

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2017

OR

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

For the transition period from _____ to _____

Commission File Number 001-37769

VBI VACCINES INC.

(Exact name of registrant as specified in its charter)

British Columbia, Canada
(State or other jurisdiction of
incorporation or organization)

N/A
(I.R.S. Employer
Identification No.)

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 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, or a smaller reporting company.

Large accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [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, 2017, 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 \$93,487,000.

As of February 26, 2018, the registrant had 64,078,781 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 2018 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, 2017

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

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

- the timing of, and our ability to, obtain and maintain regulatory approvals for our clinical trials, products and 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 vaccine 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 in order 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™;
- 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;
- changes to legal and regulatory processes for biosimilar approval and marketing could reduce the duration of market exclusivity for our products;
- our ability to maintain our existing licenses for intellectual property;
- 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 U.S. 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 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 first marketed product is Sci-B-Vac™ a third-generation hepatitis B virus (“HBV”) vaccine that contains all three viral surface antigens of the hepatitis B virus. Sci-B-Vac is approved for use in Israel and 14 other countries. In December 2017, we initiated a global Phase III program for Sci-B-Vac designed to achieve licensure for the vaccine in the United States (“U.S.”), Europe and Canada. Our wholly-owned subsidiary, SciVac Ltd., manufactures Sci-B-Vac in Rehovot, Israel.

We are also advancing our “enveloped” virus-like particle (“eVLP”) platform technology. Our eVLP platform technology enables the development of enveloped virus-like particle vaccines that closely mimic the target virus to elicit a potent immune response. We are advancing a pipeline of eVLP vaccines, with lead programs in both infectious disease, with our congenital cytomegalovirus (“CMV”) vaccine candidate, and in immuno-oncology, with our therapeutic glioblastoma multiforme (“GBM”) vaccine candidate.

Recent Developments

Sci-B-Vac

Sci-B-Vac has not yet been approved by the U.S. Food and Drug Administration (the “FDA”), the European Medicines Agency (the “EMA”) or Health Canada. On December 19, 2017, we announced the commencement of patient dosing in the Phase III clinical program for Sci-B-Vac following discussions with the FDA, the EMA, and Health Canada. The Phase III program will be a global program, with approximately 40 sites across the U.S., Europe and Canada, consisting of two concurrent Phase III studies - a safety and immunogenicity study (“PROTECT”) and a lot-to-lot consistency study (“CONSTANT”), enrolling approximately 4,800 subjects. See “—Principal Products—Sci-B-Vac.” Headline data is expected mid-year 2019.

The study continues to enroll participants in both the U.S. and Canada. Clinical trial applications were filed in the United Kingdom, Finland, Germany and Belgium. So far, the applications were approved in the United Kingdom, Finland and in Germany.

A post-marketing Phase IV clinical study of Sci-V-Bac in Israel was completed in June 2017, and we are nearing the completion of the clinical study report.

Congenital CMV Vaccine Candidate (eVLP)

Patient enrollment was initiated in June 2016 in a Phase I clinical study for our congenital CMV vaccine candidate, VBI-1501, which is our second lead program. In July 2017, we announced interim data from the Phase I clinical study of 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; our congenital CMV vaccine candidate was well tolerated at all doses and demonstrated induced antibody responses against the CMV glycoprotein B (gB) antigen with clear evidence of dose-dependent boosting after the second vaccination. The final data read-out of safety and immunogenicity, following a third vaccination, is expected in the first half of 2018.

Therapeutic GBM Vaccine Candidate (eVLP)

On August 11, 2017, the FDA accepted an IND for a therapeutic GBM brain cancer vaccine candidate, VBI-1901, to initiate a multi-center Phase I/IIa clinical study evaluating VBI-1901 in patients with recurrent GBM. The first patient in the study received the first dose in January 2018. We expect immunologic data from ongoing biomarker analyses by mid-year 2018, and initial correlations between biomarker analyses and clinical outcomes in the second half of 2018.

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

Preclinical Research

In October 2017, we disclosed new data on a Zika vaccine candidate, VBI-2501 which was developed with 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 construct produced a surprisingly superior neutralization of Zika, relative to monovalent versions. We believe that such data further supports the flexibility of eVLP platform.

Additionally, we have recently completed research collaborations with both Sanofi Vaccine Technologies S.A.S, (“Sanofi”) and Glaxo Smith Kline Biologicals SA (“GSK”) to stabilize other vaccine candidates. No further work on these collaboration candidates is anticipated at this time.

Financing Activities

During the year ended December 31, 2017, we raised an aggregate of \$71.9 million in equity financing to support our vaccine development programs, to continue the advancement of our research programs and for other general corporate purposes, including 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, which closed on October 30, 2017. In connection with the registered direct offering, we issued four-year warrants to purchase 550,000 common shares at an exercise price of \$3.34 per share. Since inception, we have collectively raised approximately \$196.6 million in total equity and debt financing for those purposes.

Corporate History

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

On July 9, 2015, we, then known as Levon Resources Ltd. (“Levon”), completed a plan of arrangement (the “Levon Merger”) pursuant to which SciVac 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. Other than approximately CAD \$27 million in cash retained by us, all of our other assets and liabilities were transferred or assumed by 1027949 BC Ltd., our then wholly-owned subsidiary (“BC Ltd.”). Upon consummation of the Levon Merger, each of our shareholders received 0.5 of a common share of BC Ltd., resulting in our shareholders holding 100% of the issued and outstanding shares of BC Ltd.; therefore, we no longer own any equity interest in BC Ltd.

On July 14, 2015, our common shares commenced trading on the Toronto Stock Exchange (the “TSX”) under the symbol “VAC” and our common shares also began to be quoted on the OTCQX marketplace (the “OTCQX”) maintained by the OTC Markets Group Inc. under the symbol “SVACF.”

On May 6, 2016, we completed our acquisition of VBI Vaccines (Delaware) Inc. (“VBI DE”), pursuant to which Senicav Acquisition Corporation, a Delaware corporation and our wholly-owned subsidiary, merged with and into VBI DE, with VBI DE continuing as the surviving corporation and as our wholly-owned subsidiary (the “VBI-SciVac Merger”). Upon completion of the VBI-SciVac Merger, we (then named “SciVac Therapeutics Inc.”) changed our name to “VBI Vaccines Inc.” and received approval for the listing of our common shares on 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.”

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. (“PIC”), 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 (the “Reincorporation”) pursuant to an Agreement and Plan of Merger dated March 20, 2014 by and between Paulson Oregon, and Paulson Oregon’s wholly-owned subsidiary, Paulson Capital (Delaware) Corp., a Delaware corporation (“Paulson Delaware”). As a result of the Reincorporation, Paulson Oregon became Paulson Delaware, its name became “Paulson Capital (Delaware) Corp.” and Paulson Oregon ceased to exist. Paulson Oregon’s shareholders approved the Reincorporation pursuant to the Agreement and Plan of Merger at Paulson Oregon’s 2013 annual meeting of shareholders held on November 8, 2013.

On July 25, 2014, Variation Biotechnologies (US), Inc. (“VBI US”) completed its merger (the “PLCC Merger”) with VBI Acquisition Corp. (“Merger Sub”), a Delaware corporation and wholly-owned subsidiary of VBI DE, whereby Merger Sub merged with and into VBI US, with VBI US continuing as the surviving corporation. As a result of the PLCC Merger, VBI US was acquired by, and became a wholly-owned subsidiary of VBI DE and VBI DE changed its name to VBI Vaccines Inc. and then subsequently changed its name to VBI Vaccines (Delaware) Inc. on July 19, 2016.

The PLCC Merger was consummated pursuant to an Agreement and Plan of Merger, dated May 8, 2014 (the “PLCC Merger Agreement”), by and among VBI US, VBI DE and Merger Sub. The PLCC Merger Agreement and the transactions contemplated thereby were approved by VBI DE’s board of directors on May 1, 2014 and by VBI DE’s stockholders at a special meeting of stockholders held on July 14, 2014.

At the effective time of the VBI-SciVac Merger, the stockholders of VBI DE received our common shares which, together with options to purchase shares of VBI DE common stock that were converted into options to purchase our common shares represented approximately 46.2% of our common shares on a fully diluted basis after the VBI-SciVac Merger.

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, is 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 the primary research facility of VBI DE. VBI Cda was founded in 2001 as a spin-out company from an ongoing research collaboration between researchers at the University of California, Davis and the Children’s Hospital of Eastern Ontario. VBI Cda was involved in the early stage development of vaccine discovery platforms and adjuvant technologies. From 2001 until 2006, VBI Cda’s major stockholders included its founders and several individual “angel” investors. On December 28, 2006, VBI US closed a financing of its Series A Preferred Stock, which resulted in the opening of VBI US’s U.S. headquarters with VBI Cda as its Canadian research-focused subsidiary.

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.

Contractual Arrangements

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 \$35, \$6 and \$21, were recorded in cost of revenues for the year ended December 31, 2017, 2016 and 2015, respectively. In addition, we are committed to pay 30% of any and all non-royalty consideration, in any form, received by us from such 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 ten (10) years after the date of commencement of the first royalty year in respect of such country (the "License Period"). Upon expiry of the full term of the first License Period having commenced, we have the option to extend the Ferring License Agreement in respect of all the countries that still make up the Territory (as defined in the Ferring License Agreement) (as from the respective date of expiry) for an additional seven (7) years by payment to Ferring of a one-time lump sum payment of \$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 seventeen (17) year License Period with respect to a country in the Territory, we will thereafter have a royalty-free license to market (as defined in the Ferring License Agreement) 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 \$25, \$4 and \$15 were recorded in cost of revenues for the year ended December 31, 2017, 2016 and 2015, 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, as indicated in the discussion titled "Subsidiaries", 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 completion of a "Successful Technology Transfer", as defined in the Sale and Purchase Agreement, to a contract manufacturing organization, we paid €101 to the Sellers during the year ended December 31, 2015.
- Upon the earlier to occur of (i) first approval by the FDA of a new drug application (an "NDA") permitting us or any sublicensee to market and sell any pharmaceutical product or candidate pharmaceutical product that contains or can express an eVLP (a "eVLP Product") in the U.S. or (ii) first approval by the 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 U.S., 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 U.S.; this milestone was met and paid during the year ended December 31, 2016 for the CMV candidate and an additional €50 was accrued during the year ended December 31, 2017 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 an amount of €150 is due upon initiation of a Phase I clinical trial for the GBM candidate in 2018;
- €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. There were no payments made to UPMC during the year ended December 31, 2017 and 2015.

Kevelt AS

Prior to the Levon Merger, one of the directors of SciVac was also the chairman of the board of Kevelt AS (“Kevelt”), a wholly-owned subsidiary of OAO PharmSynthet (“PharmSynthet”), and was also the chairman of the board of PharmSynthet. Following the Levon Merger, in accordance with the merger agreement, this director resigned. On April 26, 2013, prior to the Levon Merger, 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.

Principal Products

Our principal products include our Sci-B-Vac vaccine, CMV vaccine candidate, GBM vaccines candidate and 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 14 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 nearly 500,000 patients in currently licensed markets. Several clinical trials have shown more rapid and high rates of seroprotection with Sci-B-Vac.

A Phase IV post-marketing clinical study for Sci-B-Vac in Israel was completed in June 2017 and we are nearing the completion of the clinical study report. The purpose of this study was to confirm a new in-house reference standard for regulatory and quality control purposes. Additionally, we are currently enrolling participants in the Phase III clinical program with the goal of obtaining FDA, EMA, and Health Canada market approvals for commercial sale of Sci-B-Vac in the U.S., the Europe, and Canada, respectively. We estimate that the need for a next-generation hepatitis B vaccine represents an annual global market opportunity of approximately \$600 million - \$800 million.

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) and (ii) contains all three surface antigens, naturally occurring on the outer 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 also believe that Sci-B-Vac fills 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 currently licensed hepatitis B vaccines: seroconversion rates with currently licensed hepatitis B vaccines fall dramatically within the elderly and high-risk patient populations due to the immuno-senescence or immuno-compromising conditions of such patients.

Several clinical studies conducted by us 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 large percentage of vaccinated individuals. In addition, seroprotection (the attainment of immunologically protective levels of anti-hepatitis B virus antibodies) was induced with only 25-50% of the recommended dose for currently U.S.- 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). The injection site reactions included soreness, pain, tenderness, pruritus, which is itchiness, erythema, which is redness, ecchymosis, which is discoloration of the skin resulting from bleeding underneath the skin, swelling, warmth and nodule formation. 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 U.S. 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:

ABOUT PROTECT – Safety and Immunogenicity Study

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

The co-primary objectives of the study will be:

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

ABOUT CONSTANT - Lot-to-Lot Consistency Study

CONSTANT will be a double-blind, four-arm, randomized, controlled study. Approximately 3,200 adult subjects, age 18-45 years, are expected to be randomized in a 1:1:1:1 ratio to receive one of four three-dose courses: Lot A of Sci-B-Vac 10mcg, Lot B of Sci-B-Vac 10mcg, Lot C of Sci-B-Vac 10mcg, or the control vaccine Engerix-B 20mcg.

The primary objective of this study will be 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 will be to evaluate safety and efficacy of Sci-B-Vac as compared to Engerix-B.

Congenital CMV Vaccine Candidate (eVLP)

Our second lead program is a vaccine candidate for congenital CMV, a leading cause of birth defects. Our congenital CMV vaccine candidate uses our eVLP platform, based on the CMV glycoprotein B (“gB”) antigen and is adjuvanted with alum, an adjuvant used in FDA-approved products. CMV is an infection that, while common, can lead to serious complications in babies and people with weak immune systems, and is associated with a number of solid tumors, including Glioblastoma Multiform (GBM), which is a form of adult brain cancer. According to the Centers for Disease Control and Prevention, each year approximately 30,000 infants are born with CMV infection in the U.S, of which about 5,000 will develop permanent problems including deafness, blindness, and developmental delays. We estimate that vaccination of all adolescent women and pre-pregnant women correlates to annual sales in the U.S. of approximately \$1 billion with a \$5 billion catch-up market.

The CMV vaccine candidate has demonstrated in early preclinical animal models, including rabbits and mice, the ability to generate anti-CMV antibodies neutralizing responses in both fibroblasts and epithelial cells.

Clinical Development

Patient enrollment was initiated in June 2016 in a Phase I clinical study for our congenital CMV vaccine candidate. In July 2017, we announced interim data from the Phase I clinical study of 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. The data was as follows:

- Safety: The vaccine was well tolerated at all doses, with no safety signals.
- Immunogenicity:
 - The vaccine induced antibody responses against the CMV glycoprotein B (gB) antigen with clear evidence of dose-dependent boosting after the second vaccination.
 - Immunization with the highest dose of the vaccine induced seroconversion in 100% of subjects after just two vaccinations.
 - After two of the three planned vaccinations, neutralizing antibodies against epithelial cell infection were demonstrated in 17% of subjects who received the highest dose of VBI-1501A.
 - The highest dose of VBI-1501A (2.0mcg of gB-G content with alum) has approximately 10-fold less antigen content than that typically used in several other eVLP-based vaccines or in past CMV vaccine candidates.
 - Formulation of the vaccine with alum enhanced antibody titers.

The final data read-out of safety and immunogenicity, following a third vaccination is expected in the first half of 2018.

Therapeutic GBM Vaccine Candidate (eVLP)

We have also leveraged our eVLP platform technology to develop a therapeutic GBM brain cancer vaccine candidate, VBI-1901. On August 11, 2017, the FDA accepted an IND to initiate a multi-center Phase I/IIa clinical study evaluating VBI-1901 in patients with recurrent GBM. The multi-center, open-label, two-part study will enroll up to 28 patients and is designed to evaluate safety, tolerability, and the optimal therapeutic dose level of VBI-1901. The first patient in the study received the first dose in January 2018. We expect immunologic data from ongoing biomarker analyses by mid-year 2018, and initial correlations between biomarker analyses and clinical outcomes in the second half of 2018.

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

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 glyco-proteins 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 \$0, \$211 and \$110 in milestone payments under the e-Pixis Licensing Agreement in the years ended December 31, 2017, 2016 and 2015, 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 of immunology and formulation development. We are currently exploring this technology through partnerships with other third-party collaborators.

Description of Operations

We are headquartered in Cambridge, Massachusetts, with our manufacturing facility in Rehovot, Israel and our research facility in Ottawa, Ontario, Canada. The Cambridge headquarters allows us to leverage our location in a biotechnology hub, and provides us with access to experienced consultants and executive level talent.

We operate a proprietary, mammalian cell-derived vaccine manufacturing facility in Rehovot, Israel, which we use to manufacture Sci-B-Vac. The facility was built in December 2006 and is good manufacturing practices (“GMP”) certified by the Israeli Ministry of Health (“MoH”). It has also received MoH 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 prior to marketing Sci-B-Vac in the U.S.

Current production capabilities satisfy our current manufacturing requirements for domestic 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 current production capabilities, and we may enter into agreements with various third parties for the manufacture of Sci-B-Vac.

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 U.S. 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 vaccine 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.

Our target customer base consists of other vaccine and biologics developers who may be interested in gaining access to our proprietary technologies and/or vaccine candidates.

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: (i) rapid technological change; (ii) evolving industry standards; (iii) emerging competition; and (iv) 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: (i) provide broader services and product lines; (ii) make greater investments in research and development ("R&D"); and (iii) 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: (i) large, multinational pharmaceutical companies including Sanofi, GSK, Merck, Mitsubishi Tanabe Pharma Corporation, Takeda Pharmaceutical Company Limited and Pfizer, Inc. (ii) mid-size pharmaceutical companies and emerging biotechnology companies including, Dynavax Technologies Corporation, Genocera Biosciences Inc., Vical, Inc. and Hookipa Biotech AG, and (iii) 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: (1) GSK, the manufacturer of Engerix-B, (2) Merck, the manufacturer of Recombivax HB, and (3) Dynavax, the manufacturer of Heplisav-B. Engerix-B was first approved in the U.S. 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 U.S. 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's 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 U.S. Despite the competition, we believe there are reasons our Sci-B-Vac vaccine has excellent potential, including that: (i) our vaccine contains all three surface antigens of the Hepatitis B virus, the only vaccine that contains the pre-S1 and pre-S2 antigens, which has been shown to contribute to enhanced efficacy (ii) it is adjuvanted with alum, an adjuvant that is present in several approved vaccines and has been used safely in millions of subjects commercially, in contrast to next-generation adjuvants used in other vaccines which, to the best of our knowledge, can enhance potency but does not yet have extensive safety data in commercial use, and (iii) Sci-B-Vac has an extensive data package with demonstrated efficacy and a clean safety in nearly 500,000 subjects commercially.

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 is completing a Phase I study. Interim data from the Phase I was announced in the fourth quarter of 2017. Additionally, Hookipa Biotech AG has initiated clinical development of HB - 101 a prophylactic CMV vaccine based on its Vaxwave™ technology. Despite this competition, we believe there are reasons why our CMV vaccine may have some advantages, including that: (i) our vaccine is based on the successful VLP category of vaccines, which has recently been used in the successful introduction of cervical cancer vaccines, (ii) it is currently expected to use aluminum phosphate as an adjuvant, which has an extensive history of safety through its inclusion in several pediatric vaccines, and (iii) it has demonstrated competitive anti-CMV responses in preclinical animal models.

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.

Notably, we engage CRO’s to conduct our clinical programs including the GBM Phase I/IIa clinical program, the Sci-B-Vac Global Phase III, clinical program, the Sci-B-Vac post-marketing Phase IV study and the CMV Phase I clinical program. Our reliance on these CRO’s reduces our control over these activities and involves certain risks. See risk factors on page 20.

We rely on a number of key contractors to characterize and release Sci-B-Vac for the 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 vaccine 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 U.S. 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 filed by us, which if granted, would provide patent protection extending until 2032. 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 is the owner of 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 have negotiated terms for a non-exclusive license to the HEK-293-NRC cell line. Under these terms, we will be required to pay success-based milestone payments as the CMV vaccine candidate advances into clinical development and first commercial sales. These terms also provide that no additional royalties on product sales will be required. We signed this licensing agreement in 2014.
- Key Reagent Suppliers: Characterization and release assays for our eVLP-based vaccines require specialized reagents. Once clinical development begins, we must ensure consistency and reliability of each reagent in its key quality control and release assays. Many of these reagents are being produced by, and therefore are in our control. Several key reagents including reference proteins and growth media are provided by third parties and can impact preclinical and clinical study start timelines. We have secured sufficient quantities of third party reference proteins and growth media for ongoing clinical studies. Supply of these key reagents remains a risk. See “Risk Factors” on page 20.

- 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 lead CMV vaccine candidate pursuant to the terms of a GMP-Manufacturing Services Agreement (the “Services Agreement”) dated September 26, 2014. In addition, on May 12, 2016, VBI Cda executed a new Statement of Work as part of the Services Agreement related to the process development and manufacture of an eVLP-based GBM vaccine 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 cancelable 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 U.S. 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 have applied our eVLP Platform in the development of a novel therapeutic 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 candidate is currently undergoing a Phase I/IIa clinical study.

- 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.

Employees

As of December 31, 2017, we have a total of 98 full-time and 5 part-time employees. The SciVac manufacturing site in Israel had 66 full-time employees and 1 part-time employee and the VBI Cda research site employed 27 full-time and 4 part-time employees, as of December 31, 2017. The remaining 5 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 \$919 in 2017.

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.

Business Segment and Financial Information about Geographic Areas

We operate in one segment and therefore segment information is not presented. Our principal for financial information about our one operating and reportable segment and geographic areas, refer to “Part II—Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Part II—Financial Statements and Supplementary Data—Note 17—Segment Information.”

Cost of Revenues and Services

Cost of revenues and services includes direct costs and some allocated indirect costs related to the production, manufacturing and services activities in Israel including but not limited to the costs of materials, consumables, supplies and contractors. Once sales and production volumes increase to sufficient amount, the full cost of production, manufacturing and services will be used to calculate a gross margin, however, at this time with the current volumes, a gross margin would not provide meaningful information.

Research and Development

We invest heavily in R&D. R&D expenses were \$21 million, \$10 million and \$14.1 million for the years ended December 31, 2017, 2016 and 2015, respectively. All R&D was funded by equity, term loan financings or government grants and refundable R&D tax credits. Our most significant R&D expense to date has been related mainly to Sci-B-Vac, the development of our CMV vaccine candidate, and the related eVLP platform. Our R&D expenses are expected to increase significantly as we conduct and complete the Phase III Sci-B-Vac clinical program; move other vaccine candidates through the clinical development stage and explore other vaccine opportunities and/or collaborations.

With the acquisition of VBI DE in 2016, a significant R&D priority has been the CMV vaccine candidate’s GMP manufacturing and its clinical development. Our CMV vaccine candidate was designed internally, and its manufacturing and purification processes were designed by the NRC in collaboration with our staff. Such processes and internal knowledge were transferred to our selected GMP manufacturer, Paragon, and required significant project management expertise and confirmatory R&D studies throughout 2014. In 2015, we engaged a contract research organization, ITR Laboratories Canada Inc., and completed GLP toxicology studies to confirm the safety of the CMV vaccine candidate in animals. We initiated a Phase I clinical study in June 2016 to assess the safety and tolerability of our CMV vaccine candidate in healthy, CMV-negative adults. The study will also assess the vaccine immunogenicity by measuring levels of vaccine-induced CMV neutralizing antibodies. We completed enrollment and initial dosing of 128 participants in September 2016. As of May 2017, all participants had received the third and final immunization in the series. Interim Phase I clinical study results were reported in July 2017, and complete data are expected mid-year 2018.

As previously described, we expect to make additional R&D investments in our other eVLP vaccine candidates, and in our LPV platform, which we expect will be driven by partner-led collaborations, if any.

Intellectual Property

Patents

Our IP portfolio, includes 19 active patent families consisting of 132 fully owned or exclusively licensed allowed patents and patent applications, which include 60 issued patents. The highlights of our patent portfolio include:

- CMV vaccine candidate related IP: we own two patent families which directly address our CMV vaccine candidate. These patents include a composition of matter patent describing the lead 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 three additional patent families 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.

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 lead 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 earliest filed patent family (9 of which have now been issued) have a patent term that extends to 2019 in the U.S. Our licensed patent family relating to virus like particles (7 of which have now been issued) has a patent term that extends to 2021. Our most recently filed patent family will have a patent term that extends to 2037.

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 14 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.

Before any of our products can be marketed and sold in the U.S. Europe or Canada, they must receive approval from the relevant regulatory agencies, including the FDA, EMA 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 product can be marketed in the mentioned geographical areas, the process typically required by the regulatory agencies includes:

- preclinical toxicology, laboratory and animal tests;
- submission of an investigational new drug application (an "IND"), 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 pre-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") or NDA to the FDA or Health Canada; or submission of an MAA to the EMA; and
- FDA approval of a BLA NDA, or a BLA NDA 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 U.S., 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.

Data from the clinical trials, together with preclinical data and other supporting information that establishes a vaccine drug candidate's safety, are submitted to the FDA in the form of a BLA NDA or BLA NDA supplement (for approval of a new indication if the product candidate is already approved for another indication). Under applicable laws and FDA regulations, each NDA submitted for FDA approval is usually given an internal administrative review within 45 to 60 days following submission of the BLA NDA. If deemed complete, the FDA will "file" the NDA, thereby triggering substantive review of the application. The FDA may refuse to file any BLA NDA that it deems incomplete or not properly reviewable. The FDA has established internal substantive review goals of six months for priority BLA NDAs (for vaccines or drugs addressing serious or life threatening conditions for which there is an unmet medical need) and ten months for regular BLA NDAs. 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 NDA can be approved. The FDA's review of a BLA NDA may involve review and recommendations by an independent FDA advisory committee. The FDA may deny approval of a BLA NDA or BLA NDA 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 NDA or BLA NDA 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 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 drug from distribution or withdraw approval of the NDA for that drug. 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. 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 U.S. 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, 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, BLA NDAs 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 intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting a BLA NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that FDA may not approve any other applications to market the same drug for the same disease, except in very limited circumstances, for seven years. These very limited circumstances are (i) an inability to supply the drug in sufficient quantities or (ii) a situation in which a new formulation of the drug has shown superior safety or efficacy. This exclusivity, however, also could block the approval of our product for seven years if a competitor obtains earlier approval of the same drug for the same indication.

Foreign Regulation

In addition to regulations in the U.S., we are and will continue to be subject to a variety of laws and regulations governing clinical trials 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 U.S. 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. Consultants we have hired include Florian Schodel who led the clinical development of several vaccines through licensure at Merck Research Laboratories for over a decade.

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.

Product Development Risks

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 U.S., 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;
- our lipid particle vaccine technologies, any or all of the products produced using such technologies will be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances or achieve commercial viability;
- 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:

- o adversely affect our ability to timely and successfully commercialize or market Sci-B-Vac in the U.S. and other jurisdictions where Sci-B-Vac is not currently approved;
- o result in significant additional costs;
- o potentially diminish any competitive advantages for Sci-B-Vac;
- o potentially limit the markets for Sci-B-Vac;
- o adversely affect our ability to enter into collaborations or receive milestone payments or royalties from potential collaborators;
- o cause us to abandon the further development of Sci-B-Vac to comply with requests by the FDA or other jurisdictions where it is not currently approved; or
- o limit our ability to obtain additional financing on acceptable terms, if at all.

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

As part of the regulatory process, we must conduct clinical trials for each vaccine candidate to demonstrate safety and efficacy to the satisfaction of the regulatory authorities, including the FDA for the U.S., the EMA for the European Union and Health Canada for Canada. Clinical trials are subject to rigorous regulatory requirements and are expensive and time-consuming to design and implement. We may experience delays in clinical trials for any of our vaccine candidates, and the projected timelines for continued development of the technologies and related vaccine 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, which 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. If these CROs do not perform their obligations 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 may 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, 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 U.S. 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 until now 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 vaccine 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 14 other countries. In countries where we do not currently have the required approvals (including the U.S., the European Union 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 vaccine 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 vaccine candidates in another market, and the time required to obtain approval may differ in one market from that required to obtain approval for our vaccine 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 may plan to do so with other vaccine 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, 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 vaccine candidates.

The FDA has established regulations, guidelines and policies to govern the pharmaceutical development and approval process, 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, our product candidates and 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. 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 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 U.S., 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 vaccine 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 an approved biologics license application (“BLA”) 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. Application holders must also submit advertising and other promotional material to the FDA. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws, including, by way of example, the Federal Trade Commission Act. Any sales and promotional activities are also potentially subject to federal and state consumer protection and unfair competition laws. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA, or such other regulatory agencies as reflected in the product’s approved labeling. In particular, any labeling approved by such regulatory agencies for our 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 U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

We may not succeed at in-licensing product candidates or technologies to expand our product pipeline.

We may not successfully in-license product candidates or technologies to expand our product pipeline. 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 their manufacturing facilities could have a material adverse impact on our business, results of operations, financial condition and prospects.

The facilities of any of our current and future manufacturers, whether the facilities are ours or third-party manufacturer facilities, must be approved by the FDA after we submit our 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 U.S., 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 U.S. and non-U.S. 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. 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 in jurisdictions where we are seeking regulatory approval, which would result in increased costs and losses and adversely affect our business and results of operations.

If the 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 raw materials and certain reagents required for the manufacture of Sci-B-Vac. We do not have a written or oral agreement with this source of supply, as all orders are handled through individual purchase orders or 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 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 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 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 U.S. 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 U.S. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the U.S. healthcare system have been introduced or proposed in Congress and in some state legislatures, including reducing reimbursement for prescription products and reducing the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products.

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. As such, this legislation or regulations could materially and adversely affect our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products. In addition, we believe the increasing emphasis on managed care in the U.S. has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

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

In some countries, particularly the countries of the European Union, 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 clinical trial 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 U.S. with established hepatitis B virus vaccines marketed by Merck & Co. and GlaxoSmithKline plc and outside the U.S. with vaccines from those companies 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 vaccine candidates may never achieve market acceptance, even if we obtain regulatory approvals.

Even if we receive regulatory approvals for the commercial sale of our vaccine candidates, the commercial success of these vaccine 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 vaccine 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 (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 vaccine 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 vaccine candidates require access to, or development of, facilities to manufacture our eVLP vaccine candidates at sufficient yields and at commercial-scale. We have limited experience manufacturing any of our eVLP vaccine 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 vaccine 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. Although we regularly evaluate potential manufacturers, we have a third party manufacturing agreement in place with Paragon and have reserved resource capability for the manufacture of our Phase I and Phase I/IIa clinical trial materials. We have conducted technology transfer related to our proprietary product. Despite progress achieved to date, any delays experienced by Paragon, whether directly by Paragon or by its raw material suppliers in relation to our project, may result in delays in clinical development of our eVLP 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 experience, we may need to establish successful third-party relationships to successfully commercialize our product candidates.

The near and long-term viability of our vaccine 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 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 a sufficient number of collaborations or government relationships on acceptable terms, we may not be able to commercialize our vaccine candidates or generate sufficient revenue to fund further research and development efforts.

Even if we establish new collaborations or obtain government funding, these relationships may never result in the successful development or commercialization of any vaccine 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 vaccine candidates, in a timely manner or at all;
- such partners may not devote sufficient resources to our vaccine 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 vaccine 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 vaccine candidates.

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.

Since inception, we and our subsidiaries collectively have raised approximately \$196.6 million in total equity and debt financing to support clinical and research development and general business operations. Our revenue generating activities include product sales and research and development services pursuant to fee for service agreements, research 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 \$39 million in 2017, \$23.2 million in 2016 and \$26.2 million in 2015. As of December 31, 2017, we had an accumulated deficit of \$144 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 and fees from research and development services. We expect to incur significant and increasing operating losses for the next several years as we continue to advance Phase III clinical program for Sci-B-Vac and support regulatory submissions, expand our research and development, advance other vaccine candidates into and through clinical development, including CMV and GBM vaccine candidates, 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 Sci-B-Vac Phase III clinical program, 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 26, 2018 EisnerAmper LLP, our independent registered public accounting firm, expressed substantial doubt about our ability to continue as a going concern as we have suffered recurring losses from operations and have insufficient liquidity to fund our future operations. If we are unable to improve our liquidity position we may not be able to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or substantial portion of their investment. As of December 31, 2017, we had \$67.7 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

Our future results will suffer if we do not effectively manage our expanded operations.

As a result of our acquisition of VBI DE on May 6, 2016 in the VBI-SciVac Merger, we became a larger company than either we or VBI DE was, on a stand-alone basis, prior to the VBI-SciVac Merger, and our business became more complex. There can be no assurance that we will effectively manage this increased complexity without experiencing operating inefficiencies or control deficiencies. Our failure to successfully manage the increased complexity could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We have international operations, which subject us to risks inherent with operations outside of the U.S.

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 U.S. 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 healthcare program Anti-Kickback Statute, 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 for, or the purchase, order or recommendation of, any good or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;
- the federal Ethics in Patient Referrals Act of 1989, commonly known as the Stark Law, which prohibits a physician from referring a patient for certain items or services covered by Medicare or Medicaid to an entity in which the physician or a family has a financial interest;
- the federal False Claims Act and related laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;
- the so-called qui tam provisions of the federal and state false claims acts which permit whistleblowers to sue in the name 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;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers;

- the Patient Protection and Affordable Care Act (the “Affordable Care Act”) which imposes reporting requirements on device and pharmaceutical manufacturers to make annual public disclosures of payments to healthcare providers and ownership of their stock by healthcare providers. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for “knowing failures”), for all payments, transfers of value, or ownership or investment interests that are not reported;
- The Prescription Drug Marketing Act, as amended, which governs the distribution of prescription drug samples to healthcare practitioners;
- The 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
- 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 for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians.

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 U.S. 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 has also recently 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 U.S. 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 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 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 U.S., Canadian and Israeli law, we may not be able to enforce covenants not to compete or to prevent the breach of confidentiality agreements, and therefore, may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

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

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

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 as recently as 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, internal conflict in Syria has escalated, and evidence indicates that chemical weapons have been used in the region. Intervention may be contemplated by outside parties in order to prevent further chemical weapon use. The extreme Sunni jihadist group ISIS has taken over large parts of Syria and its neighbor to the east, Iraq, and committed widespread massacres against the local civilian populations in those areas, all the while continuing in its efforts to conquer further territories. Syria and Iraq are now widely viewed as failed states 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 U.S. dollar, Canadian dollar and the New Israeli Shekel currencies may negatively affect our earnings cash flows.

Our functional currency is the U.S. dollar. We incur expenses in New Israeli Shekel, which we refer to as NIS, Canadian Dollars and U.S. dollars. As a result, we are exposed to the risks that the U.S. dollar may devalue relative to the Canadian Dollar or NIS, or, if the U.S. dollar appreciates relative to the Canadian Dollar or NIS, that the inflation rate in the U.S. may exceed such rate of devaluation of the U.S. dollar, or that the timing of such devaluation may lag behind inflation in the U.S. The average exchange rate for the year ended December 31, 2017, was US\$1.00 = NIS 3.5971 and US\$ 1.00 = Canadian Dollar 1.2973. We cannot predict any future trends in the rate of inflation in the U.S. or the rate of devaluation, if any, of the U.S. 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 132 fully 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 U.S. 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 manufacture, use or sale 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 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 vaccine candidates, including composition, methods of manufacture and use, our patents do not provide us with complete protection against the development of competing products. Furthermore, generic versions of patented biologic products (i.e. biosimilars) may have structural differences which 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 production, and therefore, we will seek to rely on non-patent data exclusivity in the BPCIA, which is described further under “—Risks Related to our Intellectual Property—We may not be able to obtain marketing exclusivity in the U.S. under the BPCIA or equivalent regulatory data exclusivity protection in other jurisdictions for our products.”

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 without the appropriate authorization from the FDA, regardless of the existence of a patent covering the product. Further, the invention, even if patented itself, cannot be commercialized 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 U.S. 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 eVLP technology, including the licenses from the L'Universite Pierre et Marie Curie ("UPMC"). 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 U.S. 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. 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.

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 infringing technologies, we will not be able to compete effectively in the drug discovery and development business.

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

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

We may not be able to enforce our intellectual property rights throughout the world. This risk is exacerbated for us because it expects that one or more of its 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 U.S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This risk is exacerbated for us 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 U.S., 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 U.S. Additionally, due to uncertainty in patent protection law, we have not filed applications in many countries where significant markets exist.

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

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 U.S. under the BPCIA or equivalent regulatory data exclusivity protection in other jurisdictions for our products.

The BPCIA, which is included in the Affordable Care Act, creates an approval pathway for biosimilar and interchangeable biological products and provides the manufacturer of innovator biologic 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 U.S. We intend to seek the maximum period of market exclusivity for our Sci-B-Vac product and our other vaccine candidate products in each jurisdiction, but there is no guarantee that any of our products will receive any marketing exclusivity under the BPCIA, or under analogous legislation in other jurisdictions. Furthermore, changes in legislation could alter the period of market exclusivity or limit its availability. Our failure to obtain exclusivity for any product that is ultimately approved by the FDA, the EMA or Health Canada may expose us to substantial competition, which could have significant adverse financial consequences.

Risks Related to Our Indebtedness

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

Perceptive Credit Holdings, LP (“Perceptive Credit”), the lender under the Amended and Restated Credit Agreement and Guaranty, dated December 6, 2016 (the “Amended Credit Agreement”) 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, 2017, was \$15 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 Agreement or any of the other loan documents, a breach of covenants under the Amended Credit Agreement, our insolvency, a material adverse effect occurring, the occurrence of certain defaults under certain other indebtedness or certain final judgments against us.

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

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

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

- incur additional debt;
- pay 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 Agreement 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 Agreement, the lender made a term loan to us in aggregate amount of \$15.0 million. We are required to make average monthly payments of interest in the amount of approximately \$143 (based on the one-month London Interbank Offered Rate being 1% or less until April 2018) and monthly payments of interest and principal in the amount of approximately \$200 per month from May 2018 until the loan matures. The principal amount of the term loan as of December 31, 2017, was \$15 million (\$15.3 million including the exit fee). The term loan under the Amended Credit Agreement matures on December 6, 2019.

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, 2017, our common shares traded as high as \$6.60 per share and as low as \$3.04 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 Agreement 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 common shares by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate shareholders may sell freely after six months, subject only to the current public information requirement (which disappears after one year). Of the 64,078,781 common shares outstanding as of December 31, 2017, approximately 38,286,208 common shares are held by “non-affiliates,” all of which are freely tradable without restriction 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, 2017, we had outstanding options, awards, and warrants for the purchase of 5,394,598 common shares. Of this amount, options, awards and warrants for the purchase of 846,162 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.

As compared to previous years, we are required to comply with the domestic reporting regime under the Securities Exchange Act of 1934, as amended, and will incur significant legal, accounting and other expenses and resources, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

Prior to December 31, 2016, we were a foreign private issuer and therefore were not required to comply with all of the periodic disclosure and current reporting requirements of the Securities Exchange Act of 1934, as amended, applicable to U.S. domestic issuers. As we are no longer a foreign private issuer as of January 1, 2017, 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 U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. In addition, our officers, directors and principal shareholders are no longer exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act and are no longer exempt from the requirements of Regulation FD promulgated by the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended. We are also no longer permitted to follow our home country rules in lieu of the corporate governance obligations imposed by The NASDAQ Stock Market LLC, and may be required to comply with the governance practices required of U.S. domestic issuers. The regulatory and compliance costs associated with the reporting and governance requirements applicable to U.S. domestic issuers may be significantly higher than the costs we previously incurred as a foreign private issuer. As a result, we expect that the loss of foreign private issuer status will increase our legal and financial compliance costs and will make some activities highly time consuming and costly. In addition, we need to develop our reporting and compliance infrastructure and may face challenges in complying with the new requirements applicable to us.

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

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act require us to identify material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the U.S. Our management, including our chief executive officer and 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.

U.S. civil liabilities may not be enforceable against us or certain of our officers.

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

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

We are governed by the BCBCA and other relevant laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a U.S. jurisdiction, and may, together with our charter documents, including the advance notice provisions in our Articles for the nomination of directors, have the effect of delaying, deferring or discouraging another party from acquiring control of our company by means of a tender offer, a proxy contest or otherwise, or may affect the price an acquiring party would be willing to offer in such an instance. The material differences between the BCBCA and Delaware General Corporation Law, 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, 2017, approximately 39.2% 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 comprised of approximately 2,359 square feet of office space, is held pursuant to a lease agreement that was entered into on May 31, 2012 with ATLP. The lease has been amended five 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 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. Six months following the first anniversary of the date of the fourth amendment and so long as we are not in breach of the terms of the lease, either we or ATLP may terminate the lease upon 60 days' notice. We are exploring a lease extension or alternative space for the balance of 2018 and the foreseeable future.
- 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 renewed lease includes a five-year option to extend until January 31, 2027 with an increase of 10%. 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 lease is 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. VBI Cda has a right to terminate the sub-sublease after one year by providing no less than 6 months' notice to Iogen Corporation, while Iogen Corporation has the right to terminate the sub-sublease after the second year by providing no less than 6 months' notice to VBI Cda. 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 \$919 in 2017.

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.

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." On that same day, our common shares began trading under the symbol "VBV" in Canada on the TSX. Prior to May 9, 2016, our common shares were traded in Canada on the TSX under the symbol "VAC" and quoted in the U.S. on the OTCQX under the symbol "SVACF." The table below presents the range of high and low sales prices of our common shares for the four quarters of the year ended December 31, 2017, and the last two quarters of the year ended December 31, 2016, and the high and low bid prices of our common shares for the first two quarters of the year ended December 31, 2016. The bid quotations reported by the OTCQX reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. All prices reported below are adjusted to reflect the 1:40 reverse share split we effected on April 29, 2016.

Period	TSX (Canadian Dollars)		OTCQX (U.S. Dollars)		NASDAQ Capital Market (U.S. Dollars)	
	High	Low	High	Low	High	Low
2017:						
Fourth Quarter	\$ 6.61	\$ 4.10	\$ N/A	\$ N/A	\$ 5.10	\$ 3.18
Third Quarter	\$ 6.40	\$ 3.85	\$ N/A	\$ N/A	\$ 5.05	\$ 3.04
Second Quarter	\$ 7.60	\$ 5.22	\$ N/A	\$ N/A	\$ 5.72	\$ 4.00
First Quarter	\$ 8.94	\$ 4.25	\$ N/A	\$ N/A	\$ 6.60	\$ 3.07
2016:						
Fourth Quarter	\$ 5.05	\$ 3.61	N/A	N/A	\$ 3.85	\$ 2.75
Third Quarter	\$ 5.76	\$ 4.66	N/A	N/A	\$ 4.15	\$ 3.26
Second Quarter (May 9 through June 30)	\$ 5.76	\$ 4.51	N/A	N/A	\$ 4.40	\$ 3.55
Second Quarter (April 1 through May 8)	\$ 6.40	\$ 4.40	\$ 4.75	\$ 4.05	N/A	N/A
First Quarter	\$ 7.60	\$ 4.80	\$ 5.08	\$ 3.60	N/A	N/A

Holders

As of February 22, 2018, we had approximately 834 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 Agreement with Perceptive Credit prohibits us from declaring or paying cash dividends or making distributions on any class of our capital stock.

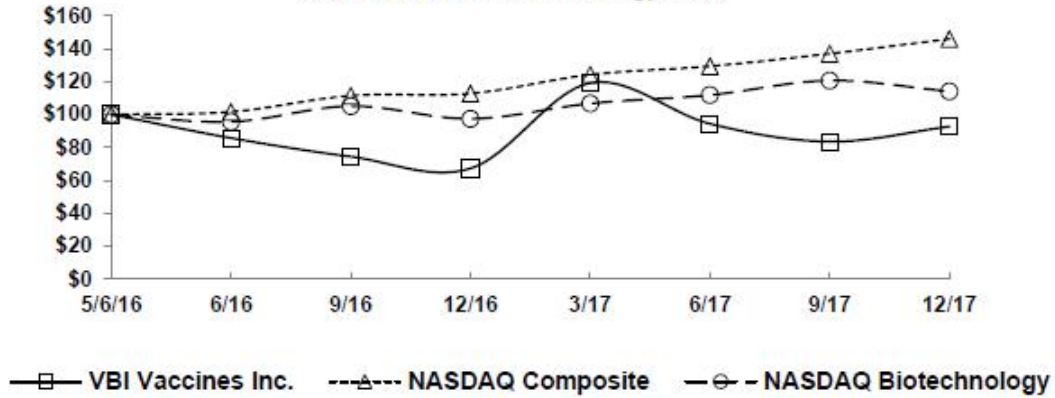
Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the performance of our common stock to the NASDAQ Composite Index and to the NASDAQ Biotechnology Index from May 6, 2016 (the first date that shares of our common stock were registered on a U.S. national securities exchange) through December 31, 2017. The comparison graph shows the cumulative total stockholder return assuming \$100 was invested after the market closed on May 6, 2016, in our common stock and in each of the foregoing indices, and it assumes reinvestment of dividends, if any. The comparisons in the graph below are based upon historical data and are not indicative of, or intended to forecast, future performance of our common stock or the foregoing indices.

COMPARISON CUMULATIVE TOTAL RETURN*

Among VBI Vaccines Inc., the NASDAQ Composite Index and the NASDAQ Biotechnology Index



*\$100 invested on 5/6/16 in stock or 4/30/16 in index, including reinvestment of dividends.
Fiscal year ending December 31.

Recent Issuances of Unregistered Securities

On December 18, 2017, we issued 274,000 common shares to Kevelt, pursuant to a settlement agreement, dated November 8, 2017, between SciVac and Kevelt, entered into to settle Kevelt’s claims made in connection with the DMA, See “Part I.—Item 1. Business—Contractual Arrangements—Kevelt AS.” 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. The common shares were issued to Kevelt pursuant to an exemption from registration requirements of U.S. federal and state securities laws in reliance on Regulation S promulgated under the Securities Act of 1933, as amended. The certificate representing the shares contained a restricted legend. Kevelt provided representation that Kevelt is not a “U.S. Person,” as defined in Rule 902 under the Securities Act of 1933, as amended, and, at the time of each of the origination of contact concerning the transactions contemplated by the settlement agreement and the execution and delivery of the settlement agreement, Kevelt was outside of the U.S.

Purchase of Equity Securities

Not applicable.

ITEM 6: SELECTED FINANCIAL DATA.

The selected consolidated financial information set forth below for the five years ended December 31, 2017, is not necessarily indicative of results of future operations, and should be read in conjunction with Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and related notes thereto included in Part II, Item 8 of this Form 10-K to fully understand factors that may affect the comparability of the information presented below. The selected statements of operations data for each of the three years in the period ended December 31, 2017, and the balance sheet data at December 31, 2017 and 2016 have been derived from our audited financial statements included elsewhere in this Form 10-K. The selected balance sheet data at December 31, 2015 have been derived from our audited financial statements not included in this Form 10-K. The selected statements of operations data for the period ended December 31, 2014 and 2013 and the balance sheet data at December 31, 2014 and 2013 have been derived from unaudited financial information not included in this Form 10-K.

The share and per share amounts set forth below reflect the 1:40 reverse share split we effected on April 29, 2016.

	Years Ended December 31,				
	2017	2016	2015	2014	2013
	(in thousands, except per share amounts)				
Consolidated statements of operations data:					
Revenue	\$ 865	\$ 548	\$ 955	\$ 2,868	\$ 1,661
Expenses:					
Cost of revenue	5,193	3,671	3,753	3,699	3,986
Research and development	20,918	9,966	14,123	634	613
General and administration	12,034	11,761	6,838	2,728	2,852
Total operating expenses	<u>38,145</u>	<u>25,398</u>	<u>24,714</u>	<u>7,061</u>	<u>7,451</u>
Net loss from operations	(37,280)	(24,850)	(23,759)	(4,193)	(5,790)
Interest expense, net	(2,882)	(324)	(1,105)	(991)	(3,595)
Foreign exchange gain (loss)	736	189	(1,458)	(1,607)	348
Loss before income taxes	<u>(39,426)</u>	<u>(24,985)</u>	<u>(26,322)</u>	<u>(6,791)</u>	<u>(9,037)</u>
Income tax benefit	<u>431</u>	<u>1,780</u>	<u>129</u>	<u>1,119</u>	<u>176</u>
Net loss	<u>\$ (38,995)</u>	<u>\$ (23,205)</u>	<u>\$ (26,193)</u>	<u>\$ (5,672)</u>	<u>\$ (8,861)</u>
Net loss per share of common shares - basic and diluted	\$ (0.61)	\$ (0.77)	\$ (2.07)	\$ (0.93)	\$ (1.37)
Weighted-average number of common shares outstanding - basic and diluted	44,158,692	30,043,501	12,630,184	6,097,923	6,478,780

	As of December 31,				
	2017	2016	2015	2014	2013
	(in thousands)				
Consolidated balance sheet data:					
Cash and cash equivalents	\$ 67,694	\$ 32,282	\$ 12,476	\$ 393	\$ 2
Working capital	57,190	26,744	11,593	(53)	(2,722)
Total assets	145,656	104,754	17,045	5,619	4,576
Other long-term obligations	12,633	13,409	1,922	11,953	30,257
Common stock and additional paid-in capital	262,697	191,907	94,932	47,115	21,256
Total stockholders’ equity (deficit)	119,787	83,731	12,194	(9,413)	(30,621)

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*Levon Merger*

On July 9, 2015, the Company, then known as 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. Other than approximately CAD \$27 million in cash retained by Levon, all other assets and liabilities of Levon were transferred or assumed by BC Ltd., Levon’s then wholly owned subsidiary. Upon consummation of the Levon Merger, each Levon shareholder received 0.5 of a common share of BC Ltd., resulting in the Levon shareholders holding 100% of the issued and outstanding shares of BC Ltd; therefore, the Company no longer owns any equity interest in BC Ltd.

On May 6, 2016, the Company completed its acquisition of VBI DE, pursuant to which Senicav Acquisition Corporation, a Delaware corporation and a wholly owned subsidiary of SciVac, merged with and into VBI DE in the VBI-SciVac Merger, with VBI DE continuing as the surviving corporation and as a wholly-owned subsidiary of SciVac . Upon completion of the VBI-SciVac Merger, SciVac changed its name to “VBI Vaccines Inc.” and received approval for the listing of its common shares on The Nasdaq Capital Market. The common shares began trading on The Nasdaq Capital Market at the opening of trading on May 9, 2016 under the Company’s new name and the ticker symbol, VBIV. Prior to the VBI-SciVac Merger, the Company’s common shares had been also listed on the Toronto Stock Exchange (the “TSX”) under the symbol “VAC”. Following the Effective Time of the VBI-SciVac Merger, the common shares began to trade on the TSX under the new symbol, “VBV”.

Overview

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 hepatitis B vaccine for adults, children and newborns, which is approved for use in Israel and 14 other countries. Sci-B-Vac, but has not yet been approved by the FDA or the EMA. The Sci-B-Vac vaccine has demonstrated safety and efficacy in nearly 500,000 patients in currently licensed markets. Several clinical trials have shown 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. We are currently enrolling patients in a Phase III clinical program to obtain FDA, EMA, and Health Canada market approvals for commercial sale of Sci-B-Vac in the U.S., Europe, and Canada respectively. Our wholly-owned subsidiary in Rehovot, Israel currently manufactures and sells Sci-B-Vac.

As a result of our acquisition of VBI DE on May 6, 2016 (see Background of VBI DE below), we are also developing novel technologies that seek to enhance vaccine protection in large, underserved markets. These include an enveloped “Virus Like Particle” or “eVLP” vaccine platform technology 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 lead programs in human cytomegalovirus (“CMV”), an infection that, while common, can lead to serious complications in babies and people with weak immune systems, and is involved in the progression of glioblastoma multiforme (“GBM”), which is a form of brain cancer. In September 2016, the Company completed the enrollment and initial dosing of 128 participants in the Phase I clinical study to evaluate its preventative CMV vaccine candidate. In July 2017, we announced interim data from the Phase I clinical study of 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. Final data read out is anticipated mid-year 2018. In January 2018, VBI initiated dosing of its GBM candidate in a Phase I/IIa clinical program. We expect immunologic data from ongoing biomarker analyses by mid-year 2018 and initial correlations between biomarker analyses and clinical outcomes in the second half of 2018.

The Company may also seek to in-license clinical-stage vaccines 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:

- manufacturing in Rehovot, Israel and sale of Sci-B-Vac in territories where it is currently registered;
- Conducting the Sci-B-Vac Phase III clinical program to support various marketing authorization applications in the U.S., Europe, Canada;
- Completing the Phase I clinical study for our CMV vaccine candidate, VBI-1501;
- Conducting the planned Phase I/IIa clinical study of our GBM vaccine candidate, VBI-1901;
- scaling-up Sci-B-Vac manufacturing capabilities to further commercialize this product 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;
- adding operational, financial and management information systems and human resources support, including additional personnel to support our vaccine development and commercialization activities; and
- maintaining, expanding and protecting our intellectual property portfolio.

VBI’s income generating activities have been from sales of its Sci-B-Vac product in markets that have generated a limited number of sales to-date as well as fees from R&D services. VBI has incurred significant net losses and negative operating cash flows since inception, and expect 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 vaccine candidates. As of December 31, 2017, VBI had an accumulated deficit of approximately \$144 million and stockholders’ equity of approximately \$120 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, 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 \$39 million for the year ended December 31, 2017 and we expect to continue to incur substantial losses in future periods. We anticipate that our operating expenses will increase substantially as we continue our clinical studies. These include expenses related to:

- continuing the Phase III clinical program for Sci-B-Vac and the of the Phase I/IIa clinical study of our GBM vaccine candidate;
- continuing the research and development of our product candidates;
- scaling-up manufacturing capabilities, both at Rehovot and through sub-contractors to commercialize products and dose forms for which we may obtain regulatory approval;
- maintaining, expanding and protecting our intellectual property portfolio;
- hiring additional clinical, manufacturing, and scientific personnel or contractors; and
- adding operational, financial and management information systems and human resources support, including additional personnel, to support our vaccine development.

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, the Canadian securities regulators and the TSX.

In 2017, we raised \$71.9 million from equity financings to support our Sci-B-Vac, CMV and GBM vaccine programs, to continue the advancement of our research programs and for other general corporate purposes. 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, into 2018. We expect, however, 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 vaccine candidates.

Since inception, VBI and its subsidiaries collectively have raised approximately \$196.6 million in total equity and debt financing to support clinical and research development and general business operations.

Research & 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 lead 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 in the standards and quality required for clinical trials for human use. In 2017 and 2016 the Company provided services to more than 10 biotechnology companies including analytical development, upstream development process, protein purification and formulation and filling for Phase I clinical studies.

VBI Cda also provides some R&D services pursuant to a research agreement and certain governmental research and development grants.

Financial Overview

Overall Performance

The Company had net losses of approximately \$39 million and \$23.2 million for the years ended December 31, 2017, and 2016, respectively. The Company has an accumulated deficit of \$144 million as December 31, 2017. The Company had \$67.7 million of cash at December 31, 2017 and net working capital of approximately \$57.2 million.

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.

Research and Development Expenses

R&D expenses consist primarily of costs incurred for the development of our CMV, GBM and Sci-B-Vac vaccines, 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 to advance the vaccines into 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 entered into on July 25, 2014 and subsequently amended on December 6, 2016.

Results of Operations

Year Ended December 31, 2017 Compared to the Year Ended December 31, 2016

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

	Years ended December 31		Change \$	Change %
	2017	2016		
Revenue	\$ 865	\$ 548	\$ 317	58%
Expenses:				
Cost of revenue	5,193	3,671	1,522	41%
Research and development	20,918	9,966	10,952	110%
General and administration	12,034	11,761	273	2%
Total operating expenses	38,145	25,398	12,747	50%
Net loss from operations	(37,280)	(24,850)	(12,430)	50%
Interest expenses, net	(2,882)	(324)	(2,558)	790%
Foreign exchange gain	736	189	547	289%
Loss before income taxes	(39,426)	(24,985)	(14,441)	58%
Income tax benefit	431	1,780	(1,349)	(76)%
NET LOSS	\$ (38,995)	\$ (23,205)	\$ (15,790)	68%

Revenues

Revenue for the year ended December 31, 2017 was \$865 as compared to \$548 for the year ended December 31, 2016. The revenue increased by \$317, or 58%, largely as a result of a full year of sales in the year ended December 31, 2017 subsequent to the partial shutdown of production during the first half of 2016 for maintenance and construction.

Revenue by Geographic Region

	Years ended December 31		\$ Change	% Change
	2017	2016		
Revenue in Israel	\$ 520	\$ 320	\$ 200	63%
Revenue in Asia	151	4	147	3675%
Revenue in Europe	194	224	(30)	(13%)
Total Revenue	\$ 865	\$ 548	\$ 317	58%

Cost of Revenues

Cost of revenues for the year ended December 31, 2017 was \$5,193 as compared to \$3,671 for the year ended December 31, 2016. The increase in the cost of revenues of \$1,522, or 41%, was a result of a full year of manufacturing in the year ended December 31, 2017, subsequent to the partial shutdown in the first half of 2016, as noted above.

Research and Development

Research and development ("R&D") expenses for the year ended December 31, 2017 were \$20,918 as compared to \$9,966 for the year ended December 31, 2016. The increase in R&D of \$10,952 or 110% was as a result of a full year of post-acquisition activity in 2017 compared to eight months in 2016 and as a result of increased costs related to the clinical trials of CMV, GBM and Sci-B-Vac.

General and Administration

General and administration (“G&A”) expenses for the year ended December 31, 2017 were \$12,034 as compared to \$11,761 for the year ended December 31, 2016. The G&A expense increase of \$273 or 2% is comparable; however, there was a full year of post-acquisition activity in the year ended December 31, 2017 compared to eight months in the year ended December 31, 2016 which was offset by the additional costs in the year ended December 31, 2016 as a result of additional professional and transaction related costs incurred by the Company related to the VBI-SciVac Merger.

Net Loss from Operations

The net loss from operations for the year ended December 31, 2017 was \$37,280 as compared to \$24,850 for the year ended December 31, 2016. The \$12,430 increase in the net loss from operations resulted from the increased cost of revenues and R&D as discussed above.

Interest Expense, net

The interest expense increase of \$2,558 is as a result of an increase in the principal amount outstanding debt of \$13.2 million which occurred in December of 2016. The interest paid on long-term debt during the year-ended December 31, 2017 and 2016 was \$1,850 and \$283, respectively. The Company also accreted \$1,181 of non-cash interest expense related to the debt discount during 2017.

Foreign Exchange Gain

The foreign exchange gain for the year ended December 31, 2017 was \$736 compared to \$189 for the year ended December 31, 2016. The gain results from the fluctuation of foreign currency exchange rates related to transactions and balances in foreign currencies (currencies that differ from the functional currencies of the respective entities).

Income tax benefit

The income tax benefit for the year ended December 31, 2017 was \$431 as compared to \$1,780 for the year ended December 31, 2016. The tax benefit recognized in 2017 and 2016 related to the deferred taxes recorded for the increase in net operating loss carry forwards in the acquired Company subsequent to the VBI-SciVac Merger. The tax benefit recorded in 2017 was limited to the amount of the deferred tax asset that is more likely than not to be realized.

Net Loss

The net loss increased by \$15,790 or 68%, from \$23,205 for the year ended December 31, 2016 to \$38,995 for the year ended December 31, 2017. The increase in our net loss is mainly attributable to the increase in our loss from operations, discussed above.

Year Ended December 31, 2016 Compared to the Year Ended December 31, 2015

Overall Performance

The Company had net losses of approximately \$23.2 million and \$26.2 million for the years ended December 31, 2016 and 2015, respectively. The Company has an accumulated deficit of \$105 million as December 31, 2016. The Company had \$32.3 million of cash at December 31, 2016 and net working capital of approximately \$26.7 million.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred for the development of our CMV vaccine candidate, which include:

- the cost of acquiring, developing and manufacturing clinical trial materials and other consumables and lab supplies used in our pre-clinical studies
- expenses incurred under agreements with contractors or Contract Manufacturing Organizations to advance the CMV vaccine candidate into clinical trials; 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 administrative 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 a clinical candidate 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 and on R&D tax refunds.

Interest Expense

Interest expense is associated with our credit facility entered into on July 25, 2014 and subsequently amended on December 6, 2016.

Results of Operations

	Years ended December 31		Change \$	Change %
	2016	2015		
Revenue	\$ 548	\$ 955	\$ (407)	(43)%
Expenses:				
Cost of revenue	3,671	3,753	(82)	(2)%
Research and development	9,966	14,123	(4,157)	(29)%
General and administration	11,761	6,838	4,923	72%
Total operating expenses	25,398	24,714	684	3%
Net loss from operations	(24,850)	(23,759)	(1,091)	5%
Interest expenses, net	(324)	(1,105)	781	(71)%
Foreign exchange gain	189	(1,458)	1,647	(113)%
Loss before income taxes	(24,985)	(26,322)	1,337	(5)%
Income tax benefit	1,780	129	1,651	1280%
NET LOSS	\$ (23,205)	\$ (26,193)	\$ 2,988	(11)%

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

Revenues

Revenue for the year ended December 31, 2016 was \$548 as compared to \$955 for the year ended December 31, 2015. The revenue decreased by \$407, or 43%, largely as a result of the partial shutdown of production during the first quarter of 2016 for maintenance and construction as well as the subsequent slower ramp-up of revenues and the reduction of the number of larger service contacts in 2016 compared to 2015. These reductions were partially offset by \$220 of collaboration revenue generated through VBI DE since the VBI-SciVac Merger.

Revenue by Geographic Region

	Years ended December 31		\$ Change	% Change
	2016	2015		
Revenue in Israel	\$ 320	\$ 534	\$ (214)	(40%)
Revenue in Asia	4	8	(4)	(50%)
Revenue in Europe	224	413	(189)	(46%)
Total Revenue	\$ 548	\$ 955	(407)	(43%)

Revenue earned in Israel for the year ended December 31, 2016 was \$320 as compared to \$534 for the year ended December 31, 2015. The revenue earned in Israel decreased by \$ 214 or 40% primarily as a result of a reduction in the production of Sci-B-Vac due to the partial closure during the year for maintenance and upgrades. Manufacturing was fully restored during the second quarter of 2016.

Revenue earned in Asia for the years ended December 31, 2016 and 2015 were insignificant.

Revenue earned in Europe for the year ended December 31, 2016 was \$224 as compared to \$413 for the year ended December 31, 2015. Although there were some research service-related revenues during the year ended December 31, 2016, there was significantly more services revenue earned in Europe during the year ended December 31, 2015 from the completion of two large service projects.

Cost of Revenues

Cost of revenues for the year ended December 31, 2016 was \$3,671 as compared to \$3,753 for the year ended December 31, 2015. The decrease in the cost of revenues of \$82, or 2.2%, was a result of a decrease of production activities as a result of a partial shutdown of the manufacturing facility for maintenance and upgrades during the first half of 2016 which was offset by a provision of approximately \$341 for inventory which largely related to some excess raw materials in inventory which are no longer expected to be used in the manufacturing process.

Research and Development

Research and development (“R&D”) expenses for the year ended December 31, 2016 were \$9,966 as compared to \$14,123 for the year ended December 31, 2015. During the year ended December 31, 2015, the Company incurred \$13,505 in costs related to the acquisition of DNASE technology. This one-time cost was not repeated during the year ended December 31, 2016. During the year ended December 31, 2016, the decrease in the cost of R&D due to the non-recurrence of the technology acquisition was largely offset by the R&D expenses incurred by VBI DE since the VBI-SciVac Merger in the amount of \$2.3 million. These costs included fees paid to CROs and other contractors in support of the trials as well as R&D salaries, contractors, consumables, license and patent related fees and well as a \$637 share-based compensation expense related to the issuance of options and restricted shares.

General and Administration

General and administration (“G&A”) expenses for the year ended December 31, 2016 were \$11,761 as compared to \$6,838 for the year ended December 31, 2015. The G&A expense increase of \$4,923 or 72%, was primarily a result of an additional \$3,694 in operating costs incurred by VBI DE since the VBI-SciVac Merger. These costs included salaries, facilities related costs, administrative, legal and professional fees. In addition, subsequent to the VBI-SciVac Merger there was share-based compensation expense of \$2,521 related to the issuance of options and restricted shares compared to \$2,127 for the year ended December 31, 2015 related to advisory services received in connection with the Levon merger. In addition, during 2016 there were additional professional and transaction related costs incurred by the Company related to the VBI-SciVac Merger which were partially offset by the non-recurrence of professional and transaction fees arising from the Levon Merger that closed July 9, 2015.

Net Loss from Operations

The net loss from operations for the year ended December 31, 2016 was \$24,850 as compared to \$23,759 for the year ended December 31, 2015. The \$1,091 increase in the net loss from operations resulted from the increased R&D and G&A costs resulting from the VBI-SciVac Merger, largely offset by the non-recurrence of \$13,505 in costs related to the DNASE technology that were incurred during the year ended December 31, 2015, discussed above.

Interest Expense, net

The interest expense decrease of \$781 is a result of the deemed interest of certain previously outstanding related party loans that were held in SciVac prior to the Levon Merger (these loans and capital notes were exchanged for common shares of the Company as part of the Levon Merger). This decrease was partially offset by \$392 of interest recorded in 2016 related to the long-term loan. In 2016, the interest expense relates to the interest on the debt facility that was assumed upon the VBI-SciVac Merger and the interest on the debt facility received in December 2016. The interest paid on long-term debt during the year-ended December 31, 2016 and 2015 was \$283 and \$0, respectively. The Company also accreted \$109 of non-cash interest expense related to the debt discount during 2016.

Foreign Exchange Gain (Loss)

The foreign exchange gain of \$189 as compared to a foreign exchange loss in the 2015 period of \$1,458, is the result of the fluctuation in the foreign currency exchange rate of the Canadian dollar (“CAD”) and the New Israeli Shekel (“NIS”) as compared to the U.S. dollar.

Income tax benefit

The income tax benefit for the year ended December 31, 2016 was \$1,780 as compared to \$129 for the year ended December 31, 2015. The tax benefit recognized in 2016 related to the deferred taxes recorded for the increase in net operating loss carry forwards in the acquired Company subsequent to the VBI-SciVac Merger. In 2015, the income tax benefit recognized related to the deemed interest expense on the related party loans.

Net Loss

The net loss decreased by \$2,988 or 11.4%, from \$26,193 for the year ended December 31, 2015 to \$23,205 for the year ended December 31, 2016. The decrease in our net loss is mainly attributable to the decrease in our loss from operations and the increase in the income tax benefit, discussed above.

Liquidity and Capital Resources

	Year ended December 31		\$ Change	% Change
	2017	2016		
Cash	\$ 67,694	\$ 32,282	\$ 35,412	110%
Current Assets	70,426	34,358	36,068	105%
Current Liabilities	13,236	7,614	5,482	72%
Working Capital	57,190	26,744	30,586	114%
Accumulated Deficit	(143,975)	(104,980)	(38,995)	37%

As of December 31, 2017, we had cash of \$67,694 as compared to \$32,282 as at December 31, 2016. As at December 31, 2017, the Company had working capital of \$57,190 as compared to working capital of \$26,744 at December 31, 2016. 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 vaccine 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 in the form of additional debt, equity or a combination of both 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 June 20, 2016, the Company closed an equity financing in a private placement. Under the terms of the financing, the Company sold an aggregate of 3,269,688 of its common shares at a price of approximately \$4.16 per share for total gross proceeds of approximately \$13.7 million. As previously disclosed, the Company has and will continue to use the proceeds from the private placement for working capital and general corporate purposes, including the continued development of its growing vaccine pipeline. The securities sold in the private placement have not been registered under the Securities Act of 1933, as amended, and may not be resold absent registration under or exemption from such Act. Contemporaneously with the December 2016 transaction discussed below, 77,787 common shares were issued pursuant to an anti-dilution provision included in the share purchase agreement.

On December 6, 2016, we raised \$10.6 million in an equity financing transaction with Perceptive Life Sciences Master Fund Ltd. and Titan-Perc Ltd. Under the terms of the equity financing, we sold an aggregate of 3,475,000 of our common shares at a price of \$3.05 per share, for total gross proceeds of approximately \$10.6 million. In a concurrent debt financing transaction with Perceptive Credit Holdings, LP ("Perceptive Credit"), we raised an additional \$12.8 million net of \$360 in deferring financing charges. The principal amount of the secured term loan under the Amended and Restated Credit Agreement with Perceptive Credit as of December 31, 2017, was \$15 million (\$15.3 million including the exit fee). In conjunction with the additional debt funding, we issued a 5-year warrant to Perceptive Credit for the purchase of an aggregate of 1,705,053 common shares. Up to 363,771 of the common shares underlying the warrant may be exercised at a price of \$4.13 per share and up to 1,341,282 of the common shares underlying the warrant may be exercised at a price of \$3.355 per share.

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 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 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 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 U.S. 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, 2017 Compared to the Year Ended December 31, 2016

Net cash used by Operating Activities

The Company incurred net losses of \$38,995 and \$23,205 in the years ended December 31, 2017 and 2016, respectively. The Company used \$31,381 and \$18,517 in cash for operating activities during the years ended December 31, 2017 and 2016, respectively. The increase in cash outflows is largely as a result of increased professional fees and increased R&D expenses related to the advancement of the CMV, GBM Sci-B-Vac vaccines.

Net cash used in/ provided by Investing Activities

The Company's net cash used in investing activities for the year ended December 31, 2017 consisted of purchases equipment of \$640 and \$61 provided by long term deposits. Our net cash provided by investing activities for the year ended December 31, 2016 resulted primarily from the \$2,126 cash acquired from the VBI-SciVac Merger which was offset by the \$585 used for purchases of equipment and \$41 used for long-term deposits.

Net cash received from Financing Activities

Cash flows provided by financing activities increased by \$30,755, from \$36,483 for the year ended December 31, 2016 to \$67,238 for the year ended December 31, 2017. In 2017, the Company closed an underwritten public offering for gross proceeds of \$71,905 offset by \$4,683 of cash issuance costs. During the year ended December 31, 2016 there were two private offerings of securities providing net proceeds of \$24,109 and there was \$13,200 of gross proceeds from a long-term loan issued together with warrants. There were \$360 of financing costs related to the long term debt and \$525 related to repayment of long-term debt.

Year Ended December 31, 2016 Compared to the Year Ended December 31, 2015

Net cash used by Operating Activities

The Company incurred net losses of \$23,205 and \$26,193 in the years ended December 31, 2016 and 2015, respectively. The Company used \$18,517 and \$8,863 in cash for operating activities during the years ended December 31, 2016 and 2015, respectively. The increase in cash outflows is largely as a result of increased professional fees and additional operating costs related to the VBI-SciVac Merger transaction as well as increased R&D expenses related to the advancement of the CMV and Sci-B-Vac vaccines.

Net cash used in/ provided by Investing Activities

The Company's capital purchases did not change significantly in the years ended December 31, 2016 and 2015, \$585 and \$583, respectively. Our net cash provided by investing activities for the year ended December 31, 2016 resulted primarily from the \$2,126 cash acquired from the Merger which was offset by the \$585 used for purchases of equipment and \$41 used for long-term deposits. In the prior year, \$20,872 was received in cash from the Levon Transaction which was largely offset by the \$583 used for purchases of equipment.

Net cash received from Financing Activities

Cash flows provided by financing activities increased by \$35,933, from \$550 for the year ended December 31, 2015 to \$36,483 for the year ended December 31, 2016. In 2016, the Company closed two private offering of its securities for net proceeds of \$24,109 and obtained an additional gross proceeds of \$13,200 from a long-term loan issued together with warrants, thereby increasing the total principal amount of long-term loan outstanding under our credit facility to \$15,000 (\$15,300 including the exit fee). These proceeds were offset by \$360 of financing costs related to the long-term debt as well as \$525 related to repayments of long-term debt.

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, 2017, the Company had NOL's aggregating approximately \$125.1 million. The NOL's are available to reduce taxable income of future years expire as follows:

	<u>U.S.</u>	<u>Canada</u>	<u>Israel</u>	<u>Total</u>
2024	\$ -	\$ 483	\$ -	\$ 483
2025	-	1,503	-	1,503
2026	10	3,791	-	3,801
2027	446	4,393	-	4,839
2028	718	1,701	-	2,419
2029	672	3,185	-	3,857
2030	2,556	1,031	-	3,587
2031	3,617	1,275	-	4,892
2032	2,962	-	-	2,962
2033	3,126	1,490	-	4,616
2034	5,625	5,580	-	11,205
2035	4,661	1,638	-	6,299
2036	5,812	8,902	-	14,714
2037	5,137	9,930	-	15,067
No expiration	-	-	44,941	44,941
Total losses	<u>\$ 35,342</u>	<u>\$ 44,902</u>	<u>\$ 44,941</u>	<u>\$ 125,185</u>

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, 2017, 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.

Tabular Disclosure of Contractual Obligations

The following table summarizes our long term contractual obligations and commitments as of December 31, 2017:

	Payments due by period				
	Total	Less than 1 year	1 – 3 years	3 -5 years	More than 5 years
Debt, including interest (1)	\$ 18,507	\$ 3,382	\$ 15,125	\$ -	\$ -
Operating lease obligations	2,479	828	1,156	495	-
Purchase obligations (2)	102	102	-	-	-
Total	<u>\$ 21,088</u>	<u>\$ 4,312</u>	<u>\$ 16,281</u>	<u>\$ 495</u>	<u>\$ -</u>

(1) As at December 31, 2017 we had a total of \$15.0 million in long-term debt. We are obliged to pay interest at a minimum rate of 12.00%. We have included an amount of \$3,207 of interest payable in this table in addition to an exit fee of \$300 payable with the final installment.

(2) purchase obligations include non-cancellable purchase orders and contracts

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, 2017, 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:

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), an entity should perform its goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. Under Accounting Standards Update ("ASU") 2017-04, "Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment", Step 2 from the goodwill impairment test has been eliminated and goodwill impairment is measured as the excess of the carrying amount of the reporting unit over its fair value. Early application is permitted. We have established August 31st as the date for our annual impairment test of goodwill. There was no goodwill impairment determined as a result of our annual testing on August 31, 2017. 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, 2017.

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. The Company performed its annual impairment test on its IPR&D assets on August 31, 2017 and recorded an impairment of \$300 for the year ended December 31, 2017, included in research and development on the consolidated statement of operations and comprehensive loss, related to certain IPR&D assets. The fair value of the IPR&D assets included in the impairment test on August 31, 2017 was determined using the income approach method and is considered Level 3 in the fair value hierarchy.

Some of the more significant estimates and assumptions inherent in the estimate of the fair value of IPR&D assets include the amount and timing of costs to develop the IPR&D into viable products, the amount and timing of future cash inflows, the discount rate and the probability of technical and regulatory success applied to the cash flows. The discount rate used was 12% and the cumulative probability of technical and regulatory success to achieve approval to market the products ranged from approximately 6% to 19%.

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.

Recording of Assets Acquired and Liabilities Assumed in Business Combination

Our acquisition of VBI DE has been accounted for using the acquisition method of accounting, which generally requires that most assets acquired and liabilities assumed be recorded at fair value as of the acquisition date. A single estimate of fair value results from a complex series of judgments about future events and uncertainties and relies heavily on estimates and assumptions. Our judgments used to determine the estimated fair value assigned to each class of assets acquired and liabilities assumed, can materially impact our results of operations. For instance, actual results related to our recorded IPR&D assets can differ from our estimates and result in impairment losses that would negatively affect our results of operations.

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

Prior to the Levon Merger, one of our directors 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, 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. on December 18, 2017. As part of the settlement, the DMA was terminated and Kevelt and SciVac released the other from all claims and liabilities arising under the DMA.

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 which was amended January 25, 2016, pursuant to which SciVac agreed to provide certain aseptic process filling services to OPKO Bio. The terms of the service agreements are based on market rates and comparable to other non-related party service agreements.

	Year ended December 31		
	2017	2016	2015
<u>Services revenues from related parties:</u>			
OPKO Bio	\$ 4	\$ 90	\$ 140
Kevelt	-	-	129
	<u>\$ 4</u>	<u>\$ 90</u>	<u>\$ 269</u>

During the year ended December 31, 2015, the Company recorded \$1,128 of related party interest expense, all of which was paid by December 31, 2015. There was no related party interest expense recorded during the year ended December 31, 2016 and 2017.

Subsequent to the VBI-SciVac Merger on May 6, 2016, Kevelt and Pharmsynthez are no longer considered related parties due to the common shareholder no longer having significant influence.

Our credit facility is from a lender that is affiliated with the Company’s largest shareholder and is a related party, see Note 10 of Notes to Consolidated Financial Statements.

JOBS Act

In April 2012, the JOBS Act was enacted in the U.S. 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, 2017, and 2016, we had cash of \$67.7 million and \$32.3 million, respectively, which is deposited in a 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, 2017 and 2016 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, 2017 and 2016 was 12.56% and 12.00%, 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 U.S. and therefore we incur expenses in NIS, Canadian Dollars and U.S 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, 2017, and December 31, 2016, 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 Senior Vice-President, Finance (our principal financial 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 Senior Vice-President, Finance concluded that, as of December 31, 2017, 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 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 Senior Vice-President, Finance assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. 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 Senior Vice-President, Finance determined that, as of December 31, 2017, 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 2018 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:

- Reports of Independent Registered Public Accounting Firm(s)
- Consolidated Balance Sheets as of December 31, 2017 and 2016
- Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2017, 2016 and 2015
- Consolidated Statements of Stockholders' Equity - For the Years Ended December 31, 2017, 2016 and 2015
- Consolidated Statements of Cash Flows - For the Years Ended December 31, 2017, 2016 and 2015
- Notes to Consolidated Financial Statements

2. Exhibits

See Index to Exhibits



VBI Vaccines Inc.
(formerly SciVac Therapeutics, Inc.)

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
VBI Vaccines, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of VBI Vaccines, Inc. and Subsidiaries (the “Company”) as of December 31, 2017 and 2016, 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, 2017 and 2016, 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 consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated 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 consolidated 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.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
Iselin, New Jersey
February 26, 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

TO THE DIRECTORS AND STOCKHOLDERS OF VBI VACCINES INC.

(formerly SciVac Therapeutics, Inc.)

We have audited the accompanying consolidated statements of operations and comprehensive loss, stockholder's equity and cash flows of VBI Vaccines Inc. for the year ended December 31, 2015. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform an audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of the operations of VBI Vaccines Inc. and its cash flows for the year ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

/S/ SMYTHE LLP

Chartered Professional Accountants

Vancouver, Canada

March 20, 2017

VBI Vaccines Inc. and Subsidiaries

Consolidated Balance Sheets
(in thousands, except share amounts)

	<u>December 31, 2017</u>	<u>December 31, 2016</u>
CURRENT ASSETS		
Cash	\$ 67,694	\$ 32,282
Accounts receivable, net	143	10
Inventory, net	788	830
Prepaid expenses	951	686
Other current assets	850	550
Total current assets	70,426	34,358
NON-CURRENT ASSETS		
Other long-term assets	675	654
Property and equipment, net	2,245	1,850
Intangible assets, net	63,336	59,507
Goodwill	8,974	8,385
Total non-current assets	75,230	70,396
TOTAL ASSETS	\$ 145,656	\$ 104,754
CURRENT LIABILITIES		
Accounts payable	\$ 1,810	\$ 2,018
Other current liabilities	9,826	5,562
Deferred revenues	-	34
Current portion of long-term debt – related party	1,600	-
Total current liabilities	13,236	7,614
NON-CURRENT LIABILITIES		
Long-term debt, net of debt discount – related party	11,538	11,956
Long-term deferred tax liability	-	428
Liabilities for severance pay	426	356
Deferred revenues, net of current portion	669	669
Total non-current liabilities	12,633	13,409
COMMITMENTS AND CONTINGENCIES (NOTE 15 and 16)		
STOCKHOLDERS' EQUITY		
Common shares (unlimited authorized; no par value) (2017 issued – 64,078,781; 2016 - issued 40,018,495)	201,806	133,312
Additional paid-in capital	60,891	58,595
Accumulated other comprehensive income (loss)	1,065	(3,196)
Accumulated deficit	(143,975)	(104,980)
Total stockholders' equity	119,787	83,731
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 145,656	\$ 104,754

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		
	<u>2017</u>	<u>2016</u>	<u>2015</u>
Revenues	\$ 865	\$ 548	\$ 955
Operating expenses:			
Cost of revenues	5,193	3,671	3,753
Research and development	20,918	9,966	14,123
General and administration	12,034	11,761	6,838
Total operating expenses	<u>38,145</u>	<u>25,398</u>	<u>24,714</u>
Net loss from operations	(37,280)	(24,850)	(23,759)
Interest expense, net (including related party - see Note 10)	(2,882)	(324)	(1,105)
Foreign exchange gain (loss)	736	189	(1,458)
Loss before incomes taxes	<u>(39,426)</u>	<u>(24,985)</u>	<u>(26,322)</u>
Income tax benefit	<u>431</u>	<u>1,780</u>	<u>129</u>
NET LOSS	<u>\$ (38,995)</u>	<u>\$ (23,205)</u>	<u>\$ (26,193)</u>
Other comprehensive income (loss) - Currency translation adjustment	<u>4,261</u>	<u>(2,233)</u>	<u>-</u>
COMPREHENSIVE LOSS	<u>\$ (34,734)</u>	<u>\$ (25,438)</u>	<u>\$ (26,193)</u>
Net loss per share of common shares, basic and diluted	\$ (0.88)	\$ (0.77)	\$ (2.07)
Weighted-average number of common shares outstanding, basic and diluted	44,158,692	30,043,501	12,630,184

See accompanying Notes to Consolidated Financial Statements

VBI Vaccines Inc. and Subsidiaries

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

	<u>Number of Common Shares</u>	<u>Share Capital</u>	<u>Additional Paid-in Capital</u>	<u>Accumulated Other Comprehensive Income (Loss) - Currency Translation Adjustments</u>	<u>Accumulated Deficit</u>	<u>Total Stockholder's Equity</u>
BALANCE AS OF JANUARY 1, 2015	6,810,809	\$ 529	\$ 46,586	\$ (963)	\$ (55,582)	\$ (9,430)
Issuance of shares for intangible assets	3,685,075	13,814	-	-	-	13,814
Share-based payments to advisors	567,457	2,127	-	-	-	2,127
Common shares issued for loans assigned by related party	1,874,507	7,027	3,584	-	-	10,611
Issuance of shares on reverse takeover	5,977,262	20,872	-	-	-	20,872
Deemed capital contribution in respect of related party loans, net of taxes of \$129	-	-	393	-	-	393
Net loss	-	-	-	-	(26,193)	(26,193)
BALANCE AS OF DECEMBER 31, 2015	18,915,110	\$ 44,369	\$ 50,563	\$ (963)	\$ (81,775)	\$ 12,194
Common shares, options and warrants issued on acquisition of VBI Vaccines (Delaware) Inc.	13,781,783	63,534	3,960	-	-	67,494
Common shares issued for cash related to private placements, net of \$100 issuance costs	6,822,475	24,109	-	-	-	24,109
Warrants issued in financing transaction	-	-	2,792	-	-	2,792
Common shares issued for services	69,000	219	-	-	-	219
Stock-based compensation	406,313	1,022	1,280	-	-	2,302
Common shares issued on exercise of stock options	23,814	59	-	-	-	59
Net loss	-	-	-	-	(23,205)	(23,205)
Currency translation adjustments	-	-	-	(2,233)	-	(2,233)
BALANCE AS OF DECEMBER 31, 2016	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

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

	2017	2016	2015
CASH FLOWS FROM:			
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (38,995)	\$ (23,205)	\$ (26,193)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	730	606	492
Non-cash interest on related party loans	-	-	469
Impairment of intangible assets	300	-	-
Stock-based compensation	2,410	2,521	2,127
Amortization of debt discount	1,181	109	-
Deferred taxes	(431)	(1,780)	-
Stock issued for in-process research and development acquisition expense	-	-	13,814
Inventory reserve	217	341	-
Net change in operating working capital items, net of business acquisitions:			
(Increase) decrease in accounts receivable	(127)	113	-
(Increase) decrease in inventory	(89)	(93)	511
Increase in prepaid expenses	(265)	(396)	(253)
(Increase) decrease in other current assets	(230)	763	71
Increase in other long-term assets	(14)	(221)	(10)
(Decrease) increase in accounts payable	(675)	11	20
Decrease in deferred revenues, including related parties	(107)	(15)	(140)
Increase in other current liabilities	4,714	2,729	-
Net cash flows used in operating activities	<u>(31,381)</u>	<u>(18,517)</u>	<u>(9,092)</u>
INVESTING ACTIVITIES			
Cash acquired in acquisitions	-	2,126	20,872
Changes in other long-term assets	61	(41)	23
Purchase of property and equipment	(640)	(585)	(583)
Net cash flows (used in) provided by investing activities	<u>(579)</u>	<u>1,500</u>	<u>20,312</u>
FINANCING ACTIVITIES			
Proceeds from issuance of common shares for cash	71,905	24,209	-
Share issuance costs	(4,683)	(100)	-
Proceeds from issuance of common shares for cash, upon exercise of stock options	16	59	-
Proceeds from long-term loan and issuance of warrants net of \$360 of financing costs – related party	-	12,840	-
Repayment of long-term loan	-	(525)	-
Loan received from related parties	-	-	2,025
Loans repaid to related parties	-	-	(1,475)
Net cash flows provided by financing activities	<u>67,238</u>	<u>36,483</u>	<u>550</u>
Effect of exchange rates on cash	<u>132</u>	<u>340</u>	<u>84</u>
CHANGE IN CASH FOR THE YEAR	\$ 35,412	19,806	11,854
CASH, BEGINNING OF YEAR	\$ 32,282	12,476	393
CASH, END OF YEAR	<u>\$ 67,694</u>	<u>\$ 32,282</u>	<u>\$ 12,476</u>
Supplementary information:			
Interest paid	\$ 1,850	\$ 283	\$ -
Non-cash investing and financing:			
Shares issued for loans assigned by related party	\$ -	\$ -	\$ 10,611
Issuance of shares in reverse takeover	\$ -	\$ -	\$ 20,878
Common shares, options and warrants issued for acquisition of VBI	\$ -	\$ 67,494	\$ -
Shares issued as part of settlement agreement with Kevelt	\$ 1,142	\$ -	\$ -
Warrants issued in connection with financing transaction	\$ 611	\$ -	\$ -
Purchase of property and equipment in accounts payable	\$ 272	\$ -	\$ -

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 immunoncology. We currently manufacture our product, Sci-B-Vac a third generation Hepatitis B (“HBV”) vaccine for adults, children and newborns, which is approved for use in Israel and 14 other countries. Sci-B-Vac has not yet been approved by the U.S. Food and Drug Administration (the “FDA”), the European Medicines Agency (the “EMA”) or Health Canada (“HC”). 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.

Following our May 6, 2016 acquisition of VBI DE (Note 4), 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 lead programs in human cytomegalovirus (“CMV”), an infection that, while common, can lead to serious complications in babies and people with weak immune systems, and is involved in the progression of glioblastoma multiforme (“GBM”), which is a form of brain cancer.

Mergers and Acquisitions

On July 9, 2015, 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. Other than approximately CAD \$27 million in cash retained by Levon, all other assets and liabilities of Levon were transferred or assumed by 1027949 BC Ltd., Levon’s wholly owned subsidiary (“BC Ltd.”). Additionally, upon consummation of the Levon Merger, each Levon shareholder received 0.5 of a common share of BC Ltd., resulting in the Levon shareholders holding 100% of the issued and outstanding shares of BC Ltd; therefore, the Company no longer owns any equity interest in BC Ltd.

On May 6, 2016, the Company completed its acquisition of VBI DE, pursuant to which Senicav Acquisition Corporation, a Delaware corporation and a wholly owned subsidiary of the Company, merged with and into VBI DE, with VBI DE continuing as the surviving corporation and as a wholly-owned subsidiary of the Company (the “VBI-SciVac Merger”). Upon completion of the VBI-SciVac Merger, the Company (then named “SciVac Therapeutics, Inc.”) changed its name to “VBI Vaccines Inc.” See Note 4.

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 \$143,975 as of December 31, 2017 and cash outflows from operating activities of \$31,381, for the year-ended December 31, 2017.

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, 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 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.

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Consolidation

The consolidated financial statements include the accounts of VBI and its wholly owned subsidiaries, SciVac, and from May 6, 2016 the accounts of VBI DE, VBI US and VBI Cda.

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

Reclassification

Certain prior year amounts have been reclassified to conform with the current year presentation and were not material to our consolidated financial statements.

Foreign currency

The functional and reporting currency of the Company is the U.S. dollar. Each of the Company’s subsidiaries determines its own respective functional currency, 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 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, the inputs in determining the fair value of equity-based awards and warrants issued as well as the values ascribed to assets acquired and liabilities assumed in business combinations. 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, 2017 and 2016, 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, 2017 and 2016, the Company had \$240 and \$0 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.

	<u>Number of years</u>
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.

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), an entity should perform its goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. Under Accounting Standards Update (“ASU”) 2017-04, “Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment”, Step 2 from the goodwill impairment test has been eliminated and goodwill impairment is measured as the excess of the carrying amount of the reporting unit over its fair value. Early application is permitted. 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, 2017. 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, 2017.

The goodwill is in VBI Cda and the change in carrying value from December 31, 2016 relates to currency translation adjustments which increased goodwill by \$589 for the year ended December 31, 2017. The change in carrying value from the acquisition date until December 31, 2016 relates to currency translation adjustments which decreased goodwill by \$329 for the year ended December 31, 2016.

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. The Company performed its annual impairment test on its IPR&D assets on August 31, 2017 and recorded an impairment of \$300, included in research and development on the consolidated statement of operations and comprehensive loss, related to certain IPR&D assets. The fair value of the IPR&D assets included in the impairment test on August 31, 2017 was determined using the income approach method and is considered Level 3 in the fair value hierarchy. Some of the more significant estimates and assumptions inherent in the estimate of the fair value of IPR&D assets include the amount and timing of costs to develop the IPR&D into viable products, the amount and timing of future cash inflows, the discount rate and the probability of technical and regulatory success applied to the cash flows. The discount rate used was 12% and the cumulative probability of technical and regulatory success to achieve approval to market the products ranged from approximately 6% to 19%.

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.

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

The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred or service has been performed and completed, the sales price is fixed or determinable and collectability of the sales price is reasonably assured.

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 an employee benefit expense 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, 2017 and 2016. 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 and related investment tax credits for income tax purposes are based upon management's interpretation of the applicable legislation in the Income Tax Act (Canada). These amounts are subject to review and acceptance by the Canada Revenue Agency and may be subject to adjustment.

Fair value measurements of financial instruments

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

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

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

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

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

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

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

The fair value of our outstanding debt, including the current portion, is estimated to be approximately \$15,157 and \$15,102 at December 31, 2017 and 2016, 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. The Company had no outstanding debt at December 31, 2015.

In determining the fair value of the long-term debt as of December 31 the Company used the following assumptions:

	2017	2016
Long-term debt:		
Interest rate	12.56%	12.0%
Discount rate	12.00%	13.5%
Expected time to payment in months	23	35

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 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 leases 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. While we continue to evaluate the effect of adopting this guidance on our consolidated financial statements and related disclosures, we expect our operating leases, as disclosed in Note 15, will be subject to the new standard. We will recognize right-of-use assets and operating lease liabilities on our consolidated balance sheets upon adoption, which will increase our total assets and liabilities.

Revenue from Contracts with Customers

In May 2014, 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. The Company will adopt the guidance in the first quarter of 2018 using the modified retrospective method. Given the Company’s current level of revenue, the impact from the adoption of this new accounting guidance on our consolidated financial statements and related footnote disclosures will not be material.

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. There is no impact from the adoption of this new accounting guidance on our consolidated financial statements and related footnote disclosures, other than we will not be required to disclose the fair value assumptions in determining the fair value of the long-term debt in the footnote disclosures.

4. VBI-SCIVAC MERGER

On May 6, 2016 (the “Closing Date”), the Company completed its acquisition of VBI DE. Pursuant to the VBI-SciVac Merger Agreement, a wholly owned subsidiary of the Company merged with and into VBI DE, with VBI DE continuing as the surviving corporation and as a wholly owned subsidiary of the Company.

At the effective time of the VBI-SciVac Merger (the “Effective Time”), each issued and outstanding share of VBI DE’s common stock, par value \$0.0001 per share (“VBI DE Common Shares”), was converted into the right to receive common shares of the Company, having no par value per share (“Common Shares”), in the ratio of 0.520208 Common Shares for each share of VBI DE Common Shares (the “Exchange Ratio”). The Exchange Ratio gives effect to the 1:40 share consolidation of Common Shares effected on April 29, 2016. In addition, each outstanding option or warrant to purchase a share of VBI DE Common Shares was converted into an option or warrant to purchase, on the same terms and conditions, a number of Common Shares (rounded down to the nearest whole share) equal to the product of (i) the number of shares of VBI DE Common Shares subject to such option or warrant multiplied by (ii) the Exchange Ratio at an exercise price per share computed by dividing the per share exercise price under each such option or warrant by the Exchange Ratio and rounding up to the nearest cent.

The consideration was approximately \$67.5 million and consisted of approximately (i) \$63.5 million in the Company’s Common Shares (13,781,783 shares) the value of which was based on the closing price of the Common Shares on May 6, 2016 or \$4.61, (ii) \$3 million representing the relative portion of the fair value of the Company’s options for the purchase of Common Shares issued to VBI DE employees attributable to past service periods and (iii) \$0.9 million representing the fair value of the Company’s Common Share warrants issued to VBI DE warrant holders.

The options and warrants were valued based on the Black-Scholes model with the following assumptions:

	<u>Options</u>	<u>Warrants</u>
Outstanding	\$ 2,104,312	\$ 363,771
Weighted average exercise price	4.50	4.13
Volatility	80.0%	80.0%
Risk-free interest rate	1.29%	0.93%
Expected dividend rate	0%	0%
Expected life (years)	5.3	3.2

The fair value of the assets acquired and liabilities assumed was based on management estimates. The significant intangible assets that were recognized were IPR&D related to three primary products all of which have been determined to have indefinite lives until the underlying development programs are completed. Acquired IPR&D represents the fair value assigned to IPR&D assets that were acquired as part of business combinations, and which have not been completed at the date of acquisition. The acquired IPR&D 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. We utilized a discounted probability weighted future cash flow model on a project-by-project basis to value acquired IPR&D. Significant assumptions used in the model include the period in which material net cash inflows from significant projects are expected to commence, the level of cash inflows to be generated from these assets and expense levels as well as an appropriate risk adjusted discount rate applied to the projected cash flows. Following is a summary of assets acquired and liabilities assumed as of the acquisition date:

Current assets	\$ 3,308
Property and equipment	138
Identifiable intangible assets - IPR&D	61,500
Total assets acquired	64,946
Current Liabilities	(1,505)
Long-term deferred tax liability	(2,300)
Long-term debt	(2,361)
Total liabilities assumed	(6,166)
Net identifiable assets acquired	\$ 58,780
Goodwill	8,714
Total purchase consideration	\$ 67,494

The purchase price exceeded the fair value of the net identifiable assets acquired by \$8,714, which was recorded as goodwill.

The intangible assets and goodwill reside in VBI Cda. From the acquisition date until December 31, 2016 the carrying value of IPR&D and goodwill has decreased due to currency translation adjustments of \$2,324 and \$329 respectively.

The consolidated results of operations do not include any results of operations related to the acquired business on or prior to May 6, 2016, the date of the acquisition. Approximately \$10,517 of the consolidated net loss for the year ended December 31, 2016 relates to the acquired business since May 6, 2016. The Company's unaudited pro-forma results for the years ended December 31, 2016 and 2015 reflect the historical financial information of the Company and the acquired companies assuming the acquisition had occurred on January 1, 2015.

These unaudited pro-forma results have been prepared for comparative purposes only and do not purport to be indicative of what the combined Company's results would have been had the acquisition occurred on January 1, 2015, nor do they project the future results of operations of the combined Company.

(in thousands, except per share data)	2016	(unaudited) 2015
Revenue	\$ 578	\$ 1,343
Net loss	(28,583)	(35,763)
Net loss per share – basic and diluted	\$ (0.82)	\$ (1.29)
 Weighted-average number of common shares outstanding, basic and diluted	 34,825,705	 27,736,402

5. PROPERTY AND EQUIPMENT

	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
	<u>\$ 4,608</u>	<u>\$ (2,363)</u>	<u>\$ 2,245</u>
	December 31, 2016		
	Cost	Accumulated Depreciation	Net Book Value
Machinery and equipment	\$ 1,430	\$ (539)	\$ 891
Furniture and office equipment	67	(20)	47
Computer equipment and software	254	(83)	171
Leasehold improvements	1,980	(1,239)	741
	<u>\$ 3,731</u>	<u>\$ (1,881)</u>	<u>\$ 1,850</u>

Depreciation expense for the years ended December 31, 2017, 2016 and 2015 was \$667, \$540 and \$428, respectively.

6. INVENTORY, NET

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

	<u>2017</u>	<u>2016</u>
Finished goods	\$ 99	\$ 93
Work-in-process	119	203
Raw materials	570	534
	<u>\$ 788</u>	<u>\$ 830</u>

The Company recorded a provision of approximately \$217 and \$341 for inventory largely related to excess raw materials which are no longer expected to be used in the manufacturing process as of December 31, 2017 and 2016, respectively. No inventory provision was recorded for the year ended December 31, 2015.

7. INTANGIBLES

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

	<u>December 31, 2016</u>			
	Gross Carrying amount	Accumulated Amortization	Cumulative Currency Translation	Net Book Value
Patents	\$ 669	\$ (334)	\$ (4)	\$ 331
IPR&D assets	61,500	-	(2,324)	59,176
	<u>\$ 62,169</u>	<u>\$ (334)</u>	<u>\$ (2,328)</u>	<u>\$ 59,507</u>

Amortization expenses for the years ended December 31, 2017, 2016 and 2015 amounted to \$63, \$66, and \$64 respectively. Amortization is expected to be approximately \$58 per year for each of the next five years. These amounts do not include any amortization related to the IPR&D assets, which will not begin amortizing until the Company commercializes its products.

8. OTHER CURRENT LIABILITIES

Other current liabilities consisted of the following:

	<u>2017</u>	<u>2016</u>
Accrued expenses (including clinical trial accrued expenses)	\$ 7,931	\$ 1,942
Payroll and employee-related costs	1,699	1,497
Other current liabilities	206	2,123
	<u>\$ 9,826</u>	<u>\$ 5,562</u>

9. LOSS PER SHARE OF COMMON SHARES

Basic loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common shares outstanding during each period. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as warrants, and stock options, which would result in the issuance of incremental shares of common shares unless such effect is anti-dilutive. In computing the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remained the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation. These potentially dilutive securities are more fully described in Note 13, Stockholders' Equity and Additional Paid-in Capital.

The following potentially dilutive securities outstanding at December 31, 2017, 2016 and 2015 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Warrants	2,618,824	2,068,824	-
Stock options	2,775,774	2,807,277	-
	<u>5,394,598</u>	<u>4,876,101</u>	<u>-</u>

10. LONG-TERM DEBT – RELATED PARTY

	<u>2017</u>	<u>2016</u>
Long-term debt, net of debt discount	\$ 13,138	\$ 11,956
Less: current portion	<u>1,600</u>	<u>-</u>
	<u>\$ 11,538</u>	<u>\$ 11,956</u>

As a result of the Merger, the Company through VBI DE assumed a term loan facility with Perceptive Credit Holdings, LP (the “Lender”) in the amount of \$6 million (the “Facility”), with an initial advance of \$3 million drawn down on prior to the Merger. As of the merger date the Company assumed an amount of \$2,361 in the Facility. On December 6, 2016, the Company amended the Facility (the “Amended Facility”) and raised an additional \$13.2 million which was combined with the remaining balance from the facility of \$1,800. The total principal outstanding at December 31, 2017 and 2016, including the \$300 exit fee discussed below, is \$15.3 million. Borrowings under the Amended Facility are secured by all of VBI assets. The principal on the facility accrues interest at an annual rate equal to the greater of (a) one-month LIBOR (subject to a 5.00% cap) or (b) 1.00%, plus the Applicable Margin. The Applicable Margin will be 11.00%. The first eighteen months are interest only. The interest rate as of December 31, 2017 and 2016 was 12.56% and 12%, respectively. Upon the occurrence, 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 matures December 6, 2019 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, 2017. Pursuant to the Amended Facility, the Company agreed to appoint a representative of the Lender to the Board who is also a portfolio manager of the Company’s largest shareholder.

In connection with the Amended Facility, on December 6, 2016 the Company issued to the lender two tranches of warrants. The first tranche to purchase 363,771 shares of the Company’s common shares at an exercise price of \$4.13 and the second tranche was a warrant to purchase 1,341,282 shares of the Company’s common shares at an exercise price of \$3.355. The total proceeds attributed to the warrants was \$2,792 based on the relative fair value of the warrants as compared to the sum of the fair values of the warrants and debt. This resulted in the debt being issued at a discount. See Note 13 for further disclosures related to these warrants. The Company incurred \$360 of debt issuance costs and is required to pay an exit fee of \$300 upon full repayment of the debt resulting in additional debt discount.

The total debt discount of \$3,453 is being charged to interest expense using the effective interest rate method over the term of the debt based on an imputed interest rate of 21.51% and 20.5% for year ended December 31, 2017 and 2016 respectively. As of December 31, 2017, and 2016, the unamortized debt discount is \$2,163 and \$3,344 respectively. The Company recorded \$1,181 and \$109 of interest expense related to the amortization of the debt discount during the year ended December 31, 2017 and 2016 respectively.

Total related party interest expense, including the amortization of the debt discount, was \$3,031, \$392 and \$1,128 for years ended December 31, 2017, 2016 and 2015, respectively. Such amounts are included in Interest expense, net in the accompanying consolidated statements of operations and comprehensive loss.

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

Year ending December 31,	
2018	\$ 1,600
2019	13,700
	<u>\$ 15,300</u>

11. DEFERRED REVENUE AND RELATED PARTY TRANSACTIONS

	<u>2017</u>	<u>2016</u>
Short-term deferred revenue	\$ -	\$ 34
Long-term deferred revenue	<u>669</u>	<u>669</u>
	<u>\$ 669</u>	<u>\$ 703</u>

On December, 29, 2014, SciVac entered into an exclusive distribution agreement with Pharmsynthez, pursuant to which SciVac appointed Pharmsynthez as the exclusive distributor of Sci-B-Vac in the Russian Federation for a term of five years. The term of the agreement will automatically continue at the expiration of the initial term, unless either party provides written notice to the other party at least 90 days prior to the termination of the initial term. The agreement provides that Pharmsynthez must purchase certain minimum quantities of Sci-B-Vac per each quarter during the term of the agreement, and failure to do so will entitle SciVac to either terminate Pharmsynthez's exclusivity rights or terminate the agreement. The aggregate amount of \$469 already remitted to SciVac by Pharmsynthez is to be credited against future orders of products by Pharmsynthez in accordance with the terms and conditions of the Distribution Agreements. The deposit has been classified as long-term deferred revenue in December 31, 2017 and 2016. During the years ended December 31, 2017 and 2016, no revenue was recognized with respect to this contract.

	Years ended December 31		
	2017	2016	2015
Services revenues from related parties:			
OPKO Bio	\$ 4	\$ 90	\$ 140
Kevelt	-	-	129
	<u>\$ 4</u>	<u>\$ 90</u>	<u>\$ 269</u>

- i. 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.
- ii. Prior to the Levon Merger, one of the Company’s directors was also the chairman of the board of Kevelt AS (“Kevelt”), a wholly owned subsidiary of OAO Pharmsynthez (“Pharmsynthez”), a shareholder of the Company and was also the chairman of the board of Pharmsynthez. Following the Merger, in accordance with the merger agreement, this director resigned.

On April 26, 2013, 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 \$4,279. 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 renews thereafter for successive additional one-year periods, unless the parties fail to agree on the terms applicable to any renewal term and either party provides at least 30 days prior written notice of non-renewal to the other. On July 30, 2016, the Company received a letter of termination from Kevelt, in part containing a request for refund of \$2.5 million it had previously transferred to the Company. The Company reclassified this amount to other current liabilities as of June 30, 2016.

On November 8, 2017, SciVac entered into a settlement agreement with Kevelt, whereby SciVac agreed to pay Kevelt \$1,000 in cash by November 10, 2017, and issue 274,000 common shares of the Company by no later than December 18, 2017, to settle the ongoing disputes arising out of DMA. As part of the settlement, the DMA was terminated and Kevelt and SciVac entered into mutual release agreements, whereby each of them released the other from all claims and liabilities arising under the DMA. The cash and common shares were offset against the current liability, with the remaining amount of \$88 recorded against general and administration expenses.

See Note 10, for Facility from a lender that is also affiliated with the Company’s largest shareholder and is a related party.

12. 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, 2017, 2016, and 2015 was \$190, \$139 and \$97, 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 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.

Included in years ended December 31, 2016 and 2015 general and administration expenses is \$120 and \$7 respectively, of severance payments pursuant to the aforementioned statutory or contractual obligations.

13. STOCKHOLDERS' EQUITY AND ADDITIONAL PAID-IN CAPITAL

Authorized

Unlimited number of common shares without par value.

Common shares issuances

2015 common shares issuances

- i. On April 20, 2015, the Company entered into a license agreement (the "CLS License Agreement") with CLS Therapeutics Limited, a Guernsey company ("CLS"), pursuant to which CLS has granted to the Company, effective as of the completion of the reverse merger with Levon Resources Ltd. on July 9, 2015, (Note 1) an exclusive, worldwide, perpetual and fully paid-up license (including the right to sublicense) to all of CLS' patents, know-how and related improvements with respect to the Deoxyribonuclease enzyme ("DNASE"), including the exclusive right to research, develop, manufacture, have manufactured, use, sell, offer for sale, import, export, market and distribute products with respect to DNASE for all indications (collectively, the "Licensed Technology"). Pursuant to the CLS License Agreement, SciVac Ltd. agreed to issue to CLS 3,685,075 of its common shares.
- ii. On July 8, 2015, Levon issued 567,457 common shares to various advisors for services provided to it in connection with the Levon Merger. The fair value of the shares was recognized as an expense in the amount of \$2,127.
- iii. The Company received loans from its shareholders and their affiliates in the amount of approximately \$2,025 during the year ended December 31, 2015. These loans either were non-interest bearing or had an interest rate of 4.5% per annum. The loans were repayable within one year from date of receipt but were automatically extended for an additional year unless otherwise agreed between the parties. In 2015, the Company calculated the fair value of these loans in the amount of \$1,501 using an effective interest rate of approximately 15%. The differences between the principal amount of the loan and their fair value in the amount of \$522, was expensed over the term of the loan in 2015, and was recorded as an increase in equity of \$393, net of \$129 in income taxes.

On July 9, 2015, as part of the Levon Merger, certain related party loans and capital notes plus accrued interest were assigned from SciVac Ltd. to Levon. These loans with a carrying value of \$10,611 were deemed to be converted into 1,874,507 common shares.

- iv. On July 9, 2015, when the Levon Merger was completed 5,977,262 shares of Levon's common shares were issued to SciVac Ltd. shareholders with a fair value of \$20,872. See Note 1.

2016 common share issuances

- i. On May 6, 2016, the Company completed the VBI-SciVac Merger pursuant to which the company issued 13,781,783 shares of the Company's common shares to VBI DE's shareholders. See Note 4.
- ii. On June 14, 2016, the Company granted 762,500 stock awards pursuant to the 2016 Plan. On June 22, 2016, 25% of these stock awards vested and the Company issued 194,561 shares of the Company's common shares (out of which 27,746 common shares were withheld for payroll tax withholding purposes). Twenty-five percent of unvested stock awards vest on each anniversary over the next three years. During 2016, an additional 11,998 shares of common shares were vested and issued to employees.
- iii. On June 20, 2016, the Company closed an equity private placement. Under the terms of the financing, the Company sold an aggregate of 3,269,688 of its common shares at a price of approximately \$4.16 per share for total gross proceeds of approximately \$13.6 million. The Company incurred \$23 of issuance costs.

Contemporaneously with the December 2016 transaction discussed below, an additional 77,787 common shares were issued pursuant to an anti-dilution provision included in the share purchase agreement.

- iv. On September 23, 2016, the Company granted an additional 227,500 stock awards pursuant to the 2016 Plan. Pursuant to Israeli tax requirements, these awards were issued to a Trustee on behalf of SciVac employees, whereby 25% of these stock awards vested on the grant date and the balance vests 25% on each anniversary over the next three years.
- v. On December 6, 2016, the Company raised \$10.6 million in an equity financing transaction with Perceptive Life Sciences Master Fund Ltd. and Titan-Perc Ltd. Under the terms of the equity financing, the Company sold an aggregate of 3,475,000 of its common shares at a price of \$3.05 per share in a private placement to the investors for total gross proceeds of approximately \$10.6 million. The securities sold in the private placement have not been registered under the Securities Act of 1933, as amended, and may not be resold absent registration under or exemption from such Act. The Company incurred \$77 of issuance costs.
- vi. The Company issued 23,814 common shares related to stock options that were exercised during the year.
- vii. The Company issued 69,000 common shares of the Company to three consultants for services provided to the Company's shareholders in connection with their respective consulting agreements. The fair value of the common shares of \$219 was recognized as an expense.

2017 common share issuances

- i. 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.
- ii. 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.
- iii. 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.
- iv. 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.
- v. On December 18, 2017, the Company issued 274,000 common shares of the Company to Kevelt as part of the settlement agreement as described in Note 11. 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.

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, 2017, there were 1,273,527 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, 2017, there were 4,613 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, 2017, there were 685,755 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 following the VBI-SciVac Merger 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, 2017, there were 387,500 options and 424,379 RSUs outstanding 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 3,127,355 at December 31, 2017.

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 a 5- day volume weighted average 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, 2017 and 2016.

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, 2017 and 2016. All RSUs issued under the plan at December 31, 2017 and 2016 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, 2017.

Stock-based compensation expense

The table below provides information, as of December 31, 2017, 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	1,273,527	\$ 4.11
2013 Plan	4,613	\$ 7.31
2014 Plan	685,755	\$ 5.36
2016 Plan	811,879	\$ 3.90
Total	2,775,774	\$ 4.36

Activity related to stock options is as follows:

	Number of Stock Options	Weighted Average Exercise Price
Balance outstanding at January 1, 2015 and December 31, 2015	-	\$ -
Adopted Option Plans	2,104,312	\$ 4.50
Granted	108,750	\$ 3.61
Exercised	(23,814)	\$ 2.50
Forfeited	(21,345)	\$ 3.57
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
Exercisable at December 31, 2017	1,740,816	\$ 4.47

Exercise Price	Outstanding		Exercisable	
	Number Of Options	Weighted Average Remaining Contractual Life (Years)	Number Of Options	Weighted Average Exercise Price
\$ 2.50 - \$ 3.49	196,420	4.0	196,420	\$ 2.65
\$ 3.50 - \$ 4.49	1,136,759	7.4	766,258	\$ 4.09
\$ 4.50 - \$ 5.49	928,291	6.4	694,587	\$ 4.96
\$ 5.50+	89,925	6.5	83,551	\$ 8.12
	2,351,395	6.7	1,740,816	\$ 4.47

The weighted average remaining contractual life of exercisable options was 5.57 years and 6.05 years at December 31, 2017 and 2016, 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, 2015 and December 31, 2015	-	-
Granted	990,000	\$ 3.88
Vested	(263,434)	\$ 3.88
Forfeited	(87,192)	\$ 3.87
Unvested shares outstanding at 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

The intrinsic value of outstanding options at December 31, 2017 was \$594 (the intrinsic value of vested options was \$452, and the intrinsic value of those expected to vest was \$142). The fair value of the vested RSU's was \$899 for the year ended December 31, 2017. The intrinsic value of exercised options was not significant for the years ended December 31, 2017 and 2016.

Stock options are issued with exercise prices equal to the underlying share's fair value on the date of grant, subject to a four-year vesting periods as follows: 25% at the first anniversary of the grant date and 2.083% on the last day of each month for the 36 months thereafter until 100% vested or monthly over 48 months, with a contractual term of 10 years.

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:

	2017	2016
Volatility	87.22%	80.36%
Risk free interest rate	2.31%	1.25%
Expected term in years	6.3	6.3
Expected dividend yield	0%	0%
Weighted average fair value per option	\$ 3.12	\$ 3.09

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 U.S. 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:

	<u>2017</u>	<u>2016</u>
Research and development	\$ 702	\$ 637
General and administration	1,648	1,591
Cost of revenue	60	74
Total stock-based compensation expense	<u>\$ 2,410</u>	<u>\$ 2,302</u>

There was no stock-based compensation expense recorded in the year ended December 31, 2015.

There is \$3,081 of unrecognized compensation from all equity awards as at December 31, 2017. This expense will be recognized over a weighted average period of 1.8 years.

The number of restricted stock awards vested during the year ended December 31, 2016 includes 27,746 shares withheld or repurchased by the Company on behalf of employees to satisfy \$105 of tax obligations relating to the vesting of such shares.

Warrants

The warrants issued on December 6, 2016, as part of the facility described in Note 10, entitle the Lender to purchase:

- 1,341,282 common shares with an exercise price of \$3.355 per share which is equal to the price per share of the common shares paid by investors in the December PIPE;
- an additional 363,771 common shares with an exercise price of \$4.13; and,
- the warrants are exercisable at any time on or prior to the fifth anniversary of their issue date.

The value of \$2,792 attributed to the warrants issued on December 6, 2016 was based on the Black-Scholes option pricing model determined by applying the following assumptions:

Volatility	85%
Risk free interest rate	1.35%
Expected dividend yield	-%
Expected term in years	5

The warrants issued on October 30, 2017, as part of the share underwritten public offering and concurrent registered direct offering described earlier in Note 13, 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 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 January 1, 2015 and December 31, 2015	-	\$ -
Issued as part of business combination	363,771	\$ 4.13
Issued	1,705,053	\$ 3.52
Balance outstanding at December 31, 2016	2,068,824	\$ 3.63
Issued	550,000	\$ 3.34
Balance outstanding at December 31, 2017	2,618,824	\$ 3.57

14. INCOME TAXES

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

	2017	2016	2015
United States	\$ (7,220)	\$ (4,225)	\$ (262)
Canada	(10,568)	(7,913)	(4,828)
Israel	(21,638)	(12,847)	(21,232)
Total	\$ (39,426)	\$ (24,985)	\$ (26,322)

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

	2017	2016	2015
Current Tax			
Canada	\$ 3	\$ -	\$ -
Israel	-	(5)	(2)
	3	(5)	(2)
Deferred Tax			
Canada	428	1,785	-
Israel	-	-	131
	428	1,785	131
Total			
Canada	431	1,785	-
Israel	-	(5)	129
	\$ 431	\$ 1,780	\$ 129

The Company operates in U.S., 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:

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Loss before income taxes	\$ (39,425)	\$ (24,985)	\$ (26,322)
Canadian statutory tax rate	26%	26%	26%
Expected recovery of income tax	10,251	6,496	6,844
Research and development tax credits	227	139	-
Change in valuation allowance	(5,496)	(5,054)	(6,741)
Difference between Canadian and foreign tax rates	1,011	560	-
Other	706	373	-
Change in tax rates	(5,749)	-	26
Stock based compensation	(519)	(734)	-
Income tax benefit	<u>\$ 431</u>	<u>\$ 1,780</u>	<u>\$ 129</u>

The income tax benefit for the years ended December 31, 2017 and 2016 related to the deferred tax assets recorded for the increase in net operating loss carry forwards in the acquired company subsequent to the VBI-SciVac Merger. In 2015, the income tax benefit related to the deemed interest on the related party loans.

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 statutory 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:

	<u>2017</u>	<u>2016</u>
<u>Deferred tax assets (liabilities):</u>		
Net operating losses	\$ 31,858	\$ 28,722
Research and development tax credits	10,550	7,392
Property and equipment	581	807
Reserves and other	1,250	265
Intangible assets	<u>(16,814)</u>	<u>(15,685)</u>
Net deferred tax assets	27,425	21,501
Less: valuation allowance	<u>(27,425)</u>	<u>(21,929)</u>
Net deferred tax assets (liabilities)	<u>\$ (0)</u>	<u>\$ (428)</u>

As of December 31, 2017 the Company has U.S. federal net operating loss carryovers ("NOLs") of approximately \$35.3 million (2016 - \$30.8 million) including \$29 million related to the acquisition of VBI, available to offset taxable income which expire beginning in 2026. The NOL's related to the acquisition of VBI 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, 2017, the Company also has Canadian net operating loss carryovers of approximately \$44.9 million (2016 - \$31.0 million) available to offset future taxable income which expire beginning in 2024. As at December 31, 2017 the Company also has Israel net operating loss carryovers of approximately \$44.9 million (2016 - \$32.0 million) respectively, which can be carried forward indefinitely.

At December 31, 2017 the Company has \$5.0 million (2016 - \$3.7 million) of investment tax credits available to carry forward and reduce future years' Canadian income taxes which expire beginning in 2026.

As of December 31, 2017, the Company has unclaimed research and development expenses in Canada of approximately \$17.0 million (2016 - \$14.4 million) which are available to offset future taxable income indefinitely.

At December 31, 2017, the Company had NOL's aggregating approximately \$125.1 million. The NOL's are available to reduce taxable income of future years expire as follows:

	U.S.	Canada	Israel	Total
2024	\$ -	\$ 483	\$ -	\$ 483
2025	-	1,503	-	1,503
2026	10	3,791	-	3,801
2027	446	4,393	-	4,839
2028	718	1,701	-	2,419
2029	672	3,185	-	3,857
2030	2,556	1,031	-	3,587
2031	3,617	1,275	-	4,892
2032	2,962	-	-	2,962
2033	3,126	1,490	-	4,616
2034	5,625	5,580	-	11,205
2035	4,661	1,638	-	6,299
2036	5,812	8,902	-	14,714
2037	5,137	9,930	-	15,067
No expiration	-	-	44,941	44,941
Total losses	<u>\$ 35,342</u>	<u>\$ 44,902</u>	<u>\$ 44,941</u>	<u>\$ 125,185</u>

15. COMMITMENTS AND CONTINGENCIES

Licensing

(a) In connection with the acquisition of the ePixis technology, VBI 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 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 Transfer Payment was not recognized as a liability in the Company's prior financial statements because the probability of payment had previously been deemed remote.

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 U.S. 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 sublicensees 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 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 \$35, \$6 and \$21 were recorded in cost of revenues for the years ended December 31, 2017, 2016 and 2015, respectively. In addition, the Company is committed to pay 30% of any and all non-royalty consideration, in any form, received by Company from such 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).

The Company is to pay Ferring the above-mentioned royalties on a country-by-country basis until the date which is ten (10) years after the date of commencement of the first royalty year in respect of such country ("License Period"). Upon expiry of the full term of the first License Period having commenced, the Company shall have the option to extend the License Agreement in respect of all the countries that still make up the Territory (as defined in the License Agreement) (as from the respective date of expiry) for an additional seven (7) years by payment to Ferring of a one-time lump sum payment of \$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 seventeen (17) year License Period with respect to a country in the Territory, the Company shall thereafter have a royalty-free license to market (as defined in the License Agreement) in such country and when all the License Periods have expired in each country in the Territory, the Company shall have a royalty-free license to manufacture the product in India and the People's Republic of China.

- (c) Under an Assignment and Assumption Agreement, the Company is required to pay royalties to SciGen Singapore equal to 5% of Net Sales. Royalty payments of \$25, \$4 and \$15 were recorded in cost of revenues for the years ended December 31, 2017, 2016, and 2015 respectively.

Legal Proceedings

From time to time, the Company may be involved in certain claims and litigation arising out of the ordinary course 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. As at December 31, 2017 the Company believes that they maintain adequate insurance coverage for any such litigation matters arising in the normal course of business.

16. OPERATING LEASES

The Company has entered into various non-cancelable lease agreements for its office, lab and manufacturing facilities. These arrangements expire at various times through 2027. Rent expense for the years ended December 31, 2017, 2016 and 2015 was \$919, \$541, and \$223 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	
2018	\$ 828
2019	699
2020	457
2021	457
Thereafter	38
Total	<u>\$ 2,479</u>

17. SEGMENT INFORMATION

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

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

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Revenue in Israel	\$ 520	\$ 320	\$ 534
Revenue in Asia	151	4	8
Revenue in Europe	194	224	413
Total	<u>\$ 865</u>	<u>\$ 548</u>	<u>\$ 955</u>

There was no revenue attributed to our country of domicile, Canada, for years ended December 31, 2017, 2016 and 2015.

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

For the year ended December 2016, the Company had 5 customers that individually accounted for 22%, 18%, 16%, 14% and 11% of revenues, respectively.

For the year ended December 2015 the Company had 5 customers, of which 3 were related parties, that individually accounted for 30%, 20%, 15%, 13% and 10% of revenues, respectively.

Long lived assets attributed to geographic areas are as follows:

	<u>2017</u>	<u>2016</u>
Long lived assets in Israel	\$ 2,421	\$ 2,039
Long lived assets in Canada (country of domicile)	72,134	67,703
Total	<u>\$ 74,555</u>	<u>\$ 69,742</u>

18. Selected Quarterly Financial Data (Unaudited, in thousands, except per share amounts)

	Three months ended 2017			
	March	June	September	December
Revenues	\$ 127	\$ 344	\$ 193	\$ 201
Net loss	\$ (8,638)	\$ (9,013)	\$ (9,802)	\$ (11,542)
Basic and Diluted net loss per share	\$ (0.22)	\$ (0.22)	\$ (0.24)	\$ (0.20)
Shares used to compute basic and diluted net loss per share	40,026	40,089	40,229	56,673

	Three months ended 2016			
	March	June	September	December
Revenues	\$ 48	\$ 82	\$ 281	\$ 137
Net loss	\$ (1,079)	\$ (6,416)	\$ (7,299)	\$ (8,411)
Basic and Diluted net loss per share	\$ (0.06)	\$ (0.23)	\$ (0.20)	\$ (0.23)
Shares used to compute basic and diluted net loss per share	18,915	26,619	36,151	37,342

19. SUBSEQUENT EVENTS

On January 23, 2018, the Company approved to grant 1,415,000 stock options and awards to existing employees, directors and an eligible service provider pursuant to the 2016 Plan. The granted options vest on a monthly basis over 36 months and automatically expire on January 23, 2028.

EXHIBIT INDEX

Exhibit No.	Description
2.1 ⁽¹⁾	<u>Agreement and Plan of Merger, dated as of October 26, 2015 (incorporated by reference to Annex A to the proxy statement/prospectus filed as part of the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on December 23, 2015).</u>
2.2	<u>First Amendment to Agreement and Plan of Merger, dated as of December 17, 2015 (incorporated by reference to Annex A to the proxy statement/prospectus filed as part of the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on December 23, 2015).</u>
2.3	<u>Arrangement Agreement, dated as of March 19, 2015, by and between SciVac Ltd., Levon Resources Ltd. and 1027949 BC Ltd. (incorporated by reference to Exhibit 99.1 to the Report on Form 6-K (SEC File No. 000-13248), filed with the SEC on June 9, 2015).</u>
2.4	<u>Sale and Purchase Agreement, dated as of July 18, 2011, by and between Variation Biotechnologies, Inc., EPixis SA and the Persons Listed on Schedule 1 therein (incorporated by reference to Exhibit 2.4 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).</u>
3.1	<u>Articles (incorporated by reference to Exhibit 3.1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on December 23, 2015).</u>
3.2	<u>Notice of Articles (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761), filed with the SEC on February 5, 2016).</u>
3.3	<u>Form of Notice of Alteration (incorporated by reference to Exhibit 3.3 to Amendment No. 1 to the registration statement on Form F-4 (SEC File No. 333-208761) filed with the SEC on February 5, 2016).</u>
4.1	<u>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).</u>
4.2	<u>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).</u>
4.3	<u>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).</u>
4.4	<u>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).</u>
4.5	<u>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).</u>
4.6	<u>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).</u>
10.1(A)+	<u>2016 VBI Vaccines Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).</u>
10.1(B)+	<u>2016 VBI Vaccines Equity Incentive Plan forms of award agreements (incorporated by reference to Exhibit 10.2 to the Annual Report on Form 10-K (SEC File No. 001-37769), filed with the SEC on March 20, 2017).</u>

- 10.2+ [VBI DE 2014 Equity Incentive Plan \(incorporated by reference to Annex C to VBI DE's definitive proxy statement on Schedule 14A \(SEC File No. 000-18188\), filed with the SEC on June 30, 2014\).](#)
- 10.3+ [2006 VBI US Stock Option Plan \(incorporated by reference to Exhibit 10.2 to the registration statement on Form S-8 \(SEC File No. 333-198247\), filed with the SEC on August 20, 2014\).](#)
- 10.4 [License Agreement, dated June 2004, by and between Savient Pharmaceuticals, Inc. and SciGen, Ltd., as amended \(incorporated by reference to Exhibit 99.2 to the report on Form 6-K \(SEC File No. 000-13248\), filed with the SEC on July 20, 2015\).](#)
- 10.5 [Voting and Support Agreement, dated as of October 26, 2015, by and among SciVac Therapeutics Inc., Senicav Acquisition Corporation and ARCH Venture Fund VI, L.P \(incorporated by reference to Exhibit 10.5 to Amendment No. 1 to the registration statement on Form F-4 \(SEC File No. 333-208761\), filed with the SEC on February 5, 2016\).](#)
- 10.6 [Voting and Support Agreement, dated as of October 26, 2015, by and among SciVac Therapeutics Inc., Senicav Acquisition Corporation and Clarus Lifesciences I, L.P. \(incorporated by reference to Exhibit 10.6 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\).](#)
- 10.7+ [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\).](#)
- 10.14+ [Director Services Agreement with Steven Gillis, dated May 8, 2014 \(incorporated by reference to Exhibit 10.10 to VBI DE's current report on Form 8-K \(SEC File No. 000-18188\), filed with the SEC on July 28, 2014\).](#)
- 10.15+ [Director Services Agreement with Jeff Baxter, dated May 8, 2014 \(incorporated by reference to Exhibit 10.11 to VBI DE's current report on Form 8-K \(SEC File No. 000-18188\), filed with the SEC on July 28, 2014\).](#)
- 10.16+ [Director Services Agreement with Michel De Wilde, dated May 8, 2014 \(incorporated by reference to Exhibit 10.13 to VBI DE's current report on Form 8-K \(SEC File No. 000-18188\), filed with the SEC on July 28, 2014\).](#)

- 10.18+ [Amendment No. 1 to Director Services Agreement with Steven Gillis, dated July 25, 2014 \(incorporated by reference to Exhibit 10.17 to VBI DE's current report on Form 8-K \(SEC File No. 000-18188\), filed with the SEC on July 28, 2014\).](#)
- 10.19+ [Amendment No. 1 to Director Services Agreement with Michel de Wilde, dated July 25, 2014 \(incorporated by reference to Exhibit 10.19 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⁽²⁾ [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\).](#)
- 10.25+ [Director Services Agreement with Scott Requadt, dated as of December 8, 2015 \(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 December 11, 2015\).](#)
- 10.26 [License Agreement, dated May 31, 2012, by and among University Pierre and Marie Curie, The National Institute of Health and Medical Research Public National Scientific and Technological and Ecole Normale Superieure de Lyon, and Epixis SA \(incorporated by reference to Exhibit 10.45 to Amendment No. 1 to the registration statement on Form F-4 \(SEC File No. 333-208761\), filed with the SEC on February 5, 2016\).](#)
- 10.27 [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⁽²⁾ [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\).](#)
- 10.34+ [Director Services Agreement with Adam Logal, dated as of July 26, 2016 \(incorporated by reference to Exhibit 10.34 to the annual report on Form 10-K \(SEC File No. 001-37769\), filed with the SEC on March 20, 2017\).](#)
- 10.35+ [Director Services Agreement with Steven D. Rubin, dated as of July 26, 2016 \(incorporated by reference to Exhibit 10.35 to the annual report on Form 10-K \(SEC File No. 001-37769\), filed with the SEC on March 20, 2017\).](#)
- 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\).](#)
- 10.37+ [Amendment No. 1 to Director Services Agreement with Jeff Baxter, dated October 25, 2016 \(incorporated by reference to Exhibit 10.37 to the annual report on Form 10-K \(SEC File No. 001-37769\), filed with the SEC on March 20, 2017\).](#)
- 10.38+ [Amendment No. 1 to Director Services Agreement with Scott Requadt, dated October 25, 2016 \(incorporated by reference to Exhibit 10.38 to the annual report on Form 10-K \(SEC File No. 001-37769\), filed with the SEC on March 20, 2017\).](#)
- 10.39+ [Amendment No. 2 to Director Services Agreement with Steven Gillis, dated October 25, 2016 \(incorporated by reference to Exhibit 10.39 to the annual report on Form 10-K \(SEC File No. 001-37769\), filed with the SEC on March 20, 2017\).](#)
- 10.41+ [Amendment No. 2 to Director Services Agreement with Michel De Wilde, dated October 25, 2016 \(incorporated by reference to Exhibit 10.41 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 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 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](#)
- 10.57+ [Amendment to Consulting Agreement with F. Diaz-Mitoma Professional Corporation, dated February 19, 2018.](#)
- 10.58 [Amendment to Sublease Lease, dated January 21, 2018, by and between Green Power YE and SciVac Ltd.](#)
- 10.59 [Waiver Agreement, dated February 21, 2018, by and among Variation Biotechnologies \(US\), Inc., the Guarantors party thereto, and Perceptive Credit Holdings, LP](#)
- 21.1* [Subsidiary List of VBI Vaccines Inc.](#)
- 23.1* [Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.](#)
- 23.2* [Consent of Smythe LLP, Independent Registered Public Accounting Firm.](#)
- 24.1* [Powers of Attorney \(attached to the signature page hereto\).](#)
- 31.1* [Certification of Principal Financial Officer pursuant to Rule 13a-14\(a\) or Rule 15d-14\(a\) of the Securities Exchange Act of 1934.](#)
- 31.2* [Certification of Principal Financial Officer 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 Principal Financial 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.](#)

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) The schedules and exhibits to the Agreement and Plan of Merger have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. We will furnish copies of any such schedules and exhibits to the SEC upon request.

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts, on this 26th day of February, 2018.

VBI VACCINES INC.

By: /s/ Jeff Baxter

Jeff R. Baxter, President and Chief Executive Officer

By: /s/ Athena Kartsaklis

Athena Kartsaklis, Senior Vice-President, Finance
(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 Athena Kartsaklis, 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 26, 2018

/s/ Jeff R. Baxter

Jeff Baxter, President, Chief Executive Officer and
Director (Principal Executive Officer)

Date: February 26, 2018

/s/ Athena Kartsaklis

Athena Kartsaklis, Senior Vice-President, Finance
(Principal Financial and Accounting Officer)

Date: February 26, 2018

/s/ Steven Gillis,

Steven Gillis,
Director

Date: February 26, 2018

/s/ Michel De Wilde

Michel De Wilde
Director

Date: February 26, 2018

/s/ Adam Logal

Adam Logal
Director

Date: February 26, 2018

/s/ Scott Requadt

Scott Requadt
Director

Date: February 26, 2018

/s/ Steven D. Rubin

Steven D. Rubin
Director

Date: February 26, 2018

/s/ Tomer Kariv

Tomer Kariv
Director

EMPLOYMENT AGREEMENT

This Employment Agreement (the “**Agreement**”) is made as of the DATE by and between NAME, on the one hand (the “**Executive**”), and VBI Vaccines (Delaware) Inc., a Delaware corporation (the “**Company**”), on the other hand.

WHEREAS, the Company and the Executive desire to set forth, in a definitive employment agreement, their respective rights and obligations with respect to the Executive’s employment by the Company;

WHEREAS, the Executive’s employment by the Company shall commence at the effective time (the “**Effective Time**”); and

WHEREAS, the Executive will be a key employee of the Company with significant access to information concerning the Company, its subsidiaries and their respective businesses, and the disclosure or misuse of such information or the engaging in competitive activities by the Executive would cause substantial harm to the Company.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Employment. The Company agrees to employ the Executive, and the Executive agrees to accept such employment, upon the terms and conditions hereinafter set forth.

2. Term. The Executive’s employment shall commence at the Effective Time and shall continue until termination by either party in accordance with Section 10 of this Agreement.

3. Duties. The Executive will serve as TITLE of the Company and shall have such duties of a senior executive nature as the Company’s Board of Directors (the “**Board**”) shall determine from time to time. The Executive shall report to the Chief Executive Officer.

4. Full Time; Best Efforts. The Executive shall use the Executive’s best efforts to promote the interests of the Company, and shall devote the Executive’s full business time and efforts to its business and affairs. The Executive shall not engage in any other activity which could reasonably be expected to interfere with the performance of the Executive’s duties, services and responsibilities hereunder without the approval of the Board in its sole discretion.

5. Compensation and Benefits. During the term of the Executive’s employment under this Agreement, the Executive shall be entitled to compensation and benefits as follows:

(a) Base Salary. The Executive shall receive a salary at the rate of \$SALARY annually (the “**Base Salary**”), payable in accordance with regular payroll practices of the Company.

(b) Bonus. The Executive shall be eligible to be considered for an annual cash bonus of up to PERCENTAGE percent (xx%) of the Executive’s then applicable Base Salary (the “**Bonus**”), commencing with the YEAR calendar year (and pro-rated with respect to FIRST YEAR). Bonus entitlement shall be based on the Executive’s meeting of certain performance objectives, which shall be mutually established by the Executive and the Board within thirty (30) days after the Effective Time and shall be re-established on an annual basis thereafter. Bonus eligibility and entitlement will be at the sole discretion of the Board and will be contingent upon the Executive remaining actively employed with the Company through the date any Bonus is paid. The Bonus will be paid in March of the following calendar year. The Executive shall not be entitled to any portion of any Bonus that might otherwise have been awarded for any calendar year during which the Executive’s employment terminates for any reason. All determinations regarding any Bonus will be made by the Board in its sole discretion.

(c) Benefits/Business Expense Reimbursement. In addition to the Base Salary and the Bonus, the Executive shall be entitled to receive customary benefits that are generally available to employees of the Company in accordance with the then-existing terms and conditions of its benefits policies. The Executive's benefits will include (i) four (4) weeks of paid vacation per year, which will accrue monthly, (ii) term life insurance with a death benefit in the amount of the Base Salary payable to a beneficiary designated by the Executive, (iii) standard short and long term disability benefits, (iv) standard health insurance benefits, and (v) participation in the Company's 401(k) plan. Other than the 401(k) plan, the Company shall not be required to provide any pension or retirement benefits to the Executive. In the event the Executive receives payments from the disability insurer, the Company shall have the right to offset such payments against the Base Salary otherwise payable to Executive during the period for which such payments are made. The Executive represents and warrants that he has no reason to believe that he is not insurable with a reputable insurance company for the limits of the coverage discussed herein. If the Executive is deemed to be uninsurable for any of the coverage discussed herein, the Company shall not be deemed to be in breach of this Agreement for failing to provide such coverage. The Company may change any benefits contractor, in its sole discretion, and any such change will not be a breach of this Agreement. The Executive shall be entitled to reimbursement of all reasonable expenses incurred in the ordinary course of business on behalf of the Company, subject to the presentation of appropriate supporting documentation, expense statements, vouchers and/or such other supporting documentation as approved by or in accordance with policies established by the Board.

(d) Withholding. The Company may withhold from any compensation payable to the Executive all applicable U.S. withholding and employment taxes and other statutory deductions.

(e) Stock Options. While the Executive remains an employee of the Company, option grants to the Executive may be granted at such times as the Board shall deem appropriate. The amount and vesting terms related to any such grant shall be in the discretion of the Board. Any options granted to the Executive shall be subject to the terms and conditions of the equity incentive plan of the Company pursuant to which such options are granted and the applicable award agreement thereunder (if any), save and except that (A) the vesting of any such option shall accelerate fully if the Executive is terminated without Cause, is terminated during the period that begins when negotiations with an unrelated third party for a Change of Control begin and ends on the twelve (12) month anniversary of the closing of the Change of Control transaction ("**Change of Control Termination**") or terminates his employment for Good Reason, and (B) if the Executive is terminated for Cause under clause (v) of the definition of Cause hereunder (i.e. failure to meet performance expectations of the Board), the Executive shall have a period of three (3) months following such termination to exercise any outstanding vested options before the exercise period of such vested options expires.

6. Confidentiality; Intellectual Property. The Executive agrees that during the Executive's employment with the Company, whether or not under this Agreement, and at all times thereafter:

(a) The Executive will not at any time, directly or indirectly, disclose or divulge any Confidential Information (as hereinafter defined), except as required in connection with the performance of the Executive's duties for the Company, and except to the extent required by law (but only after the Executive has provided the Company with reasonable notice and opportunity to take action against any legally required disclosure). As used herein, "**Confidential Information**" means all trade secrets and all other information of a business, financial, marketing, technical or other nature relating to the business of the Company including, without limitation, any customer or vendor lists, prospective customer names, financial statements and projections, know-how, pricing policies, operational methods, methods of doing business, technical processes, formulae, designs and design projects, inventions, computer hardware, software programs, business plans and projects pertaining to the Company and including any information of others that the Company has agreed to keep confidential; provided, however, that Confidential Information shall not include any information that has entered or enters the public domain through (i) no fault of the Executive, and (ii) no breach by any other current or former employee of his/her confidentiality obligations to the Company.

(b) The Executive shall make no use whatsoever, directly or indirectly, of any Confidential Information at any time, except as required in connection with the performance of the Executive's duties for the Company.

(c) Upon the Executive's termination of employment for any reason, and upon the request of the Company at any time and for any reason, the Executive shall immediately deliver to the Company all materials (including all electronic and hard copies) in the Executive's possession which contain or relate to Confidential Information.

(d) All inventions, modifications, discoveries, designs, developments, improvements, processes, software programs, works of authorship, documentation, formulae, data, techniques, know-how, secrets or intellectual property rights or any interest therein (collectively, the "**Developments**") made by the Executive, either alone or in conjunction with others, at any time or at any place during the Executive's employment with the Company, whether or not reduced to writing or practice during such period of employment, which relate to the business in which the Company is engaged or in which the Company intends to engage, shall be and hereby are the exclusive property of the Company, without any further compensation to the Executive. In addition, without limiting the generality of the prior sentence, all Developments which are copyrightable work by the Executive are intended to be "work made for hire" and shall be and hereby are the property of the Company.

(e) The Executive shall promptly disclose any Developments to the Company. If any Development is not the property of the Company by operation of law, this Agreement or otherwise, the Executive will, and hereby does, assign to the Company all right, title and interest in such Development, without further consideration, and will assist the Company and its nominees in every way, at the expense of the Company, to secure, maintain and defend its rights in such Development. The Executive shall sign all instruments necessary for the filing and prosecution of any applications for, or extension or renewals of, letters patent (or other intellectual property registrations or filings) of the United States, Canada or any other country in which the Company desires to file and that relates to any Development. The Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as such Executive's agent and attorney-in-fact (which designation and appointment shall be deemed coupled with an interest and shall survive the Executive's death or incapacity), to act for and on the Executive's behalf to execute and file any such applications, extensions or renewals and to do all other lawfully permitted acts to further the prosecution and issuance of such letters patent, other intellectual property registrations or filings, or such other similar documents with the same legal force and effect as if executed by the Executive.

(f) Attached hereto as Exhibit A is a list of all inventions, modifications, discoveries, designs, developments, improvements, processes, software programs, works of authorship, documentation, formulae, data, techniques, know-how, secrets or intellectual property rights or any interest therein made by the Executive prior to the date of this Agreement (collectively, the “**Prior Inventions**”), which belong to the Executive and which relate to the business or reasonably anticipated business of the Company and which are not assigned to the Company hereunder; or, if no such list is attached, the Executive represents that there are no such Prior Inventions. If in the course of the Executive’s employment with the Company, the Executive incorporates into a Company product, process, or machine a Prior Invention owned by the Executive or in which the Executive has an interest, then 1) the Executive will notify the Company in writing at least 60 days before efforts are made to develop or commercialize such Prior Inventions, and 2) the Company is hereby granted a 60 day right of first negotiation to license the Prior Invention(s) on terms mutually agreeable to relevant parties. If the Company elects to pursue negotiations, the parties agree to negotiate exclusivity for a period of 90 days.

(g) The Executive waives in whole all moral rights which he may have in the Developments, including the right to the integrity of the Developments, the right to be associated with the Developments, the right to restrain or claim damages for any distortion, mutilation or other modification of the Developments, and the right to restrain use or reproduction of the Developments in any context and in connection with any product, service, cause or institution. The Executive agrees to confirm such waiver from time to time as requested by the Company.

7. Non-competition. The Executive acknowledges and agrees that the consideration for the following covenants is the Company’s agreement to provide Severance (as defined in Section 10 below) in the event of the Executive’s termination without Cause (other than as a result of the death or Disability of the Executive) or by the Executive for Good Reason.

The Executive agrees that, during the Executive’s employment with the Company and for one year thereafter, irrespective of whether the Executive resigns or is terminated either with or without Cause, the Executive will not, directly or indirectly, individually or as a consultant to, or an employee, officer, director, manager, stockholder (except as a stockholder owning less than one percent (1%) of the shares of a corporation whose shares are traded on a national securities exchange), partner, member, or other owner or participant in any business entity other than the Company:

(a) carry on, participate in, or engage in any business that competes directly with the Business of the Company in the United States or Canada. For purposes of this Agreement, the term “**Business of the Company**” means the research, development or commercialization of virus-like particle vaccines for prophylactic and therapeutic use in both humans and animals;

(b) solicit, employ, hire, endeavor to entice away from the Company, or offer employment or any consulting arrangement to, any person or entity who is, or was within the one-year period immediately prior thereto, employed by, or a consultant to, the Company; or

(c) solicit or endeavor to entice away from the Company, any person or entity who is, or was within the one-year period immediately prior thereto, a customer or client of, supplier to, or other party having material business relations with the Company;

provided, however; that if the Executive is terminated for Cause under clause (v) of the definition of Cause hereunder (i.e. failure to meet performance expectations of the Board), the non-competition requirement of this Section 7 shall not apply.

8. Remedies. Without limiting the remedies available to the Company, the Executive acknowledges that a breach of any of the covenants contained in Sections 6 or 7 herein could result in irreparable injury to the Company for which there might be no adequate remedy at law, and that, in the event of such a breach or threat thereof, the Company shall be entitled to obtain a temporary restraining order and/or a preliminary injunction and a permanent injunction restraining the Executive from engaging in any activities prohibited by Sections 6 or 7 herein or such other equitable relief as may be required to enforce specifically any of the covenants of Sections 6 or 7 herein. For purposes of Sections 6, 7, and 8 of this Agreement, the term “**Company**” shall include Variation Biotechnologies, Inc., a corporation incorporated under the Canada Business Corporation Act, the Company, their respective subsidiaries and affiliated companies, and the respective successors and assigns of each of the foregoing.

9. Review of Agreement; Reasonable Restrictions. The Executive: (a) has carefully read and understands all of the provisions of this Agreement and has had the opportunity for this Agreement to be reviewed by counsel; (b) is voluntarily entering into this Agreement; (c) has not relied upon any representation or statement made by the Company (or its subsidiaries, affiliates, equity holders, agents, representatives, employees, or attorneys) with regard to the subject matter or effect of this Agreement; (d) acknowledges that the duration, geographical scope, and subject matter of Sections 6, 7, and 8 of this Agreement are reasonable and necessary given the Executive’s unique position within the Company and special knowledge of the Company and its customers; (e) acknowledges that the duration, geographical scope, and subject matter of Sections 6, 7, and 8 of this Agreement are reasonable and necessary to protect the goodwill, customer relationships, legitimate business interests, and Confidential Information of the Company and its affiliates, and that the Company would not have entered into this Agreement without the benefit of such provisions; (f) acknowledges the significant consideration which he is receiving for entering into this Agreement; and (g) will be able to earn a satisfactory livelihood without violating this Agreement.

10. Termination.

(a) General. The Executive’s employment with the Company may be terminated at any time by the Company with Cause or without Cause. Any decision regarding termination of the Executive shall be made by the Board.

(b) Disability. The Executive’s employment with the Company may be terminated at any time by the Company in the event of the Disability of the Executive.

(c) Change of Control. For purposes of this Agreement, the term “Change of Control” shall mean the sale or disposition by Company to an unrelated third party of substantially all of its business or assets, or the sale of the capital stock of the Company in connection with the sale or transfer of a controlling interest in the Company to an unrelated third party, or the merger or consolidation of the Company with another corporation as part of a sale or transfer of a controlling interest in the Company to an unrelated third party. For purposes of this definition, the term “controlling interest” means the sale or transfer of the Company’s securities representing more 50% of the voting power.

(d) Definitions. As used herein, the following terms shall have the following meanings:

“**Cause**” means that, in the good faith and reasonable determination of the Board, the Executive has (i) breached any fiduciary duty or legal or contractual obligation to the Company or any of its subsidiaries or affiliates, where written notice is given to the Executive and the Executive does not cure the breach within fourteen (14) days; (ii) engaged in gross negligence, willful misconduct, fraud, embezzlement, acts of dishonesty, or a conflict of interest relating to the affairs of the Company or any of its subsidiaries or affiliates; (iii) been convicted of or pleaded nolo contendere to: (A) any misdemeanor relating to the affairs of the Company or any of its subsidiaries or affiliates (with the exception of minor misdemeanors not involving moral turpitude); or (B) any felony or indictable offence; (iv) engaged in a violation of any federal or state laws (with the exception of minor misdemeanors not involving moral turpitude), or federal or state securities laws; or (v) the Executive has materially failed to meet minimum performance expectations of the Company’s Chief Executive Officer after reasonable notice of the material performance deficiency and a reasonable opportunity to remedy such deficiency.

“**Good Reason**” means (i) a material breach of any material provision of this Agreement, which breach is not cured by the Company within thirty (30) days after receipt of written notice thereof from the Executive; (ii) the assignment of duties or responsibilities to the Executive by the Board, which are inconsistent in a material and adverse respect with the Executive’s position with the Company as of the date of this Agreement; or (iii) the relocation of the Executive, without the Executive’s prior consent, by the Company to a work location more than fifty (50) miles from the location of the Company’s headquarters; provided that, in the case of each of (i), (ii) and (iii), the Company shall have been given written notice by the Executive describing in reasonable detail the occurrence of the event or circumstance for which the Executive believes the Executive may resign for Good Reason within fifteen (15) days of the first occurrence thereof and the Company shall not have cured such event or circumstance within thirty (30) days after the receipt of such notice.

“**Disability**” means the Executive is unable to perform the Executive’s duties as an employee of the Company for a period of four (4) consecutive months in any twelve-month period as a result of illness (mental or physical) or an accident.

“**Severance**” means a lump sum payment equal to six (6) months of Base Salary (at the rate in effect on the date of termination) plus (ii) an additional one (1) month’s payment of Base Salary for each full year served by the Executive following the Effective Time.

(e) Effects of Termination.

(i) Termination Without Severance. If the Executive’s employment is terminated during the term of this Agreement because of the Executive’s death or Disability, or if the Company terminates the employment of the Executive with Cause, then the Company shall have no further obligation to provide the Executive with notice or to make any payments or provide any benefits (except for the continuation of benefits as and to the extent required by law under the Consolidated Budget Reconciliation Act (“**COBRA**”), or applicable state equivalent laws, or the Employee Retirement Income Security Act of 1974, as amended (“**ERISA**”)) to the Executive hereunder after the date of termination, except for payments of Base Salary and properly documented expense reimbursement that had accrued but had not been paid prior to the date of such termination, and payments for any accrued but unused vacation time.

(ii) Termination With Severance. If the Executive's employment is terminated by the Company without Cause (other than as a result of the death or Disability of the Executive), the termination is a Change of Control Termination, or the termination is by the Executive for Good Reason, the Executive shall be entitled to payments of Base Salary and properly documented expense reimbursement that had accrued but had not been paid prior to the date of such termination, payments for any accrued but unused vacation time, and payments of the Severance.

(f) Conditions and Limitations to Severance. Notwithstanding the foregoing, the obligation of the Company to make Severance payments to the Executive shall be subject to the following provisions and conditions:

(i) Release of Claims. If the Executive is entitled to Severance under this Agreement, the obligation of the Company to pay Severance shall be contingent upon the Executive signing a general release of claims in the form attached hereto as Exhibit B.

(ii) Consequences of Breach. If the Executive breaches the Executive's obligations under Sections 6, 7, or 23 of this Agreement, the Company may immediately cease payments of Severance and may recover all Severance paid to the Executive after the date of such breach, subject to any statutory obligations which the Company has in respect of the payment of statutory notice and severance. The cessation and recovery of these payments shall be in addition to, and not as an alternative to, any other remedies at law or in equity available to the Company, including without limitation the right to seek specific performance or an injunction.

(g) Survival. The provisions of Sections 6 through 23 of this Agreement shall survive the term of this Agreement and the termination of the Executive's employment with the Company and shall continue thereafter in full force and effect in accordance with their terms.

11. Enforceability, etc. This Agreement shall be interpreted in such a manner as to be effective and valid under applicable law, but if any provision hereof shall be prohibited or invalid under any such law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating or nullifying the remainder of such provision or any other provisions of this Agreement. If any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, such provisions shall be construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by applicable law.

12. Notices. Any notice, demand or other communication given pursuant to this Agreement shall be in writing and shall be personally delivered, sent by nationally recognized overnight courier or express mail, or mailed by first class certified or registered mail, postage prepaid, return receipt requested as follows:

(a) If to the Executive:

NAME
ADDRESS

(b) If to the Company:

Variation Biotechnologies (US), Inc.
222 Third Street, Suite 2241
Cambridge, MA 02142
Attention: Chief Financial Officer

or at such other address as may have been furnished by such person in writing to the other party.

13. Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Massachusetts, without regard to their conflict-of-law provisions.

14. Amendments and Waivers. This Agreement may be amended or modified only by a written instrument signed by the Company and the Executive. No waiver of this Agreement or any provision hereof shall be binding upon the party against whom enforcement of such waiver is sought unless it is made in writing and signed by or on behalf of such party. The waiver of a breach of any provision of this Agreement shall not be construed as a waiver or a continuing waiver of the same or any subsequent breach of any provision of this Agreement. No delay or omission in exercising any right under this Agreement shall operate as a waiver of that or any other right.

15. Binding Effect; Assignment. This Agreement shall be binding on and inure to the benefit of the Executive and the Executive's heirs, executors and administrators, and on the Company and its successors and assigns. The rights and obligations of the Executive hereunder are personal and may not be assigned without the prior written consent of the Company.

16. Entire Agreement. This Agreement constitutes the final and entire agreement of the parties with respect to the matters covered hereby and replaces and supersedes all other agreements and understandings relating hereto and to the Executive's employment.

17. Counterparts. This Agreement may be executed in two counterparts, including counterpart signature pages or counterpart facsimile signature pages, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

18. No Conflicting Agreements. The Executive represents and warrants to the Company that the Executive is not a party to or bound by any confidentiality, non-competition, non-solicitation, employment, consulting or other agreement or restriction which could conflict with, or be violated by, the performance of the Executive's duties to the Company or obligations under this Agreement.

19. Captions. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

20. No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises under any provision of this Agreement, this Agreement shall be construed as if drafted jointly by the parties thereto, and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of authoring any of the provisions of this Agreement.

21. Notification of New Employer. For or a period of up to one year after Executive's termination, the Executive consents to notification by the Company to the Executive's new employer or its agents regarding the Executive's rights and obligations under this Agreement.

22. Key Man Insurance. The Executive acknowledges that the Company may wish to purchase insurance on the life of the Executive, the proceeds of which would be payable to the Company or an affiliate of same. The Executive hereby consents to such insurance and agrees to submit to any medical examination and release of medical records required to obtain such insurance.

23. Cooperation. The Executive agrees to cooperate fully with the Company in the defense or prosecution of any threatened or actual claims, actions, arbitrations, audits, hearings, investigations, litigations or suits (whether civil, criminal, administrative, judicial or investigative, whether formal or informal, whether public or private) commenced, brought, conducted or heard by or before, or otherwise involving, any governmental body or self-regulatory organization ("**Proceedings**") which may be brought against or on behalf of the Company which relate to events that occurred or allegedly occurred during his employment with the Company. The Executive's full cooperation in connection with such claims or actions shall include, without implication or limitation, being available to meet with counsel for the Company to prepare for discovery or trial and to testify truthfully as a witness when reasonably requested by the Company at reasonable times designated by the Company. The Company agrees to reimburse the Executive for any reasonable out-of-pocket expenses that he incurs in connection with cooperation pursuant to this section, subject to the presentation of reasonable documentation.

[Remainder of Page Intentionally Omitted]

This Agreement has been executed and delivered as of the date first above written.

COMPANY:

VBI Vaccines Inc.

By

Title: Chief Executive Officer

EXECUTIVE:

NAME:

[SIGNATURE PAGE TO EMPLOYMENT AGREEMENT]

EXHIBIT A

PRIOR INVENTIONS

EXHIBIT B

FORM OF GENERAL RELEASE

In consideration of the severance benefits (the "**Severance**") offered to me by VBI Vaccines Inc., a Delaware corporation (the "Company"), pursuant to my Employment Agreement with the Company dated DATE ("**Employment Agreement**") and in connection with the termination of my employment, I agree to the following general release (the "**Release**").

1. On behalf of myself, my heirs, executors, administrators, successors, and assigns, I hereby fully and forever generally release and discharge the Company, its current, former and future parents, subsidiaries, affiliated companies, related entities, employee benefit plans, and their fiduciaries, predecessors, successors, officers, directors, shareholders, agents, employees and assigns (collectively, the "**Company**") from any and all claims, causes of action, and liabilities up through the date of my execution of the Release. The claims subject to this release include, but are not limited to, those relating to my employment with the Company and/or any predecessor to the Company and the termination of such employment. All such claims (including related attorneys' fees and costs) are barred without regard to whether those claims are based on any alleged breach of a duty arising in statute, contract, or tort. This expressly includes waiver and release of any rights and claims arising under any and all laws, rules, regulations, and ordinances, including, but not limited to: Title VII of the Civil Rights Act of 1964; the Older Workers Benefit Protection Act; the Americans With Disabilities Act; the Age Discrimination in Employment Act; the Fair Labor Standards Act; the National Labor Relations Act; the Family and Medical Leave Act; the Employee Retirement Income Security Act of 1974, as amended ("**ERISA**"); the Workers Adjustment and Retraining Notification Act; the Equal Pay Act of 1963; and any similar laws of the state of Washington and/or any other state or governmental entity. The parties agree to apply Washington law in interpreting the Release. This Release does not extend to, and has no effect upon, any benefits that have accrued, and to which I have become vested, under any employee benefit plan within the meaning of ERISA sponsored by the Company.

2. In understanding the terms of the Release and my rights, I have been advised to consult with an attorney of my choice prior to executing the Release. I understand that nothing in the Release shall prohibit me from exercising legal rights that are, as a matter of law, not subject to waiver such as: (a) my rights under applicable workers' compensation laws; (b) my right, if any, to seek unemployment benefits; (c) my right to file a charge or complaint with a government agency such as but not limited to the Equal Employment Opportunity Commission, the National Labor Relations Board, or any applicable state agency. To the fullest extent permitted by law, any dispute regarding the scope of this general release shall be resolved through binding arbitration pursuant to Section 9 below, and the arbitration provision set forth in my Employment Agreement.

3. I understand and agree that the Company will not provide me with the Severance set forth in my Employment Agreement unless I execute the Release. I also understand that I have received or will receive, regardless of the execution of the Release, all wages owed to me together with any accrued but unused vacation pay, less applicable withholdings and deductions, earned through my termination date.

4. As part of my existing and continuing obligations to the Company, I have returned to the Company all the Company documents (and all copies thereof) and other the Company property that I have had in my possession at any time, including but not limited to the Company files, notes, drawings, records, business plans and forecasts, financial information, specification, computer-recorded information, tangible property (including, but not limited to, computers, laptops, pagers, etc.), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions thereof).

I understand that, even if I did not sign the Release, I am still bound by the Company's Proprietary Information, Invention, Assignment and Noncompete Agreement signed by me in connection with my employment with the Company, pursuant to the terms of such agreement.

5. I represent and warrant that I am the sole owner of all claims relating to my employment with the Company and/or with any predecessor of the Company, and that I have not assigned or transferred any claims relating to my employment to any other person or entity.

6. I agree to keep the Severance set forth in my Employment Agreement and the provisions of the Release confidential and not to reveal its contents to anyone except my lawyer, my spouse or other immediate family member, and/or my financial consultant, or as required by legal process or applicable law.

7. I understand and agree that the Release shall not be construed at any time as an admission of liability or wrongdoing by either the Company or me.

8. Any controversy or any claim arising out of or relating to the interpretation, enforceability or breach of the Release shall be settled by arbitration in accordance with the arbitration provision set forth in my Employment Agreement. If for any reason this arbitration provision is not enforceable, I agree to arbitration under the employment arbitration rules of the American Arbitration Association or any successor hereto. The parties further agree that the arbitrator shall not be empowered to add to, subtract from, or modify, alter or amend the terms of the Release. Any applicable arbitration rules or policies shall be interpreted in a manner so as to ensure their enforceability under applicable state or federal law.

9. I agree that I have had at least twenty-one (21) calendar days in which to consider whether to execute the Release, no one hurried me into executing the Release during that period, and no one coerced me into executing the Release. I understand that the offer of the Severance and the Release shall expire on the sixtieth (60th) calendar day after my employment termination date if I have not accepted the Release and the Release has not become effective by that time. I further understand that the Company's obligations under the Release shall not become effective or enforceable until the eighth (8th) calendar day after the date I sign the Release provided that I have timely delivered it to the Company (the "**Effective Date**") and that in the seven (7) day period following the date I deliver a signed copy of the Release to the Company I understand that I may revoke my acceptance of the Release. I understand that the Severance will become available to me only if the Release becomes effective, on the sixty-first (61st) calendar day after my termination date.

10. In executing the Release, I acknowledge that I have not relied upon any statement made by the Company, or any of its representatives or employees, with regard to the Release unless the representation is specifically included herein. Furthermore, the Release contains our entire understanding regarding eligibility for and the payment of severance benefits and supersedes any or all prior representation and agreement regarding the subject matter of the Release. Once effective and enforceable, this agreement can only be changed by another written agreement signed by me and an authorized representative of the Company.

11. Should any provision of the Release be determined by an arbitrator, court of competent jurisdiction, or government agency to be wholly or partially invalid or unenforceable, the legality, validity and enforceability of the remaining parts, terms, or provisions are intended to remain in full force and effect. Specifically, should a court, arbitrator, or agency conclude that a particular claim may not be released as a matter of law, it is the intention of the parties that the general release and the waiver of unknown claims above shall otherwise remain effective to release any and all other claims.

I acknowledge that I have obtained sufficient information to intelligently exercise my own judgment regarding the terms of the Release before executing the Release.

[Signature Page to General Release Agreement Follows]

EMPLOYEE'S ACCEPTANCE OF RELEASE

BEFORE SIGNING MY NAME TO THE RELEASE, I STATE THE FOLLOWING: I HAVE READ THE RELEASE, I UNDERSTAND IT AND I KNOW THAT I AM GIVING UP IMPORTANT RIGHTS. I HAVE OBTAINED SUFFICIENT INFORMATION TO INTELLIGENTLY EXERCISE MY OWN JUDGMENT. I HAVE BEEN ADVISED THAT I SHOULD CONSULT WITH AN ATTORNEY BEFORE SIGNING IT, AND I HAVE SIGNED THE RELEASE KNOWINGLY AND VOLUNTARILY.

Date delivered to employee _____, _____.

Executed this _____ day of _____, _____.

Employee Signature

Employee Name (Please Print)

[SIGNATURE PAGE TO GENERAL RELEASE AGREEMENT]

AMENDMENT TO CONSULTING AGREEMENT

This Amendment to Consulting Agreement (the “**Amendment**”), effective as of January, 1st, 2018 (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 (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, 2018 (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\$42,257.00 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 Parties and their respective successors and assigns.

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

(Signature page follows.)

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed by their respective authorized officers on February 19, 2018 to take effect 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 23, 2018 – CAD \$108,697.30.
 2. The Company shall cause VBI Vaccines Inc., a British Columbia corporation (the “**Parent**”) to grant to Francisco Diaz-Mitoma, as designee of Consultant, 100,000 stock options (the “**Options**”), each Option exercisable for one common share of Parent, to be granted effective as of January 23, 2018, 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.
-

**Agreement to Extend the Lease of an Unprotected Leased Premises of
January 16, 2017**

Which was written and signed on January 21st, 2018

By and between: Green Power Ye. Ym Ltd. Co. no. 514876952
13 Gad Feinstein St, Rehovot
(hereinafter the “**Company**”)

Of the first part:

And: SciVac Ltd. Co. no. 513679555
13 Gad Feinstein St. Rehovot
P.O. Box 580 7610303
(hereinafter the “**Tenant**”)

Of the second part:

Whereas: On November 5th, 2013 Ayalot Investments (Ramat Vered) 1994 Ltd. and Sharda Ltd. (hereinafter collectively referred to as the “**Original Lessor**”) signed a Main Lease Agreement including all appendixes thereof with the Company with respect to the leased premises (the Main Lease Agreement including all appendixes thereof shall be referred to hereinafter as the “**Main Lease Agreement**”);

And whereas: A Sub- Lease Agreement including all appendixes thereof was signed between the Company and the Tenant (hereinafter the lease agreement and all of its appendixes shall be hereafter referred to as the “**Sub- Lease Agreement**”) with respect to the leased premises, from January 16th, 2017 till January 22nd, 2018 for a period of twelve (12) months (hereinafter the “**Original Sub- Lease Period**”);

And whereas: It was agreed by and between the parties that the Tenant will be given an Option to extend the sub- lease period for an additional period of twelve (12) additional months, under the same terms and conditions as were agreed upon in the original sub- lease period (hereinafter the “**Option**”);

And whereas: The Tenant wishes to exercise the Option granted to him and the Company agrees to this, all in accordance with the terms set forth in the Sub- Lease Agreement and subject to the changes set forth in this agreement hereafter;

Therefore it is agreed, declared and stipulated by and between the parties as follows:

1. The preamble of this addendum and its appendixes thereof constitute an integral part hereof.
2. The terms used in this addendum shall have the meaning assigned to in the original Sub- Lease Agreement.
3. The provisions in this addendum amends and changes the Sub- Lease Agreement only in sections and/or provisions that shall be amended and/or added in this addendum. The sections that will be amended and/or added will prevail over the provisions in the Sub- Lease Agreement. The other terms of the Sub- Lease Agreement will apply in full, without any change to the lease of the leased premises.
4. It is hereby agreed that the lease term in the leased premises will be extended for an additional period of twelve (12) additional months which will begin on the 23rd of January 2018 and it will end on the 22nd of January 2019 (hereinafter the “**Additional Lease Period**” or the “**Option Exercise Period**”), in accordance with the Option in the Sub- Lease Agreement.
5. The rent will include all current payments that are required by virtue of the Main Lease Agreement and the Sub- Lease Agreement including however not limited to, the management fees, municipal taxes, water and electricity, that will be in the amount of twenty- five thousand NIS (25,000) per month in addition to VAT (hereinafter the “**Rent**”). Notwithstanding the aforesaid, in a month in which the consumption of electricity in the leased premises is greater than one thousand five hundred NIS (1,500) the Tenant shall pay the Company the difference.
6. Upon signing this agreement the Tenant will deliver to the Company four (4) checks each in the amount of seventy five thousand NIS (75,000) in addition to VAT.
7. It is agreed by and between the parties that in the event of a delay in payment of the rent to the Company, provided that written notice was given to the Company, twenty- one (21) days in advance, during which the debt was not paid, the Tenant will pay to the Company liquidated damages in the amount of ten thousand NIS (10,000). This compensation will not derogate from any other remedy to which the Company will be entitled for this delay.
8. Except for the modifications specified above, the entire provisions set forth in the Sub- Lease Agreement shall apply, *mutatis mutandis*, and this addendum shall be deemed as part of the Sub-Lease Agreement for all intents and purposes with respect to the Additional Lease Period.

And in witness hereof the parties are hereby undersigned:

Avi Mazaltov General Manager
Scivac Ltd.
/s/ Avi Mazaltov

The Tenant

Green Power Ye. Ym Ltd.
Co. no.514876952
/s/ Green Power Ye. Ym Ltd.

The Company

WAIVER AGREEMENT

THIS WAIVER AGREEMENT (this “Agreement”), dated as of February 21, 2018, 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 amended from time to time (the “Credit Agreement”), pursuant to which the Lender has made certain loans and financial accommodations available to 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, 2017 (the “2017 Audited Financial Statements”), has informed Parent and the Borrower that its audit opinion letter with respect to such audit will contain an Impermissible Qualification;

WHEREAS, a true and correct copy of the Auditor’s draft audit opinion for the 2017 Audited Financial Statements containing the Impermissible Qualification is attached hereto as Annex A (the “Proposed Audit Opinion”);

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 2017 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 2017 Audited Financial Statements are delivered to the Lender on a timely basis as required pursuant to Section 7.1(c) of the Credit Agreement, (ii) the Proposed Audit Opinion, in substantially the form as attached as Annex A, is delivered along with the 2017 Audited Financial Statements (without any material change or modification thereto) and (iii) at the time of delivery of such 2017 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 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.** 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.

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 WITNESS WHEREOFF, THE PARTIES HAVE ENTERED 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.,

as Guarantor

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, 2017 and 2016, 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, 2017 and 2016, 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 consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated 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 consolidated 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.

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%

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 (No. 333-217995) and Form S-8 (No. 333-212160) of our report dated February 26, 2018 on our audits of the consolidated financial statements as of December 31, 2017 and 2016 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 26, 2018. 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 26, 2018

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement of VBI Vaccines, Inc. and subsidiaries on Form S-3 (No. 333-217995) of our report dated March 20, 2017, on our audit of the consolidated financial statements as of December 31, 2015 and for the year then ended, which report is included in this Annual Report on Form 10-K to be filed on or about February 23, 2018.

/s/ Smythe LLP

Chartered Professional Accountants

Vancouver, Canada

February 26, 2018

CERTIFICATION

I, Jeff Baxter, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2017 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 26, 2018

/s/ Jeff Baxter

Jeff Baxter
Chief Executive Officer (Principal Executive Officer)

CERTIFICATION

I, Athena Kartsaklis, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2017 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 26, 2018

/s/ Athena Kartsaklis

Athena Kartsaklis

Senior Vice-President, Finance

(Principal Financial and Accounting Officer)

CERTIFICATION

In connection with the annual report of VBI Vaccines Inc. (the "Company") on Form 10-K for the year ended December 31, 2017 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 26, 2018

/s/ Jeff Baxter

Jeff Baxter

Chief Executive Officer (Principal Executive Officer)

CERTIFICATION

In connection with the annual report of VBI Vaccines Inc. (the "Company") on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission (the "Report"), I, Athena Kartsaklis, Senior Vice-President, Finance (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 26, 2018

/s/ Athena Kartsaklis

Athena Kartsaklis

Senior Vice-President, Finance

(Principal Financial and Accounting Officer)
