maintenance of the VBI Patents in the Licensed Territory. Specifically, VBI shall: (A) provide Brii Bio with a draft of any filing of a patent application at least ten (10) days prior to filing and VBI shall consider in good faith any comments or revisions suggested by Brii Bio or its counsel; (B) consult with Brii Bio regarding filing strategy and Regions where VBI Patents should be filed and maintained; (C) promptly provide Brii Bio with a copy of each patent application as filed, together with a notice of its filing date and serial number; (D) provide periodic status reports to Brii Bio regarding the status of each patent application or patent in each VBI Patent family in the Licensed Territory; (E) provide Brii Bio with a copy of any examiner's report that raise substantive patentability issues and consult with Brii Bio regarding responding to the same and shall consider in good faith any comments, strategies, and the like proposed by Brii Bio; and (F) promptly notify Brii Bio of the issuance of a VBI Patent in the Licensed Territory.

(ii) **Step-In Right.** In the event that VBI elects not to prosecute or maintain any VBI Patent in mainland China, or register a VBI Patent in Hong Kong or Macau, VBI shall provide reasonable prior written notice to Brii Bio of such intention (which notice shall, to the extent possible, be given no later than one hundred and twenty (120) calendar days prior to the next deadline for any action that must be taken with respect to such VBI Patent in the relevant patent office). In such case, at Brii Bio's sole discretion, upon written notice from Brii Bio, Brii Bio will have the right but not the obligation to assume responsibility for prosecution and/or maintenance of any such VBI Patent in mainland China or registration of a VBI Patent in Hong Kong or Macau at Brii Bio's cost and expense, and shall pay any required fees to maintain such VBI Patents in the applicable Region. If Brii Bio elects to assume such rights with respect to a VBI Patent, Brii Bio shall keep VBI reasonably informed in accordance with the criteria set forth in Section 12.2(a)(i)(A) – (F) above.

(b) Joint Patents.

(i) **Initial Responsibility**. Brii Bio shall be responsible for the preparation, filing, prosecution and maintenance of Joint Patents, subject to the rest of this Section 12.2(b). In carrying out its obligations pursuant to this Section 12.2(b), Brii Bio shall retain patent counsel registered to practice before the U.S. Patent and Trademark Office, which patent counsel will be instructed to copy both VBI and Brii Bio on all correspondence relating to the Joint Patents.

(ii) **Cooperation.** For any Joint Patents, Brii Bio shall keep VBI fully informed of progress with regard to the preparation, filing, prosecution and maintenance of the Joint Patents in and outside of the Licensed Territory. Brii Bio shall:

(1) provide VBI with a draft of any first filing of a patent application at least ten days prior to filing and Brii Bio shall consider in good faith any comments or revisions suggested by VBI or its counsel;

(2) consult with VBI regarding filing strategy and jurisdictions where Joint Patents should be filed and maintained provided, however, that unless otherwise agreed in writing, Joint Patents shall be filed in the United States, Europe, Canada and China;

(3) promptly provide VBI with a copy of each patent application as filed, together with a notice of its filing date and serial number;

(4) provide periodic status reports to VBI regarding the status of each patent application or patent in each Joint Patent family;

(5) provide VBI with a copy of any examiner's report that raise substantive patentability issues and consult with VBI regarding responding to the same and shall consider in good faith any comments, strategies, and the like proposed by VBI; and

(6) promptly notify VBI of the issuance of a Joint Patent.

(iii) **Option of VBI to Prosecute, Maintain and Enforce.** In the event that Brii Bio desires to give up responsibility for the prosecution or maintenance of any Joint Patent, Brii Bio shall provide reasonable prior written notice to VBI of such intention (which notice shall, to the extent possible, be given no later than sixty (60) calendar days prior to the next deadline for any action that must be taken with respect to such Joint Patent in the relevant patent office). In such case, at VBI's sole discretion, upon written notice from VBI, VBI may elect to assume responsibility for prosecution and/or maintenance of any such Joint Patent, and VBI shall thereafter keep Brii Bio reasonably informed in accordance with the criteria set for in Section 12.2(b)(ii).

(iv) **Costs for Joint Patents.** Brii Bio will bear the costs associated with preparation, filing, prosecution and maintenance of Joint Patents except for the costs associated with filing, prosecution and maintenance in the VBI Territory, which will be borne by VBI. The Party incurring costs associated with preparation, filing, prosecution and maintenance of Joint Patents of behalf of the other Party will issue an invoice to the other Party on a quarterly basis (as applicable), setting out such Party's share of the costs incurred during the prior quarter and providing copies of supporting invoices or other documentation. Each such invoice will be payable within thirty (30) days of receipt and the provisions of Article 8 shall apply to such payments.

(v) **Withdrawal of Support**. In the event that a Party decides to cease paying the costs associated with the preparation, filing, prosecution and maintenance of any Joint Patents in its respective territory, such Party shall advise the other Party of such decision in writing. Upon receipt of such notice, the recipient Party may elect to abandon the Joint Patents identified in the notice, or may elect to assume sole responsibility for the ongoing costs of such Joint Patent, in which event the Party wishing to cease sharing in the costs shall forthwith execute an assignment of its entire right, title and interest in such Joint Patents to the recipient Party, and the assigning Party shall cease being responsible for its share of the costs associated with any Joint Patents listed on the assignment effective as of the date of the assignment. In the event that the Party relinquishing responsibility for the costs of a Joint Patent has responsibility for prosecution and maintenance of such Joint Patent, that Party will be deemed to have given up responsibility for such prosecution and maintenance as of the date of the notice referred to in this section.

(c) Brii Bio Patents. Brii Bio shall have the sole right to prepare, file, prosecute and maintain the Brii Bio Patents on a worldwide basis.

12.3 Infringement by Third Parties.

(a) Notice. In the event that either VBI or Brii Bio becomes aware of any infringement or threatened infringement by a Third Party of the VBI Patents or the Joint Patents, it will notify the other Party in writing to that effect. Any such notice shall include any available evidence to support an allegation of infringement or threatened infringement by such Third Party.

(b) Licensed Territory. Subject to this Section 12.3(b), Brii Bio shall have the first right (but not the obligation), as between VBI and Brii Bio, to bring and control any action or proceeding with respect to infringement of any VBI Patent or Joint Patent in the Licensed Territory. VBI shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and VBI and its counsel will reasonably cooperate with Brii Bio and its counsel in strategizing, preparing and presenting any such action or proceeding provided, however, that Brii Bio may not make any submissions in any such action challenging the validity of a VBI Patent without the prior consent of VBI, such consent not to be unreasonably withheld. If Brii Bio fails to bring an action or proceeding with respect to infringement of any VBI Patent or Joint Patent in the Licensed Territory within sixty (60) days following the notice of alleged infringement or (ii) ten (10) days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, then VBI shall have the right (but not the obligation) to bring and control any such action, and Brii Bio shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding shall be used first to pay the legal costs of both Parties associated with the enforcement action and second to compensate Brii Bio for losses directly associated the infringement. Any additional recovery or damages shall be shared equally between the Parties. In the event that the legal costs associated with an enforcement action exceed the amount recovered in such action, then Brii shall pay any such additional costs.

(c) VBI Territory. VBI shall have the first right (but not the obligation) to bring and control any action or proceeding with respect to infringement of any Joint Patent in the VBI Territory, and Brii Bio shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If VBI fails to bring an action or proceeding within (i) sixty (60) days following the notice of alleged infringement or (b) ten (10) days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, Brii Bio shall have the right (but not the obligation) to bring and control any such action, and VBI shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any recovery or damages from an action or proceeding relating to Joint Patents shall be used first to pay the legal costs associated with the enforcement action and second to compensate the Parties pro rata for their respective losses directly associated the infringement. Any additional recovery or damages shall be shared equally between the Parties. In the event that the legal costs associated with an enforcement action exceed the amount recovered in such action, VBI shall pay any such additional costs.

(d) Cooperation. In the event a Party brings an infringement action in accordance with this Section 12.3, the other Party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being named as a party to such action.

(e) Brii Bio Patents. Brii Bio shall have the sole right to bring and control any action or proceeding with respect to infringement of any Brii Bio Patent on a worldwide basis.

12.4 Infringement of Third Party Rights. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either of the Parties pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party. VBI shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by VBI's activities and Brii Bio shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Subject to Article 14, Brii Bio shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by Brii Bio's activities and VBI shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

12.5 Consent for Settlement. Neither Party shall enter into any settlement or compromise of any action or proceeding under this Article 12 which would in any manner (a) limit the scope, validity or enforcement of any of the VBI Patents or Joint Patents, (b) admit fault or wrongdoing on the part of the other Party, or (c) impose any obligations or restriction on the other Party (whether financial or otherwise) without the prior written consent of such other Party.

12.6 Patent Term Extensions. The JSC shall make recommendations regarding patent term extensions for Joint Patents, including supplementary protection certificates and any other extensions that are now or become available in the future, wherever applicable; provided that Brii Bio shall have final decision making authority with respect to any decisions related to patent term extensions for Joint Patents in the Licensed Territory, and VBI shall have final decision-making authority with respect to any decisions related to patent term extensions for Joint Patents in the VBI Territory. Notwithstanding the foregoing, the Parties shall coordinate their activities with respect to any patent term extension with respect to all Joint Patents in order to secure the optimal protection for each Licensed Product available under Applicable Law.

12.7 Trademarks. VBI, or its Affiliates shall own and be responsible for all trademarks, trade names, branding, logos and domain names related to Licensed Products and shall be responsible for selecting, registering, enforcing, defending, and maintaining the same.

12.8 Maintenance of Patents. During the Term, each Party shall take all steps required to maintain in good standing any Patents licensed to the other Party hereunder, including with respect to Brii Bio, any Patent covering the Brii Bio Adjuvant.

ARTICLE 13

REPRESENTATIONS, WARRANTIES AND COVENANTS

13.1 Mutual Representations, Warranties and Covenants. Each Party hereby represents and warrants to the other Party, as of the Effective Date, and covenants (as applicable) as follows:

(a) Duly Organized. Such Party is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) Due Authorization; Binding Agreement. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with the terms hereof subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

(c) Consents. Such Party has obtained, or is not required to obtain, the consent, approval, order or authorization of any Third Party, or has completed, or is not required to complete any registration, qualification, designation, declaration, or filing with, any Regulatory Authority or Governmental Authority, in connection with the execution and delivery of this Agreement and the performance by such Party of its obligations under this Agreement.

(d) No Conflicting Grant of Rights. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of Applicable Law or any provision of the articles of incorporation, bylaws or any similar instrument of such Party, as applicable, in any material way and (b) do not conflict with, violate or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

(e) Right to Grant Licenses. Such Party has the right to grant (or cause its Affiliates to grant) the licenses contemplated under this Agreement and has not granted, assigned, transferred, or conveyed, and will not during the Term, grant, assign, transfer or convey any right, title or interest in, (i) in the case of VBI, any of the VBI Technology or its interest in the Joint Technology and (ii) in case of Brii Bio, its interest in the Brii Bio Technology or the Joint Technology, in any such case which grant, assignment, transfer or conveyance would conflict with the rights granted to the other Party hereunder.

(f) Employee/Contractor Agreements. All of such Party's employees or contractors acting on its behalf pursuant to this Agreement are and will be obligated under a binding written agreement to assign to such party or its designee all VBI Technology and Joint Inventions (as applicable) and to comply with obligations of confidentiality and non-use consistent with those set forth in Article 11.

(g) Debarment. Such Party is not debarred under the FDA, NMPA or similar Regulatory Authority in any other jurisdiction and it does not, and will not during the Term, employ or use the services of any Person who is debarred, in connection with the development, manufacture or commercialization of Licensed Products. In the event that either Party becomes aware of the debarment or threatened debarment of any Person providing services to such Party, including the Party itself and its Affiliates, contractors, Sublicensees, Distributors, which directly or indirectly relate to activities under this Agreement, the other Party shall be immediately notified in writing.

(h) Compliance. As of the Effective Date, each Party is in material compliance with all Applicable Laws with respect to the subject matter of this agreement, and during the Term, each party covenants to the other that in the performance of its obligations under this Agreement, such Party shall comply with, and shall cause its and its Affiliates' employees and Sublicensees to comply, with all Applicable Laws.

(i) No Third Party Rights. Neither Brii Bio nor VBI is a party to or otherwise bound by any oral or written contract or agreement that would result in any Third Party obtaining any interest in, or that would give to any Third Party any right to assert any claim in or with respect to, any Joint Inventions or Joint Patents except as disclosed on Schedule 13 hereto.

13.2 Additional Representations, Warranties and Covenants of Brii Bio. Brii Bio represents and warrants to VBI as of the Effective Date that, to Brii Bio's knowledge, there are no Third Party intellectual property rights that cover or claim the Brii Bio Adjuvant and that there are [*****].

13.3 Additional Representations, Warranties and Covenants of VBI. VBI represents and warrants to Brii Bio as of the Effective Date, or covenants, as applicable, that:

(a) Right to Grant License. Except for VBI's obligations pursuant to the [*****], no royalties, license fees or other payments are required to be paid to any Third Party in connection with the manufacture, use, sale or importation of Licensed Products in the Field in the Licensed Territory.

(b) Ownership. VBI is the sole and exclusive owner of, or Controls, the VBI Technology licensed by VBI to Brii Bio under this Agreement.

(c) VBI Patents. Schedule A is a true, complete and correct list of the VBI Patents existing as of the Effective Date. (i) The VBI Patents are to the best of VBI's knowledge, valid and enforceable, (ii) no Third Party has made any claim against VBI or its Affiliates asserting the invalidity, unenforceability, or non-infringement of any VBI Patents (including, by way of example, through the institution or written threat of institution of interference, nullity, opposition, inter partes or post-grant review or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Regulatory Authority), (iii) the VBI Patents are being diligently prosecuted in the respective patent offices in in accordance with Applicable Law, and (iv) the VBI Patents have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for such payments.

(d) Non-Infringement by Third Parties. To VBI's knowledge, no Third Party is infringing or misappropriating or threatening to infringe or misappropriate any VBI Technology.

(e) Non-Infringement of Third Party Rights. Neither VBI nor any of its Affiliates has received any written notice from any Person, or has knowledge of, any actual or threatened claim or assertion that the use or practice of the VBI Patents, infringes or misappropriates the intellectual property rights of a Third Party.

(f) Claims; Judgements; Settlements. Except as disclosed in Schedule B, there are no claims, judgments or settlements against or pending, or amounts with respect thereto, owed by VBI or any of its Affiliates, with respect to the VBI Technology licensed by VBI to Brii Bio under this Agreement and VBI has not received written notice threatening any such claims, judgments or settlements.

(g) Employee Agreements. All current and former employees and consultants of VBI and its Affiliates who are or have been substantively involved in the design, review, evaluation or development of the VBI Patents have executed written contracts or are otherwise obligated to assign their rights to VBI or its designee.

(h) No Third Party Rights. VBI is not a party to or otherwise bound by any oral or written contract or agreement that will result in any Third Party obtaining any interest in, or that would give to any Third Party any right to assert any claim in or with respect to, any VBI Technology exclusively licensed to Brii Bio hereunder except as disclosed on Schedule 13 hereto.

(i) Manufacture of Licensed Product. VBI shall manufacture, store and transfer the Licensed Product supplied pursuant to Section 7.1(a) (and Schedule 7.1(a)) in accordance with applicable Licensed Product specifications and all Applicable Laws, including GMP.

(j) No Other Technology. To VBI's knowledge, the VBI Technology in existence as of the Effective Date comprises all of the intellectual property rights used by or on behalf of VBI and its Affiliates in the research, development, and manufacturing of the Licensed Compound and VBI-2601.

(k) [*****]**.** VBI is not in breach of its obligations under [*****], and during the Term, VBI shall take all actions necessary to maintain the [*****] in good standing, and shall not materially breach the [*****]. In the event that [*****] notifies VBI during the Term that VBI is in material breach of the [*****], VBI shall promptly notify Brii Bio and, to the extent VBI fails to cure such breach, Brii Bio shall have the right to do so.

13.4 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, OR ANY OTHER AGREEMENT CONTEMPLATED HEREUNDER, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW OR OTHERWISE AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OR ENFORCEABILITY OF PATENTS OR NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR THE PROSPECTS OR LIKELIHOOD OF DEVELOPMENT OR COMMERCIAL SUCCESS OF THE LICENSED PRODUCT.

ARTICLE 14

INDEMNIFICATION

14.1 Indemnification of VBI. Brii Bio shall indemnify and hold harmless VBI and its Affiliates, and its and their directors, officers, employees and agents of such entities (the "**VBI Indemnitees**") from and against any and all losses, liabilities, damages, penalties, fines, costs and expenses (including reasonable attorneys' fees and other expenses of litigation) ("**Losses**") from any claims, actions, suits or proceedings brought by a Third Party (a "**Third Party Claims**") incurred by any VBI Indemnitee, arising from, or occurring as a result of: (a) the development, manufacture, use, handling, storage, sale or other disposition of Licensed Product by Brii Bio or its Affiliates or Sublicensees in the Licensed Territory; (b) gross negligence or willful misconduct by or on behalf of Brii Bio or its Affiliates in performing any activities in connection with this Agreement; and (c) any material breach of any representations, warranties or covenants by Brii Bio under this Agreement; except, in each case ((a) – (c)), to the extent such Third Party Claims fall within the scope of the indemnification obligations of VBI set forth in Section 14.2.

14.2 Indemnification of Brii Bio. VBI shall indemnify and hold harmless each of Brii Bio and its Affiliates and its and their directors, officers, employees and agents of such entities (the "**Brii Bio Indemnitees**"), from and against any and all Losses from any Third Party Claim incurred by any Brii Bio Indemnitee arising from, or occurring as a result of: (a) the development, manufacture, use, handling, storage, sale or other disposition of Licensed Product by VBI or its Affiliates; (b) gross negligence or willful misconduct by or on behalf of VBI or its Affiliates in performing any activities in connection with this Agreement; and (c) any material breach of any representations, warranties or covenants by VBI under this Agreement; except, in each case ((a) – (c)) to the extent such Third Party Claims fall within the scope of the indemnification obligations of Brii Bio set forth in Section 14.1.

14.3 Procedure. A Party that intends to claim indemnification under this Article 14 (the "**Indemnitee**") shall promptly notify the indemnifying Party (the "**Indemnitor**") in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification. The Indemnitee shall provide the Indemnitor with reasonable assistance, at the Indemnitor's expense, in connection with the defense of the Third Party Claim for which indemnity is being sought. The Indemnitee may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnitor shall have the right to assume and conduct the defense of the Third Party Claim with counsel of its choice, which counsel shall be reasonably acceptable to Indemnitee. The Indemnitor shall not settle any Third Party Claim without the prior written consent of the Indemnitee, not to be unreasonably withheld. So long as the Indemnitor is actively defending the Third Party Claim in good faith, the Indemnitee shall not settle any such Third Party Claim without the prior written consent of the Indemnitee. If the Indemnitor does not assume and conduct the defense of the Third Party Claim as provided above, (a) the Indemnitee may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim in any manner the Indemnitee may deem reasonably appropriate (and the Indemnitee need not consult with, or obtain any consent from, the Indemnitor in connection therewith), and (b) the Indemnitor will remain responsible to indemnify the Indemnitee as provided in this Article 14. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 14 if and to the extent the Indemnitor is actually prejudiced thereby.

14.4 Insurance. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (including D&O insurance) in an amount consistent with industry standards, for a company in a similar position to such Party, during the Term, which shall include, but not be limited to ten million Dollars ($10,000,000). Each Party shall provide the other Party with written notice at least thirty (30) days prior to any cancellation, nonrenewal or material change in the insurance described above. Each Party shall provide a certificate of insurance evidencing such coverage to the other Party upon request. Each Party shall provide a certificate of insurance evidencing its D&O insurance annually. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 14.

ARTICLE 15

TERM AND TERMINATION

15.1 Term. This Agreement shall commence on the Effective Date, and unless terminated earlier as provided in this Article 15, shall continue in full force and effect on a Region-by-Region and Licensed Product-by-Licensed Product basis until the last-to-expire Royalty Term in the last Region in the Licensed Territory (the "**Term**"). Upon expiration (but not an earlier termination) of this Agreement in a Region of the Licensed Territory, VBI shall grant to Brii Bio a perpetual, non-exclusive, fully paid-up, royalty free license under the VBI Technology in such Region to make, have made, use, sell, offer for sale and import such Licensed Product in the Field in such Region.

15.2 Early Termination. Each Party shall have the right to terminate this Agreement in its entirety before the end of the Term:

(a) upon written notice by either Party if the other Party is in material breach of this Agreement and has not cured such breach within sixty (60) days (or thirty (30) days for a breach payment obligations) after notice from the terminating Party requesting cure of the breach. Any such termination shall become effective at the end of such sixty (60) or thirty (30) day period, as applicable, unless the breaching Party has cured any such breach or default prior to the end of such period; provided that, such time periods shall be tolled during the pendency of any good faith dispute that has been deferred to resolution pursuant to Article 16 with respect to the validity of such allegation of breach; or

(b) at any time if the other Party shall (i) file in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, (ii) propose an out-of-court restructuring of substantially all of VBI's indebtedness outside the ordinary course of business, (iii) be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, (iv) propose or be a party to any dissolution or liquidation, (v) make an assignment for the benefit of its creditors, or (vi) admit in writing its inability generally to pay its debts as they fall due in the general course.

15.3 Other Brii Bio Termination Rights.

(a) Voluntary Termination. Brii Bio shall have the right in its sole and absolute discretion, to terminate this Agreement, either with respect to a Region or in its entirety, upon one hundred and eighty (180) days prior written notice to VBI for convenience, without cause, and for any or no reason.

(b) Termination for Safety Reasons. Brii Bio may terminate this Agreement at any time during the Term immediately upon providing written notice to VBI if a 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 (6) consecutive months.

15.4 Other VBI Termination Right. VBI shall have the right to terminate this Agreement immediately upon written notice to Brii Bio if Brii Bio or any of its Affiliates, Distributors or Sublicensees 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 VBI Patent.

15.5 Effects of Termination.

(a) VBI Technology. Upon any termination of this Agreement, the licenses granted by VBI to Brii Bio in the VBI Technology shall automatically terminate.

(b) Joint Patents, Joint Inventions and Joint Know How. Effective upon termination of this Agreement:

(i) Brii Bio shall automatically be deemed to, and hereby does, grant to VBI, an exclusive, royalty free right and license under the Brii Bio Technology that covers or claims the Brii Bio Adjuvant or the Novel Composition and Brii Bio's interest in the Joint Technology in the Field in the VBI Territory, which, for greater certainty, shall include a license to use the Brii Bio Adjuvant in the Field; and

(ii) VBI shall automatically be deemed to, and hereby does, grant to Brii Bio an exclusive, royalty free right and license under VBI's interest in the Joint Technology in the Field in the Licensed Territory, which, for greater certainty, shall include a license to use the Brii Bio Adjuvant in the Field.

15.6 Clinical Trials Upon Termination. In the event there are any on-going Clinical Trials of the Licensed Product in the Field in the Licensed Territory as of the date of termination hereof, the Parties shall negotiate in good faith and adopt a plan to wind-down such Clinical Trials in an orderly fashion or, at VBI's election, promptly transition such development activities to VBI or its designee, with due regard for patient safety and the rights of any subjects that are participants in any Clinical Trials and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all Applicable Laws.

15.7 Brii Bio Regulatory Filings (including Marketing Approval). Upon termination of this Agreement, at VBI's request and to the extent not already held by VBI, Brii Bio shall assign or cause to be assigned to VBI or its designee (or to the extent not assignable in accordance with Applicable Law, Brii Bio shall take all reasonable actions to make available to VBI or its designee the benefits of all Regulatory Documentation and Marketing Approvals for the Licensed Products in the Licensed Territory) at no cost to VBI, unless such termination is the result of VBI's material breach of this Agreement pursuant to Section 15.2(a), in which case VBI shall bear the cost of such assignment.

15.8 Clinical Supply. Immediately upon termination of this Agreement, Brii Bio shall, at its own cost, return to VBI any unused Licensed Product supplied by VBI for use in Clinical Trials hereunder.

15.9 Inventory. Upon termination of this Agreement, Brii Bio, its Affiliates, Distributors and Sublicensees, shall have the option to continue, to the extent that Brii Bio, its Affiliates, Distributors and Sublicensees have stocks of Licensed Product remaining, to fulfill orders received from customers for Licensed Products in the Field in the Licensed Territory until up to thirty (30) days after VBI notifies Brii Bio in writing that VBI intends to commercialize such Licensed Product or has secured an alternative Distributor or licensee for the Licensed Product, but in no event for more for than six (6) months after the date of notice of termination. For Product sold by Brii Bio or its Affiliates, Distributors or Sublicensees after the effective date of a termination Brii Bio shall continue to pay royalties on the amount of Net Sales pursuant to Article 9. Notwithstanding the foregoing, Brii Bio and its Affiliates, Distributors and Sublicensees shall cease such activities in the Licensed Territory upon sixty (60) days written notice given by VBI at any time after the effective date of a termination requesting that such activities (or portion thereof) cease. In the case where VBI has given notice to Brii Bio requesting the cessation of activities pursuant to the provision of this Section, Brii Bio shall notify VBI of an estimate of the quantity of Licensed Product and its shelf life remaining in the inventory of Brii Bio, its Affiliates, Distributors or Sublicensees and VBI shall have the right to purchase any such quantities of Licensed Product from Brii Bio at a price mutually agreed by the Parties.

15.10 Transition. Brii Bio shall use Commercially Reasonable Efforts to cooperate with VBI or its designee to effect a smooth and orderly transition in the development, sale and marketing, promotion and commercialization of Licensed Product in the Licensed Territory following termination of this Agreement.

15.11 Return of Confidential Information. Upon termination or expiration of this Agreement, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one (1) copy of such materials for archival purposes only subject to a continuing confidentiality obligations.

15.12 [*****] **and** [*****]**.** In the event of a termination of this agreement by Brii Bio pursuant to Section 15.2(a) or Section 15.2(b), then VBI shall use Commercially Reasonable Efforts to facilitate a direct license for Brii Bio under the [*****].

ARTICLE 16

DISPUTE RESOLUTION AND GOVERNING LAW

16.1 Dispute Resolution Process. The Parties recognize that disputes as to certain matters may from time to time arise during the Term that relate to interpretation of a Party's rights and/or obligations hereunder or any alleged breach of this Agreement. If the Parties cannot resolve any such dispute within thirty (30) days after written notice of a dispute from one (1) Party to another, either Party may, by written notice to the other Party, have such dispute referred to the Senior Executives. The Senior Executives shall negotiate in good faith to resolve the dispute within thirty (30) days. During such period of negotiations, any applicable time periods under this Agreement shall be tolled. If the Senior Executives are unable to resolve the dispute within such time period then either Party may submit the dispute as follows:

(a) for final resolution of matters not expressly referred to expert determination hereunder, by binding arbitration in accordance with Section 16.2(b). Notwithstanding anything in this Article 16 to the contrary, VBI and Brii Bio shall each have the right to apply to any court of competent jurisdiction for appropriate interim or provisional relief, as necessary to protect the rights or property of that Party;

(b) for final resolution of matters designated hereunder to be resolved by expert determination, by expert determination in accordance with Section 16.3.

16.2 Arbitration.

(a) If the parties are unable to resolve such dispute through the procedures described in Section 16.1, then, except in the case of a dispute, controversy or claim that concerns (a) the validity or infringement of a patent, trademark or copyright, or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory, the dispute shall be resolved by expedited binding arbitration before a panel of three (3) independent and neutral experienced arbitrators, one chosen by VBI, one chosen by Brii Bio and the third chosen by the foregoing two (2) arbitrators. Each Party shall select its arbitrator within ten (10) days of one party notifying the other party that it is exercising its rights under this Section 16.2(a), and the two (2) arbitrators shall select the third arbitrator within five (5) days of their selection. Any such arbitration proceeding shall be administered by the Expedited Procedure Rules, irrespective of the amount in dispute, of International Court of Arbitration of the International Chamber of Commerce, with limited discovery, in accordance with its then current rules governing commercial disputes; provided, that, such rules shall be modified by this Section 16.1(b), to the extent any such modifications are necessary.

(b) Any arbitration shall be conducted in the English language and applicable arbitration association shall use New York as the governing law for this Agreement and the parties' obligations hereunder. Within ten (10) days after the arbitrators are selected, the Parties will each submit to the arbitrators, and to one another, a written statement of their respective positions regarding the alleged dispute. The Parties will also provide the arbitrators a copy of this Agreement, as may be amended at such time. Each party will have ten (10) days from receipt of the other party's submission to provide to the arbitrator a written response thereto. Neither party may have any communication (either written or oral) with the arbitrators other than for the sole purpose of engaging the arbitrator at the outset or as expressly permitted in this Section 16.1(b); provided, that the arbitrator will have the right to meet with the parties, either alone or together, as necessary in the arbitrator's opinion to make a determination. Based on the materials submitted, the arbitrators will determine whether any discovery process is necessary, and, if it is, the parameters of such process with the intent of resolving the arbitration as expeditiously as possible (e.g., limiting the number of depositions and the time discovery is permitted to take). The Parties and arbitrators shall employ procedures designed to resolve the conflict by arbitration within twelve (12) months of the dispute being referred for arbitration.

16.3 Expert Determination. For final resolution of matters designated hereunder to be resolved by expert determination, the Parties hereby agree that such decision shall be conducted expeditiously by an independent expert selected unanimously by the Parties. Either Party may initiate the expert determination by giving written notice to the other Party. If the Parties are unable to agree upon an expert within ten (10) days after receipt of the notice of request for an expert determination, then, the International Centre for Expertise of the International Chamber of Commerce (ICC) shall appoint such expert. The expert, once appointed, shall have no ex parte communications with either Party concerning the expert determination or the underlying dispute. The Parties agree to cooperate fully in the expeditious conduct of such expert determination and to provide the expert with access to all facilities, books, records, documents, information and personnel necessary to make a fully informed decision in an expeditious manner. Before issuing a final decision, the expert shall issue a draft report and allow the parties to the dispute to comment on it. The expert shall endeavor to resolve the dispute within thirty (30) days (but no later than sixty (60) days) after his or her appointment, taking into account the circumstances requiring an expeditious resolution of the matter in dispute. The expert's decision shall be final and binding on the Parties. The costs of the expert determination shall be shared by the Parties, regardless of the outcome of the determination.

16.4 Governing Law; Litigation; Exclusive Venue. This Agreement and all questions regarding its existence, validity, interpretation, breach or performance, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles. Any dispute shall be finally settled in a United States Federal Court of competent jurisdiction (or state court if no Federal Court has jurisdiction) located in the State of New York, United States, and the Parties hereby attorney to the jurisdiction of such courts.

ARTICLE 17

GENERAL PROVISIONS

17.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, extreme weather, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not) or terrorism, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any Governmental Authority (each of the foregoing, a "**Force Majeure Event**"). The non-performing Party shall notify the other Party of such force majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform; *provided*, *however*, that in the event the suspension of performance continues for sixty (60) days after the date of the occurrence, the Parties shall meet to discuss in good faith how to proceed in order to accomplish the goals outlined in this Agreement.

17.2 Waiver of Breach. No delay or waiver by either Party of any condition or term in any one (1) or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

17.3 Further Assurances. Each Party agrees to execute, acknowledge and deliver such further instruments, and to perform all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

17.4 Amendment. No amendment or modification of any provision of this Agreement shall be effective unless in writing and signed by both Parties hereto.

17.5 Severability. In the event any provision of this Agreement should be held invalid, illegal or unenforceable, the Parties shall negotiate, in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties. All other provisions of this Agreement shall remain in full force and effect in such jurisdiction.

17.6 Entire Agreement. This Agreement (including the Schedules attached hereto) constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all previous agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof. Each of the Parties acknowledges and agrees that, in entering into this Agreement, it does not rely on, and shall have no remedy in respect of, any statement, representation, warranty or understanding (whether negligently or innocently made) of any Person (whether party to this Agreement or not) other than as expressly set out in this Agreement.

17.7 Notices. Any notice or communication required or permitted under this Agreement shall be in writing in the English language, delivered personally, sent by email (and promptly confirmed by personal delivery, registered mail or overnight courier), sent by courier or sent by registered mail, postage prepaid to the following addresses of the Parties (or such other address for a Party as may be at any time thereafter specified by like notice):

To VBI:

VBI Vaccines Inc.
2241-222 Third Street
Boston, MA 0212
Attention: Chief Executive Officer
Email:

To Brii Bio:

Brii Biosciences Limited
Vistra (Cayman) Limited
PO Box 3119
Grand Pavilion Hibiscus Way
802 West Bay Road Grand Cayman KYI-1205
Chapel Hill, NC 27517
Attention: Zhi Hong
Email:

Any such notice shall be deemed to have been given: (a) when delivered if personally delivered; (b) on the next Business Day if sent by email; and/or (c) on the fifth (5^{th}) Business Day following the date of mailing if sent by mail or courier. Notices hereunder will not be deemed sufficient if provided only between or among each Party's representatives on the Joint Steering Committee.

17.8 Assignment. This Agreement shall not be assigned or otherwise transferred, nor may any right or obligations hereunder be assigned or transferred, by either Party without the prior written consent of the other Party; except that either Party may assign or otherwise transfer this Agreement without the consent of the other Party to an Affiliate or to an entity that acquires all or substantially all of the business or assets of the assigning Party relating to the subject matter of this Agreement, whether by merger, acquisition or otherwise, provided that the acquiring Person assumes this Agreement in writing or by operation of law. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 17.8 shall be null and void.

17.9 Relationship of the Parties. The Parties shall be independent contractors of one another and nothing in this Agreement or any action which may be taken pursuant to its terms is intended, or shall be deemed, to establish a partnership, joint venture or agency between the Parties. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

17.10 Headings. The heading of the Articles and Sections of this Agreement are included for convenience of reference and shall not affect its meaning or interpretation.

17.11 Survival. The following provisions shall survive any termination of this Agreement: 10.5, 12.1, 12.2(b), 12.2(c), 12.5, 15.5, 15.6, 15.7, 15.8, 15.9, 15.10, 15.11 and Articles 1 (as applicable), 11, 14, 16 and 17.

17.12 Counterparts. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Executed signature pages of this Agreement may be scanned and delivered electronically and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

17.13 Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity shall be construed to include the person's or entity's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, or Schedules shall be construed to refer to Sections, or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise, including by e-mail, (j) unless stated otherwise, references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or", and (l) references to any Sections include Sections and subsections that are part of the related Section (*e.g.*, a section numbered "Section 2.2" would be part of "Section 2", and references to "Section 2.2" would also refer to material contained in the subsection described as "Section 2.2(a)").

[Signature Page Follows]

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE "COMMISSION") PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "*****"

IN WITNESS WHEREOF, the Parties have executed this Collaboration and License Agreement as of the Effective Date.

VBI VACCINES INC.

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

BRII BIOSCIENCES LIMITED

By: */s/ Zhi Hong*
Name: Zhi Hong
Title: Chief Executive Officer

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE "COMMISSION") PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "*****"

Schedule A

VBI Patents

US Provisional Patent Application 62/760439 filed November 13, 2018.

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE "COMMISSION") PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "*****"

Schedule B

Claims; Judgments; Settlements

1. Civil Action 9750-09-18 Stern (minor) et al v. Ministry of Health

2. Class Action 09-18 Anonymous ID 340395698 et al v. SciVac Company Ltd

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE "COMMISSION") PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "*****"

Schedule C

Development Plan

The Parties hereby agree on the following initial development plan and budget for Licensed Compound(s) (the "Development Plan").

[*****]

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE "COMMISSION") PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "*****"

Schedule 7.1(a)

[*****]

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE "COMMISSION") PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "*****"

Schedule 7.3

[*****]

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE "COMMISSION") PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "*****"

Schedule 13

Disclosures

All of the assets of VBI and its subsidiaries are subject to a security agreement entered into pursuant Amended and Restated Credit Agreement and Guaranty between Variation Biotechnologies (US), Inc. et al and Perceptive Credit Holdings, LP, dated December 6, 2016 as amended on September 28, 2017 and July 17, 2018.

Exhibit 10.63

STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "**Agreement**"), dated as of December 4, 2018, by and between VBI Vaccines Inc., a British Columbia corporation (the "**Company**"), and Brii Biosciences Limited, an exempted company organized under the laws of the Cayman Islands ("**Investor**").

PREAMBLE

A. Contemporaneously with the execution and delivery of this Agreement, the Company and the Investor are entering into that certain Collaboration and License Agreement, dated as of the date hereof (the "**License Agreement**"), relating to, among other things, the development and commercialization by the Company of the Company's therapeutic vaccine product; and

B. The Investor wishes to purchase, and the Company wishes to sell, upon the terms and conditions stated in this Agreement, 2,295,082 Common Shares (the "**Shares**").

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and the Investor agree as follows:

ARTICLE 1
DEFINITIONS

In addition to the terms defined elsewhere in this Agreement, the following terms have the meanings indicated:

"**Affiliate**" means, with respect to a Person, any Person that controls, is controlled by or is under common control with such first Person. For purposes of this definition only, "**control**" means (a) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise, or (b) to own, directly or indirectly, fifty percent (50%) or more of the outstanding securities or other ownership interest of such Person. For the purposes of this Agreement, neither Party shall be considered an Affiliate of the other, and the Affiliates of each Party shall not be considered Affiliates of the other Party or of any of such other Party's Affiliates.

"**Agreement**" has the meaning set forth in the Preamble.

"**Business Day**" means any day (other than a Saturday, Sunday or a legal holiday) on which banks are open for general business in New York, New York.

"**Closing**" means the closing of the purchase and sale of the Shares pursuant to Section 2.1.

"**Closing Date**" means the date and time of the Closing which shall take place as set forth in Section 2.1, on the date hereof, simultaneously with the execution of this Agreement.

"**Common Shares**" means the common shares of the Company, no par value per share.

"Company" has the meaning set forth in the Preamble.

"**Company Intellectual Property**" has the meaning set forth in Section 3.1(h).

"**Company U.S. Counsel**" means Haynes and Boone, LLP, U.S. counsel to the Company.

"**Competitor**" means any Person that, during the Term (as defined in the License Agreement), commercializes or develops a product which competes directly or indirectly with a Licensed Product (as such term is defined in the License Agreement).

"**Convertible Securities**" means any share or securities (other than Options) convertible into or exercisable or exchangeable for Common Shares.

"**Disclosure Materials**" has the meaning set forth in Section 3.1(g).

"**Equity Securities**" means any all Common Shares and any securities of the Company convertible into, or exchangeable or exercisable for, such shares, and options, warrants or other rights to acquire such shares.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

"**GAAP**" has the meaning set forth in Section 3.1(g).

"**Indemnified Party**" has the meaning set forth in Section 5.2(a).

"**Indemnifying Party**" has the meaning set forth in Section 5.2(a).

"**Intellectual Property**" means patents, patent applications, trademarks, trademark applications, service marks, trade names, trade dress, trade secrets, inventions and discoveries and invention disclosures whether or not patented, copyrights in both published and unpublished works, including without limitation all compilations, data bases and computer programs, materials and other documentation, licenses, internet domain names and other intellectual property rights and similar rights.

"**Investor**" has the meaning set forth in the Preamble.

"**knowledge"** of the Company means with respect to any statement made to the knowledge of the Company, that the statement is based upon the actual knowledge, after reasonable due inquiry, of any executive officer of the Company as of the date of this Agreement.

"**License Agreement**" has the meaning set forth in the Preamble.

"**Lien**" means any lien, charge, claim, security interest, encumbrance, right of first refusal or other restriction.

"**Losses**" means any and all losses, claims, damages, liabilities, settlement costs and expenses, including, without limitation, reasonable attorneys' fees.

"**Material Adverse Effect**" means (i) a material adverse effect on the results of operations, assets, business or financial condition of the Company and the Subsidiaries taken as a whole on a consolidated basis or (ii) a material and adverse effect on the legality, validity or enforceability of this Agreement, provided, that none of the following alone shall be deemed, in and of itself, to constitute a Material Adverse Effect: (x) a change in the market price or trading volume of the Common Shares, (y) changes in general economic conditions or changes affecting the industry in which the Company operates generally (as opposed to Company-specific changes) so long as such changes do not have a disproportionate effect on the Company and the Subsidiaries taken as a whole or (z) effects resulting from or relating to the announcement or disclosure of the sale of the Shares or other transactions contemplated by, or being taken in connection with, this Agreement.

"**Options**" means any outstanding rights, warrants or options to subscribe for or purchase Common Shares or Convertible Securities.

"**Person**" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, a government or any department or agency thereof and any other legal entity.

"**Proceeding**" means an action, claim, suit, investigation or proceeding (including, without limitation, a partial proceeding, such as a deposition), whether commenced or threatened in writing.

"**Purchase Price**" means Seven Million Dollars ($7,000,000).

"**Rule 144**" means Rule 144 promulgated by the SEC pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the SEC having substantially the same effect as such Rule.

"SEC" means the United States Securities and Exchange Commission.

"**SEC Reports**" has the meaning set forth in Section 3.1(g).

"**Securities Act**" means the Securities Act of 1933, as amended.

"**Shares**" has the meaning set forth in the Preamble.

"**Short Sales**" means all "short sales" as defined in Rule 200 promulgated under Regulation SHO under the Exchange Act and all types of direct and indirect stock pledges, forward sale contracts, options, puts, calls, swaps, derivatives and similar arrangements.

"**Subsidiary**" means any entity in which the Company, directly or indirectly, owns capital stock or holds an equity or similar interest.

"**Trading Day**" means (i) a day on which the Common Shares are traded on a Trading Market (other than the OTCQB or OTCQX), or (ii) if the Common Shares are not listed or quoted on a Trading Market (other than the OTCQB or OTCQX), a day on which the Common Shares are traded in the over-the-counter market, as reported by the OTCQB or OTCQX, or (iii) if the Common Shares are not listed or quoted on any Trading Market, a day on which the Common Shares are quoted in the over-the-counter market as reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices); provided, that in the event that the Common Shares are not listed or quoted as set forth in (i), (ii) and (iii) hereof, then a Trading Day shall mean a Business Day.

"**Trading Market**" means whichever of the New York Stock Exchange, the NYSE American, the Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market, the OTCQB or OTCQX on which the Common Shares are listed or quoted for trading on the date in question.

"**Transaction**" has the meaning set forth in Section 3.2(h).

"**Transaction Documents**" means this Agreement and the License Agreement and the schedules and exhibits referred to herein.

"**Transfer Agent**" means Computershare, or any successor transfer agent for the Company.

ARTICLE 2
PURCHASE AND SALE

2.1 Closing. Subject to the terms and conditions set forth in this Agreement, at the Closing, the Company shall issue and sell to the Investor, and the Investor shall purchase from the Company, the Shares for the Purchase Price. The date and time of the Closing shall be simultaneously with the execution of this Agreement at the offices of Company U.S. Counsel or such other location as the parties shall mutually agree.

2.2 Closing Deliveries.

(a) At the Closing, the Company shall deliver or cause to be delivered to the Investor a copy of the Company's irrevocable instructions to the Transfer Agent instructing the Transfer Agent to register the Shares, free and clear of all restrictive and other legends (except for a customary legend to the effect that the Shares have not been registered under the Securities Act), in book-entry form in the name of the Investor.

(b) At the Closing, the Investor shall deliver or cause to be delivered to the Company the Purchase Price in United States dollars by wire transfer to an account designated in writing to the Investor by the Company for such purpose.

ARTICLE 3
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. The Company hereby represents and warrants to the Investor that, except as set forth in the SEC Reports or in the schedules delivered concurrently herewith:

(a) Organization and Qualification. The Company is an entity duly organized, validly existing and in good standing under the laws of British Columbia, Canada, with the requisite legal authority to own and use its properties and assets and to carry on its business as currently conducted. Each Subsidiary is an entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation. Neither the Company nor any Subsidiary is in violation of any of the provisions of its respective certificate or articles of incorporation, formation, bylaws or other organizational or charter documents. The Company and each Subsidiary is duly qualified to do business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(b) Subsidiaries. The Company owns or controls, directly or indirectly, all of the capital stock or comparable equity interests of each Subsidiary free and clear of any Lien except as described in Section 3.1(b), and all issued and outstanding shares of capital stock or comparable equity interest of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights; and the Company has no Subsidiaries other than the corporations, partnerships, limited liability partnerships, limited liability companies, associations or other entities set forth on Schedule I.

(c) Authorization; Enforcement. The Company has the requisite corporate authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents to which it is a party and otherwise to carry out its obligations hereunder and thereunder including the issuance and sale of the Shares. The execution and delivery by the Company of this Agreement and each of the other Transaction Documents to which it is party and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary corporate action on the part of the Company and no further consent or action is required by the Company, its Board of Directors or its stockholders. Each of the Transaction Documents to which to Company is party to has been duly executed by the Company and is the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, and (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents it is party to and the consummation by the Company of the transactions contemplated hereby and thereby do not, and will not, (i) conflict with or violate any provision of the Company's certificate or articles of incorporation, bylaws or other organizational or charter documents, (ii) in any material respect, conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company debt or otherwise) or other understanding to which the Company is a party or by which any property or asset of the Company is bound, or affected, or (iii) in any material respect, result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company is subject (including, assuming the accuracy of the representations and warranties of the Investor set forth in Section 3.2 hereof, federal, state and provincial securities laws and regulations and the rules and regulations of any self-regulatory organization to which the Company or its securities are subject, including all applicable Trading Markets), or by which any property or asset of the Company is bound or affected.

(e) The Shares. The Shares are duly authorized and, when issued and paid for in accordance with this Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens (other than restrictions on transfer set forth in this Agreement or imposed by applicable securities laws) and will not be subject to preemptive or similar rights of stockholders (other than those imposed by the Investor).

(f) Capitalization. The aggregate number of shares and type of all authorized, issued and outstanding classes of capital stock, Options and other securities of the Company (whether or not presently convertible into or exercisable or exchangeable for shares of capital stock of the Company) is set forth on Schedule 3.1(f). All outstanding shares of capital stock are duly authorized, validly issued, fully paid and nonassessable and have been issued in compliance in all material respects with all applicable securities laws. Except as set forth on Schedule 3.1(f), the Company does not have outstanding any Options, script rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, nor has it entered into any agreement giving any Person any right to subscribe for or acquire, any Common Shares, or securities or rights convertible or exchangeable into Common Shares. Except for customary adjustments as a result of stock dividends, stock splits, combinations of shares, reorganizations, recapitalizations, reclassifications or other similar events, there are no anti-dilution or price adjustment provisions contained in any security issued by the Company (or in any agreement providing rights to security holders) and the issuance and sale of the Shares will not obligate the Company to issue Common Shares or other securities to any Person (other than the Investor) and will not result in a right of any holder of securities to adjust the exercise, conversion, exchange or reset price under such securities.

(g) SEC Reports; Financial Statements. The Company has filed all reports required to be filed by it under the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. Such reports required to be filed by the Company under the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, together with the exhibits thereto and the documents incorporated by reference therein, being collectively referred to herein as the "**SEC Reports**" and, together with this Agreement and the schedules to this Agreement, the "**Disclosure Materials**". As of their respective dates (or, if amended or superseded by a filing prior to the Closing Date, then on the date of such filing), the SEC Reports filed by the Company complied in all material respects with the requirements of the Securities Act and the Exchange Act and the rules and regulations of the SEC promulgated thereunder, and none of the SEC Reports, when filed (or, if amended or superseded by a filing prior to the date hereof, then on the date of such filing) by the Company, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the SEC with respect thereto as in effect at the time of filing (or, if amended or superseded by a filing prior to the Closing Date, then on the date of such filing). Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("**GAAP**"), except as may be otherwise specified in such financial statements, the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP or may be condensed or summary statements, and fairly present in all material respects the consolidated financial position of the Company and the Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, year-end audit adjustments. All material agreements to which the Company or any Subsidiary is a party or to which the property or assets of the Company or any Subsidiary are subject are included as part of or identified in the SEC Reports, to the extent such agreements are required to be included or identified pursuant to the rules and regulations of the SEC.

(h) Intellectual Property. Except as described in Schedule 3.1(h), the Company owns, or has the right pursuant to a valid, written license agreement to use and exploit, all Intellectual Property used in or necessary for the conduct of the business of the Company and that is material to the business of the Company as conducted as of the Closing (the "**Company Intellectual Property**"). To the knowledge of the Company, (i) all issued patents and registered trademarks that are Company Intellectual Property and that are owned by the Company are valid and enforceable and are currently in compliance with formal legal requirements (including without limitation, as applicable, payment of filing, examination and maintenance fees, proofs of working or use, timely post registration filing of affidavits of use and incontestability and renewal applications), and (ii) there is no existing infringement or misappropriation by another Person of any of the Company Intellectual Property. Except as disclosed in the SEC Reports, no claims have been asserted by a third party in writing (a) alleging that the conduct of the business of the Company has infringed or misappropriated any Intellectual Property rights of such third party, or (b) challenging or questioning the validity or effectiveness of any Intellectual Property right of the Company, and, to the knowledge of the Company, there is no valid basis for any such claim. No loss or early expiration of any of the Company's material Intellectual Property is pending, or, to the knowledge of the Company, threatened. The Company has taken reasonable steps in accordance with standard industry practices to protect its rights in the Company Intellectual Property and at all times has maintained the confidentiality of all information used in connection with the business that constitutes or constituted a trade secret of the Company.

(i) Bad Actor Disqualification. With respect to the Shares to be offered and sold hereunder in reliance on Regulation D under the Securities Act, none of the Company, any of its predecessors, any affiliated issuer, any director, executive officer, other officer of the Company participating in the offering hereunder, any beneficial owner of 20% or more of the Company's outstanding voting equity securities, calculated on the basis of voting power, nor any promoter (as that term is defined in Rule 405 under the Securities Act) connected with the Company in any capacity at the time of sale (each, an "**Issuer Covered Person**" and, together, "**Issuer Covered Persons**") is subject to any of the "**Bad Actor**" disqualifications described in Rule 506(d)(1)(i) to (viii) under the Securities Act (a "**Disqualification Event**"), except for a Disqualification Event covered by Rule 506(d)(2) or (d)(3). The Company has exercised reasonable care to determine whether any Issuer Covered Person is subject to a Disqualification Event. The Company has complied, to the extent applicable, with its disclosure obligations under Rule 506(e), and has furnished to the Investor a copy of any disclosures provided thereunder.

3.2 Representations and Warranties of the Investor. The Investor hereby represents and warrants to the Company as follows:

(a) Organization; Authority. The Investor is a corporation duly organized, validly existing and in good standing under the laws of the Cayman Islands with the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and otherwise to carry out its obligations hereunder. The purchase by the Investor of the Shares hereunder has been duly authorized by all necessary corporate action on the part of the Investor. This Agreement has been duly executed and delivered by the Investor and constitutes the valid and binding obligation of the Investor, enforceable against it in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, and (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

(b) No Public Sale or Distribution. The Investor is acquiring the Shares for its own account and not with a view towards, or for resale in connection with, the public sale or distribution thereof, except pursuant to sales registered under the Securities Act or under an exemption from such registration and in compliance with applicable federal, state and provincial securities laws, and the Investor does not have a present arrangement to effect any distribution of the Shares to or through any person or entity; provided, however, that by making the representations herein, such Investor does not agree to hold any of the Shares for any minimum or other specific term and reserves the right to dispose of the Shares at any time in accordance with or pursuant to a registration statement or an exemption under the Securities Act.

(c) Investor Status. At the time the Investor was offered the Shares, it was, and at the date hereof it is an "accredited investor" as defined in Rule 501(a) under the Securities Act or a "qualified institutional buyer" as defined in Rule 144A(a) under the Securities Act. Such Investor is not a registered broker dealer registered under Section 15(a) of the Exchange Act, or a member of the Financial Industry Regulatory Authority, Inc. or an entity engaged in the business of being a broker dealer.

(d) Experience of Such Investor. The Investor, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such investment. The Investor understands that it must bear the economic risk of this investment in the Shares indefinitely, and is able to bear such risk and is able to afford a complete loss of such investment.

(e) Access to Information. The Investor acknowledges that it has reviewed the Disclosure Materials and has been afforded: (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Shares and the merits and risks of investing in the Shares; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment. Neither such inquiries nor any other investigation conducted by or on behalf of the Investor or its representatives or counsel shall modify, amend or affect the Investor's right to rely on the truth, accuracy and completeness of the Disclosure Materials and the Company's representations and warranties contained in the Transaction Documents.

(f) No Conflicts. The execution, delivery and performance by the Investor of this Agreement and the consummation by the Investor of the transactions contemplated hereby will not (i) result in a violation of the organizational documents of the Investor or (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Investor is a party, or (iii) result in a violation of any law, rule, regulation, order, judgment or decree (including federal, state and provincial securities laws) applicable to the Investor, except in the case of clauses (ii) and (iii) above, for such that are not material and do not otherwise affect the ability of the Investor to consummate the transactions contemplated hereby.

(g) Restricted Securities. The Investor understands that the Shares are characterized as "restricted securities" under the U.S. federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances. The Investor further understands that Shares in book-entry form shall be subject to the following legend:

> THESE SECURITIES HAVE NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**SECURITIES ACT**"), OR ANY APPLICABLE STATE SECURITIES LAWS AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN COMPLIANCE WITH APPLICABLE STATE SECURITIES LAWS OR BLUE SKY LAWS.

(h) Prohibited Transactions. The Investor has not, directly or indirectly, and no Person acting on behalf of or pursuant to any understanding with the Investor has, engaged in any purchases or sales in the securities, including derivatives, of the Company (including, without limitation, any Short Sales (a "**Transaction**") involving any of the Company's securities) since the time that the Investor was first contacted by the Company or any other Person regarding an investment in the Company. The Investor covenants that neither it nor any Person acting on its behalf or pursuant to any understanding with the Investor will engage, directly or indirectly, in any Transactions in the securities of the Company (including Short Sales) prior to the time the transactions contemplated by this Agreement are publicly disclosed.

ARTICLE 4
OTHER AGREEMENTS OF THE PARTIES

4.1 Filing of Reports. Until the date that the Investor (or any transferee that is an Affiliate of the Investor) ceases to own any Shares, the Company covenants to use its commercially reasonable efforts to (a) timely file (or obtain extensions in respect thereof and file within the applicable grace period) all reports required to be filed by the Company after the date hereof pursuant to the Securities Act and the Exchange Act, (b) comply with the requirements of Rule 144(c) under the Securities Act with respect to current public information about the Company, and (c) furnish to the Investor promptly upon request therefor (i) a written statement by the Company as to its compliance with the requirements of Rule 144(c) under the Securities Act, and the reporting requirements under the Securities Act and the Exchange Act, and (ii) such reports and documents of the Company as the Investor may reasonably request to avail itself (or its Affiliates) of any similar rule or regulation of the SEC allowing it (or its Affiliates) to sell any such securities without registration.

4.2 Listing of Shares. Promptly following the date hereof, the Company shall take all necessary action to cause the Shares to be qualified for trading on the Nasdaq Capital Market. If the Company applies to have its Common Shares traded on any other principal stock exchange or market, it shall include in such application the Shares and will take such other action as is necessary to cause such Shares to be so listed.

4.3 Use of Proceeds. The Company will use the net proceeds from the sale of the Shares to meet its obligations under the License Agreement and for other working capital and general corporate purposes.

4.4 Lock-Up. During the six (6) month period following the Closing, the Investor shall not, without the consent of the Company, issue, sell, offer or agree to sell, grant any option for the sale of, pledge, enter into any swap, derivative transaction or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any of the Shares (whether any such transaction is to be settled by delivery of Shares, other securities, cash or other consideration) or otherwise dispose (or publicly announce the undersigned's intention to do any of the foregoing) of, directly or indirectly, any Shares. Notwithstanding anything in this Agreement to the contrary, subject to the requirements of Section 6.6 (including the obligation to be bound by this Section 4.4), the Investor shall not be restricted from transferring any of the Shares to any Affiliate of the Investor.

4.5 Public Statements. Except as required by applicable law or regulation, neither party hereto shall issue any press release or other public announcement concerning the existence of or terms of this Agreement or the Transaction Documents without the prior written consent of the other Party, which consent shall not be unreasonably withheld. Each Party agrees to provide to the other Party a copy of any proposed press release or other public announcement as soon as reasonably practicable under the circumstances prior to the proposed date of dissemination thereof. The party proposing such press release or other public announcement shall consider in good faith any changes to such proposed press release or public announcement that are requested by the other party.

4.6 Legend Removal. The Company shall, or shall cause, the legend set forth in Section 3.2(g) to be removed and shall issue, or cause to be issued, a certificate (or shares in book-entry form) without such legend or any other legend upon the Investor's request, if such Shares are (a) sold or transferred pursuant to Rule 144 or (b) such Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such securities and without volume or manner-of-sale restrictions.

ARTICLE 5
INDEMNIFICATION

5.1 Indemnification by the Company. The Company shall, notwithstanding any termination of this Agreement, indemnify and hold harmless the Investor, its officers, directors, partners, members, agents and employees, each Person who controls the Investor (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) and the officers, directors, partners, members, agents and employees of each such controlling Person, to the fullest extent permitted by applicable law, from and against any and all Losses, as incurred, arising out of or relating to (i) any misrepresentation or breach of any representation or warranty made by the Company in this Agreement or any other agreement, certificate, instrument or document delivered in connection with the consummation of the transactions hereby (which, for the avoidance of doubt, shall not include the License Agreement or any agreements, certificates, instruments or documents ancillary thereto), (ii) any breach of any covenant, agreement or obligation of the Company contained in this Agreement or any other agreement, certificate, instrument or document delivered in connection with the consummation of the transactions contemplated hereby (which, for the avoidance of doubt, shall not include the License Agreement or any agreements, certificates, instruments or documents ancillary thereto), or (iii) any cause of action, suit or claim brought or made against such Indemnified Party (as defined in Section 5.2(a) below) by a third party (including for these purposes a derivative action brought on behalf of the Company), arising out of or resulting from (x) the execution, delivery, performance or enforcement of this Agreement or any other agreement, certificate, instrument or document delivered in connection with the consummation of the transactions contemplated hereby (which, for the avoidance of doubt, shall not include the License Agreement or any agreements, certificates, instruments or documents ancillary thereto), or (y) the status of Indemnified Party as a holder of Common Shares (unless, and only to the extent that, such action, suit or claim is based, including in part, upon a breach of the Investor's representations, warranties or covenants in this Agreement or any other agreement, certificate, instrument or document delivered in connection with the consummation of the transactions contemplated hereby (which, for the avoidance of doubt, shall not include the License Agreement or any agreements, certificates, instruments or documents ancillary thereto), or any conduct by the Investor that constitutes fraud, gross negligence or willful misconduct).

5.2 Conduct of Indemnification Proceedings.

(a) If any Proceeding shall be brought or asserted against any Person entitled to indemnity hereunder (an "**Indemnified Party**"), such Indemnified Party shall promptly notify the Person from whom indemnity is sought (the "**Indemnifying Party**") in writing, and the Indemnifying Party shall assume the defense thereof, including the employment of counsel reasonably satisfactory to the Indemnified Party and the payment of all fees and expenses incurred in connection with defense thereof; provided, that the failure of any Indemnified Party to give such notice shall not relieve the Indemnifying Party of its obligations or liabilities pursuant to this Agreement, except (and only) to the extent that it shall be finally determined by a court of competent jurisdiction (which determination is not subject to appeal or further review) that such failure shall have proximately and materially adversely prejudiced the Indemnifying Party.

(b) An Indemnified Party shall have the right to employ separate counsel in any such Proceeding and to participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnified Party or Parties unless: (i) the Indemnifying Party has agreed in writing to pay such fees and expenses; or (ii) the Indemnifying Party shall have failed promptly to assume the defense of such Proceeding and to employ counsel reasonably satisfactory to such Indemnified Party in any such Proceeding; or (iii) the named parties to any such Proceeding (including any impleaded parties) include both such Indemnified Party and the Indemnifying Party, and such Indemnified Party shall have been advised by counsel that a conflict of interest is likely to exist if the same counsel were to represent such Indemnified Party and the Indemnifying Party (in which case, if such Indemnified Party notifies the Indemnifying Party in writing that it elects to employ separate counsel at the expense of the Indemnifying Party, the Indemnifying Party shall not have the right to assume the defense thereof and the reasonable fees and expenses of separate counsel shall be at the expense of the Indemnifying Party). It shall be understood, however, that the Indemnifying Party shall not, in connection with any one such Proceeding (including separate Proceedings that have been or will be consolidated before a single judge) be liable for the fees and expenses of more than one separate firm of attorneys at any time for all Indemnified Parties, which firm shall be appointed by a majority of the Indemnified Parties. The Indemnifying Party shall not be liable for any settlement of any such Proceeding effected without its written consent, which consent shall not be unreasonably withheld. No Indemnifying Party shall, without the prior written consent of the Indemnified Party, effect any settlement of any pending Proceeding in respect of which any Indemnified Party is a party, unless such settlement includes an unconditional release of such Indemnified Party from all liability on claims that are the subject matter of such Proceeding.

(c) All reasonable fees and expenses of the Indemnified Party (including reasonable fees and expenses to the extent incurred in connection with investigating or preparing to defend such Proceeding in a manner not inconsistent with this Section) shall be paid to the Indemnified Party, as incurred, within 20 Trading Days of written notice thereof to the Indemnifying Party (regardless of whether it is ultimately determined that an Indemnified Party is not entitled to indemnification hereunder; provided, that the Indemnifying Party may require such Indemnified Party to undertake to reimburse all such fees and expenses to the extent it is finally judicially determined that such Indemnified Party is not entitled to indemnification hereunder).

The indemnity and agreements contained in this Article 6 are in addition to any liability that the Indemnifying Parties may have to the Indemnified Parties.

ARTICLE 6
GENERAL PROVISIONS

6.1 Fees and Expenses. Except as expressly set forth in the Transaction Documents to the contrary, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement. The Company shall pay all Transfer Agent fees, stamp taxes and other taxes and duties levied in connection with the sale and issuance of the Shares.

6.2 Entire Agreement. This Agreement, together with the exhibits and schedules hereto, contains the entire understanding of the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules. At or after the Closing, and without further consideration, the Company will execute and deliver to the Investor such further documents as may be reasonably requested in order to give practical effect to the intention of the parties under this Agreement.

6.3 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of (a) the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address specified in this Section prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address specified in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the Trading Day following the date of deposit with a nationally recognized overnight courier service, or (d) upon actual receipt by the party to whom such notice is required to be given. The addresses, facsimile numbers and email addresses for such notices and communications are those set forth on the signature pages hereof, or such other address or facsimile number as may be designated in writing hereafter, in the same manner, by any such Person.

6.4 Amendments; Waivers. No provision of this Agreement may be waived or amended except in a written instrument signed, in the case of an amendment, by the Company and the Investor or, in the case of a waiver, by the party against whom enforcement of any such waiver is sought. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

6.5 Construction. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof. The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent, and no rules of strict construction will be applied against any party.

6.6 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Investor, which consent may be withheld by the Investor in its sole discretion. The Investor may assign its rights under this Agreement to any Person to whom the Investor assigns or transfers any Shares, *provided* (i) the Investor agrees in writing with the transferee or assignee to assign such rights, and a copy of such agreement is furnished to the Company after such assignment, (ii) the Company is furnished with written notice of (x) the name and address of such transferee or assignee and (y) the number of Shares which are being transferred or assigned, (iii) following such transfer or assignment, the further disposition of such securities by the transferee or assignee is restricted under the Securities Act and applicable state securities laws, (iv) such transferee agrees in writing to be bound, with respect to the transferred Shares, by the provisions hereof that apply to the "Investor" and such transferee is not a Competitor of, or Affiliated with a Competitor of, the Company and (v) such transfer shall have been made in accordance with the applicable requirements of this Agreement and with all laws applicable thereto.

6.7 No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except that each Indemnified Party is an intended third party beneficiary of Section 5.1, as applicable, and (in each case) may enforce the provisions of such Section directly against the parties with obligations thereunder.

6.8 Governing Law; Venue; Waiver of Jury Trial. ALL QUESTIONS CONCERNING THE CONSTRUCTION, VALIDITY, ENFORCEMENT AND INTERPRETATION OF THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK. THE COMPANY AND THE INVESTOR HEREBY IRREVOCABLY SUBMIT TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN FOR THE ADJUDICATION OF ANY DISPUTE BROUGHT BY THE COMPANY OR THE INVESTOR HEREUNDER, IN CONNECTION HEREWITH OR WITH ANY TRANSACTION CONTEMPLATED HEREBY OR DISCUSSED HEREIN, AND HEREBY IRREVOCABLY WAIVE, AND AGREE NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING BROUGHT BY THE COMPANY OR THE INVESTOR, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT, OR THAT SUCH SUIT, ACTION OR PROCEEDING IS IMPROPER. EACH PARTY HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF VIA REGISTERED OR CERTIFIED MAIL OR OVERNIGHT DELIVERY (WITH EVIDENCE OF DELIVERY) TO SUCH PARTY AT THE ADDRESS IN EFFECT FOR NOTICES TO IT UNDER THIS AGREEMENT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW. THE COMPANY AND THE INVESTOR HEREBY WAIVE ALL RIGHTS TO A TRIAL BY JURY.

6.9 Survival. The representations and warranties, agreements and covenants contained herein shall survive the Closing.

6.10 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or email attachment, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or email-attached signature page were an original thereof.

6.11 Severability. If any provision of this Agreement is held to be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Agreement shall not in any way be affected or impaired thereby and the parties will attempt to agree upon a valid and enforceable provision that is a reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Agreement.

6.12 Replacement of Certificates. If any certificate or instrument evidencing any Shares is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof, or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction and the execution by the holder thereof of a customary lost certificate affidavit of that fact, an agreement to indemnify and hold harmless the Company for any Losses in connection therewith and the posting by the Investor of any bonds as may be required by the Transfer Agent.

6.13 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Investor and the Company will be entitled to seek specific performance under this Agreement. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations described in the foregoing sentence and hereby agree to waive in any action for specific performance of any such obligation (other than in connection with any action for a temporary restraining order) the defense that a remedy at law would be adequate.

[SIGNATURE PAGES TO FOLLOW]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

VBI VACCINES INC.

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

Address for Notice:

VBI Vaccines Inc.
222 3rd Street, Suite 2241
Cambridge, MA 02142
Attn: Chief Executive Officer

With a copy (which shall not constitute notice) to:

Haynes and Boone, LLP
30 Rockefeller Plaza, 26th Floor
New York, NY 10112
Attention: Rick A. Werner

BRII BIOSCIENCES LIMITED

By: */s/ Zhi Hong*
Name: Zhi Hong
Title: Chief Executive Officer

Address for Notice:

Brii Biosciences Limited
Vistra (Cayman) Limited
PO Box 3119
Grand Pavilion Hibiscus Way
802 West Bay Road Grand Cayman KYI-1205
Attn: Zhi Hong
Email: zhi.hong@briibio.com

Schedule 3.1(b)

The shares of SciVac Ltd. are pledged in favor of Perceptive Credit Holdings LP as part of a credit agreement between Variation Biotechnologies (US), Inc. and Perceptive Credit Holdings LP.

Schedule 3.1(f)

Share Type	Common Shares	Warrants & Options	Total	Fully Diluted %
Issued and outstanding Common Shares	**64,383,391**	**-**	**64,383,391**	**88.6%**
Equity Plans (outstanding and available)		5,674,307	**5,674,307**	**7.8%**
Warrants		2,618,824	**2,618,824**	**3.6%**
Dilutive equity	**-**	**8,293,131**	**8,293,131**	**11.4%**
Total issued and outstanding	**64,383,391**	**8,293,131**	**72,676,522**	**100.0%**

Schedule 3.1(h)

The patent family covering the VBI-1501 vaccine candidate for cytomegalovirus is co-owned by Universite Sorbonne.

Schedule I

Subsidiaries

Name of Subsidiary	Country of Incorporation	Ownership Interest (direct or indirect)
VBI Vaccines (Delaware) Inc.	Delaware (U.S.A)	100%
SciVac Ltd.	Rehovot (Israel)	100%
Variation Biotechnologies (US), Inc.	Delaware (U.S.A)	100%
Variation Biotechnologies Inc.	Ottawa, Ontario (Canada)	100%

Exhibit 10.64

Addendum to the Rental Agreement dated 16 January 2017 and the Rental Extension Agreement for an Unprotected Rental Property dated 21 January 2018 Drawn and entered into on 15 January 2019

Between: **Green Power Ye.Ym. Ltd. P.C. 514876952**
Of 13 Gad Finstein Street, Rehovot
(Hereinafter: "**The Company**")

Party of the First Part;

And **SciVac Ltd. P.C. P.C. 513679555**
13 Gad Finestein Street, Rehovot
POB 580, 7610303
(Hereinafter: "**The Tenant**")

Party of the Second Part;

Whereas on November 5, 2013, Ayalot Investments (Ramat Vered) 1994 Ltd. and Sarda Ltd. (Hereinafter jointly: "**The Original Landlord**") and the Company signed a primary rental agreement and its addendums with regards to the Rental Property (The Rental Agreement and its addendums will hereinafter be known as: "**The Primary Rental Agreement**");

And whereas a secondary rental agreement and its addendums were (The Rental Agreement and its addendums will hereinafter be known as **"The Secondary Rental Agreement**") was signed with regards to the Rental Property on January 16, 2017 and until January 22, 2018 for a period of twelve (12) months (Hereinafter: "**The Original Secondary Rental Agreement"**);

And whereas on January 21, 2018, the Parties signed an agreement to exercise the option and extension of the Secondary Rental Period for an additional period of twelve (12) additional months (Hereinafter: "**The Option Exercise Agreement**") (**The Secondary Rental Agreement and the Option Exercise Agreement will jointly be known as "The Secondary Rental Agreement");**

And whereas the Rental Period of the Tenant in the Rental Property expires in accordance with the Option Exercise Agreement on January 22, 2019 (Hereinafter: **The Option Exercise Period**");

And whereas the Tenant wishes to extend the Rental Period in the Rental Property at the end of the Option Exercise Period, and the Company agrees to this, in accordance with the conditions specified in the Secondary Rental Agreement, and subject to the changes specified in this Agreement below;

Now, wherefore, the Parties have agreed, declared and stipulated as follows:

1. The introduction to this addendum and its appendices are an integral part thereof.

2. The terms appearing in this Agreement will be assigned the definitions assigned to them in the Original Secondary Rental Agreement.

3. The specified in this addendum amends and changes the Secondary Rental Agreement only in the sections and/or provisions to be amended and/or added in this addendum. The sections to be amended and/or added will supersede the specified in the Secondary Rental Agreement. The other terms of the Secondary Rental Agreement will apply in full, without change with regards to the rental of the Rental Property.

4. The Tenant is in possession of the Rental Property by virtue of the Secondary Rental Agreement, is familiar with the physical condition and has no claims and/or demands regarding the state of the Rental Property.

5. The Rental Period in the Rental Property will be extended for an additional period of an additional thirty-six (36) months and nine (9) days that will commence on 23 January 2019 and end on 31 January 2022 (Hereinafter: "**The Additional Rental Period**" or **"The Third Rental Period of the Rental Property**").

6. The monthly rent for the Third Rental Period of the Rental Property will include all current mandatory payments required by virtue of the Primary Rental Agreement and the Secondary Rental Agreement including, but not limited to, management fees, property tax, water and electricity, and will amount to twenty-six thousand five hundred New Israeli Shekels (NIS 26,500) per month plus VAT (Hereinafter: "**The Rent**"). Without derogating from the specified above, in a month in which electricity consumption in the Rental Property exceeds one thousand five hundred New Israeli Shekels (NIS 1500) only, the Tenant will pay the Company the difference.

7. At the start of the Third Rental Period, the Tenant will pay the Company monthly rent plus VAT that will be paid in accordance with the following provisions:

   7.1 On 23 January 2019, an amount of thirty-four thousand, one hundred ninety-four New Israeli Shekels (NIS 34,194) plus VAT will be paid for the period of January 23, 2019 till February 28, 2019.

   7.2 Commencing on March 1, 2019 and until the end of the Rental Period, monthly rent in the amount of twenty-six thousand five hundred New Israeli Shekels (NIS 26,500) plus VAT will be paid at the start of every calendar month, on the 1st of every month.

   7.3 Rent will be paid via bank transfer on the 1st of every month to:
   Bank 20
   Branch No. 418
   Account No. 187722
   Under the name Green Power Ye.Ym. Ltd.

8. For the removal any and all doubt, it is hereby clarified that a delay of up to three (3) days in payment of the Rent for Sabbatical, Saturday and/or holiday reasons, will not be considered a breach of Section 7 above.

9. The Parties do hereby agree that in the vent of delay in payment of Rent to the Company, and pursuant to the Tenant having been sent written notice in advance, twenty-one (21) days, during which the debt was not paid, the Tenant will pay the Company the accepted and estimated compensation of ten thousand New Israeli Shekels (NIS 10,000). This compensation will not derogate from any other remedy afforded to the Company for said delay.

10. The terms for the validity of this Agreement is approval of the Original Landlord of this Agreement. The Company undertakes to contact the Original Landlord immediately after the signing of this contract by the two parties in order to obtain said approval (Hereinafter: "Approval of the Original Landlord"). If the Original Landlord does not approve this Agreement with in ninety (90) days from the date of its signing, it is hereby agreed that the Tenant will be entitled to immediately terminate the Agreement, without the Company and/or the Original Landlord having any allegation and/or demand and/or claim against the Tenant. Approval of the Original Landlord will be attached to this Agreement as **Appendix A**.

11. If this Agreement is cancelled and the end of the Rental period comes prior to the end of the Rental Period in accordance with that set forth in the Primary Agreement, the Tenant will not have any claims or demands against the Company and/or the Original Landlord. It is hereby clarified that if the Agreement is terminated, the Company undertakes to transfer to the Tenant written notice immediately upon its receipt from the Original Landlord.

12. Any change, amendment and/or addition to this Agreement will only be valid if done in writing and signed by the Parties to this Agreement.

13. The other terms of the Secondary Rental Agreement that were not changed in this addendum will remain valid and binding on the parties for the Third Rental Period of the Rental Property.

In Witness Whereof, the Parties come to set their hands and seal:

SciVac Ltd. 513679555	Green Power Ye.Ym. Ltd. PC 514876952
/s/ SciVac Ltc. The Tenant	*/s/ Green Power Ye.Ym. Ltd.* The Company

Exhibit 10.65+

AMENDMENT TO CONSULTING AGREEMENT

This Amendment to Consulting Agreement (the "**Amendment**"), effective as of January 1st, 2019 (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, as amended as of January 1, 2017, and further amended as of January 1, 2018 (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, 2019 (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 CAD$43,350.00 per month (plus any HST or GST payable).

3. **Replacement of Appendix C.** As of the Effective Date, Appendix C of the Consulting Agreement shall be deleted in its entirety and replaced with the version of Appendix C attached as Schedule A to this Amendment.

4. Consulting Agreement to Remain in Full Effect. Except as amended by this Amendment, the Consulting Agreement shall continue to be in full force and effect, without amendment, and is hereby ratified and confirmed. The Consulting Agreement shall henceforth be read and construed in conjunction with this Amendment.

5. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the Province of Ontario and the federal laws of Canada applicable therein.

6. Further Assurances. Each Party shall do such further acts and execute such further documents as may be required to give effect to this Amendment and carry out the intent thereof.

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

8. Execution and Counterparts. This Amendment may be executed in counterparts, including counterpart signature pages or counterpart facsimile or scanned signature pages (each of which shall be deemed an original), all of which together shall constitute one and the same instrument.

(*Signature page follows.*)

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

VARIATION BIOTECHNOLOGIES INC.

/s/ Jeff Baxter

Name: Jeff Baxter
Title: Chief Executive Officer

F. DIAZ-MITOMA PROFESSIONAL CORPORATION

/s/ Francisco Diaz-Mitoma

Name: Francisco Diaz-Mitoma
Title: President

Schedule A

Appendix C – Performance Incentives

1. Bonus payable as of January 31, 2019 – CAD $156,181.00.

2. The Company shall cause VBI Vaccines Inc., a British Columbia corporation (the "**Parent**") to grant to Francisco Diaz-Mitoma, as designee of Consultant, 300,000 stock options (the "**Options**"), each Option exercisable for one common share of Parent, to be granted effective as of January 31, 2019, 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 10.66

WAIVER AGREEMENT

THIS WAIVER AGREEMENT (this "Agreement"), dated as of February 14, 2019, 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, 2018 (the "2018 Audited Financial Statements"), has informed Parent and the Borrower that its audit opinion letter with respect to the 2018 Audited Financial Statements will contain an Impermissible Qualification;

WHEREAS, a true and correct copy of the Auditor's draft audit opinion for the 2018 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 2018 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 2018 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 2018 Audited Financial Statements (without any material change or modification thereto) and (iii) at the time of delivery of such 2018 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 WHEREOFF, THE PARTIES HAVE TNERED INTO THIS Agreements 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, 2018 and 2017, 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, 2018 and 2017, 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 U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Exhibit 21.1

VBI Vaccines Inc. – List of Subsidiaries

Name of Subsidiary	Country of Incorporation	Ownership Interest (direct or indirect)
VBI Vaccines (Delaware) Inc.	Delaware (U.S.A)	100%
SciVac Ltd.	Rehovot (Israel)	100%
Variation Biotechnologies (US), Inc.	Delaware (U.S.A)	100%
Variation Biotechnologies Inc.	Ottawa, Ontario (Canada)	100%
SciVac Hong Kong Limited	Hong Kong	100%

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 February 25, 2019 on our audits of the consolidated financial statements as of December 31, 2018 and 2017 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 February 25, 2019. 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
February 25, 2019

Exhibit 31.1

CERTIFICATION

I, Jeff Baxter, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2018 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: February 25, 2019

/s/ Jeff Baxter

Jeff Baxter
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Chris McNulty, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2018 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: February 25, 2019

/s/ Chris McNulty

Chris 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, 2018 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: February 25, 2019

/s/ Jeff Baxter

Jeff 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, 2018 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: February 25, 2019

/s/ Chris McNulty

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