

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

For the three months ended March 31, 2016

#### LETTER TO SHAREHOLDERS

Dear Fellow Shareholder,

In the first quarter of 2016, we made diligent, steady progress on the three components that will support the long-term success of Immunovaccine and our DepoVax™-based pipeline by:

- Leveraging the unique aspects of our DepoVax™ platform to strengthen our immuno-oncology program;
- Deploying our DepoVax™-based technology in key areas of high unmet medical need in the realm of infectious diseases; and
- Evolving of our leadership to support the Company's progress from discovery towards clinical development and commercialization.

Progress in our immuno-oncology program was realized through our collaboration with Incyte Corporation, as we achieved a key regulatory milestone. In January 2016, the U.S. Food and Drug Administration (FDA) and Health Canada provided clearance for us to initiate a clinical study with our novel T cell activating therapy, DPX-Survivac. The Phase 1b clinical trial will assess the safety and effectiveness of DPX-Survivac with Incyte's investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360), and low-dose cyclophosphamide in patients with recurrent ovarian cancer who have measurable disease.

Having previously established that that DPX-Survivac combined with low-dose oral cyclophosphamide is well tolerated and can induce a strong immune response, this new trial will add Incyte's promising, clinically advanced immunotherapy. We hope that this triple combination can lead to a new and potent therapeutic option for the high unmet medical need in ovarian cancer. We anticipate starting the trial, which Incyte will co-fund under the terms of our agreement, in the first half of 2016.

Recent widespread outbreaks of the Zika virus, which has no viable treatment options and has been linked to neurological birth defects in infants, propelled the next application of our DepoVax™ platform in infectious disease. In early 2016, we initiated a Zika vaccine research project, thereby joining the global race to combat this significant public health threat. We believe that the unique DepoVax™ delivery system offers significant value to potential collaborators because it has demonstrated its ability to provide durable immune responses and a consistent safety profile when tested among several infectious diseases. Our goal here is to build upon the promising results of our earlier research with DepoVax™-based vaccines for Ebola virus, anthrax and respiratory syncytial virus (RSV) to accelerate the development of a vaccine that combats the mosquito-borne virus.

Shortly after the quarter ended, we significantly advanced the Zika project by entering into a collaboration with <u>Leidos</u> (NYSE: LDOS), a health, national security and infrastructure solutions company. Leidos will lead the antigen discovery and development, and we will formulate the new antigens in our DepoVax<sup>™</sup> delivery system. We believe that this project could serve as a replicable model for expediting the development and manufacture of vaccines to address current and future health emergencies

Finally, in Q1 2016, our management team experienced a transformation. Company veteran Marc Mansour, Ph.D., stepped down as of March 31, 2016, and I am honored to have been named the Company's new Chief Executive Officer. During my tenure as the Chief Business Officer at Immunovaccine, I witnessed first-hand the strength of the team here and its ability to develop our pipeline of DepoVax™-based programs. In addition, the unique technology inherent in the DepoVax™ delivery system offers advantages that position Immunovaccine as a preferred partner among immuno-oncology and infectious disease collaborators. I am looking forward to working with the team to expand relationships and progress our programs, taking advantage of the myriad of opportunities on our horizon.

We also bolstered our Board of Directors with the appointment of Medicago CEO Andy Sheldon. In addition to being named to the Board, Andy was unanimously elected to lead the Board as Chairman at our 2016 Annual General Meeting. Andy's experience across the pharmaceutical and biotech industries is a tremendous asset, and, ultimately, gives our potential commercial partners and investors further confidence that we understand our markets and are ready to serve them.

Carrying forward the momentum of the first quarter, we are well positioned to make significant strides for the remainder of 2016. Already, within in the first few weeks of Q2, we presented a poster at the American Association of Cancer Research

(AACR) 2016 meeting, in which a pre-clinical study showed that DepoVax™-based cancer vaccines may improve the efficacy of checkpoint inhibitors, even among tumors that do not respond to anti-PD-1 therapies alone. Study findings indicated that our vaccine delivery system has the potential to increase the susceptibility of tumors to PD-1 blockades, thereby potentially improving outcomes and broadening the range of cancers treatable by these types of therapies. We are evaluating opportunities to pursue collaborations that can leverage our DepoVax™-based vaccines to increase the efficacy of the checkpoint inhibitors in development or currently on the market.

To read our Press Release on our 2016 Q1 Financial Results, please click here.

Thank you for your continued support this year. We look forward to providing you with more updates on the progress of our DepoVax™-based pipeline throughout 2016.

Frederic Ors

**Chief Executive Officer** 

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

The following analysis provides a review of the unaudited interim condensed consolidated results of operations, financial condition and cash flows for the three months ended March 31, 2016 ("Q1 2016"), with information compared to the three months ended March 31, 2015 ("Q1 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 year ended December 31, 2015 and the year ended December 31, 2014.

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

Additional information regarding the business of the Corporation, including the Corporation's Annual Information Form, 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. 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, which may include merger and acquisitions activities;
- 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 Annual Information Form of the Corporation for the year ended December 31, 2015, 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 May 10, 2016; the date of the Board's approval of the MD&A and the Q1 2016 unaudited interim condensed 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> adjuvanting/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 vaccine applications.

The DepoVax<sup>TM</sup> platform is being used in multiple vaccine candidates, including two cancer vaccine candidates that have completed Phase 1 clinical trials. The Corporation's lead cancer vaccine, DPX-Survivac, is currently being tested in a company-sponsored Phase 2 trial in lymphoma and a Phase 1b trial in ovarian cancer. DPX-Survivac will also be 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. The Corporation also has an investigator-sponsored exploratory Phase 2 trial in glioblastoma (brain cancer) in Italy for which it is waiting for regulatory approval. The Corporation's infectious disease vaccine against respiratory syncytial virus ("RSV") is in a Phase 1 clinical trial in Halifax, Nova Scotia. The Corporation also has several research and clinical collaborations, including with the Dana Farber Cancer Institute and Leidos in the U.S.

The Corporation entered into an exclusive worldwide license agreement with PharmAthene, Inc. ("PharmAthene") to develop and commercialize an anthrax vaccine candidate formulated in Immunovaccine's DepoVax<sup>TM</sup> vaccine platform. The Corporation has licensed the delivery technology to Zoetis, formerly the animal health division of Pfizer, Inc. ("Pfizer"), for the development of vaccines for livestock.

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 22 full-time and part-time employees and three part-time consultants as of March 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 five employees holding PhD degrees and nine 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**

The DepoVax<sup>TM</sup> vaccine delivery platform drives the operating strategy for the Corporation. All of the Corporation's development relies on this adjuvanting platform improving the effectiveness of vaccines against cancer and infectious diseases. While this platform may have broad application across multiple areas, the Corporation is mainly focusing on the field of Immuno-Oncology, advancing the clinical development of products combining DepoVax<sup>TM</sup> with proprietary cancer antigens.

The Corporation has two clinical-stage cancer vaccines: DPX-Survivac and DPX-0907. Immunovaccine believes the principles behind a successful therapeutic cancer vaccine should include a targeted antigen and an effective adjuvanting and vaccine delivery technology, combined with a complementary therapeutic strategy. Antigens used in both DPX-Survivac and DPX-0907 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, ideally soon after a tumor has been identified and treated by surgery, chemotherapy and/or other therapies that reduce tumor bulk. 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 an adjuvanting 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 vaccines that are unusually non-immunogenic, the platform may significantly reduce the number of immunizations required. The Corporation's goal in infectious diseases is to out-license the  $DepoVax^{TM}$  platform to partners in order to generate revenues earlier.

## 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 over \$43 million in equity through prospectus offerings, private placement offerings and the exercise of stock options and warrants.

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 immuno-oncology products. The Corporation announced a collaboration with Incyte, to evaluate the combination of the Corporation's lead cancer vaccine, 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. The Corporation is also in discussions with potential large pharmaceutical partners and the Canadian Cancer Trials Group to test DPX-Survivac in combination with other immunotherapies in clinical trials, DPX-Survivac will also be tested in an investigator-initiated Phase 2 study in glioblastoma patients at the University of Rome, Italy, once regulatory clearance is received.

Other programs include: a clinical research collaboration with the Canadian Centre for Vaccinology ("CCfV") for a Phase 1 clinical trial funded by the Canadian Institutes of Health Research ("CIHR") of an RSV vaccine; and a collaboration with the Dana Farber Cancer Institute for producing a DepoVax<sup>TM</sup>-based vaccine for Human Papilloma virus ("HPV") related cancers funded by the Stand Up to Cancer-Farrah Fawcett Foundation. The underlying goal of these types of partnerships is to produce pre-clinical and clinical data that will 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.

As part of its licensing strategy in infectious diseases, the Corporation recently signed a worldwide exclusive agreement with PharmAthene for the use of the DepoVax<sup>TM</sup> platform for the development and commercialization of a novel, rapid response anthrax vaccine candidate. Immunovaccine is also collaborating with Leidos on the development of a Zika virus vaccine.

Immunovaccine also maintains a commercial relationship with Zoetis, formerly the animal health division of Pfizer, which has licensed the Corporation's delivery technology platform to develop vaccines for livestock.

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, and merger and acquisitions opportunities. The Corporation may seek additional equity and non-dilutive funding and partnerships to advance the development of its vaccine candidates.

## PLATFORM AND PRODUCTS IN DEVELOPMENT

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

The DepoVax<sup>TM</sup> platform is a combination of antigens, plus adjuvant (immune enhancers) formulated in lipids and then suspended in oil. With the ability to retain the active components in the oil phase, the DepoVax<sup>TM</sup> platform creates a long-lasting "depot effect" that prolongs the exposure of vaccine ingredients to immune cells at the site of vaccination. The DepoVax<sup>TM</sup> platform forms the basis of Immunovaccine's therapeutic cancer and infectious diseases vaccine candidates.

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 Corporation believes the ability of DepoVax<sup>TM</sup> to induce robust cellular immune responses makes the platform uniquely suitable for therapeutic cancer vaccines, which are designed to target tumor cells, helping patients remain in remission and combating the dissemination of micro-metastases. DepoVax<sup>TM</sup> can induce antigen-specific "polyfunctional" cellular responses, which are postulated to be required for effective tumor control.

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 versatility and the 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>TM</sup> based vaccines for the therapy of cancer and for the protection from infectious diseases are expected 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 the DepoVax<sup>TM</sup> vaccine delivery platform. 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 is an inhibitor of cancer cell death, known as apoptosis. The presence of survivin in cancer cells is believed to make them susceptible to a survivin-specific vaccine. The Corporation's survivin-based vaccine candidate, DPX-Survivac, aims to train the immune system to recognize and kill survivin-containing cancer cells, 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 therapeutic cancer vaccine 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 proceed with pre-clinical testing of DPX-Survivac in a broader range of cancer indications to evaluate additional opportunities.

## Clinical Trial Development - Current and Planned Trials

The Corporation initiated a Phase 2 clinical trial 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 will seek 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.

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 will co-fund and conduct a multicenter, open-label Phase 1b study to evaluate the safety, tolerability and efficacy of the novel combination in platinum-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, is expected to be filed this year in the United States and Canada. The study is expected to enroll approximately 20 patients. Results from this study may lead to an expansion of the clinical collaboration to investigate other cancers.

An ongoing Phase 1b trial is continuing to enroll patients to optimize the dose and schedule of vaccinations. Interestingly, a patient enrolled in the Phase 1b 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 also has an agreement with Professor Marianna Nuti, Ph.D., Department of Experimental Medicine at the University of Rome, to conduct an investigator-led trial on DPX-Survivac in patients with glioblastoma. This multicenter study based in Rome will be conducted in collaboration with neurosurgeons and oncologists coordinated

by Professor Maurizio Salvati, M.D. The study design has been modified to a Phase 2a, expected to enroll up to 20 patients to explore the immunogenicity and safety of DPX-Survivac in patients with glioblastoma. Results from this trial could lead to additional clinical studies in glioblastoma. Testing DPX-Survivac in glioblastoma patients has not yet been initiated as it is pending regulatory clearance from the Italian Medicines Agency.

The Corporation is pursuing opportunities for additional trials with pharmaceutical companies, including combination therapies with DPX-Survivac and other complementary immunotherapies such as anti-PD-1 in a variety of indications including as part of its collaboration with the Canadian Cancer Trials Group.

## Clinical Trial Development – Completed Trials

Immunovaccine completed a Phase 1 clinical trial of DPX-Survivac in ovarian cancer patients, which was conducted at six clinical sites in the US and Canada. The Phase 1 trial was an open-label clinical trial designed to evaluate sequentially the safety of two DPX-Survivac dosing regimens in 18 patients. This Phase 1 clinical trial established the safety and immunogenicity of DPX-Survivac in patients with advanced ovarian cancer.

The Corporation released interim results in October 2012, in January 2013 and final detailed positive results in June 2013 on the Phase 1 clinical trial. The analysis, which includes all 18 patients enrolled in the study, confirmed that 12 of the 18 patients, who received the DPX-Survivac combination therapy, demonstrated antigen-specific immune responses. They were measured by at least one of the study's three immune monitoring assays (ELISpot, tetramer analysis and multi-parametric intracellular cell staining). In 11 of 12 patients, the immune responses were confirmed by two assays (five patients) or three assays (six patients) performed. These immune responses were established with one or two vaccinations and further increased or maintained with follow-up booster vaccinations. Importantly, polyfunctional CD8 responses were reported, indicating the activation of high quality CD8 T cells, and the responses were maintained with booster vaccinations. The activation and maintenance of these specific immune cells is of particular interest in immunotherapy since CD8 T cells are implicated in identifying cancer cells, infiltrating tumors and killing cancer targets.

Also, in the Phase 1 clinical trial, DPX-Survivac was deemed well-tolerated with no significant systemic adverse events reported in any patients recruited in this study. Reported adverse events were related primarily to grade 1-2 injection site reactions, which were experienced by the majority of patients after repeated vaccinations. Those patients presenting the strongest immune responses were more likely to exhibit more pronounced injection site reactions. Grade 3 injection site ulcerations, which were an expected adverse event with this vaccine, were experienced by three patients during the trial. Upon a six month follow-up for the majority of patients, a trend of delayed progression was observed in patients who had strong immune responses to DPX-Survivac. The trend of delayed cancer progression, which was not statistically significant, may be attributed to the therapy or may be attributed to other unrelated factors. The results from this clinical trial were recently published in the peer-reviewed scientific journal *Oncoimmunology*.

Immunovaccine highlighted results demonstrating that metronomic cyclophosphamide ("mCPA"), an immune modulating agent, enhanced the immunogenicity of DepoVax<sup>TM</sup>-based vaccines in preclinical cancer models consistent with previously reported Phase 1 data showing a similar enhancement of DPX-Survivac in patients. Importantly, the animal studies demonstrated the combination therapy's ability to eliminate advanced tumors that could not be treated with vaccine or mCPA alone. Tumors exposed to the combination therapy specifically exhibited an increase in T cell activation markers, suggesting increased immune-mediated anti-tumor activity at the tumor site with the vaccine/mCPA therapy and further supporting the use of the combination therapy in clinical trials. This work was published in the peer reviewed scientific journal *Oncoimmunology*.

### Orphan Drug Status and Fast Track Designation

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 also 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>TM</sup> delivery technology with seven HLA-A2-restricted cancer-specific antigens licensed from Immunotope. The vaccine is designed to stimulate an immune response specific to cancer antigens that are believed to be involved in critical tumor cell processes. The seven peptide antigens in DPX-0907 are believed to be present on the surface of breast, ovarian, prostate, colon and pancreatic cancer cells. In preclinical studies, the seven antigens could not be found on the surface of normal cells, and therefore, DPX-0907 is expected to kill tumor cells without harming normal, healthy cells.

The Corporation believes DPX-0907 has particular utility for the treatment of ovarian, breast, prostate, colon and pancreatic cancers. The multi-antigen approach of DPX-0907 addresses the heterogeneity of cancers in patients and ensures that more than one antigen is targeted in a cancer patient to ensure that an immune response continues to recognize the cancer as the tumor evolves and possibly displaying different antigens.

Clinical Trial Development - Completed and Planned 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 US. 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.

The Phase 1 trial met the primary objective of safety with overall results demonstrating that DPX-0907 is generally well tolerated by all patients and is considered safe at both dose levels. There were no vaccine-related serious adverse events reported. Final safety was assessed in 11 patients in the 0.25 mL dose group and 11 patients in the 1.0 mL dose group.

The secondary objective was to assess whether administration of DPX-0907 could generate an immune response specific to the seven cancer antigens. Immunovaccine performed a detailed analysis of patients' blood samples that showed cell-mediated immunity (CMI) to vaccine targets in all three breast cancer patients, 5 of 6 ovarian cancer patients, and 3 of 9 prostate cancer patients. Both dose levels produced a targeted immune response in vaccinated patients. The immunogenicity results were based on an analysis of nine evaluable patients in the 0.25 mL dose group and nine evaluable patients in the 1 mL dose group.

This study also demonstrated a key association between the achievement of immune responses during the study and the patients' level of disease. The breast and ovarian cancer patients who responded well to prior therapies responded favorably, with the majority of these patients (8 out of 9) producing the desired immunity. In contrast, the majority of prostate cancer patients who had more advanced disease and were less responsive to prior therapies exhibited a lower immune response rate.

The Corporation is currently exploring other opportunities for commercialization of DPX-0907 and is considering investigator funded trials or partnership opportunities at various stages of clinical development, including at the Phase 1 and Phase 2 clinical trial stages.

## 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 the 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

Immunovaccine obtained clearance from Health Canada to conduct a Phase 1 clinical study of its RSV vaccine in healthy adults. The RSV vaccine is formulated in Immunovaccine's proprietary DepoVax™ 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™-based vaccine in an infectious disease indication, evaluating the safety and immune response profile of the RSV vaccine candidate in approximately 40 healthy adults between the ages of 50 to 64 years of age. The first patient was enrolled on June 30, 2015, at the Canadian Center for Vaccinology in Halifax. The vaccine will be tested at two different vaccine dose levels and study investigators will assess the vaccine's safety and immune response profile following one or two immunizations of each dose level. The trial is being co-funded by Immunovaccine. Early results from the first 20 volunteers in the clinical study were considered safe, which allowed the enrolment of volunteers in the high vaccine dose portion of the study, which is still ongoing. The Corporation intends to out-license this product after completion of the Phase 1 trial.

## Zika Virus vaccine antigen

Immunovaccine and Leidos (NYSE: LDOS), a health, national security and infrastructure solutions company collaborate 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 research project in which the company 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. Together, the companies hope 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.

The Corporation entered into an exclusive worldwide license agreement with PharmAthene to develop and commercialize a recombinant protective antigen anthrax vaccine ("rPA") candidate utilizing Immunovaccine's proprietary DepoVax<sup>TM</sup> vaccine platform. Under the terms of this agreement, PharmAthene is working exclusively with Immunovaccine to develop an adjuvanted, non-alum based, rPA vaccine. In return, Immunovaccine has granted PharmAthene exclusive worldwide rights to use DepoVax<sup>TM</sup> for the development and commercialization of the novel single dose anthrax vaccine. This license agreement includes an upfront signing fee, annual payments, and regulatory and commercial milestone payments totalling up to USD \$50 million, in addition to royalties from future vaccine sales.

In addition to the most recent license agreement with PharmAthene described above, the Corporation also has multiple license agreements with Zoetis, formerly the animal health division of Pfizer, for the use of the Corporation's delivery technology in cattle and other livestock vaccine applications. These license agreements include upfront signing fees, milestone payments and royalties from future vaccine sales.

Immunovaccine intends to pursue additional licensing and revenue opportunities to help fund the research and development of its vaccine candidates.

## MARKET OVERVIEW

Therapeutic cancer vaccines

Cancer is considered one of the most widespread and prevalent diseases globally. According to *Global Cancer Facts & Figures, 3<sup>rd</sup> 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. Andrew Baum, an analyst at CITIGROUP, has projected that immunotherapies, including vaccines, will dominate cancer therapy by the year 2020, representing a market up to \$35 billion.

Cancer immunotherapy seeks to harness the immune system to assist in the destruction of tumors and to prevent their recurrence. There has been significant excitement 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 significant 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 US 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 excitement 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 and AstraZeneca, 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 \$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 GSK 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 SARS and 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 at USD\$66.4 billion in 2012. 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, Novartis, Merck and Johnson & Johnson. 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 available to companies 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 USA 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. IMV expects that the development of a vaccine with these improved characteristics will 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 transactions 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 change this 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.

Emerging Infectious Diseases: Zika Virus

The unpredicted emergence of new infectious diseases represents a significant challenge to public health. In the past decades, diseases such as severe acute respiratory syndrome (SARS), pandemic H1N1 influenza, MERS (Middle East Respiratory Syndrome) and most recently Zika virus have underlined the challenges in rapidly addressing potential disease threats with countermeasures such as vaccines.

Zika virus is a flavivirus, in the same virus family as dengue, yellow fever, West Nile, and Japanese encephalitis virus. Although it had been discovered in 1947, it had been isolated to relatively small outbreaks in Africa and Southeast Asia and associated with a fairly benign infection. Typical symptoms include a rash, fever, joint pain and red eyes (conjunctivitis); yet, as many as 80% of those infected have no symptoms at all. In 2007, Zika virus was associated with a significant outbreak on the Polynesian island of Yap and was later detected to have spread to Brazil in 2015. It is through this larger expansion of infection particularly in the Northeastern region of Brazil, as well as the abundance of the viral vector, the mosquito *Aedes aegypti*, that late last year, viral infection had been potentially linked with birth defects such as microcephaly, as well as other neurological defects in adults, including Guillian-Barre syndrome and post-infection autoimmune neuropathy. In February 2016, the World Health Organization (WHO) declared a public health emergency of international concern around Zika virus, and in April 2016 confirmed a 'causal link' between Zika virus infection and neurological defects, The WHO has also indicated that this virus is spreading very rapidly in the Americas, and travellers to infected regions have returned home to many countries infected with the virus.

Vaccination has been effective in controlling other flaviviruses including yellow fever virus and Japanese encephalitis virus. In December 2015, the first vaccine for dengue virus (Dengvaxia®) completed Phase 3 clinical trials and has been approved for use in several countries, including Brazil, the Phillipines and Mexico. With no proven vaccine or treatment available for Zika virus infection, many groups, including academic, governmental and industry scientists are working to rapidly develop vaccine candidates. Several biotechnology companies, such as Bharat Biotech International Ltd, NewLink, Inovio and Immunovaccine have announced plans to develop a Zika virus vaccine. An ideal vaccine candidate should be easily produced, with scalable manufacture and stability. It should also be able to rapidly generate immunity. For these reasons, a DepoVax formulated vaccine makes an excellent candidate for dealing with this emerging health crisis.

## Bio-defense

Anthrax disease is caused by the bacteria *Bacillus anthracis*. Infection in humans occurs under natural circumstances after contact with contaminated livestock. Infection in humans most often involves the skin, gastrointestinal tract, or lungs. However, the ability to produce and weaponize anthrax spores generates a possibility for it to be disseminated as a bioweapon, as evidenced by the sending of anthrax spore laden letters to members of the United States Congress in 2001. For this reason, there have been substantial investments made in the acquisition of medical countermeasures for the Strategic National Stockpile as well as focused research, development and procurement activities.

The next-generation of anthrax vaccines has focused largely on the use of rPA as the antigen. However, the rPA-based vaccines require the use of potent adjuvants or adjuvant platforms, such as DepoVax<sup>TM</sup>, to achieve single-dose capability, as the current vaccine available requires three doses. The ideal anthrax vaccine would provide rapid protection with a single dose, generate a durable immune response, and have enhanced stability for stockpiling purposes. An anthrax vaccine formulated in DepoVax<sup>TM</sup> is expected to provide these characteristics.

#### 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, Merial, Merck Animal Health, Novartis and AgriLabs. 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 April 20, 2016, 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>TM</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 16, 2016, announced Andrew Sheldon joined the Board of Directors and was made the new Chairman.
- On April 13, 2016, announced Frederic Ors has been appointed Chief Executive Officer.
- On April 7, 2016, 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>TM</sup> platform to development of a Zika virus vaccine candidate. The project builds upon earlier promising results with DepoVax<sup>TM</sup> vaccines targeting the Ebola virus, anthrax and respiratory syncytial virus (RSV).
- On March 15, 2016, announced that Marc Mansour, Ph.D., will step down as Chief Executive Officer, effective on March 31, 2016 after 14 years with the Corporation. Frederic Ors, Chief Business Officer, has been named Acting Chief Executive while the Corporation conducts a search for Dr. Mansour's replacement.
- On March 3, 2016, announced it will begin a research project towards development of a vaccine formulated in its DepoVax<sup>TM</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 U.S. Food and Drug Administration (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 investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360), and low-dose

cyclophosphamide in patients with recurrent ovarian cancer who have measurable disease. Immunovaccine anticipates starting the trial, which Incyte will co-fund under the terms of the agreement between the two companies, by Q2 2016.

- On December 17, 2015, the Corporation announced the publication of research that used magnetic resonance imaging (MRI) to predict and optimize the efficacy of its cancer vaccines by measuring size changes in vaccine-draining lymph nodes. The preclinical study demonstrated that the increase in size of lymph nodes after vaccination with DepoVax™ technology indicated the strength of the immune response to the vaccine, and could help monitor and predict therapy success.
- On November 2, 2015, the Corporation announced that the initial results from a Phase 2 study demonstrated
  that DPX-Survivac can induce a strong immune response in diffuse large B cell lymphoma (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 tumorinfiltrating T cells following administration of the DPX-Survivac therapy, which correlated with an immune
  response produced by DPX-Survivac and detected in the blood.
- On October 29, 2015, the Corporation announced that safety data from a Phase 1 clinical study showed that its DepoVax<sup>TM</sup> prophylactic Respiratory Syncytial Virus vaccine candidate ("DPX-RSV") was well tolerated in the Phase 1 study's first 20 volunteers, of whom 8 subjects received the DPX-RSV vaccine. This data marks an important milestone for Immunovaccine as it provides the first safety profile of the DepoVax<sup>TM</sup>-based vaccines for infectious diseases in healthy adults. Based on the vaccine candidate's safety and immunogenicity demonstrated in the study, the independent Safety Review Committee ("SRC") has allowed the study to proceed to its next step, which includes vaccinating volunteers with DPX-RSV at a higher dose.
- On July 15, 2015, the Corporation announced 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.
- On July 8, 2015, the Corporation announced that it had entered into an exclusive worldwide license agreement with PharmAthene to develop and commercialize a Recombinant Protective Antigen Anthrax vaccine (rPA) candidate utilizing Immunovaccine's proprietary DepoVax<sup>TM</sup> vaccine platform. Under the terms of this agreement, PharmAthene will work exclusively with Immunovaccine to develop an adjuvanted non-alum based rPA vaccine. In return, Immunovaccine has granted PharmAthene exclusive worldwide rights to use DepoVax<sup>TM</sup> for the development and commercialization of the novel single-dose anthrax vaccine. In addition to the annual payments of U.S. \$200,000, Immunovaccine will receive payments of up to USD \$8 million for the achievement of development, U.S. and international regulatory milestones, and initial product sales, and up to USD \$42 million for the achievement of certain sales targets. This will total up to USD \$50 million if all milestones are achieved. Additionally, Immunovaccine will receive a royalty on net sales and will not be responsible for product development costs.
- On July 2, 2015, the Corporation announced that data from its completed Phase 1 clinical trial with lead cancer immunotherapy candidate, DPX-Survivac, was published in the peer-reviewed journal Oncoimmunology. The manuscript "Survivin targeted immunotherapy drives robust polyfunctional T cell generation and differentiation in advanced ovarian cancer patients," which was published in the June 26, 2015, edition of the journal, outlines the safety and immunogenicity of DPX-Survivac when combined with a low dose of cyclophosphamide taken orally by patients.
- On June 30, 2015, the Corporation announced that it had enrolled the first healthy adult volunteer in a Phase 1 clinical study of its respiratory syncytial virus (RSV) vaccine. The Phase 1 study will evaluate the safety and immune response profile of the DPX-RSV vaccine candidate in healthy adults. The study, conducted at the Canadian Center for Vaccinology (CCfV) in Halifax and led by Joanne Langley, M.D., will enroll 40 healthy adults who are 50 to 64 years of age. Immunovaccine and the Canadian Institutes of Health Research (CIHR) are co-funding the trial.

- On June 25, 2015, the Corporation announced that it had entered into a non-exclusive clinical trial collaboration with Incyte Corporation to evaluate the combination of Immunovaccine's novel T cell activating immunotherapy, DPX-Survivac, with Incyte's investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360). Immunovaccine and Incyte will co-fund and conduct a multicenter, open-label Phase 1B study to evaluate the safety, tolerability and efficacy of the novel combination in platinum-sensitive ovarian cancer patients who are at high risk of recurrence.
- On April 27, 2015, the Corporation announced its common shares have been approved to trade on the OTCQX® Best Marketplace in the United States under the symbol "IMMVF".
- On April 16, 2015, the Corporation announced that Frederic Ors had joined Immunovaccine's senior management team as Chief Business Officer. The Corporation also announced the voting results of the annual and special meeting of shareholders of the Corporation, held in Halifax, Nova Scotia.
- On March 24, 2015, the Corporation announced that it had treated the first patient with diffuse large B cell lymphoma (DLBCL) in a Phase 2 clinical study of its lead cancer immunotherapy DPX-Survivac. The Corporation-sponsored trial is evaluating DPX-Survivac in combination with oral cyclophosphamide, an immune modulating agent, in patients with recurrent DLBCL. DPX-Survivac is designed to activate killer T cells of the immune system against the survivin antigen found in a wide variety of solid tumors and blood cancers.
- On January 28, 2015, the Corporation announced results that three different recombinant protective antigen ("rPA") vaccines formulated with its novel DepoVax<sup>TM</sup> enhancement technology protected animals against a lethal anthrax challenge after a single vaccination. The NIH led study demonstrates the potential of DepoVax<sup>TM</sup> as a universal enabler of single dose rPA-based anthrax vaccines. The anthrax challenge study was designed to evaluate the early protection potential of single dose DepoVax<sup>TM</sup>-rPA vaccines. A very low dose of rPA that is known to provide partial protection in the rabbit model was used. This allowed a comparison of the potency of the various rPA vaccines formulated in DepoVax<sup>TM</sup>.
- On January 20, 2015, the Corporation received clearance from Health Canada to conduct a Phase 1 clinical study of its respiratory syncytial virus vaccine in healthy adults. The RSV vaccine is formulated in Immunovaccine's proprietary DepoVax<sup>TM</sup> adjuvanting platform and is initially being developed to protect the elderly population from infection.

## 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.

Ouarter Ended In	Total Revenue	Total Expenses	Loss	Basic and Diluted
Quarter Ended III	\$	\$	\$	Loss Per Share \$
Q1 - March 31, 2016	65,000	1,916,000	(1,852,000)	(0.02)
Q4 - December 31, 2015	65,000	2,514,000	(2,449,000)	(0.02)
Q3 - September 30, 2015	65,000	2,069,000	(2,004,000)	(0.02)
Q2 - June 30, 2015	-	2,553,000	(2,553,000)	(0.02)
Q1 - March 31, 2015	-	1,769,000	(1,769,000)	(0.02)
Q4 - December 31, 2014	-	2,032,000	(2,032,000)	(0.02)
<i>Q3</i> - September 30, 2014	-	1,263,000	(1,263,000)	(0.02)
Q2 - June 30, 2014	-	1,330,000	(1,330,000)	(0.02)
Q1 - March 31, 2014	-	1,943,000	(1,943,000)	(0.02)

Results for the three months ended March 31, 2016 ("Q1 Fiscal 2016"), compared to the three months ended March 31, 2015 ("Q1 Fiscal 2015").

#### Net loss and comprehensive loss

The net loss and comprehensive loss of \$1,852,000 for Q1 Fiscal 2016 was \$83,000 higher than the net loss and comprehensive loss for Q1 Fiscal 2015. This relates mainly to an \$85,000 increase in general and administrative expenditures, a \$59,000 increase in business development expenses, and a \$28,000 increase in accreted interest, offset by an increase in revenue of \$65,000 and a \$24,000 decrease in research and development costs.

#### Revenue

In Fiscal 2015, the Corporation signed a license agreement with PharmAthene which included a signing fee of USD \$200,000. As the revenue is spread over the year, the Corporation recognized \$65,000 for Q1 Fiscal 2016.

## **Operating expenses**

Overall operating expenses increased by \$147,000 (8%) during Q1 Fiscal 2016 compared to Q1 Fiscal 2015. Explanations of the nature of costs incurred, along with explanations for those changes in costs are discussed below:

Research and development ("R&D") 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, lab supplies, peptides and other chemicals, rental of lab facilities, insurance, as well as other minor 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 Q1 Fiscal 2016 included costs surrounding the Corporation's Phase 1b in ovarian cancer, Phase 1b with Incyte Inc. and Phase 2 in lymphoma clinical trials of DPX-Survivac, 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:

	Q1 Fiscal 2016	Q1 Fiscal 2015
	\$	\$
General research and development expenses	424,000	302,000
DPX-Survivac preclinical and clinical expenses	283,000	193,000
Salaries and benefits	351,000	299,000
Stock-based compensation	40,000	97,000
Depreciation of equipment and amortization of intangible	20,000	19,000
Government loans and assistance	(279,000)	(52,000)
Investment tax credits	(70,000)	(65,000)
Total	769,000	793,000

The increase in general R&D expenses from \$302,000 in Q1 Fiscal 2015 to \$424,000 in Q1 Fiscal 2016 is attributable mainly to \$242,000 in costs related to a research project the Corporation is undertaking to advance the DepoVax<sup>TM</sup> platform, which is substantially funded by a government grant. Also included in general R&D is cost recoveries of approximately \$70,000 associated with the work supporting the licensing deal with PharmAthene, Inc. and \$40,000 lower consulting costs in comparison to prior year.

The DPX-Survivac expenses increased by \$90,000 due mainly to the increase in clinical trial costs for the Corporation's Phase 1b clinical trial in ovarian cancer patients, the Phase 2 clinical trial in DLBCL, and the Phase 1b clinical trial collaboration with Incyte in ovarian cancer patients, offset by cost recoveries of approximately \$50,000 associated with the work supporting the clinical trial collaboration with the Dana Farber Cancer Institute.

General and administrative ("G&A") expenses

G&A expenses consist of the following:

	Q1 Fiscal 2016 \$	Q1 Fiscal 2015 \$
General and adminstrative expenses, excluding salaries	515,000	453,000
Salaries and benefits	173,000	157,000
Stock-based compensation	118,000	111,000
Depreciation of equipment	3,000	3,000
Total	809,000	724,000

G&A expenses, excluding salaries, increased by \$62,000 mainly due to an increase of \$210,000 in consulting fees mainly related to management organizational restructuring costs, offset by a \$133,000 decrease in legal fees for patent expenses.

#### Business development expenses

The Corporation's business development activities increased in Q1 Fiscal 2016 by \$59,000, compared to Q1 Fiscal 2015, to a total of \$211,000. This is mainly due to an increase of \$56,000 and \$63,000 in salary and benefits and stock-based compensation, respectively, relating to the hiring of a Chief Business Officer in April 2015, offset by a decrease of \$60,000 in business development related travel and conferences.

## CASH FLOWS, LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2016, the Corporation had cash and cash equivalents of \$2,082,000 and working capital of \$1,779,000, 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 Q1 2016, the Corporation recorded \$65,000 of revenue from PharmAthene.

During Q1 2016, cash of \$1,738,000 was used in operating activities. This included the reported net loss of \$1,852,000 prior to being decreased for non-cash amortization, non-cash depreciation, non-cash accretion of long-term debt and non-cash stock-based compensation. The Corporation had a net use of cash of \$258,000 as a result of changes in working capital balances.

Sources of cash raised through financing activities were \$9,800 through the exercise of stock options. Use of cash through financing activities was \$18,000 in repayment of long-term debt.

During Q1 2016, the Corporation purchased \$15,000 worth of equipment for ongoing research and operating activities.

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 lymphoma, initiation of the Phase 1b combination trial with DPX-Survivac and Incyte's IDO1 inhibitor epacadostat, other research and development activities, business development efforts, administration costs, and intellectual property maintenance and expansion. At March 31, 2016, the Corporation had approximately \$5.35 million of existing and identified potential sources of cash including:

- cash and equivalents of \$2.1 million;
- amounts receivable and investment tax credits receivable of \$2.0 million; and
- the 4<sup>th</sup> disbursement of the loan from the Province of Nova Scotia of \$1.25 million.

For Q1 2016, the Corporation's quarterly "cash burn rate" (defined as net loss for the period adjusted for non-cash transactions including amortization, depreciation, accretion of long-term debt, and stock-based compensation) was approximately \$1.48 million. The Corporation forecasts the cash burn rate to be between \$1.4 million to \$1.9 million per quarter over the next 12 months, as it initiates the Phase 1b combination trial with DPX-Survivac and Incyte's IDO1 inhibitor epacadostat, continues to execute the Phase 2 clinical trial for DPX-Survivac in lymphoma, and completes the clinical studies for DPX-RSV.

It is common for early-stage biotechnology companies to require additional funding to further develop product-candidates 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.

While the Corporation has \$5.35 million of cash and cash resources, which includes the final disbursement of the loan from the Province of Nova Scotia for \$1.25 million, management believes that its cash and cash resources will not be sufficient to fund operations for the next twelve months unless significant reduction of Corporation's discretionary expenditures are made and further financing is obtained. Although the addition of the loan with the current existing and identified sources of cash and significant reduction of Corporation's discretionary expenditures appears to provide the Corporation with sufficient funding for the next twelve months, the Corporation's liabilities and commitments, including the clinical trial with Incyte Inc, significantly reduce this available cash. The ability of the Corporation to continue as a going concern is dependent upon raising additional financing through equity and non-dilutive funding and partnerships. There can be no assurance that the Corporation will have sufficient capital to fund its ongoing operations, develop or commercialize any products without future financings. There can be no assurance that additional financing will be available on acceptable terms or at all. The Corporation is currently pursuing financing alternatives that may include equity, debt, and non-dilutive financing alternatives including co-development through potential collaborations, strategic partnerships or other transactions with third parties, that may or may not include merger and acquisitions activities. If the Corporation is unable to obtain additional financing when required, the

Corporation may have to substantially reduce or eliminate planned expenditures or the Corporation may be unable to continue operations. These uncertainties cast doubt as to the ability of the Corporation to meet its obligations as they come due and, accordingly, the appropriateness of the use of accounting principles applicable to a going concern.

#### USE OF PROCEEDS

The following table provides an update on the anticipated use of proceeds raised in the 2014 public offering, along with amounts actually expended.

## CONTRACTUAL OBLIGATIONS

(in millions)	Previously	Spent to	Remaining
TOTAL	disclosed	1 <b>D.a</b> te	to be spent
	(\$)	(\$)	(\$)
Clinical trial research in multiple indications, including ovarian cancer and lymphoma, as well as activities to ensure regulatory compliance of cancer vaccine candidates, DPX-Survivac and DPX-0907	2.5	2.7	(0.2)
Preclinical efficacy and safety studies of infectious disease vaccine candidates, formulation and analytical development, that include one or more of DPX-RSV, Ebola and anthrax	1.0	0.9	0.1
General Corporate Purposes	6.8	6.70	0.1

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

Contractual	Payments Due by Period				
Obligations	Total	Less than 1	1 - 3 years	4 - 5 years	After 5 years
		year			
Accounts	2,330,268	2,330,268	-	-	-
payable and					
accrued					
liabilities					
Amounts due to	72,334	72,334	-	-	-
directors					
Long-term debt	14,183,281	166,611	4,093,861	133,920	9,788,889
Operating	40,291	39,468	823	-	-
Leases					
TOTAL	16,626,174	2,608,681	4,094,684	133,920	9,788,889

## RELATED PARTY TRANSACTIONS

During Q1 2016, there were no related party transactions (Q1 2015 - \$nil).

# DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROLS OVER FINANCIAL REPORTING

Following the graduation of the Corporation to the Toronto Stock Exchange in November 2014, 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.

There have been no changes in the Corporation's ICFR that occurred during Q1 2016 that have materially affected or are reasonably likely to materially affect the Corporation's ICFR.

## SIGNIFICANT ESTIMATES

The unaudited interim condensed consolidated financial statements as at March 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 scientific research and experimental development ("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 SR&ED 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 Q1 2016, management has estimated the amount of accrued liabilities to be recorded.

#### **OUTSTANDING SECURITIES**

The number of issued and outstanding common shares of the Corporation on May 10, 2016 is 92,195,670. The number of outstanding stock options on May 10, 2016 is 6,206,765. The outstanding stock options have a weighted average exercise price of \$0.69 per share and a weighted average remaining term of 3.15 years.

## 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 for its vaccine platform technology includes seven patent families, the first of which contains eight patents issued in five jurisdictions (US, Europe, Canada, Japan and Australia). The six other families collectively contain thirteen patents issued in six jurisdictions (Europe, Australia, China, Japan, India and Singapore) and 39 pending patent applications in eleven jurisdictions. US 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 US, Canada and Europe.

Additional granted patents and allowed applications include:

- European Patent 1,333,858, Patent granted February 8, 2006;
- Australian Patent 2002214861, Patent granted January 11, 2007;
- Japanese Patent 4164361, Patent granted August 1, 2008;
- United States Patent 7,824,686, Patent granted November 2, 2010;

- Australian Patent, 2006301891, Patent granted December 20, 2012;
- Chinese Patent 200680036783, Patent granted September 18, 2013;
- European Patent 1,948,225, Patent Granted December 11, 2013;
- United States Patent 8,628,937, Patent granted January 14, 2014;
- Australian Patent 2008303023, Patent granted April 24, 2014;
- Japanese Patent 5528703, Patent granted April 25, 2014;
- Australian Patent 2008307042, Patent granted May 15, 2014;
- Singaporean Patent 166901, Patent granted May 27, 2014;
- Japanese Patent 5591705, Patent granted August 8, 2014;
- European Patent 2,296,696, Patent granted August 27, 2014;
- Australian Patent 2009253780, Patent granted November 27, 2014;
- Japanese Patent No. 5715051, Patent granted March 20, 2015;
- Japanese Patent No. 5731198, Patent granted April 17, 2015;
- Indian Patent No. 266563, Patent granted May 18, 2015;
- Canadian Patent No. 2,428,103, Patent granted June 9, 2015;
- United States Patent 9,114,174, Patent granted August 25, 2015.
- European Patent Application No. 08800369.4, Allowed December 4, 2015 (to grant shortly);
- Chinese Patent Application No. 200880110239.7, Allowed January 7, 2016 (to grant shortly); and
- Chinese Patent Application No. 200980120883.7, Allowed January 18, 2016 (to grant shortly).

Since 2008, the Corporation has filed five Patent Cooperation Treaty ("PCT") applications relating to the Corporation's technologies, some or all of which have now been filed in the US, 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. These patents, together with the other pending applications if allowed, extend patent protection for some or all DepoVax<sup>TM</sup>-based vaccines approximately up to the year 2028 or 2032. The latest PCT application, covering methods for improving the efficacy for a survivin vaccine in the treatment of cancer, could extend patent protection for these uses of DepoVax<sup>TM</sup>-based survivin vaccines until the year 2033.

The licensing agreement between the Corporation and Immunotope for the seven antigens included in the DPX-0907 vaccine candidate stipulates that the Corporation will assume the cost of prosecuting and maintaining the fees associated with patent applications and issued patents relating to the peptide antigens under license. These antigens are protected by two issued patents in the US and a pending application in Europe. A European patent application is pending. The DPX-0907 vaccine candidate thus remains protected by granted patents and patent applications (Canada, US, Europe, Japan, Australia, China, India, Brazil, Israel, Hong Kong and Singapore) relating to the core vaccine delivery platform, as well as US patents (7,083,789 and 7,919,467) and a patent application in Europe relating to the peptide antigens.

The Corporation also has a licensing agreement with VIB in relation to patent applications for a Respiratory Synctial Virus Vaccine (PCT/EP2011/070161) pending 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.

### 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.

#### RISK ASSESSMENT

The Corporation's activities are subject to certain risk factors and uncertainties that generally affect development-stage 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 and DPX-0907, as the Corporation depends heavily on their success;
- 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 products;
- 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 payors 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;
- 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 payors;
- obtain market approval and commercialize its product candidates with recently enacted and future legislation;
- retain key executives and attract, retain and motivate qualified personnel;
- establish or maintain strategic collaborations with third parties; 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 Annual Information Form for Fiscal 2015, under the heading "Risk Factors and Uncertainties".

## OFF BALANCE SHEET ARRANGEMENTS

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

## ADDITIONAL INFORMATION

Additional information relating to Immunovaccine, including Immunovaccine's December 31, 2015 annual information form and other disclosure documents, are available on SEDAR at www.sedar.com.