

**Management's Report on Financial Position and Operating Results** 

For the year ended December 31, 2016

## LETTER TO SHAREHOLDERS

Dear Fellow Shareholder,

Here at Immunovaccine, we are committed to building a company that can deliver value for our shareholders, patients and communities. We work with a sense of purpose, using the best science and management practices to create market opportunities designed to address urgent unmet medical needs in cancer and other diseases. 2016 has been transformative for Immunovaccine. We successfully leveraged the competitive advantage provided by our proprietary products and DepoVax<sup>TM</sup> technology to advance multiple phase 1/2 clinical programs with key partners. In our view, we are now emerging as one of the major forces among clinical stage companies seeking to develop combination immunotherapies. Consider:

- Our DepoVax<sup>™</sup> technology has yielded three novel and proprietary clinical stage disease product candidates: DPX-Survivac, DPX-RSV, and DPX-E7;
- We continue to expand our work with world-class collaborators, which currently include Merck, Incyte Corporation, the Dana Farber Cancer Institute, Leidos and UConn Health; and
- Our leadership team has attracted several industry veterans with the necessary experience to support our advancing clinical programs as well as our anticipated commercialization opportunities.

# Immuno-Oncology Is Our Internal Focus

During 2016, our immuno-oncology program focused on developing our lead product candidate, DPX-Survivac, for ovarian cancer. This strategic emphasis aligns with our core strengths for several key reasons:

- There is a strong market opportunity as this disease is a severely unmet medical need, in which current treatment options are associated with poor outcomes for patients;
- Research has shown that ovarian cancer can be positively impacted by the activation of T cells the hallmark of our DPX-Survivac mechanism of action (MOA); and
- Combination therapies are emerging as a means to address the complexities of this disease, and we believe that DPX-Survivac is uniquely positioned to be the enabling agent of choice. It has a novel, clinically demonstrated ability to generate relevant, sustained immune responses.

With this strategy in place, we initiated our Phase 1b trial with Incyte Corporation in 2016, which we believe to be the first triple combination immunotherapy in development for ovarian cancer. We announced early data from this trial in Q12017, in which we saw the first clinical demonstration of DPX-Survivac's potential to increase T-cell activity in actively progressing tumors. This finding provides another component of our clinical arsenal, as research has consistently shown that this mechanism of action is integral to improving tumor response rates, particularly among tumors that are unlikely to respond to monotherapies alone.

We also announced additional topline data from our Phase 1/1b trial evaluating DPX-Survivac in ovarian cancer. These findings provided new insights that will inform future trials – including an optimal dosing schedule and the potential for DPX-Survivac to evoke T-cell responses. We believe that the DPX-Survivac clinical findings position it as an ideal component of future combination therapies.

In addition, the European Medicines Agency (EMA) granted Orphan Drug Designation (ODD) status to DPX-Survivac for the treatment of ovarian cancer in the European Union (EU). Following receipt of ODD status, we have access to incentives that include protocol assistance, market exclusivity for a ten-year period following approval, and potential fee reductions.

We also presented research critical to our collaboration strategy at the 2016 American Association for Cancer Research (AACR) Annual Meeting, showing enhanced activity of anti-PD-1 agents when combined with DPX-

based agents. This combination also showed anti-cancer activity for tumors previously unresponsive to checkpoint inhibitor therapies. These data are another tool in our arsenal to pursue additional collaborations with DepoVax<sup>TM</sup>-based anti-cancer combinations. So far, in early 2017, we have already announced plans for one investigator-sponsored Phase 2 trial in ovarian cancer that will evaluate DPX-Survivac and low-dose cyclophosphamide in combination with Merck's approved anti-PD-1 drug, pembrolizumab. We plan to pursue additional opportunities throughout 2017.

Finally, with an eye to the future of our immuno-oncology pipeline, we initiated our DPX-NEO program, partnering initially with UConn Health. Our proof-of-concept preclinical study indicated that neoepitopes formulated with the DepoVax<sup>TM</sup> platform show enhanced anti-cancer activity. Researchers are currently preparing a manuscript for submission to a peer-reviewed journal to discuss the future implications of this study.

# Applying DepoVax<sup>TM</sup>-Based Vaccines to Other Serious Diseases

We have operated under the premise that DepoVax<sup>TM</sup>-based vaccines have applications in multiple disease areas, and our DPX-RSV program is a convincing proof-of-concept indicator that underscores this potential. While others in our industry have struggled with setbacks in clinical programs for respiratory syncytial virus (RSV), our vaccine candidate, DPX-RSV, generated positive topline clinical data from our Phase 1 study this year. The findings demonstrated a positive safety profile and robust immunogenicity, with antigen-specific immune responses six months or more after the last vaccination in over 90% of participants. We are completing additional analyses to further demonstrate the mechanism of action of our unique RSV vaccine target.

Other work in infectious disease has included anti-malarial programs via collaborations with Leidos and the University of Edinburgh – the latter of which presented pre-clinical research at the World Vaccine Congress. This study showed the potential of a DepoVax<sup>TM</sup>-based vaccine to impede the form of the infection most likely to cause patient deaths. We also have an ongoing preclinical program in collaboration with Leidos researching DepoVax<sup>TM</sup>-based vaccines in the Zika virus.

#### **Bolstering Our Corporate Infrastructure**

As our clinical program has grown, so too has the leadership of the Corporation. I was honored to be appointed CEO in April 2016. Since then, we have welcomed Gabriela Rosu, M.D. from Janssen Inc. as our first Chief Medical Officer (CMO). Her experience and leadership are instrumental as we refine the strategy for our expanding clinical program. We recently welcomed Pierre Labbé for the role of Chief Financial Officer (CFO). I am looking forward to leveraging his depth of expertise in expanded financing and business development activities throughout 2017 and beyond. Finally, Andy Sheldon became Chairman of our Board of Directors after our last annual shareholders meeting. His broad experience in commercialization in the pharmaceutical/biotechnology industry and the public markets will serve us well as we move forward.

Additionally, two \$8M CAN financings in 2016 were instrumental in extending the runway of our clinical and research activities, providing tangible recognition of our recent achievements and long-term potential. One of the largest mutual fund and financial group in the world, Fidelity, along with CTI Life Sciences Fund and long-standing IMV supporter Ruffer LLP, participated in these deals. They have strengthened our investor base, further supporting, in our view, our growth and value creation.

Immunovaccine has evolved significantly since the Corporation's inception. To honor this progress, and recognize the new strategic focus and reinvigorated spirit of our investors, employees, and collaborators, we embarked on a new creative campaign to update the Corporation's logo and corporate brand. We believe our new look is fresh, modern and impactful, and it connotes the energy that our team and supporters bring to our work every day.

In closing, in 2016, we have seen that our core technology, fundamental science, and clinical strategy are strong, and the right people are in place to drive value from them. The nature of the organizations partnering with us, and the clinical results we have seen thus far from our vaccine candidates, lend, in our mind, credibility to the inherent value of our DepoVax<sup>TM</sup>-based approach.

Our financial situation has improved as our company marches toward late-stage clinical development, with commercialization on the horizon. We plan to expand our investor base in 2017 to further reinforce our financial strength, out-license our technology where it's optimally positioned to drive revenue, and increase the breadth and depth of our industry collaborations.

In evolving from a DepoVax<sup>TM</sup>-focused biotechnology corporation into a drug developer with multiple clinical candidates, we have made continued progress in our mission to make immunotherapies more effective, more broadly applicable, and more widely available to people facing cancer and other serious diseases.

Thank you for your ongoing support. We are looking forward to another remarkable year at Immunovaccine in 2017.

Frederic Ors Chief Executive Officer

# MANAGEMENT DISCUSSION AND ANALYSIS ("MD&A")

The following analysis provides a review of the audited annual consolidated results of operations, financial condition and cash flows for the year ended December 31, 2016 ("Fiscal 2016"), with information compared to the year ended December 31, 2015 ("Fiscal 2015"), for Immunovaccine Inc. ("Immunovaccine", "IMV" or the "Corporation"). This analysis should also be read in conjunction with the information contained in the audited consolidated financial statements and related notes for the years ended December 31, 2016 and December 31, 2015.

The Corporation prepares its audited consolidated financial statements in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

Additional information regarding the business of the Corporation, including the Annual Information Form of the Corporation for the year ended December 31, 2016 (the "AIF"), is available on SEDAR at www.sedar.com.

Amounts presented in this MD&A are approximate and have been rounded to the nearest thousand except for per share data. Unless specified otherwise, all amounts are presented in Canadian dollars.

Statistical information and other data relating to the pharmaceutical and biotechnology industry included in this MD&A are derived from recognized industry reports published by industry analysts, industry associations and/or independent consulting and data compilation organizations. Market data and industry forecasts used throughout this MD&A were obtained from various publicly available sources. Although the Corporation believes that these independent sources are generally reliable, the accuracy and completeness of the information from such sources are not guaranteed and have not been independently verified.

# FORWARD-LOOKING STATEMENTS

Certain statements in this MD&A may constitute "forward-looking" statements which involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Corporation, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. When used in this MD&A, such statements use such words as "will", "may", "could", "intends", "potential", "plans", "believes", "expects", "projects", "estimates", "anticipates", "continue", "potential", "predicts" or "should" and other similar terminology. These statements reflect current expectations regarding future events and operating performance and speak only as of the date of this MD&A. Forward looking statements include, among others:

- the Corporation's business strategy;
- statements with respect to the sufficiency of the Corporation's financial resources to support its activities;
- potential sources of funding;
- the Corporation's ability to obtain necessary funding on favorable terms or at all;
- the Corporation's expected expenditures and accumulated deficit level;
- the Corporation's expected outcomes from its ongoing and future research and research collaborations;
- the Corporation's exploration of opportunities to maximize shareholder value as part of the ordinary course of its business through collaborations, strategic partnerships and other transactions with third parties;
- the Corporation's plans for the research and development of certain product candidates;
- the Corporation's strategy for protecting its intellectual property;
- the Corporation's ability to identify licensable products or research suitable for licensing and commercialization;
- the Corporation's ability to obtain licences on commercially reasonable terms;
- the Corporation's plans for generating revenue;
- the Corporation's plans for future clinical trials; and
- the Corporation's hiring and retention of skilled staff.

Forward-looking statements involve significant risks and uncertainties, should not be read as guarantees of future performance or results, and will not necessarily be accurate indications of whether or not such results will be achieved. A number of factors could cause actual results to differ materially from the results discussed in the forward-looking statements, including, but not limited to, the factors discussed in the AIF, under the heading "Risk Factors and Uncertainties". Although the forward-looking statements contained in this MD&A are based upon what management of the Corporation believes are reasonable assumptions, the Corporation cannot provide any assurance to investors that actual results will be consistent with these forward-looking statements and should not be unduly relied upon by investors.

Actual results and developments are likely to differ, and may differ materially, from those expressed or implied by the forward-looking statements contained in this MD&A. Such statements are based on a number of assumptions which may prove to be incorrect, including, but not limited to, assumptions about:

- obtaining additional funding on reasonable terms when necessary;
- positive results of pre-clinical and clinical tests;
- the Corporation's ability to successfully develop existing and new products;
- the Corporation's ability to hire and retain skilled staff;
- the products and technology offered by the Corporation's competitors;
- general business and economic conditions;
- the Corporation's ability to protect its intellectual property;
- the Corporation's ability to manufacture its products and to meet demand; and
- regulatory approvals.

These statements reflect management's current beliefs and are based on information currently available to management. The information contained herein is dated as of March 30, 2017; the date of the Board's approval of the MD&A and the Fiscal 2016 audited annual consolidated financial statements. A more detailed assessment of the risks that could cause actual results to materially differ from current expectations is contained in the section entitled "Risk Assessment" of this MD&A.

#### **CORPORATE OVERVIEW**

Immunovaccine is a clinical-stage biopharmaceutical company that develops products based on its proprietary vaccine enhancement platform with a primary focus on T cell activating therapies for cancer. The Corporation also capitalizes on licensing opportunities of its platform for other applications, including infectious diseases. The Corporation's proprietary DepoVax<sup>TM</sup> delivery platform is believed to produce a strong, high-quality immune response that has a specific and sustained immune effect and enables the Corporation to pursue vaccine candidates in cancer, infectious diseases and other applications.

The DepoVax<sup>TM</sup> platform is being used in multiple vaccine candidates, including a cancer immunotherapy candidate that is in the process of completing Phase 1/1b clinical trials. The Corporation's cancer immunotherapy, DPX-Survivac, is currently being tested in a co-funded Phase 1b trial with Incyte Corporation ("Incyte"), which will evaluate the combination of DPX-Survivac with Incyte's investigational oral indoleamine 2,3-dioxygenase 1 ("IDO1") inhibitor, epacadostat, in ovarian cancer patients. DPX-Survivac is also being tested in a company-sponsored Phase 2 trial in lymphoma and in an investigator-sponsored Phase 2 clinical trial in ovarian cancer in combination with Merck's checkpoint inhibitor Pembrolizumab in patients with recurrent, platinum-resistant ovarian cancer. The Corporation's infectious disease vaccine against respiratory syncytial virus ("RSV") is completing a Phase 1 clinical trial in Halifax, Nova Scotia. The Corporation is also conducting several research and clinical collaborations, including ones with the Dana Farber Cancer Institute for the Human Papillomavirus ("HPV") and Leidos, Inc. ("Leidos") in the United States for the development of vaccine candidates for malaria and the Zika virus.

The common shares of the Corporation are currently listed on the Toronto Stock Exchange under the symbol "IMV" and trade on the OTCQX under the symbol "IMMVF".

Based in Halifax, Nova Scotia, the Corporation had 26 full-time and part-time employees and two part-time consultants as of December 31, 2016. Being involved in a scientific and technical business, the Corporation requires

staff with significant education, training and scientific knowledge that cannot be recruited or replaced easily. As a result, the Corporation recruits talented expertise locally, nationally and internationally. The business of the Corporation requires personnel with specialized skills and knowledge in the fields of basic and applied immunology, chemistry, formulation research and analytical chemistry method development. The Corporation employs trained scientists with broad experience in these fields including six employees holding PhD degrees, including one MD, and a number of other employees holding MSc or MBA degrees. In addition to the core team, the Corporation has also assembled a Scientific Advisory Board ("SAB") of experienced and internationally recognized scientific advisors to assist management in dealing with industry-related issues and how these issues may affect the Corporation's scientific research and product development.

## **BUSINESS STRATEGY**

## **Operating Strategy**

Immunovaccine is a clinical-stage immuno-oncology company dedicated to making immunotherapy more effective, more broadly applicable and more widely available to people facing cancer. The Corporation's lead product, DPX-Survivac has demonstrated the ability to induce robust immune responses with the potential of tumor shrinkage in advanced ovarian cancer and is currently being used in clinical trials in combination with Checkpoint inhibitors from the Corporation's collaborators, Incyte and Merck. The target of this T cell stimulating therapeutic cancer vaccine is broadly applicable to many different cancers. The novel mechanism of action of the underlying delivery platform, DepoVax<sup>TM</sup>, is to promote uptake and extend exposure of antigens and adjuvants to cells of the immune system, which enhances and sustains immune responses. This allows Immunovaccine to leverage this technology to become a preferred partner in combination trials in hard to treat cancers, and to explore additional immune-oncology targets, such as infectious disease vaccines, where the Corporation has demonstrated safety and immunogenicity with a novel proprietary vaccine to prevent RSV infections. The Corporation is currently collaborating with partners such as Incyte, Merck, Leidos and the Dana Farber Cancer Institute to explore novel applications for the DepoVax<sup>TM</sup> platform.

The Corporation has a clinical-stage cancer immunotherapy, DPX-Survivac. Immunovaccine believes the principles behind a successful cancer immunotherapy should include a targeted antigen and an effective adjuvanting and vaccine delivery technology, combined with a complementary therapeutic strategy. Antigens used in DPX-Survivac are believed to specifically target tumor cells without harming normal, healthy cells. These antigens are combined with the Corporation's DepoVax<sup>TM</sup> platform in an effort to optimize the presentation of these antigens to the immune system, resulting in an enhanced immune response. To be successful against cancer, the Corporation believes the vaccine must be administered in the right therapeutic setting, which includes a combination of therapies that help target various aspects of cancer. Immunovaccine also believes that the effect of the vaccine may be enhanced if an immune modulator is used simultaneously to prevent a patient's immune system from overriding the positive response to the vaccine. The Corporation's goal in immuno-oncology is to advance its proprietary vaccines in combination trials with pharmaceutical and large biotechnology companies to establish strategic partnerships and support further development and commercialization.

In collaboration with commercial and academic partners, the Corporation is also expanding the application of  $DepoVax^{TM}$  as a delivery platform for vaccines targeted against infectious diseases. Pre-clinical studies have indicated that the platform may allow the development of enhanced vaccines for a wide range of infectious diseases by generating a stronger and more durable immune response more quickly than is possible with existing delivery methods. For vaccine targets that are poorly immunogenic, the platform may significantly reduce the number of immunizations required. The Corporation's goal in infectious diseases is to out-license the DepoVax<sup>TM</sup> platform to selected partners. The Corporation is also exploring new applications of the DepoVax<sup>TM</sup> platform on its own and with partners.

#### Financing and Partnering Strategy

Immunovaccine relies on equity financing and non-dilutive private and public partnerships to fund its development programs. Applying this strategy, the Corporation has obtained more than \$15 million in government funding, including interest-free loans and government grants, from both the Province of Nova Scotia and from the Federal

government through the Atlantic Canada Opportunities Agency ("ACOA"). The Corporation has raised more than \$64 million in equity through prospectus offerings, private placement offerings and the exercise of stock options and warrants. Most recently, the Corporation completed two private placement offerings for an aggregate of approximately \$16 million in 2016.

In addition to using its own resources to develop its products through clinical trials, the Corporation is also involved in various collaborations and licensing deals to accelerate the development of its DepoVax<sup>TM</sup> platform and immunooncology products. The Corporation is conducting a collaboration with Incyte, to evaluate the combination of the Corporation's lead cancer immunotherapy, DPX-Survivac, with their IDO1 inhibitor epacadostat in a co-funded Phase 1b clinical trial in ovarian cancer patients. Results from this study may lead to an expansion of the clinical collaboration to investigate other cancers. In February 2017, the Corporation announced an Investigator-Sponsored Phase 2 Clinical Trial in ovarian cancer in combination with Merck's checkpoint inhibitor Pembrolizumab in patients with recurrent, platinum-resistant ovarian cancer. University Health Network's ("UHN's") Princess Margaret Cancer Centre will conduct the Phase 2 non-randomized, open-label trial designed to evaluate the potential anti-tumor activity of the combination of Pembrolizumab, DPX-Survivac, and low-dose cyclophosphamide.

Other programs include: a clinical research collaboration with the Canadian Center for Vaccinology for the Phase 1 clinical trial funded by the Canadian Institutes of Health Research of an RSV vaccine; a collaboration with the Dana Farber Cancer Institute funded by Stand Up 2 Cancer-Farrah Fawcett Foundation for producing a DepoVax<sup>TM</sup>-based vaccine for HPV related cancers; and a collaboration with UConn Health on a pre-clinical study to evaluate the immunologic and anti-tumor activity of patient specific neoepitopes. The underlying goal of these types of partnerships is to produce pre-clinical and clinical data that could lead to licensing agreements, either to allow the use of the Corporation's DepoVax<sup>TM</sup> platform by others or provide access to specific pipeline product candidates.

Immunovaccine is also collaborating with Leidos on the development of a Zika virus vaccine and a malaria vaccine. The Corporation also maintains a commercial relationship with Zoetis, which has licensed the Corporation's delivery technology platform to develop vaccines for livestock. These license agreements include upfront signing fees, milestone payments and royalties from future vaccine sales.

The Corporation intends to be opportunistic in the development of its products by exploring a variety of avenues, including co-development through potential collaborations, strategic partnerships or other transactions with third parties. The Corporation may seek additional equity and non-dilutive funding and partnerships to advance the development of its vaccine product candidates.

# PLATFORM AND PRODUCTS IN DEVELOPMENT

# **DepoVax<sup>TM</sup> Vaccine Enhancement Platform**

The DepoVax<sup>™</sup> platform is a unique and patented formulation providing a new way to present active ingredients to the immune system. It is a combination of antigens, plus adjuvant (immune enhancers) formulated in lipid nanoparticles and, after freeze drying, suspended directly into oil. DepoVax<sup>™</sup> has a novel mechanism of action whereby it promotes uptake and extends exposure of active antigens and adjuvants, which enhances and sustains the body's own immune system responses. The DepoVax<sup>™</sup> platform forms the basis of Immunovaccine's therapeutic cancer and infectious diseases vaccine candidates.

The Corporation believes the ability of DepoVax<sup>TM</sup> to induce robust cellular immune responses makes the platform uniquely suitable for cancer immunotherapies, which are designed to target tumor cells. DepoVax<sup>TM</sup> can induce antigen-specific "poly-functional" cellular responses, which are postulated to be required for effective tumor control.

DepoVax<sup>TM</sup>-formulated vaccines have shown an ability to induce rapid and robust immune responses that may protect against disease agents with as little as one dose. The single-dose capability could be a key factor for developing rapid response vaccines for pandemics and infectious disease outbreaks. The DepoVax<sup>TM</sup> platform can be combined with a variety of antigens, including recombinant proteins, synthetic peptides and nucleic acids, viruses and a wide range of adjuvants, which provides both versatility and flexibility to develop many different vaccine products using a single platform.

This unique formulation provides extended chemical stability. DepoVax<sup>TM</sup>-based products are lyophilized and stored in a dry format, which provides the added benefit of an extended shelf life. The DepoVax<sup>TM</sup> formulation is designed to be easy to re-suspend and administer.

The ongoing clinical studies with DepoVax<sup>™</sup>-based vaccines for the treatment of cancer and for protection from infectious diseases are expected by the Corporation to demonstrate the competitive advantages of this platform.

# DPX-Survivac

## Product Overview

DPX-Survivac uses survivin-based antigens licensed from Merck KGaA, on a world-wide exclusive basis, formulated in DepoVax<sup>TM</sup>. Survivin is a major tumor-associated antigen over-expressed in many cancers, making it a viable target for a broadly applicable immunotherapy. DepoVax<sup>TM</sup> delivers the survivin-based antigens in a lipid depot-based format designed to generate a strong and prolonged immune response.

Survivin is essential for the survival of cancer cells and functions as an inhibitor of cell death, known as apoptosis. The presence of high levels of survivin in cancer cells is believed to make them susceptible to a survivin-targeted vaccine. The Corporation's survivin-based vaccine candidate, DPX-Survivac, aims to train the immune system to recognize and kill survivin-containing cancer cells. This could provide a clinical benefit to patients by delaying cancer progression and/or increasing overall survival. The United States National Cancer Institute has recognized survivin as a promising antigen for cancer treatment based on its specificity, over-expression in cancer cells and immunogenicity potential.

The Corporation believes DPX-Survivac could have broad commercial potential as a cancer immunotherapy because it may be applicable for the treatment of multiple solid tumors and hematological cancers, including ovarian, glioblastoma, breast, pancreatic, multiple myeloma, B-cell lymphoma, and melanoma, among other cancers. The Corporation intends to continue the development of DPX-Survivac in a broader range of cancer indications to evaluate additional opportunities.

# Clinical Trial Development – Current and Planned Trials

In February 2017, the Corporation announced an Investigator-Sponsored Phase 2 Clinical Trial in ovarian cancer in combination with Merck's checkpoint inhibitor Pembrolizumab in patients with recurrent, platinum-resistant ovarian cancer. UHN's Princess Margaret Cancer Centre will conduct the Phase 2 non-randomized, open-label trial designed to evaluate the potential anti-tumor activity of the combination of Pembrolizumab, DPX-Survivac, and low-dose cyclophosphamide. It is expected to enroll 42 subjects with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer. The study's primary objective is to assess overall response rate. Secondary study objectives include progression free survival rate, overall survival rate, and potential side effects, over a five-year period.

In June 2015, the Corporation announced it had entered into a non-exclusive clinical trial collaboration with Incyte to evaluate the combination of Immunovaccine's novel T cell activating immunotherapy, DPX-Survivac, with Incyte's investigational oral IDO1 inhibitor, epacadostat. Immunovaccine and Incyte are co-funding and conducting a multicenter, open-label, Phase 1b study to evaluate the safety, tolerability and efficacy of the novel combination in platinum resistant or sensitive ovarian cancer patients who are at high risk of recurrence. The investigational new drug ("IND") application for the study, which will test the triple combination of DPX-Survivac, epacadostat and low dose oral cyclophosphamide, was approved by the FDA and Health Canada in January 2016. The study was initiated on September 8, 2016 and is anticipated to enroll up to 40 patients. Results from this study may lead to an expansion of the clinical collaboration to investigate other cancers. The Corporation announced in March 2017 the first interim data analysis from this clinical study. The analysis included the results of blood tests, tumor biopsies and CT scans to assess safety, disease progression and T-cell response for the first four evaluable patients in the trial. All patients enrolled in the trial have recurrent ovarian cancer with evidence of progressive disease. Based on the interim analysis, the combination therapy appears to have an acceptable tolerable safety profile, with a single grade 3 and single grade 4 event reported and no serious adverse events (SAEs). At the time of the interim analysis, three of four patients exhibited stable disease, while a fourth patient progressed and exited the trial. In addition, researchers

observed an increased T cell activity in tumors in three of the four patients based on RNA sequencing and indications of early tumor shrinkage in the patient who has been in trial for the longest duration thus far (based on CT scan at day 140).

The Corporation initiated a Phase 2 clinical trial in 2015, in diffuse large B cell lymphoma ("DLBCL") at the Ottawa Hospital Research Institute and the Odette-Sunnybrook Cancer Centre. The first patient was dosed in March 2015. Researchers are seeking to enroll up to 24 patients. The open label study is designed to determine the objective response rate of patients with recurrent survivin-expressing DLBCL when treated with DPX-Survivac in combination with low dose oral cyclophosphamide. The Corporation announced in November 2015 that the initial results from a Phase 2 study demonstrated that DPX-Survivac can induce an immune response in DLBCL tumors. This early result demonstrates that DPX-Survivac, Immunovaccine's lead cancer immune therapy, can induce immune responses in hematologic cancers, such as DLBCL. Researchers observed changes in tumor-infiltrating T cells following administration of the DPX-Survivac therapy, which correlated with an immune response produced by DPX-Survivac and detected in the blood.

The Corporation is in the process of completing a Phase 1b dose-optimizing trial in ovarian cancer. Interestingly, a patient enrolled in the Phase 1b trial with stable disease and rising blood levels of the cancer biomarker CA-125 experienced a 43% reduction in the size of her tumor within five months, and the tumor remained stable for more than a year. The partial response, defined as a shrinking of tumor size by at least 30%, using Response Evaluation Criteria In Solid Tumors, was accompanied by reduction in levels of a commonly used ovarian cancer biomarker CA-125 and a significant increase in vaccine-induced immune responses in this patient. This durable clinical response highlights the therapeutic potential of DPX-Survivac for ovarian cancer patients.

The Corporation announced additional data from its Phase 1b dose-optimizing trial in ovarian cancer in 2016, which reinforced previously reported results showing that DPX-Survivac was well tolerated with no unexpected treatment-related SAEs and that it demonstrated the ability to generate a relevant, sustained immune response. This has allowed the Corporation to select a preferred dosing schedule of DPX-Survivac for upcoming studies. New data from the Phase 1/1b trial also demonstrated increased expression of several checkpoint inhibitor molecules.

The Corporation has terminated the agreement with Professor Marianna Nuti, Ph.D., Department of Experimental Medicine at the University of Rome, who was going to conduct an investigator-sponsored trial on DPX-Survivac in patients with glioblastoma. Due to the delay in obtaining approval by the European regulatory agency to test this vaccine candidate in Europe, there was a significant delay in initiating this planned trial and in the process, access to the funding grant had expired. As this trial is not in line with the current business strategy of combination therapy with checkpoint inhibitors, it was determined to cease all efforts regarding this planned trial.

The Corporation is pursuing opportunities for additional trials with biotechnology and pharmaceutical companies, including combination therapies with DPX-Survivac as well as other applications of the DepoVax<sup>™</sup> platform.

#### Orphan Drug Status and Fast Track Designation

The Corporation announced in November 2016 that the European Medicines Agency ("EMA") granted orphan drug designation status to Immunovaccine's DPX-Survivac in ovarian cancer. The EMA grants orphan designation to medicines intended to treat, prevent or diagnose life threatening and debilitating disease, with a prevalence no greater than five in 10,000 in the European Union and where no satisfactory method of treatment, prevention or diagnosis exists, unless the proposed medicine offers a significant benefit to those with the condition.

The Corporation announced in July 2015 that the FDA had granted orphan drug status to DPX-Survivac for the treatment of ovarian cancer. This designation is valid for all applications of DPX-Survivac in ovarian cancer without restriction to a specific stage of disease.

Immunovaccine had previously received FDA fast track designation for DPX-Survivac. The designation is intended for patients with no measurable disease after their initial surgery and chemotherapy.

## DPX-0907

#### Product Overview

DPX-0907 combines the Corporation's DepoVax<sup>™</sup> delivery technology with seven HLA-A2-restricted cancerspecific antigens licensed from Immunotope Inc. ("Immunotope").

# Clinical Trial Development – Completed Trials

The Corporation completed a Phase 1 clinical trial of DPX-0907 and the results of the trial were released in June 2011, with more detailed results published in the Journal of Translational Medicine in August 2012. The Phase 1 trial was conducted at five centers in the United States. In this open-label, dose-escalating trial, patients received three injections (0.25 mL or 1 mL doses) of the active immune therapy DPX-0907, three weeks apart.

Immunovaccine also terminated its exclusive world-wide licence with Immunotope for the use of certain patented antigens that were being used in DPX-0907 as this approach is not in line with the current business strategy of combination therapy with checkpoint inhibitors.

# DPX-RSV

## Product Overview

A significant component of the Corporation's business strategy is licensing the DepoVax<sup>TM</sup> platform within infectious and other diseases. The DepoVax<sup>TM</sup> adjuvanting platform has the potential to generate a rapid and robust immune response, often in a single dose. The unique vaccine enhancement and single-dose capability could prove to be beneficial in targeting difficult infectious and other disease candidates.

The Corporation has performed pre-clinical research activities for a vaccine targeting RSV, which is the second leading cause of respiratory illness in infants, the elderly and the immunosuppressed. Currently, there is no vaccine available for this virus and Immunovaccine is seeking to develop a novel vaccine formulation to be used in elderly and healthy adults, including women of child-bearing age. Immunovaccine has in-licensed the RSV antigen exclusively from VIB, a non-profit life sciences research institute funded by the Flemish government, to expand its pipeline of vaccine candidates. The novel RSV antigen being evaluated in DepoVax<sup>TM</sup> is based on the short hydrophobic protein present at low levels on the surface of the RSV virion but more importantly also present on the surface of RSV-infected cells. This vaccine has a unique mechanism of action, in that the resultant antibodies bind to and destroy infected cells rather than directly bind to and neutralize free virus.

#### Clinical Trial Development – Current Trial

A Phase 1 clinical study is being conducted in Canada with the Corporation's RSV vaccine in healthy adults. The RSV vaccine is formulated in Immunovaccine's proprietary DepoVax<sup>™</sup> adjuvanting platform and is initially being developed to protect the elderly population from infection. The Phase 1 study, which is the first clinical trial of a DepoVax<sup>™</sup>-based vaccine in an infectious disease indication, is evaluating the safety and immune response profile of the RSV vaccine candidate in 40 healthy adults. The first patient was enrolled on June 30, 2015, at the Canadian Center for Vaccinology in Halifax. The trial is being co-funded by Immunovaccine.

On July 6, 2016, the Corporation announced positive interim results from this trial. The DPX-RSV trial included 40 healthy older adult volunteers (age 50-64 years) and two dose cohorts, with 20 subjects in each cohort. Investigators analyzed the safety and immune response data of all participants up to study day 84. The safety analysis indicates that the DPX-RSV was well tolerated among all study participants, with no SAEs recorded. Furthermore, immunogenicity data supported DPX-RSV's ability to generate a relevant immune response; the vaccine candidate obtained antigen-specific antibody responses in 75 percent of subjects vaccinated with the lower dose and 100 percent of those vaccinated with the higher dose.

On October 13, 2016, the Corporation announced positive topline results from this trial. The report outlined that more than six months after the last vaccination, 15 of 16 participants (93%) who received DPX-RSV demonstrated antigen-specific immune responses. The vaccine candidate also continued to have a positive safety profile and was well tolerated with no SAEs among all study participants.

Immunovaccine has exclusive worldwide licenses on applications that target the SH ectodomain antigen in RSV. The Corporation intends to explore opportunities to out-license this product to potential partners.

## Zika Virus Vaccine Antigen

Immunovaccine and Leidos, a health, national security and infrastructure solutions company, are collaborating on developing a vaccine against the mosquito-borne Zika virus and infection, which may be linked to neurological birth defects. This collaboration, amended on June 23, 2016, is the first to expand on Immunovaccine's research project in which the Corporation will apply its DepoVax<sup>TM</sup> platform to development of a Zika virus vaccine candidate. Under the terms of the agreement, Leidos will utilize its Virtual Pharmaceutical Development Program to lead an antigen discovery and development team to identify the best candidate antigens for protecting against infection by the Zika virus. Immunovaccine will then formulate new antigens in its DepoVax<sup>TM</sup> delivery system for pre-clinical testing. The parties expect that this project could serve as a replicable model for expediting the development and manufacture of vaccines to address current and future health emergencies.

## Licensing Agreements

While the Corporation is focused on developing a pipeline of cancer immunotherapies, it is also pursuing opportunities to license the Corporation's platform technology to other parties interested in creating enhanced vaccines on an application-by-application basis.

## MARKET OVERVIEW

#### Cancer Immunotherapies

Cancer is considered one of the most widespread and prevalent diseases globally. According to Global Cancer Facts & Figures, 3rd edition (released February 2015 by the American Cancer Society), it is predicted that new cancer cases will rise to 21.7 million and the number of cancer deaths to 13 million by 2030. Conventional cancer treatment involves surgery to remove the tumor when possible, as well as chemotherapy and radiation. Chemotherapies are widely used despite their associated toxicities because they interfere with the ability of cancer cells to grow and spread. However, tumors often develop resistance to chemotherapies, limiting their efficacy in preventing tumor recurrence. Despite recent advances, independent sources note a high unmet medical need in cancer therapy, noting the median survival rate remains poor. Cancer immunotherapies, including therapeutic cancer vaccines, may provide a new and effective treatment. Transparency Market Research issued a report in December 2016 estimating the 2015 global cancer immunotherapy market at USD\$37.50 billion. With its revenue expected to progress at a very strong compound annual growth rate ("CAGR") of 14.6% within a forecast period from 2016 to 2024, the global cancer immunotherapy market is expected to reach USD\$124.88 billion by the end of 2024 based on their study.

Cancer immunotherapy seeks to harness the immune system to assist in the destruction of tumors and to prevent their recurrence. There has been significant interest in the field of cancer immunotherapy stemming from recent clinical success in prolonging patient survival with novel compounds. The ability to apply these appropriately has resulted from a greater understanding of the immune dysfunction that is characteristic of cancer. One area in which there have been breakthroughs has been in the area of checkpoint inhibitors, compounds that target key regulatory molecules of the immune system. Yervoy (anti-CTLA-4, or ipilumumab, developed by Bristol-Myers Squibb) was the first compound in this class to be approved for use in advanced metastatic melanoma. In cancer, these regulators (CTLA-4 and more recently PD-1 and its ligand PD-L1) act to inhibit CD8 T cell mediated anti-tumor immune responses that are crucial for tumor control. Monoclonal antibodies that target PD-1 and PD-L1 have shown unusual efficacy in cancer patients, with a significant percentage of patients experiencing durable response to these therapies. Several of these compounds are in advanced clinical trials, with one compound, Merck's Keytruda (pembrolizumab), having received FDA approval in September of 2014 for advanced melanoma patients who have

stopped responding to other therapies. Bristol-Myers Squibb's compound nivolumab (Opdivo) has also been approved in the United States and Japan.

In addition to clinical development of the above compounds utilized alone, there also has been additional development using these compounds in combination. Notably, the use of the PD-1 inhibitor, Opdivo, in combination with the anti-CTLA-4 inhibitor, Yervoy, has entered Phase 3 clinical trials in metastatic melanoma and renal cell carcinoma, after promising data in earlier trials. At the 2015 American Association of Cancer Research meeting and simultaneously published in the New England Journal of Medicine, it was reported that the combination in metastatic melanoma demonstrated an objective response rate of 61% as compared to 11% for Yervoy alone. This combination received approval from the FDA for use in BRAF V600 Wild-Type unresectable or metastatic melanoma in October 2015, signalling the first FDA approved combination of immune-oncology agents. There are also a number of other inhibitors in clinical development that are currently being studied in combination with these inhibitors, many at an early clinical stage.

Despite significant interest regarding the clinical potential of these inhibitors, there is an acceptance that more will be needed in a majority of patients. It will not be enough just to block the ability of tumors to inhibit the immune system. Key opinion leaders in the field have indicated that the ideal combination, with checkpoint inhibitors, is likely to be a therapy that drives tumor specific immune responses. These include novel cancer vaccines and T cell based therapies. These therapies fit well with checkpoint inhibition therapy because they simultaneously activate strong tumor specific immune responses, while releasing the brakes on immune suppression. The success of such combinations should allow pharmaceutical companies to significantly expand the market of their checkpoint inhibitors, which are currently effective in approximately 10% to 30% of patients.

Pharmaceutical companies, including Merck & Co., Inc. and AstraZeneca PLC, are becoming more receptive to combining their checkpoint inhibitors with clinical compounds belonging to other pharmaceutical and biotechnology companies. Recently, several pharmaceutical companies and large NASDAQ listed biotechnology companies have announced collaborations to test combination immunotherapies in clinical trials.

The Corporation believes that cancer vaccines will become an important component of these novel combination immunotherapies, the synergistic benefits with other T cell activation therapies could become an essential part of a multi-pronged approach for the treatment of cancer.

According to a BCC Research Report released in January 2015, the global market for cancer vaccines, including both prophylactic and therapeutic vaccines, was USD\$4.5 billion in 2013, reached USD\$4.0 billion in 2014 and is expected to reach USD\$4.3 billion by 2019. While the majority of this reflects sales of prophylactic vaccines, the area of therapeutic cancer vaccines is projected by some industry analysts to experience significant growth. Major pharmaceutical players, such as GlaxoSmithKline plc and Merck KGaA, have therapeutic cancer vaccines currently advancing in Phase 3 clinical trials.

# Infectious Diseases

Vaccines are credited with saving millions of lives since their introduction into medical practice and the healthcare system. The reduction in morbidity and mortality caused by many infectious diseases world-wide can be directly correlated to currently available vaccines. According to data from the U.S. Centers for Disease Control and Prevention, ten infectious diseases have been at least 90% eradicated in the United States thanks to vaccines.

However, during the past decade, diseases thought to be under control or retreating, such as measles, mumps and pertussis have re-emerged, mostly due to decline in childhood vaccination rates. In addition, infectious diseases such as influenza, meningitis and yellow fever continue to be a significant public health concern, despite the availability of vaccines. Other diseases without a suitable vaccine, such as dengue and malaria have extended their geographical reach, due to expansion of the insects which carry them. While the effort to control these known infectious diseases continues, more than 30 additional emerging diseases have been identified in humans for the first time over the past two decades, such as severe acute respiratory syndrome (SARS) and Middle East respiratory virus (MERS) coronaviruses.

There is an increased awareness of the impact of current and emerging infectious diseases. Demand for newer treatments and vaccines are growing globally. Decision Resources reports that the world-wide market for vaccines against infectious diseases more than doubled between 2005 and 2011. The global market for infectious diseases treatment was valued in January 2016 by analyst Peggy Lehr of BCC Research at USD\$108.4 billion in 2015, should reach USD\$126.2 billion in 2016 and USD\$183.2 billion in 2021, demonstrating a compound annual growth rate (CAGR) of 7.7% from 2016 to 2021. According to TechNavio's analysts, the global preventable vaccines market is expected to grow at a Compound Annual Growth rate (CAGR) of 10.16% from 2014-2019.

Many infectious diseases lack effective prophylactic vaccines, and the industry faces a variety of challenges in vaccine design and production. Adjuvants and delivery methods are viewed as key technologies for the success of future vaccines. Efforts to decrease treatment duration and develop single-dose vaccines are a strong focus at the research level to improve patient compliance and decrease monitoring of therapy by the healthcare provider. Better diagnostics are being sought for many infectious diseases. This advance could result in additional market expansion by increasing the number of patients identified for vaccine treatment. The Corporation believes this current market landscape offers significant commercial opportunities for both its technology platform and vaccines.

Pharmaceutical companies dominating this infectious diseases vaccine market include Sanofi Pasteur, GSK, Merck and Pfizer. Additionally, government and non-profit institutions play a significant role in vaccine development in both industrialized and developing markets. Support for infectious disease vaccine development and commercialization is also available through government and non-profit funding and granting mechanisms.

## Respiratory Syncytial Virus (RSV)

RSV is a respiratory virus that infects the lungs and breathing passages. It can be severe in infants, the elderly, and patients with compromised immune systems. RSV is the single most common cause of severe respiratory illness in infants under the age of one and is more often being recognized as an important cause of respiratory illness in older adults. Globally, it is estimated that 64 million cases of RSV infection occur annually, with 160,000 deaths. A vaccine that strengthens the immunity of adults to this virus would lower their risk of contracting infection later in life. It would also create a cocoon of protection in the adult population (i.e. parents, grandparents and caregivers) to protect vulnerable infants from contracting this virus.

There is currently no vaccine available for the prevention of RSV.

The World Health Organization ("WHO") has designated RSV as a high-priority target for vaccine development. RSV is a significant problem in the elderly, particularly if they reside in a long-term care facility or participate in other senior day-care programs. RSV attack rates in nursing homes in the United States are approximately 5% to 10% per year with a 2% to 8% case fatality rate, amounting to approximately 10,000 deaths per year among persons greater than 64 years of age.

A vaccine would likely provide patients with a stronger efficacy profile and a more sustained immune response. The Corporation expects that the development of a vaccine with these improved characteristics could expand the market potential, adding the elderly and immunocompromised patients. With these new patient populations, market forecasts could approach \$1 billion.

Although there have been relatively few developments related to RSV over the past decade, a renewed interest in the area due to new technologies and early research into new methods of addressing immunity, such as maternal immunity transfer for pediatric RSV, could result in new transactions or alliances over the next several years. Most transactions and alliances that have taken place in this sector have minimized the risk with a relatively modest upfront payment, followed by larger milestone payments subject to successful progression through clinical development and commercialization.

#### Animal Health Market

According to industry sources, the world animal health market, defined as a sector spanning veterinary pharmaceuticals, biologics and medicated feed additives, was approximately USD\$23 billion in 2013. The animal

vaccine market, subdivided into livestock, companion animal and smaller segments including equine, poultry and aquatic, makes up approximately 20% of the total animal health market. Europe is the leading market for veterinary vaccines followed closely by North America. Asia-Pacific is the fastest growing market for veterinary vaccines.

The world-wide livestock vaccine market is comprised primarily of cattle and swine vaccines, along with, to a lesser extent, vaccines for sheep, poultry and other food animals. There are only a few players in the animal vaccine market including Zoetis, Boehringer Ingelheim, Merck Animal Health (MSD Animal Health), Novartis AG and AgriLabs, LLC. The majority of today's vaccines for the livestock market require a booster administration, which increases the handling. Therefore, a vaccine that requires fewer doses (one dose, in some cases) for efficacy could be a significant innovation and have the potential to replace existing products.

# **RECENT AND ANNUAL DEVELOPMENTS**

## Key developments and achievements

- On March 29, 2017, the Corporation announced the first interim data analysis from its triple combination Phase 1b clinical trial in ovarian cancer, in combination with Incyte's epacadostat and low-dose cyclophosphamide. The analysis included the results of blood tests, tumor biopsies and CT scans to assess safety, disease progression and T-cell response for the first four evaluable patients in the trial. All patients enrolled in the trial have recurrent ovarian cancer with evidence of progressive disease. Based on the interim analysis, the combination therapy appears to have an acceptable tolerable safety profile, with a single grade 3 and single grade 4 event reported and no serious adverse events (SAEs). At the time of the interim analysis, three of four patients exhibited stable disease, while a fourth patient progressed and exited the trial. In addition, researchers observed an increased T cell activity in tumors in three of the four patients based on RNA sequencing and indications of early tumor shrinkage in the patient who has been in trial for the longest duration thus far (based on CT scan at day 140).
- On February 20, 2017, Pierre Labbé was appointed as Chief Financial Officer replacing Kimberly Stephens. In this role, Mr. Labbé will be responsible for leading the Corporation's financial strategy and operations, with an emphasis on expanding financing and business development operations.
- On February 6, 2017, the Corporation announced an investigator-sponsored Phase 2 clinical trial in ovarian cancer in combination with Merck's checkpoint inhibitor Pembrolizumab in patients with recurrent, platinum-resistant ovarian cancer. University Health Network's ("UHN") Princess Margaret Cancer Centre (PM) will conduct the Phase 2 non-randomized, open-label trial designed to evaluate the potential anti-tumor activity of the combination of Pembrolizumab, DPX-Survivac, and low-dose cyclophosphamide.
- On December 9, 2016, the Corporation completed a bought-deal private placement of common shares, for gross proceeds of approximately \$8 million, to be used for general corporate and working capital purposes.
- On November 22, 2016, the Corporation announced that it has been granted "Orphan Drug Designation" status by the European Medicines Agency (EMA) for the use of DPX-Survivac for the treatment of ovarian cancer in the European Union.
- On November 3, 2016, the Corporation announced positive results from preclinical studies completed in collaboration with UConn Health for Immunovaccine's DPX-NEO program, which is designed to develop patient-specific neoepitope immunotherapies. Results from the first study in mouse tumor models have shown positive anti-cancer activity.
- On November 1, 2016, the Corporation announced that Gabriela Rosu, M.D. was appointed as the Corporation's first Chief Medical Officer effective November 7, 2016. In this newly created executive role, Dr. Rosu will oversee the strategy and execution of the Corporation's expanding clinical portfolio of programs.

- On October 13, 2016, the Corporation announced positive topline results from its Phase 1 trial evaluating the safety and immunogenicity of DPX-RSV, its DepoVax<sup>™</sup>-based, small B cell epitope peptide vaccine candidate for RSV. The results, six months or more after vaccination, confirmed earlier-reported interim data on the ability of DepoVax<sup>™</sup>- formulated antigens to generate a relevant, durable immune response, that the vaccine had a positive safety profile and was well tolerated with no SAEs among all study participants. Also antigen-specific immune responses were detected at least six months after the last vaccination in 93 percent (15/16) of patients receiving DPX-RSV, in both low-dose (8/8 participants) and high-dose (7/8 participants) cohorts.
- On October 11, 2016, the Corporation announced that malarial researcher J. Alexandra Rowe, D Phil, of The University of Edinburgh, presented topline preclinical data for Immunovaccine's DepoVax<sup>TM</sup>-based malarial vaccine which was presented at the World Vaccine Congress Europe in Barcelona, Spain on October 10, 2016. Results from studies in mice, conducted in collaboration with the University of Edinburgh's Centre for Immunity, Infection and Evolution ("CIIE") as part of a preclinical collaboration announced in June 2016, indicated that the novel CIIE-identified targets, when formulated in the DepoVax<sup>TM</sup> targeting platform, generated strong, sustained, antibody responses that could prevent, after a single injection, a process in severe malaria known as 'rosetting'.
- On September 8, 2016, the Corporation announced that the first patient with recurrent ovarian cancer has been treated in a Phase 1b clinical study of Immunovaccine's novel T cell activating therapy, DPX-Survivac, in combination with epacadostat and low-dose cyclophosphamide. This triple combination study is the result of collaboration between Immunovaccine and Incyte to assess the safety and effectiveness of DPX-Survivac, along with Incyte's investigational oral indoleamine IDO1 inhibitor, epacadostat, and low-dose cyclophosphamide in patients with recurrent ovarian cancer who have measurable disease.
- On August 25, 2016, the Corporation announced new data from its Phase 1/1b trial in ovarian cancer, which reinforced previously reported results showing that DPX-Survivac was well tolerated, with no unexpected treatment-related SAEs and that it demonstrated the ability to generate a relevant, sustained immune response. New data from the Phase 1/1b trial yielded positive findings on tumor clinical response, including the presence of relevant circulating T cells and increased expression of several checkpoint inhibitor molecules.
- On July 6, 2016, the Corporation announced that a team of investigators had completed an interim analysis of the safety and immunogenicity of DPX-RSV in a Phase 1 clinical trial in healthy older adult volunteers. The safety analysis indicates that the DPX-RSV was well tolerated among all study participants, with no SAEs recorded. Furthermore, immunogenicity data supported DPX-RSV's ability to generate a relevant immune response; the vaccine candidate obtained antigen-specific antibody responses in 75 percent of subjects vaccinated with the lower dose, and 100 percent of those vaccinated with the higher dose.
- On June 23, 2016, the Corporation announced it had been awarded a subcontract by Leidos to evaluate Immunovaccine's DepoVax<sup>™</sup> platform for the development of peptide based malaria vaccine targets. The subcontract is funded through Leidos' prime contract from the U.S. Agency for International Development (USAID) to provide vaccine evaluations in the preclinical, clinical and field stages of malaria vaccine development. Leidos and Immunovaccine will work together to identify adjuvant and antigen combinations that can be used to protect against malaria and with the DepoVax<sup>™</sup> delivery system, formulate promising vaccine candidates for potential clinical testing.
- On June 8, 2016, the Corporation closed a bought deal private placement of units, for gross proceeds of \$8,002,500. Each unit was comprised of one common share and one-half of one common share purchase warrant. Each whole warrant entitles the holder thereof to purchase one additional common share upon payment of the exercise price of \$0.72 per share until June 8, 2018.
- On June 8, 2016, the Corporation announced the appointment of Shermaine Tilley, PhD, Managing Partner of CTI Life Sciences Fund, to its board of directors.

- On April 20, 2016, the Corporation presented new preclinical data at the American Association for Cancer Research (AACR) Annual Meeting 2016. The investigators' findings showed that a combination immunotherapy using a DepoVax<sup>™</sup>-based vaccine could enhance the anti-tumor effects of a PD-1 blockade, controlling growth in advanced HPV-expressing tumors in animal models.
- On April 14, 2016, Andrew Sheldon joined the board of directors of the Corporation and was appointed Chairman of the board of directors.
- On April 13, 2016, the Corporation announced the appointment of Frederic Ors as appointed Chief Executive Officer, replacing Marc Mansour, Ph.D., who, prior to stepping down in March 2016, was Chief Executive Officer since June 2014, and a member of the board of directors since December 2013. Mr. Ors had been with the Corporation since April 2015 as Chief Business Officer.
- On April 7, 2016, the Corporation announced a collaboration with Leidos on developing a vaccine against the mosquito-borne Zika virus and infection, which may be linked to neurological birth defects. This collaboration is the first to expand on Immunovaccine's previously announced research project in which the Corporation will apply its DepoVax<sup>™</sup> platform to development of a Zika virus vaccine candidate. The project builds upon earlier promising results with DepoVax<sup>™</sup> vaccines targeting the Ebola virus, anthrax and RSV.
- On March 3, 2016, the Corporation announced it would begin a research project towards development of a vaccine formulated in its DepoVax<sup>™</sup> platform against the mosquito-borne Zika virus and infection, which may be linked to neurological birth defects in infants.
- On January 11, 2016, the Corporation announced FDA and Health Canada clearance to initiate a clinical study of DPX-Survivac in combination with low-dose cyclophosphamide and epacadostat. The Phase 1b clinical trial will assess the safety and effectiveness of Immunovaccine's novel T cell activating therapy, DPX-Survivac, along with Incyte's IDO1 inhibitor, epacadostat (INCB24360), and low-dose cyclophosphamide in patients with recurrent ovarian cancer who have measurable disease.

# SELECTED ANNUAL INFORMATION

The following table summarizes the selected financial data reported by the Corporation for the years ended December 31, 2016, 2015 and 2014. The information set forth should be read in conjunction with the respective audited financial statements.

	Year ended December 31, 2016	Year ended December 31, 2015	Year ended December 31, 2014
Net loss and comprehensive loss	\$(8,896,000)	\$(8,775,000)	\$(6,568,000)
Weighted-average shares outstanding	101,128,759	91,873,227	83,389,672
Basic and diluted loss per share	\$(0.09)	\$(0.10)	\$(0.08)
Total assets	\$15,101,000	\$5,952,000	\$12,448,000
Total long-term debt	\$6,090,000	\$3,718,000	\$3,126,000

## **Results for Fiscal 2016 compared to Fiscal 2015**

## Revenue

In Fiscal 2015, the Corporation signed a license agreement with PharmAthene Inc. ("PharmAthene") which included a signing fee of USD\$200,000. The agreement was subsequently terminated in August 2016. The deferred revenue at the end of 2015 related to this agreement was fully recognized in 2016.

## **Operating expenses**

Overall operating expenses increased by \$121,000 (1%) during the year ended December 31, 2016 compared to the year ended December 31, 2015. Explanations of the changes in these costs are discussed below.

#### Research and development expenses

R&D expenses include salaries and benefits, expenses associated with the Phase 1b and Phase 2 clinical trials of DPX-Survivac, clinical research and manufacturing of DPX-RSV and DPX-Survivac, consulting fees paid to various independent contractors who possess specific expertise required by the Corporation, the cost of animal care facilities, laboratory supplies, peptides and other chemicals, rental of laboratory facilities, insurance, as well as other non-material R&D related expenses. These R&D costs are offset by government loans and assistance, recoveries of costs from collaborations and by investment tax credits received in relation to the R&D expenses incurred.

The Corporation's R&D efforts and related expenses for Fiscal 2016 included costs surrounding the Corporation's clinical trials of DPX-Survivac namely Phase 1b clinical trial collaboration with Incyte in ovarian cancer patients, Phase 1b clinical trial in ovarian cancer patients and Phase 2 clinical trial in DLBCL, and costs related to the Corporation's ongoing R&D activities associated with the investigation, analysis and evaluation of other potential vaccine candidates and technologies.

	Year ended December 31, 2016 \$	Year ended December 31, 2015 \$
General research and development expenses	1,216,000	1,297,000
DPX-Survivac preclinical and clinical expenses	1,291,000	2,087,000
Salaries and benefits	1,433,000	1,306,000
Stock-based compensation	158,000	335,000
Depreciation of equipment and amortization of intangible	75,000	83,000
Government loans and assistance	(413,000)	(221,000)
Investment Tax Credits	(279,000)	(317,000)
Total	3,481,000	4,570,000

Research and development expenses consist of the following:

The decrease in general R&D expenses by \$81,000 from \$1,297,000 for the year ended December 31, 2015 to \$1,216,000 for the year ended December 31, 2016 is attributable mainly to \$490,000 in costs related to the manufacturing of the DPX-RSV clinical batch in the year ended December 31, 2015. This is offset by an increase in consulting and materials expenses of \$215,000 associated with a research project in which the Corporation is undertaking to advance the DepoVax<sup>TM</sup> platform, funded by a government grant, an increase of \$111,000 in raw materials purchased for preclinical studies and a decrease of \$30,000 in cost recoveries from collaborators.

The decrease in DPX-Survivac preclinical and clinical expenses by \$796,000 from \$2,087,000 for the year ended December 31, 2015 to \$1,291,000 for the year ended December 31, 2016 relates mainly to \$990,000 in costs related

to the manufacturing of the second clinical batch of DPX-Survivac in the year ended December 31, 2015 and a decrease in regulatory costs of \$50,000. This is offset by a \$230,000 increase in clinical trial costs associated with the Corporation's Phase 1b clinical trial collaboration with Incyte in ovarian cancer patients, Phase 1b clinical trial in ovarian cancer patients, the Phase 2 clinical trial in DLBCL, and the work supporting the clinical trial collaboration with the Dana Farber Cancer Institute.

The increase in R&D salaries is mainly attributable to the hiring of a Chief Medical Officer late in 2016 as well as the appointment of three directors to the position of Vice President in August 2016.

#### General and administrative expenses

General and administrative ("G&A") expenses were \$3,165,000 for the year ended December 31, 2016 compared to \$2,710,000 for the year ended December 31, 2015, an overall increase of \$455,000 (17%).

General and administrative expenses include salaries and benefits, directors' fees, audit and taxation costs, consulting fees, travel, rental of office facilities, insurance, regulatory fees, stock based compensation, depreciation of equipment and other minor office expenses.

	Year ended	Year ended	
	December 31, 2016	December 31, 2015	
	\$	\$	
General and administrative expenses, excluding salaries	1,772,000	1,653,000	
Salaries and benefits	860,000	656,000	
Government assistance	(314,000)	-	
Stock-based compensation	816,000	385,000	
Depreciation of equipment	31,000	16,000	
Total	3,165,000	2,710,000	

General and administrative expenses consist of the following:

G&A expenses, excluding salaries, increased by \$119,000 mainly due to a \$328,000 increase in recruitment and management restructuring fees offset by a \$130,000 decrease in audit and legal fees and a \$102,000 decrease in foreign exchange loss.

Salaries and benefits increased by \$204,000 mainly due to an overall increase in compensation for the senior executive team.

The government assistance of \$314,000 in the year ended December 31, 2016 relates entirely to the initial valuation of the low-interest bearing government loans. Under IFRS, the fourth installment of the low-interest bearing government loan from the Province of Nova Scotia in the amount of \$1,250,000, received in April 2016, must be initially valued at fair value and the difference between the fair value of the loans and the contribution received must be treated as government assistance.

Stock-based compensation increased by \$431,000 mainly due to the grant of 400,000 stock options to the new Chief Executive Officer, one third of which vested immediately while no stock options were awarded in 2015 to the former Chief Executive Officer.

## Business development and investor relations expenses

The Corporation's business development and investor relations activities decreased in the year ended December 31, 2016 by \$545,000, compared to the year ended December 31, 2015, to a total of \$678,000. This is due to a decrease of \$264,000 for investor relations activities, a decrease of \$164,000 in business development consulting, a decrease

of \$47,000 for business development travel, a decrease of \$32,000 for legal fees and a decrease of \$117,000 and \$62,000, in salary and benefits and stock-based compensation, respectively, due to the Chief Business Officer being appointed Chief Executive Officer in Q2 Fiscal 2016 resulting in salary and benefits being relocated to general and administrative expenses. This is offset by an increase of \$150,000 in marketing and public relations expenses.

## Impairment Loss

On November 7, 2016, the Corporation terminated its exclusive world-wide licence with Immunotope for the use of certain patented antigens that were being used in DPX-0907 as this approach is not in line with the Corporation's business strategy. This resulted in an impairment loss of \$195,000 on the intangible asset representing the license for the use of patented antigens.

## Accreted Interest

Accreted interest relates entirely to the valuation of low-interest bearing government loans which are repayable based on a percentage of future gross revenue. The increase is a result of a change in assumptions about the expected timing and amount of future cash flows.

#### Net loss and comprehensive loss

The net and comprehensive loss for Fiscal 2016 was \$8,896,000 or \$0.09 per basic and diluted share, \$121,000 higher than the net and comprehensive loss for Fiscal 2015 of \$8,775,000 or 0.10 per basic and diluted share.

# SUMMARY OF QUARTERLY RESULTS

The following consolidated quarterly data was drawn from the audited annual consolidated financial statements and the unaudited interim condensed consolidated financial statements. All values discussed below are rounded to the nearest thousand. The information is reported on an IFRS basis.

Quarter Ended In	Total Revenue \$	Total Expenses \$	Loss \$	Basic and Diluted Loss Per Share \$
<i>Q4</i> - December 31, 2016	-	3,741,000	(3,741,000)	(0.03)
<i>Q3</i> - September 30, 2016	-	1,899,000	(1,899,000)	(0.02)
<i>Q2</i> - June 30, 2016	65,000	1,470,000	(1,405,000)	(0.01)
Q1 - March 31, 2016	65,000	1,916,000	(1,852,000)	(0.02)
<i>Q4</i> - December 31, 2015	65,000	2,514,000	(2,449,000)	(0.03)
<i>Q3</i> - September 30, 2015	65,000	2,069,000	(2,004,000)	(0.02)
<i>Q2</i> - June 30, 2015	-	2,553,000	(2,553,000)	(0.03)
<i>Q1</i> - March 31, 2015	-	1,769,000	(1,769,000)	(0.02)

Results for the three months ended December 31, 2016 ("Q4 Fiscal 2016"), compared to the three months ended December 31, 2015 ("Q4 Fiscal 2015").

	Q4 Fiscal 2016 \$	Q4 Fiscal 2015 \$
Revenue	-	(65,000)
General and administrative	1,309,000	740,000
Research and development	1,063,000	1,205,000

	Q4 Fiscal 2016	Q4 Fiscal 2015	
	\$	\$	
Business development and investor relations	210,000	452,000	
Impairment loss	-	-	
Accreted interest and adjustments	1,159,000	117,000	
Net loss and comprehensive loss for the quarter	3,741,000	2,449,000	

## Revenue

In Fiscal 2015, the Corporation signed a license agreement with PharmAthene which included a signing fee of USD\$200,000. This agreement was subsequently terminated in August 2016. The revenue amount was fully recognized during the first six months in 2016.

# **Operating expenses**

Overall operating expenses increased by \$1,275,000 (49%) to \$3,741,000 during Q4 Fiscal 2016 compared to Q4 Fiscal 2015. Explanations of the nature of costs incurred, along with explanations for those changes in costs are discussed below:

## Research and development expenses

R&D expenses include salaries and benefits, expenses associated with the Phase 1b and Phase 2 clinical trials of DPX-Survivac, clinical research and manufacturing of DPX-RSV and DPX-Survivac, consulting fees paid to various independent contractors who possess specific expertise required by the Corporation, the cost of animal care facilities, laboratory supplies, peptides and other chemicals, rental of laboratory facilities, insurance, as well as other non-material R&D related expenses. These R&D costs are offset by government loans and assistance, recoveries of costs from collaborations and by investment tax credits received in relation to the R&D expenses incurred.

The Corporation's R&D efforts and related expenses for Q4 Fiscal 2016 included costs surrounding the Corporation's clinical trials of DPX-Survivac namely Phase 1b clinical trial collaboration with Incyte in ovarian cancer patients, Phase 1b clinical trial in ovarian cancer patients and Phase 2 clinical trial in DLBCL, and costs related to the Corporation's ongoing R&D activities associated with the investigation, analysis and evaluation of other potential vaccine candidates and technologies.

Research and development expenses consist of the following:

	Q4 Fiscal 2016 \$	Q4 Fiscal 2015 \$
General research and development expenses	348,000	216,000
DPX-Survivac preclinical and clinical expenses	255,000	671,000
Salaries and benefits	516,000	383,000
Stock-based compensation	40,000	53,000
Depreciation of equipment and amortization of intangible	20,000	23,000
Government loans and assistance	(40,000)	(43,000)
Investment tax credits	(76,000)	(98,000)
Total	1,063,000	1,205,000

The increase in general R&D expenses from \$216,000 in Q4 Fiscal 2015 to \$348,000 in Q4 Fiscal 2016 is attributable mainly to \$56,000 in cost recoveries included in Q4 Fiscal 2015 related to the work supporting the licensing agreement with PharmAthene, a \$50,000 increase in raw materials and supplies costs and a \$15,000 increase R&D training.

DPX-Survivac expenses decreased by \$416,000 mainly due to the decrease in the manufacturing costs of the second clinical batch of DPX-Survivac incurred in Q4 Fiscal 2015.

The increase in R&D salaries of \$133,000 is mainly attributable to the hiring of a Chief Medical Officer late in 2016 as well as the appointment of three directors to the position of Vice President in August 2016.

#### General and administrative expenses

G&A expenses consist of the following:

	Q4 Fiscal 2016 \$	Q4 Fiscal 2015 \$
General and administrative expenses, excluding salaries	599,000	484,000
Salaries and benefits	354,000	190,000
Stock-based compensation	338,000	59,000
Depreciation of equipment	18,000	7,000
Total	1,309,000	740,000

G&A expenses, excluding salaries, increased by \$115,000 mainly due to an increase of \$95,000 in recruitment fees for identifying new key employees and a \$20,000 increase in audit and legal fees.

Salaries and benefits increased by \$164,000 due to an overall increase in compensation for the senior executive team.

The increase in stock-based compensation is mainly attributable to the adoption of a Deferred Share Unit Plan ("DSU Plan") by the board of directors in December 2016, for non-executive Members of the board of directors, which is subject to ratification by the shareholders at the 2017 Annual and Special Meeting of shareholders. Following the adoption of the DSU Plan on December 21, 2016, DSUs having a value of \$225,000 were granted to Non-Executive Directors as transitional compensation. All DSUs awarded vest immediately which is the cause of the increase in Q4 Fiscal 2016 stock-based compensation.

#### Business development expenses

The Corporation's business development activities decreased in Q4 Fiscal 2016 by \$242,000, compared to Q4 Fiscal 2016, to a total of \$210,000. This is mainly due to a decrease of \$82,000 and \$34,000 in salary and benefits and stock-based compensation, respectively, relating to the Chief Business Officer being appointed Chief Executive Officer in April 2016, and a \$177,000 decrease in consulting costs relating to business development strategy support incurred in Q4 Fiscal 2015. This is offset by a \$51,000 increase in marketing and investor relations activities.

#### Accreted Interest

Accreted interest relates entirely to the valuation of low-interest bearing government loans which are repayable based on a percentage of future gross revenue. The increase is a result of a change in assumptions about the expected timing and amount of future cash flows.

#### Net loss and comprehensive loss

The net loss and comprehensive loss was \$3,741,000 for Q4 Fiscal 2016, \$1,292,000 higher than the net loss and comprehensive loss for Q4 Fiscal 2015.

## CASH FLOWS, LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2016, the Corporation had cash and cash equivalents of \$13,547,000 and working capital of \$12,982,000, compared to \$3,842,000 and \$3,283,000, respectively at December 31, 2015.

Since the Corporation's inception, operations have been financed through the issuance of equity securities, debt, revenue from licenses, cost recoveries from collaborations, interest income on funds available for investment, government assistance and tax credits.

During the year ended December 31, 2016, the Corporation recorded revenue of \$130,000 under the PharmAthene license agreement.

During the year ended December 31, 2016, cash of \$6,053,000 was used in operating activities. This included the reported net loss of \$8,896,000 prior to being decreased for non-cash amortization, non-cash depreciation, non-cash impairment loss, non-cash accretion of long-term debt and non-cash stock-based compensation. The Corporation had a net use of cash of \$7,000 as a result of changes in working capital balances.

Sources of cash raised through financing activities were: \$16,002,500, due to two bought deal private placements, less issuance costs of \$1,252,000; \$1,250,000, less \$314,000 recorded as government assistance against G&A as the Corporation drew down the fourth installments of the Province of Nova Scotia loan; \$47,000 through the exercise of warrants; and \$200,000 through the exercise of stock options. The Corporation used \$71,000 to repay long-term debt during the period.

During the year ended December 31, 2016, the Corporation purchased equipment for ongoing research and operating activities for \$111,000.

The Corporation aims to maintain adequate cash and cash resources to support planned activities which include the completion of the Phase 1b DPX-Survivac clinical trial program in patients with ovarian cancer, the Phase 2 DPX-Survivac clinical trial in patients with DLBCL, the Phase 1b combination trial with DPX-Survivac and Incyte's IDO1 inhibitor epacadostat, initiation of the Phase 2 investigator-sponsored combination trial with DPX-Survivac and Merck's checkpoint inhibitor, Pembrolizumab, other research and development activities, business development efforts, administration costs, and intellectual property maintenance and expansion. At December 31, 2016, the Corporation had approximately \$14.2 million of existing and identified potential sources of cash including:

- cash and equivalents of \$13.5 million; and
- amounts receivable and investment tax credits receivable of \$0.7 million.

For Q4 2016, the Corporation's quarterly "cash burn rate" (defined as net loss for the period adjusted for non-cash transactions including amortization, depreciation, impairment losses, accretion of long-term debt, and stock-based compensation) was approximately \$2.17 million. Based on the current business plan, the Corporation forecasts the cash burn rate to be between \$2 million to \$3 million per quarter over the next 12 months, as it continues to execute the Phase 1b combination trial with DPX-Survivac and Incyte's IDO1 inhibitor epacadostat, the Phase 2 clinical trial for DPX-Survivac in DLBCL and initiates the Phase 2 investigator-sponsored combination trial with DPX-Survivac and Merck's checkpoint inhibitor, Pembrolizumab.

On June 8, 2016, the Corporation completed a bought deal private placement of 14,550,000 units at a price of \$0.55 per unit, for aggregate proceeds of \$8,002,500. Each unit consisted of one common share and one-half of one warrant, with each whole warrant entitling the holder to acquire one common share at an exercise price of \$0.72 per share for a period of 24 months, expiring on June 8, 2018. The value allocated to the common shares issued was \$7,566,000 and the value allocated to the warrants was \$436,500. Total costs associated with the Offering were

\$750,054, including cash costs for commissions of \$479,549, professional fees and regulatory costs of \$174,595 and 871,908 compensation options as underwriters' fees valued at \$95,910. Each compensation option entitles the holder to acquire one common share at an exercise price of \$0.60 for a period of 24 months, expiring on June 8, 2018. The Corporation has allocated \$709,142 of the issue costs to the common shares and \$40,912 of the issue costs to the warrants.

On December 9, 2016, the Corporation completed a bought deal private placement of 10,666,667 common shares at a price of \$0.75 per common share, for aggregate proceeds of \$8,000,000. Total costs associated with the offering were \$770,770, including cash costs for commissions of \$480,000, professional fees and regulatory costs of \$117,970 and 640,000 compensation options as underwriters' fees valued at \$172,800. Each compensation option entitles the holder to acquire one common share at an exercise price of \$0.79 for a period of 24 months, expiring on December 9, 2018.

It is common for early-stage biotechnology companies to require additional funding to further develop productcandidates until successful commercialization of at least one product candidate. Immunovaccine's product candidates are still in the early-development stage of the product cycle and therefore are not generating revenue to fund operations. The Corporation continuously monitors its liquidity position, the status of its development programs including those of its partners, cash forecasts for completing various stages of development, the potential to license or co-develop each vaccine candidate, and continues to actively pursue alternatives to raise capital, including the sale of its equity securities, debt and non-dilutive funding.

Management believes that its cash resources of \$13.5 million and additional potential cash resources of \$0.7 million will be sufficient to fund operations for the next twelve months to continue to execute the Phase 1b combination trial with DPX-Survivac and Incyte's IDO1 inhibitor epacadostat, the Phase 2 clinical trial for DPX-Survivac in DLBCL, and to explore opportunities for further combination trials with partners, while maintaining adequate working capital well into 2018. Management further believes there are discretionary expenditures within the current cash forecast which could be reduced in the event that the identified potential sources of cash are not realized or receipt is delayed. The Corporation continually reassesses the adequacy of its cash resources, evaluating existing research projects and/or potential collaboration opportunities, to determine when additional funding is required.

# CONTRACTUAL OBLIGATIONS

Contractual	Payments Due by Period					
Obligations	Total	Less than 1 year	1 - 3 years	4 - 5 years	After 5 years	
Accounts payable and accrued liabilities	1,705,289	1,705,289	-	-	-	
Amounts due to directors	40,101	40,101	-	-	-	
Long-term debt	15,337,773	220,009	5,250,283	133,920	9,733,561	
Operating Leases	540,613	223,735	316,878	-	-	
TOTAL	17,623,776	2,189,134	5,567,161	133,920	9,733,561	

The following table outlines the contractual maturities for long-term debt repayable over the next five years and after:

# **RELATED PARTY TRANSACTIONS**

During Q4 2016, there were no related party transactions (Q4 2015 - \$nil).

# DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROLS OVER FINANCIAL REPORTING

Under applicable securities laws, the Corporation's Chief Executive Officer and Chief Financial Officer certify on the design of the disclosure controls and procedures ("DC&P") and the internal controls over financial reporting ("ICFR") of the Corporation. DC&P are intended to provide reasonable assurance that material information is gathered and reported to senior management to permit timely decisions regarding public disclosure and ICFR are intended to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with Canadian generally accepted accounting principles. The control framework used by the Chief Executive Officer and Chief Financial Officer of the Corporation to design the Corporation's ICFR is the Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

The Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the Corporation's DC&P and ICFR. They concluded that as of December 31, 2016, the Corporation's design and operation of its DCP and ICFR were effective in providing reasonable assurance that material information regarding this MD&A, and the annual consolidated financial statements and other disclosures was made known to them on a timely basis and reported as required and that the financial statements present fairly, in all material aspects, the financial position of the Corporation as of December 31, 2016. The Chief Executive Officer and Chief Financial Officer also concluded that no material weaknesses existed in the design of the ICFR.

There have been no changes in the Corporation's ICFR that occurred during the year ended December 31, 2016 that have materially affected or are reasonably likely to materially affect the Corporation's ICFR.

## SIGNIFICANT ESTIMATES

The audited annual consolidated financial statements as at December 31, 2016 have been prepared in accordance with IFRS. Significant accounting estimates used in preparing the audited annual consolidated financial statements include the initial fair valuation of long-term debt, the calculation of the carrying amount of long-term debt, the SRED tax credits receivable, the fair value allocation of consideration for multiple element revenue arrangements, non-cash stock-based compensation expense, amortization and depreciation of intangibles and property and equipment, and the allocation of proceeds between common shares and warrants, and accrued liabilities.

Management has calculated the fair value of the interest-free government loans based on the forecast of the Corporation's future revenue, discounted at an appropriate discount rate. The estimates and assumptions used in the valuation model were based on current information available to management and a degree of management's judgment. A change in management's assumptions used to forecast future revenue or a change in the discount rate could have a significant impact on the fair value of these interest-free government loans. Management has estimated the Scientific Research and Economic Development receivable based on its assessment of tax credits receivable on eligible expenditures incurred during the period and its experience with claims filed with and collected from the Canada Revenue Agency. Management has analyzed the amounts receivable listing for potentially uncollectible amounts and has allowed for all balances which collection is doubtful. Management has made estimates regarding when stock options might be exercised and stock price volatility in calculating non-cash stock based compensation. The timing for exercise of options is out of the Corporation's control and will depend on a variety of factors including the market value of the Corporation's shares and the financial objectives of the stock-based instrument holders. Management has made estimates about the expected useful lives of long-lived assets, and the expected residual values of the assets. Management has determined the allocation of proceeds between common shares and warrants based on the relative values of the shares and warrants issued. Through knowledge of the Corporation's activities in the year ended December 31, 2016, management has estimated the amount of accrued liabilities to be recorded.

#### **OUTSTANDING SECURITIES**

The number of issued and outstanding common shares on March 30, 2017 is 118,954,409. The number of outstanding stock options on March 30, 2017 is 6,243,947. The outstanding stock options have a weighted average exercise price of \$0.72 per share and a weighted average remaining term of 3.11 years. The number of outstanding

warrants on March 30, 2017 is 8,101,408. The outstanding warrants have a weighted average exercise price of \$0.71 per share and a weighted average remaining term of 1.23 years. The number of outstanding deferred share units on March 30, 2017 is 325,000.

# INTELLECTUAL PROPERTY RIGHTS

The Corporation strives to protect its intellectual property in established, as well as emerging, markets around the world. The Corporation's intellectual property portfolio relating to its vaccine platform technology includes nine patent families, the first of which contains eight patents issued in five jurisdictions (United States, Europe, Canada, Japan and Australia). The eight other families collectively contain twenty patents issued in nine jurisdictions (United States, Europe, Canada, Australia, Japan, India, Singapore, China and separately Hong Kong) and thirty-nine pending patent applications in eleven jurisdictions. U.S. Patent 6,793,923, issued in 2004, contains claims to the Corporation's platform, covering "any antigen, any adjuvant in any liposome and any oil". The platform name is protected by trademarks in the United States, Canada and Europe.

Additional granted patents include:

- European Patent 1,333,858, granted February 8, 2006;
- Australian Patent 2002214861, granted January 11, 2007;
- Japanese Patent 4164361, granted August 1, 2008;
- United States Patent 7,824,686, granted November 2, 2010;
- Australian Patent 2006301891, granted December 20, 2012;
- Chinese Patent 200680036783, granted September 18, 2013;
- European Patent 1,948,225, granted December 11, 2013;
- United States Patent 8,628,937, granted January 14, 2014;
- Australian Patent 2008303023, granted April 24, 2014;
- Japanese Patent 5528703, granted April 25, 2014;
- Australian Patent 2008307042, granted May 15, 2014;
- Singaporean Patent 166901, granted May 27, 2014;
- Japanese Patent 5591705, granted August 8, 2014;
- European Patent 2,296,696, granted August 27, 2014;
- Australian Patent 2009253780, granted November 27, 2014;
- Japanese Patent 5715051, granted March 20, 2015;
- Japanese Patent 5731198, granted April 17, 2015;
- Indian Patent 266563, granted May 18, 2015;
- Canadian Patent 2,428,103, granted June 9, 2015;
- Hong Kong Patent 115642, granted July 24, 2015;
- United States Patent 9,114,174, granted August 25, 2015;
- Chinese Patent 200880110239.7, granted March 9, 2016;
- Chinese Patent 200980120883.7, granted April 6, 2016;
- European Patent 2,197,497, granted June 1, 2016;
- Japanese Patent 6016970, granted October 7, 2016;
- United States Patent 9,498,493, granted November 22, 2016; and
- Canadian Patent 2,700,828, granted January 24, 2017.

Since 2008, the Corporation has filed seven Patent Cooperation Treaty ("PCT") applications relating to the Corporation's technologies, some or all of which have now been filed in the United States, Europe, Japan, Canada, Australia, China, India, Brazil, Israel, Hong Kong and Singapore. These PCT applications cover specific DepoVax<sup>TM</sup> compositions with broad utility for infectious diseases and cancer applications. Some of these applications have issued to patent as listed above. These patents, together with the other pending applications if allowed, extend patent protection for some or all DepoVax<sup>TM</sup>-based vaccines, and/or uses thereof, approximately up to the year 2036. The latest published PCT application covers methods for potentiating an immune response using a combined approach of a depot-forming vaccine (e.g. DepoVax<sup>TM</sup>) and a non-depot-forming vaccine.

The Corporation also has a licensing agreement with VIB in relation to patent applications for a Respiratory Synctial Virus Vaccine (PCT/EP2011/070161) that were filed in Australia, Canada, China, Europe, Japan, and the United States. The licensing agreement stipulates that the Corporation will assume the cost of prosecuting and maintaining the fees associated with the patent applications and issued patents. These applications if allowed, could provide patent protection for a RSV vaccine formulated in DepoVax<sup>TM</sup>, thereby extending patent protection for DepoVax<sup>TM</sup>-based vaccines. To date, a patent on this RSV vaccine technology was issued in China, Japan and the United States.

# SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies of the Corporation are detailed in the notes to its audited consolidated financial statements for the year ended December 31, 2016 filed on SEDAR at www.sedar.com.

# FINANCIAL INSTRUMENTS

Financial assets and liabilities are recognized when the Corporation becomes a party to the contractual provisions of the instrument. Financial assets are no longer recognized when the rights to receive cash flows from the assets have expired or have been transferred and the Corporation has transferred substantially all risks and rewards of ownership.

Financial assets and liabilities are offset and the net amount is reported in the statement of financial position when there is a legally enforceable right to offset the recognized amounts and there is an intention to settle on a net basis, or realize the asset and settle the liability simultaneously.

The Corporation recognizes financial instruments based on their classification. Depending on the financial instruments' classification, changes in subsequent measurements are recognized in net loss or other comprehensive loss. The Corporation has implemented the following classifications:

- Cash and cash equivalents and amounts receivable are classified as loans and receivables. After their initial fair value measurement, they are measured at amortized cost using the effective interest method; and
- Accounts payable and accrued liabilities, amounts due to directors and long-term debt are classified as other financial liabilities. After their initial fair value measurement, they are measured at amortized cost using the effective interest method.

A description of the financial instruments, their fair value and risk management is included in the Corporation's audited consolidated financial statements for the year ended December 31, 2016 filed on SEDAR at www.sedar.com.

## RISK ASSESSMENT

The Corporation's activities are subject to certain risk factors and uncertainties that generally affect developmentstage biotechnology companies. Management defines risk as the evaluation of the probability that an event might happen in the future that could negatively affect the financial condition, results of operation or perspectives of the Corporation. The success of the Corporation will depend, without limitation, on its ability to:

- achieve or maintain profitability after incurring significant losses since inception and expect to incur losses for the foreseeable future;
- obtain substantial funding when needed before being forced to delay, reduce, terminate or eliminate product development programs;
- raise additional capital on reasonable terms without causing significant dilution to existing shareholders, restrict operations or require the Corporation to relinquish rights to its technologies or product candidates;
- obtain positive results of clinical trials, including clinical trials on DPX-Survivac, as the Corporation depends heavily on the success of its product candidates;

- demonstrate safety and efficacy with its product candidates to the satisfaction of the FDA or similar regulatory authorities outside the United States, so that it does not have to incur additional costs or experience delays in completing the development and commercialization of its product candidates;
- achieve development goals and meet set time frames, including enrollment of patients in clinical trials;
- obtain positive results of clinical trials without serious adverse or inappropriate side effects;
- obtain market acceptance of its product by physicians, patients, healthcare payers and others in the medical community for commercial success;
- establish sales and marketing capabilities or enter into agreements with third parties to sell and market its product candidates;
- discover, develop or commercialize its products before its competition does;
- commercialize any products under favourable pricing regulations, third-party reimbursement practices or healthcare reform initiatives;
- continue research and commercialization of its product candidates without relying on government funding;
- market products without product liability lawsuits;
- market the product candidate that has the greater likelihood of success and profitability;
- establish collaborations with third parties, including with third parties for the development and commercialization of its product candidates;
- satisfactorily collaborate with third parties for the conduct of its clinical trials;
- establish or maintain strategic collaborations with third parties;
- prevent cyber security incidents and privacy breaches;
- secure the raw ingredients, intermediate drug substances and specialized equipment necessary for the production of its product candidates;
- commercially manufacture its products;
- preserve its intellectual property rights and comply with its obligations under its intellectual property licenses with third parties;
- successfully protect its intellectual property against competition infringement and/or protect itself against third party allegations of the Corporation infringing on their intellectual property;
- protect its trade secrets and intellectual property without spending substantial resources or distracting key personnel from their normal responsibilities;
- obtain regulatory approval of product pipeline, including regulatory approval in international jurisdictions;
- comply with environmental, health and safety laws and regulations;
- market its product without restrictions or problems with its product after its approved;
- develop legitimate relationships with its customers and third-party payers;
- obtain market approval and commercialize its product candidates with recently enacted and future legislation;
- retain key executives and attract, retain and motivate qualified personnel; and
- manage its growth as it expands its development, regulatory, manufacturing and sales and marketing capabilities.

The risks identified above do not include all possible risks as there may be other risks of which management is currently unaware. The above risks and other general risks and uncertainties relating to the Corporation and its activities are more fully described in the AIF, under the heading "Risk Factors and Uncertainties".

# **OFF BALANCE SHEET ARRANGEMENTS**

The Corporation was not party to any off balance sheet arrangements as of December 31, 2016.

# ADDITIONAL INFORMATION

Additional information relating to Immunovaccine, including the AIF and other disclosure documents, are available on SEDAR at www.sedar.com.