

### Immunovaccine Inc.

### **ANNUAL INFORMATION FORM**

FOR THE YEAR ENDED DECEMBER 31, 2013

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#### I. INTRODUCTION AND FORWARD LOOKING STATEMENTS

The information contained in this Annual Information Form is stated as at December 31, 2013, unless otherwise indicated. Unless otherwise indicated or if the context otherwise requires, "Immunovaccine", "the Corporation", "we", "us" and "our" refer collectively to Immunovaccine Inc., 1344 Summer Street, Suite 412, Halifax, Nova Scotia, Canada, B3H 0A8 and to its subsidiary, ImmunoVaccine Technologies Inc. ("IVT").

Unless otherwise indicated, all dollar amounts are expressed in Canadian dollars and references to "\$" are to Canadian dollars. Certain statements in this Annual Information Form ('AIF") 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 Annual Information Form, such statements reflect current expectations regarding future events and operating performance and speak only as of the date of this Annual Information Form. Forward-looking statements may use such words as "will", "may", "could", "intends", "potential", "plans", "believes", "expects", "projects", "estimates", "anticipates", "continue", "potential", "predicts" or "should" and other similar terminology, and may include, among others, statements with respect to the sufficiency of the Corporation's financial resources to support its activities; potential sources of funding and future financings; the Corporation's ability to obtain necessary funding on favourable terms or at all, the Corporation's expected expenditure and accumulated deficit level; the Corporation's expected outcomes from ongoing research and research collaborations; the Corporation's business strategy; the Corporation's exploration of opportunities to maximize shareholder value as part of the ordinary course of its business through collaborations; strategic partnership and other transactions with third parties; the Corporation's plans for the research and development of certain product candidates; the Corporation's strategy for protecting its intellectual property; the Corporation's ability to identify licensable products or research suitable for licensing and commercialization; the Corporation's ability to obtain licenses 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. 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 Annual Information Form. Such statements are based on a number of assumptions which may prove to be incorrect, including, but not limited to, assumptions about: (i) the availability of financing on reasonable terms; (ii) general business and economic conditions; (iii) positive results of pre-clinical and clinical tests; (iv) the Corporation's ability to successfully develop new products; (v) the Corporation's ability to attract and retain skilled staff; (vi) the products and technology offered by the Corporation's competitors; (vii) the Corporation's ability to take advantage of potential collaborations, strategic partnerships and other opportunities to maximize shareholder value; (viii) the Corporation's ability to protect patents and proprietary rights; (ix) the Corporation's ability to manufacture its products and to meet demand; and (x) the Corporation's ability to obtain regulatory approvals.

Statistical information and other data relating to the pharmaceutical and biotechnology industry included in this AIF 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 AIF 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.

Investors should not place undue reliance on forward-looking statements as the plans, intentions or expectations upon which they are based might not occur. Readers are cautioned that the foregoing list of

factors is not exhaustive. Each of the forward-looking statements contained in this Annual Information Form are expressly qualified by these cautionary statements.

#### II. CORPORATE STRUCTURE

The Corporation was incorporated on May 18, 2007 under the name of Rhino Resources Inc. pursuant to the *Canada Business Corporations Act*. On September 2009, the Corporation changed its name to Immunovaccine Inc. and consolidated its outstanding share capital on a 5 to 1 basis. The Corporation's head and registered office is located at 1344 Summer Street, Suite 412, Halifax, Nova Scotia, Canada, B3H 0A8.

The Corporation has one wholly-owned subsidiary, ImmunoVaccine Technologies Inc., which is incorporated under the laws of Nova Scotia.

#### III. GENERAL DEVELOPMENT OF THE BUSINESS

#### Overview

Immunovaccine is a clinical stage biopharmaceutical company that discovers and develops activators of the immune system to treat cancer and infectious diseases. Immunovaccine has built a proprietary product platform that is used to create immunogenic vaccines. 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 potentially other vaccine applications. The DepoVax<sup>TM</sup> platform is being used in multiple vaccine candidates, including two cancer vaccine candidates that are in or have completed Phase 1 clinical trials. One of the Corporation's cancer vaccine candidates is expected to enter large, randomized Phase 2 trials in 2014. The Corporation has research collaborations with research organizations, including the National Institutes of Health ("NIH") in the U.S. 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.

#### History

The Corporation commenced operations in March 2000, based on animal health research pioneered at Dalhousie University in Halifax, Nova Scotia, when it was contracted by the Department of Fisheries and Oceans to develop a contraceptive vaccine to control the seal population. The Corporation was able to develop a vaccine delivery system that demonstrated effectiveness such that 90% of seals, 10 years after vaccination, were still contracepted after a single dose.

From 2000 to 2004, the Corporation concentrated its research efforts on animal contraception for both wildlife and companion animals, while also working on vaccines for infectious diseases in livestock with CSL Animal Health, a division of CSL Limited, which was subsequently acquired by Pfizer. In 2004 and continuing through 2008, the Corporation began establishing its VacciMax® platform for various human applications, while simultaneously developing a scalable manufacturing process for the VacciMax® platform.

The Corporation continued its research and by 2008, developed a lipid depot-based vaccine delivery and enhancement technology called the DepoVax<sup>TM</sup> platform, an improvement on the Corporation's original VacciMax® platform. The patented DepoVax<sup>TM</sup> platform is a combination of antigens plus adjuvanting immune enhancers formulated in liposomes, and then in oil. The DepoVax<sup>TM</sup> platform creates a "depot

effect" that holds the vaccine at the site of injection, prolonging the immune system's exposure to the vaccine, resulting in rapid, potent and long-lasting cellular and/or humoral immune responses.

The DepoVax<sup>TM</sup> platform is easy to use, chemically stable, scalable and has broad applications. The Corporation has also tested the platform with several commercial vaccines such as for H5N1 pandemic influenza and hepatitis B, as well as other research collaborations with anthrax, meningitis and melioidosis. The pre-clinical studies in animals demonstrated significantly higher immune responses after a single dose with the DepoVax<sup>TM</sup> platform when compared to two or three doses of a control vaccine or other commercially available vaccines.

#### **Recent Developments**

Since January 1, 2014, the Corporation has announced it had:

- appointed Llew Keltner, M.D., Ph.D. to its board of directors in January 2014. Dr. Keltner, a consultant to IMV since early 2013, serves as chairman of Raptor Pharmaceuticals Corp (NASDAQ: RPTP), a commercial stage biotechnology company based in California; and
- granted 1,731,500 stock options to employees, consultants, officers and directors in January 2014, pursuant to terms and conditions of the Corporation's stock option plan. Employees and consultants were granted an aggregate of 457,500 options and officers and directors were granted an aggregate of 1,274,000 options. The options were granted on January 17, 2014 at an exercise price of \$0.74. The options for the employees, consultants and directors will vest in three equal tranches at 6, 12, and 18 months from date of grant and the options for the officers will vest in three equal tranches, the first on the date of grant and the others on the first and second anniversary of the date of grant. All options are set to expire five years from the date of grant.

#### Overview of the Last 3 Years

The following events significantly influenced the general development of the business of the Corporation:

#### Year ended December 31, 2013

During the year ended December 31, 2013, the Corporation announced it had:

- appointed Marc Mansour, Ph.D., the Corporation's Chief Operating Officer (COO), to its board of directors in December 2013. Since joining Immunovaccine in 2001, Dr. Mansour has led the development of Immunovaccine's DepoVax<sup>TM</sup> platform and the Corporation's lead therapeutic cancer vaccine DPX-Survivac. Previously serving as Chief Science Officer, he was appointed Chief Operating Officer in September 2013;
- completed a private placement of its common shares, raising gross proceeds of \$4.2 million in November 2013. Through the issuance of 10,511,209 common shares at a price of \$0.40 per share. Net proceeds from the private placement are being used for general corporate purposes. This private placement enables the Corporation to draw down on the second disbursement of the \$5 million loan from the Province of Nova Scotia described below:
- positive results from anthrax challenge studies in rabbits and non-human primates using its DepoVax<sup>TM</sup> delivery system in September 2013. The studies showed that all animals

administered a vaccine containing recombinant protective antigen (PA) formulated in DepoVax<sup>TM</sup> were protected against a lethal anthrax challenge. Importantly, a single dose of DepoVax<sup>TM</sup> containing five micrograms of recombinant PA protected rabbits exposed to a lethal anthrax dose. Antibody titers plateaued in rabbits within 28 days highlighting the DepoVax<sup>TM</sup> platform's potential to enable a single-dose, rapid response anthrax vaccine. These studies, conducted under the National Institute of Allergy and Infectious Diseases' (NIAID's) preclinical services program, were intended to evaluate Immunovaccine's DepoVax<sup>TM</sup> adjuvanting technology and advance the development of next generation biodefense vaccines:

- appointed Albert Scardino as Executive Chairman and Marc Mansour, Ph.D. as Chief Operating Officer of the Corporation in September 2013. Mr. Scardino has served as a director of the Corporation since 2010 and as Chairman since 2011. Dr. Mansour joined Immunovaccine's scientific team 12 years ago and has served as Chief Science Officer since 2007. The two appointments come after the employment of John Trizzino, Chief Executive Officer since 2011, came to an end on August 31, 2013. Mr. Trizzino also left as a director of Immunovaccine at that time;
- obtained a loan of \$5 million from the Province of Nova Scotia in August 2013, to be used to fund a portion of working capital through 2016. The secured loan is interest bearing and repayable in 2018. The loan will be made available in four equal installments. The Corporation received the first installment of \$1.25 million after meeting customary closing conditions. While the Corporation has met the milestones to draw down the second and third disbursement, the Corporation has not requested the funds from the Province of Nova Scotia. The remaining installment will be made available based on Immunovaccine meeting certain milestones;
- secured the NCIC Clinical Trials Group ("NCIC CTG), an organization supported by the Canadian Cancer Society, to sponsor and conduct a randomized Phase II for DPX-Survivac, in patients with advanced ovarian cancer. The study is designed to assess whether IMV's vaccine therapy can delay or prevent cancer recurrence. The Phase II trial is a randomized, blinded, placebo-controlled study with DPX-Survivac in combination with low dose oral cyclophosphamide as an immune modulator. The study will enroll approximately 250 patients with ovarian cancer at an estimated 20 clinical centers. The NCIC CTG is a Canadian-based academic clinical trials cooperative group conducting large multi-center clinical trials across Canada and internationally. The agreement between NCIC CTG and Immunovaccine will provide a framework for the NCIC CTG to sponsor the randomized Phase II trial and assume responsibility for conducting the trial in accordance with good clinical practice. The Corporation is in discussion with potential co-development partners to support the NCIC CTG-sponsored trial;
- agreed in May 2013 to use its lead cancer product, DPX-Survivac, in a study based in Rome designed to extend life for glioblastoma patients. The multicenter trial will be led by Professor Marianna Nuti, Ph.D., Department of Experimental Medicine at the University of Rome, and conducted in collaboration with neurosurgeons and oncologists coordinated by Professor Maurizio Salvati, M.D. Four major trial centers across Italy will be involved, with the cost of the trial being assumed by the university. The randomized, placebo-controlled study will enroll more than 50 patients with newly diagnosed brain tumors that have been maximally resected. The study is expected to start in 2014;

- entered into an agreement with the National Research Council of Canada Industrial Research
  Assistance Program (NRC-IRAP) in April 2013, to provide a financial contribution of up to
  \$407,700 to Immunovaccine for development of a vaccine for respiratory syncytial virus
  (RSV), a common lung disease in children, the elderly and patients with a compromised
  immune system. The funding will be used to advance the RSV program, including the
  formulation of RSV antigens in DepoVax<sup>TM</sup>;
- closed in March 2013, a non-brokered private placement of its securities, raising gross proceeds of \$1,603,880by the issuance of 4,860,244 common shares at a price of \$0.33 share. Net proceeds from the financing will be used to fund preclinical research and development efforts in the areas of infectious diseases, including respiratory syncytial virus ("RSV"), malaria and anthrax.;
- signed an Investigator-Initiated Study Agreement in January 2013 for the ongoing evaluation of its DPX-0907 cancer vaccine at the Busto Arsizio Hospital in Italy. Marco Bregni, M.D., head of the Oncology Unit of the Hospital of Busto Arsizio, will serve as the principal investigator for the Phase I/II DPX-0907 clinical trial in patients with breast and ovarian cancer. Immunovaccine expects the Phase I/II study to be initiated during 2014;
- further detailed positive results in January 2013 from a completed Phase I clinical study of the Corporation's cancer vaccine, DPX-Survivac, for the treatment of ovarian cancer. The analysis, which now includes all 18 patients enrolled in the study, confirmed previously reported results and uncovered new findings. All ten patients receiving the DPX-Survivac combination therapy who were evaluable by tetramer staining, produced survivin-specific CD8 T cells following one or two vaccinations. Importantly the CD8 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;

All 12 patients receiving the DPX-Survivac combination therapy demonstrated antigen specific immune responses as measured by at least one of the study's three immune monitoring assays (ELISpot, tetramer analysis and multiparametric 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. Analysis of immune responses by ELISpot showed that a cohort of patients receiving the higher dose of the vaccine therapy produced an average stimulation factor of greater than 600 times (600x) over baseline following their third vaccination. For one of these patients, the stimulation factor reached greater than 1,200 times (1,200x) over baseline. These immune responses are in agreement with the previously reported average increase of 350 times (350x) over baseline for these same patients following their second vaccination;

DPX-Survivac was deemed well-tolerated with no significant systemic adverse events reported in any patients recruited in this study. Reported adverse events were restricted to 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; and

• positive results from an immunogenicity study that evaluated anthrax vaccines formulated in DepoVax<sup>TM</sup> in January 2013. This study is part of an ongoing bio-defense research program

which was initiated in February 2012 to utilize DepoVax<sup>TM</sup>-adjuvanting technology in advancing the development of next generation vaccines against the most threatening biological agents. Study findings suggested that the DepoVax<sup>TM</sup>-based vaccines provided a more rapid and long lasting immune response as compared to the licensed anthrax vaccine BioThrax<sup>TM</sup>. The study, which was conducted under the National Institute of Allergy and Infectious Diseases' (NIAID) Preclinical Services Program, was designed to test multiple DepoVax<sup>TM</sup>-formulated anthrax vaccines in non-human primates, specifically examining immunogenicity and safety after either one or two doses of the vaccine. Study investigators compared the DepoVax<sup>TM</sup>-based vaccines to BioThrax, the only commercially available anthrax vaccine. BioThrax requires at least two doses to produce immune responses in animal models.

#### Year ended December 31, 2012

During the year ended December 31, 2012, the Corporation announced it had:

- positive results from a preliminary study of an anti-cocaine vaccine in collaboration with Weill Cornell Medical College. The vaccine, which added DepoVax<sup>TM</sup>-adjuvanting technology to Weill Cornell's novel anti-cocaine vaccine (dAd5GNE), was being evaluated in rodents for its ability to produce antibodies capable of blocking cocaine from being delivered to the brain in an effort to prevent its physiological effect. The study showed that the DepoVax<sup>TM</sup>-enhanced vaccine produced high levels of target antibodies that were able to sequester cocaine in the blood of immunized mice and block its delivery to the brain. Immunovaccine hopes to build on this interesting proof of concept work and is currently evaluating opportunities to further develop the program. Further potential studies would aim to confirm these results and explore the duration of immunity produced by the vaccine. There are research efforts to develop an anti-cocaine vaccine that is able to effectively induce and maintain a sufficient immune response without requiring frequent immunizations;
- positive interim results from the Phase I clinical trial of DPX-Survivac, an ovarian cancer vaccine candidate. The ongoing Phase I study is evaluating the potency, safety and tolerability of DPX-Survivac alone or in combination with low dose oral cyclophosphamide. Interim results showed that, to date, all nine patients receiving DPX-Survivac in combination with cyclophosphamide produced a targeted immune response following only one or two vaccine administrations. Patients receiving a higher dose (0.5 mL) of DPX-Survivac in combination with cyclophosphamide (n=3) produced immune responses after only one vaccination and generally exhibited higher antigen-specific immunity than those receiving the combination with a lower (0.1 mL) DPX-Survivac dose (n=6), suggesting dose-related activity. Importantly, patients in the two cohorts experienced consistent immune responses that were detected at two consecutive time points. Specifically, the first three patients enrolled in the 0.5 mL dose cohort in combination with low dose cyclophosphamide demonstrated an average stimulation factor of 350 times (350x) following the second vaccination, and in one patient greater than 850 times (850x), over baseline responses;
- welcomed Scott Halperin, M.D., to the Corporation's scientific advisory board (SAB). Dr. Halperin strengthens the SAB's broad expertise in infectious diseases vaccine research and development, particularly in the area of clinical trial design and execution;
- published positive results from a Phase I clinical trial of the Corporation's DPX-0907 cancer vaccine in the Journal of Translational Medicine. The published paper details new findings

on specific polyfunctional T cell responses generated by DPX-0907, as well as previously announced positive safety and immune response findings from the study. The peer-reviewed paper, entitled "First-in-Man Application of a Novel Therapeutic Cancer Vaccine Formulation with the Capacity to Induce Multi-functional T cell Responses in Ovarian, Breast and Prostate Cancer Patients," is now accessible in the online version of the Journal of Translational Medicine;

- received the "Best Early-Stage Vaccine Biotech" award on April 11, 2012, at the 5th Vaccine Industry Excellence (ViE) Awards ceremony during the World Vaccine Congress Washington 2012 in Washington, D.C. The annual ViE Awards honor the efforts, accomplishments and positive contributions of companies and individuals within the vaccine industry. The "Best Early-Stage Vaccine Biotech" was awarded to Immunovaccine based on the Corporation's strong early clinical trial results in immunotherapy and key collaborations that have expanded its product pipeline in infectious diseases, addiction and bio-defense vaccines:
- signed a research agreement in March 2012 with Weill Cornell Medical College to advance a vaccine for treating cocaine addiction. The new vaccine would stimulate the body's own immune system to prevent cocaine molecules from reaching the brain, blocking the addictive effects of the drug. The vaccine could become one of several methods of intervention intended to help people in rehabilitation programs;
- received on March 7, 2012, gross proceeds of \$2,788,202 through a non-brokered private placement 9,294,005 common shares at the price of \$0.30 per share;
- entered into a research collaboration with the US National Institutes of Health (NIH) and a commercial partner in February 2012 to advance the development of next generation biodefense vaccines against the most threatening biological agents. These novel vaccine candidates will be evaluated as part of a US NIH funded study, starting in the first quarter of 2012; and
- vaccinated the first patient with DPX-Survivac in December 2011. The goal of the Phase I clinical trial is to establish the safety and immune activity of DPX-Survivac in patients with advanced ovarian cancer.

#### Year ended December 31, 2011

During the year ended December 31, 2011, the Corporation announced it had:

- received clearance from Health Canada in October 2011 for its Clinical Trial Application (CTA) for a Phase I and II clinical trial with DPX-Survivac. The decision allows the Corporation to proceed with preparations in Canada to test the safety and efficacy of its immunotherapeutic vaccine in patients with advanced-stage ovarian cancer;
- received clearance from the US Food and Drug Administration (FDA) in June for its Investigational New Drug (IND) application for a Phase I and II clinical trial with DPX-Survivac, a therapeutic cancer vaccine. DPX-Survivac will be tested in patients with advanced ovarian cancer. The Phase I and II multicenter clinical trial is designed to assess the safety, immunogenicity and clinical efficacy of the DPX-Survivac vaccine. Patients will be treated with the DPX-Survivac vaccine after completing debulking surgery and chemotherapy

treatments. The vaccine will be administered to patients who will also receive an immune modulating drug to enhance the effect of the vaccine on cancer cells. The Phase I portion of the clinical trial design is an open label dose ranging study to identify the optimal dose of DPX-Survivac to use in the Phase II portion of the trial;

- completed a detailed analysis of immune responses from patients enrolled in the Phase I clinical trial assessing the safety and tolerability of DPX-0907 in June 2011. The Phase I 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. 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 3 breast cancer patients, 5 of 6 ovarian cancer patients and 3 of 9 prostate cancer patients. Both the 0.25 mL and 1 mL dose levels produced a targeted immune response in vaccinated patients;
- signed a research agreement with Cuban-based CIMAB S.A. In the agreement, the CIMAvax-EGF peptide antigen will be formulated in Immunovaccine's DepoVax<sup>TM</sup> delivery system to potentially enhance the immunogenicity of a novel therapeutic vaccine candidate. The Corporation is currently preparing initial experiments;
- released positive interim immunogenicity results for the Phase I clinical trial of its therapeutic vaccine candidate, DPX-0907, in patients with breast, ovarian and prostate cancer in April 2011. The analysis showed that the DPX-0907 vaccine elicited an antigen-specific immune response in the majority of ovarian cancer patients analyzed. This preliminary evaluation examined vaccine responses in the first 15 patients enrolled in the clinical trial; three with breast cancer, five with ovarian cancer, and seven with prostate cancer;
- received an award of \$2.9 million from the Atlantic Canada Opportunities Agency (ACOA), under the Atlantic Innovation Fund (AIF) in March 2011. This non-dilutive funding will enable Immunovaccine to develop new diagnostics to identify specific subsets of cancer patient populations that would benefit most from receiving DepoVax<sup>TM</sup>-based vaccine therapies. This funding will also help the Corporation develop additional methods for measuring vaccine activity, which will help the Corporation design future Phase II clinical trials; and
- received an official Notice of Allowance from the US Patent and Trademark Office for a new
  US patent specific to the DPX-0907 therapeutic cancer vaccine. The new US patent
  application titled "Cytotoxic T-lymphocyte-inducing immunogens for prevention, treatment,
  and diagnosis of cancer" provides additional intellectual property protection in the US for the
  seven antigens used in Immunovaccine's DPX-0907.

#### IV. DESCRIPTION OF THE BUSINESS

#### Business model and Strategy

Operating Strategy

The DepoVax<sup>TM</sup> vaccine delivery platform drives the operating strategy for the Corporation. All of the Corporation's vaccines in human and animal health utilize this adjuvanting platform to improve their effectiveness against cancer and infectious diseases and for drug addiction and animal health.

The Corporation currently has two cancer vaccine candidates in human trials: DPX-Survivac and DPX-0907. Immunovaccine believes the principles behind a successful therapeutic cancer vaccine should include a targeted antigen and an effective adjuvanting vaccine delivery technology, combined with a complementary therapeutic strategy. Antigens used in both DPX-Survivac and DPX-0907 specifically target tumor cells without harming normal, healthy cells. These antigens are combined with the Corporation's DepoVax<sup>TM</sup> platform to optimize the presentation of these antigens in the body, resulting in an enhanced immune response. To be successful against cancer, the vaccine must be administered at the right moment in the treatment cycle, which the Corporation believes to be soon after a tumor has been identified and removed. 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.

Using the same DepoVax<sup>TM</sup> adjuvanting platform and working with partners in North America and Europe, the Corporation is also developing vaccines for infectious diseases, including bio-defense vaccine candidates that will protect against anthrax. Another vaccine being tested targets RSV, the cause of respiratory complications in infants and the elderly. Pre-clinical studies have indicated that the platform may allow the development of single-dose vaccines for a wide range of infectious diseases by generating a stronger immune response more quickly than is possible with existing delivery methods. The Corporation's goal will be to advance at least one of these collaborations into human clinical trials in the next two years.

#### 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. Most recently, the Corporation completed a \$4.2 million equity private placement in November 2013 and obtained a \$5 million secured loan from the Province of Nova Scotia in August 2013, available in four equal installments based on the Corporation meeting certain milestones, three of which have been met to date. The Corporation received the first installment of \$1.25 million on August 9, 2013.

While having used its own resources to initially bring its two cancer vaccines to human clinical trials, the Corporation is involved in various partnerships and collaborations to accelerate the development of its DepoVax<sup>TM</sup>-based products. The Corporation announced the collaboration with Canada's NCIC Clinical Trials Group ("NCIC CTG"), an organization supported by the Canadian Cancer Society, in which NCIC CTG will sponsor and conduct a Phase II study of the Corporation's lead cancer vaccine, DPX-Survivac. The Corporation is currently in discussions with potential partners and may seek a co-development partnership arrangement to fund the balance of NCIC CTG-sponsored clinical trial costs. DPX-Survivac will also be tested in a fully funded investigator-initiated Phase II study in glioblastoma patients in Italy. Other programs include a clinical research collaboration with the Busto Arsizio Hospital in Italy to test

DPX-0907 in ovarian and breast cancer patients, a research partnership with the NIH for vaccines against bio-terrorism threats, as well as other collaborations. The objective of these types of partnerships is to produce pre-clinical and clinical data that would lead to licensing agreements, either to allow the use of the Corporation's DepoVax<sup>TM</sup> platform by others or to acquire antigens for use in new vaccines using DepoVax<sup>TM</sup>.

Immunovaccine has also developed 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 possible avenues, including co-development through potential collaborations, strategic partnerships or other transactions with third parties, and merger and acquisitions opportunities. The Corporation intends to continue to seek additional equity and non-dilutive funding and partnerships to advance the development of the vaccine candidates.

#### DepoVax<sup>TM</sup> Vaccine Enhancement Platform: How the technology works

Central across the Corporation's entire product pipeline is the  $DepoVax^{TM}$  delivery and adjuvanting technology.

The Corporation has developed a lipid depot-based vaccine delivery and enhancement technology called the DepoVax<sup>TM</sup> platform, an improvement on the Corporation's original VacciMax® platform. The DepoVax<sup>TM</sup> platform is easy to use, chemically stable, flexible, and forms the basis of the Corporation's therapeutic cancer vaccines and potential infectious diseases vaccines.

The DepoVax<sup>TM</sup> platform is a combination of antigens, plus adjuvant immune enhancers formulated in liposomes and then in oil. This patented combination has been shown to raise strong and long-lasting cellular or humoral immune responses which would allow the Corporation to create effective vaccines.

#### The DepoVax<sup>TM</sup> platform

The DepoVax<sup>TM</sup> technology, which is a combination of antigens and adjuvants formulated in liposomes and then in oil, results in enhanced immune responses. Due to its 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. This is believed to elicit a potent humoral response and/or cellular immunity.

This formulation is designed to be chemically stable. DepoVax<sup>TM</sup>-based products are lyophilized and anticipated to be stored in a dry format which is expected to provide the added benefit of an extended shelf life. The DepoVax<sup>TM</sup> formulation is designed to be easy to re-suspend and administer.

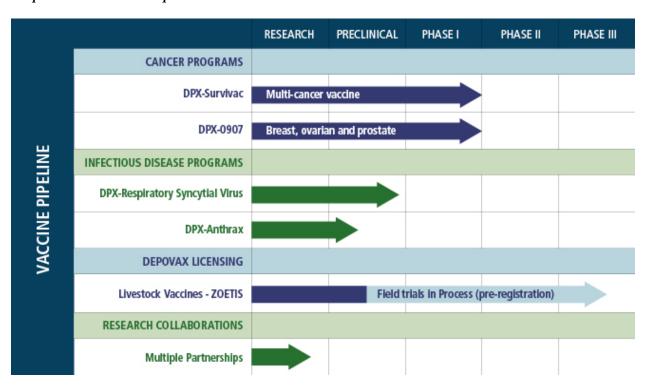
One of the significant advantages of the DepoVax<sup>TM</sup> platform is its versatility. The DepoVax<sup>TM</sup> platform can be combined with a variety of antigens, including recombinant proteins, synthetic peptides and nucleic acids, viruses and a wide range of adjuvants, which provides the flexibility to develop many different vaccine products using a single platform. This has enabled the Corporation to work with a variety of vaccine candidates, including those in cancer, infectious diseases and animal health.

DepoVax<sup>TM</sup> was used to formulate a number of antigens for emerging pathogens currently in development, such as anthrax, and enhanced immune responses were consistently demonstrated.

DepoVax<sup>TM</sup>-formulated vaccines have the ability to induce rapid and robust immune responses that are believed to protect against disease agents with as little as one dose. The potential single-dose capability is a key factor for developing rapid response vaccines for pandemics and disease outbreaks.

The ability of DepoVax<sup>TM</sup> to induce robust cellular immune responses also makes the platform suitable for therapeutic cancer vaccines, which are designed to specifically target tumor cells and to help patients remain in remission and combat the dissemination of micro-metastases. DepoVax<sup>TM</sup> can induce antigenspecific "polyfunctional" cellular responses, which have been postulated to be required for effective tumor control.

#### Corporation's Product Pipeline



#### DPX-Survivac: Therapeutic cancer vaccine

DPX-Survivac uses survivin-based antigens in-licensed from Merck KGaA, on a world-wide exclusive basis, and formulated in the DepoVax<sup>TM</sup> vaccine delivery platform. Survivin is a major tumor-associated antigen over-expressed in several cancers including ovarian cancer cells, making it a viable target for immunotherapy. DepoVax<sup>TM</sup> will deliver 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 cell death, known as apoptosis. The presence of survivin in cancer cells makes 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, with the intent to provide a clinical benefit to patients in the form of delaying cancer progression and/or increasing overall survival. The National Cancer Institute in the USA recently 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 explored in multiple solid tumors and hematological cancers, including ovarian, glioblastoma, prostate, breast, pancreatic, multiple myeloma, B-cell lymphoma, and melanoma. The Corporation intends to proceed with pre-clinical testing of DPX-Survivac with a broader range of cancer indications to evaluate additional opportunities.

Immunovaccine is nearing completion of a Phase I clinical trial of DPX-Survivac, conducted at six clinical sites in the US and Canada. In addition, the Corporation has received clearance for both Phase I and the upcoming Phase II clinical trials by both the US Food and Drug Administration ("FDA") and Health Canada. The existing clinical data generated by Immunovaccine for DPX-0907, and by Merck KGaA on the survivin antigens, facilitated the approval of a combined Phase I and Phase II protocol for testing DPX-Survivac in patients with advanced ovarian cancer. The Phase I trial was an open-label clinical trial designed to evaluate sequentially the safety of two DPX-Survivac dosing regimens in 18 patients. This Phase I clinical trial was to establish the safety and immunogenicity of DPX-Survivac in patients with advanced ovarian cancer.

The Corporation released interim results in October 2012, January 2013 and further detailed positive results in June 2013 on the Phase I clinical trial. The analysis, which now includes all 18 patients enrolled in the study, confirmed previously reported results and uncovered new findings. 12 of the 18 patients received the DPX-Survivac combination therapy demonstrated antigen-specific immune responses and they were measured by at least one of the study's three immune monitoring assays (ELISpot, tetramer analysis and multiparametric 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.

In the Phase I 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 primarily related 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 expected adverse events 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 Corporation announced that Canada's NCIC CTG, an organization supported by the Canadian Cancer Society, will sponsor and conduct a randomized Phase II study DPX-Survivac in patients with advanced ovarian cancer. The NCIC CTG is a Canadian-based academic clinical trials cooperative group conducting large multi-center clinical trials across Canada and internationally. The study is designed to assess whether the Coporations's vaccine therapy can delay or prevent cancer recurrence.

The Phase II trial will be a randomized, blinded, placebo-controlled study with DPX-Survivac in combination with low dose oral cyclophosphamide as an immune modulator. The study will enroll approximately 250 patients with ovarian cancer at an estimated 20 clinical centers.

Patients in the trial will have undergone surgery and standard post-operative chemotherapy. Patients are planned to be randomized to two groups, one receiving the combination vaccine therapy and another receiving a placebo vaccine and cyclophosphamide. Immune responses and disease-related biomarkers including CA125 will be measured for correlative analyses. The results may guide further development of DPX-Survivac.

The agreement between NCIC CTG and Immunovaccine will provide a framework for the NCIC CTG to sponsor the randomized Phase II trial and assume responsibility for conducting the trial in accordance with good clinical practice, in a significantly more capital efficient manner than if the trial was conducted by the Corporation as a sponsor. The Corporation is in discussion with possible co-development partners to potentially fund the balance of NCIC CTG-sponsored clinical trial costs. The trial is expected to get underway in 2014 with results expected in 2017.

A Phase Ib trial is currently underway to optimize and confirm the dose and schedule of vaccinations that will be employed in the randomized Phase II trial to be sponsored by the NCIC CTG. DPX-0907: Therapeutic Breast/Ovarian/Prostate cancer vaccine

The Corporation also recently announced it has signed 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 randomized, placebo-controlled study is expected to enroll up to 50 patients with newly diagnosed brain tumors that have been maximally resected. Testing DPX-Survivac in glioblastoma patients is expected to be initiated in 2014.

#### DPX-0907: Therapeutic Breast / Ovarian / Prostate cancer vaccine

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 and prostate cancer cells. In pre-clinical 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 completed a Phase I clinical trial of DPX-0907 and the results of the trial were released in June 2011. The Phase I 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 I 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 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 9 evaluable patients in the 0.25 mL dose group and 9 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 (eight out of nine) 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 recently signed an Investigator-Initiated Study Agreement for the ongoing evaluation of its DPX-0907 cancer vaccine at the Busto Arsizio Hospital in Italy. Marco Bregni, M.D., head of the Oncology Unit of the Hospital of Busto Arsizio, will serve as the principal investigator for the Phase I/II DPX-0907 clinical trial in patients with breast and ovarian cancer. Immunovaccine expects the Phase I/II study to be initiated in 2014.

The further clinical development of DPX-0907 into Phase II clinical trials will be evaluated based on safety, immunogenicity and commercial potential. The Corporation is exploring opportunities for commercialization of DPX-0907 and will consider investigator funded trials as it recently announced or partnership opportunities at various stages of clinical development, including at the Phase I and Phase II clinical trial stages.

#### Cancer Vaccines - Standard of care

Both cancer vaccine candidates developed by the Corporation are therapeutic cancer vaccines, which treat existing cancers. The intent is for the vaccine to be administered to patients who have already completed debulking surgery and chemotherapy treatments. The therapeutic cancer vaccines are intended to stimulate an immune response to attack the circulating cancer cells that remain in a patient's body after surgery and chemotherapy. This treatment approach has the potential to combat micro-metastases and keep the cancer in remission.

#### DepoVax<sup>TM</sup> in Infectious and Other Diseases

A significant component of the Corporation's business strategy is leveraging 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.

#### Respiratory Syncytial Virus ("RSV")

The Corporation is performing pre-clinical research activities for a vaccine targeting respiratory syncytial virus ("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. The novel RSV antigen being evaluated in DepoVax<sup>TM</sup> is based on the short hydrophobic protein present on the surface of the RSV virion. This vaccine has a unique mechanism of action, in that the resultant antibodies bind to and destroy infected cells rather than directly bind and neutralize free virus. The Corporation is currently testing the immunogenicity and efficacy in appropriate RSV challenge models such as mice and the cotton rat. The goal is to produce the pre-clinical data required to support a future potential IND filing leading to a Phase I clinical trial in the US and/or Canada. Immunovaccine recently had a meeting with Health Canada to evaluate the requirements for

filing a clinical trial application (CTA). Dr. Joanne Langley, professor of pediatrics and community health and epidemiology at Dalhousie Medical School and a recent recipient of the CIHR-GSK Chair in Pediatric Vaccinology, will be the principal investigator for a Phase I study to be conducted in Halifax, Canada.

#### Bio-terrorism

The Corporation entered into a research collaboration to advance the development of next generation biodefense vaccines against the most threatening biological agents. These novel vaccine candidates were evaluated as part of a study funded by the US National Institutes of Health (NIH), which was initiated in the first quarter of 2012.

The Corporation announced positive results from this immunogenicity study in January and July 2013. Study findings suggested that the DepoVax<sup>TM</sup>-based vaccines provided a more rapid and long-lasting immune response as compared to the licensed anthrax vaccine BioThrax<sup>TM</sup> with fewer doses. The study, which was conducted under the National Institute of Allergy and Infectious Diseases' ("NIAID") Preclinical Services Program, was designed to test multiple DepoVax<sup>TM</sup>-formulated anthrax vaccines in non-human primates and rabbits, specifically examining immunogenicity and safety after either one or two doses of the vaccine. Study investigators compared the DepoVax<sup>TM</sup>-based vaccines to BioThrax<sup>TM</sup>, the only commercially available anthrax vaccine. BioThrax<sup>TM</sup> requires at least two doses to produce immune responses in animal models.

Preliminary findings from the immunogenicity studies include:

- A single dose of DepoVax<sup>TM</sup>-formulated anthrax vaccine produced sustained TNA (toxin-neutralizing antibody) titers detected in six of ten animals, starting between day 21 and 49. Animals receiving one dose of Biothrax had no detectable TNA titers.
- When a second dose of the DepoVax<sup>TM</sup>-formulated vaccine was delivered, there was a significant increase in anthrax TNAs in all immunized animals within one week of the booster administration.
- Vaccination with the DepoVax<sup>TM</sup>-formulated vaccines resulted in no visible injection site reactions. Detailed microscopic examination showed robust immune cell infiltration to the site of vaccination. There was no evidence of systemic or local safety issues.

The Corporation announced additional positive results from challenge studies in non-human primates and rabbits in September 2013. These studies showed that all animals that were administered a vaccine containing recombinant protective antigen (PA) formulated in DepoVax were protected against a lethal anthrax challenge.

#### Key study findings include:

- A single dose of DepoVax<sup>TM</sup> containing five micrograms of recombinant PA protected rabbits exposed to a lethal anthrax dose.
- In rabbit studies, DepoVax<sup>TM</sup> formulated vaccines began producing detectable and potentially protective toxin neutralizing antibodies in as little as 14 days, with maximal protective antibody levels achieved within 28 days following a single vaccination. The titres were sustained for at least 70 days at which time a lethal anthrax challenge was performed.

- In rabbit studies, neutralizing antibodies rose further in animals receiving a second dose of the DepoVax<sup>TM</sup> recombinant PA vaccine.
- In non-human primate studies, two doses containing recombinant PA formulated in DepoVax<sup>TM</sup> triggered sustained toxin neutralizing antibodies sufficient to protect them from lethal anthrax challenge. A single dose response was not evaluated in this model.

An additional study with NIAID Preclinical Services was initiated in the third quarter of 2013, with another scheduled to begin in the first quarter of 2014. These will further examine the dosing and schedule of DepoVax<sup>TM</sup>-based vaccines, and their ability to protect rabbits and non-human primates from challenge with anthrax. These studies will focus on the single dose capacity of these vaccines. The Corporation expects results from these studies in the third quarter of 2014.

Data generated from these research studies is expected to facilitate access to various funding mechanisms and support the clinical development of DepoVax<sup>TM</sup>-based vaccine candidates.

#### Other Vaccine Applications

While the Corporation is now focused on developing a pipeline of cancer immunotherapies as well as vaccines for infectious diseases and bioterrorism applications, 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. In 2008, the Corporation signed its first license agreement with Zoetis, formerly the animal health division of Pfizer, which represents the Corporation's first step in validating the DepoVax<sup>TM</sup> platform technology. The Corporation now has four licensing agreements with Zoetis 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.

#### Intellectual Property

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 five patent families, the first of which contains five patents issued in four jurisdictions (US, Europe, Japan and Australia) and two pending patent applications in the US and Canada. The four other families collectively contain 33 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". An additional patent application for a DepoVax<sup>TM</sup> formulation was submitted in 2012. The platform name is protected by trademarks in the US, Canada and Europe.

Additional granted patents include:

- Europe Patent 1,333,858, Patent granted February 8, 2006;
- Japan Patent 2002-540757, Patent granted August 1, 2008;
- Australia Patent, 202214861, Patent granted January 11, 2007;

- Australia Patent, 2006301891, Patent granted December 20, 2012; and
- Chinese Patent No. ZL 2006 8 0036783.2, patent granted September 18, 2013.

Since 2008, the Corporation has filed four 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. If allowed, these patent applications may extend patent protection for some or all DepoVax<sup>TM</sup>-based vaccines approximately up to the year 2028 or 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 pending patent applications in the US and Europe. A European patent application was recently refused by the European Patent Office. An appeal is underway and the outcome for this particular application in Europe remains uncertain. Additional divisional applications have been filed in Europe. The DPX-0907 vaccine candidate 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 allowed application 11/426,16) and patent applications in the US and Europe relating to the seven peptide antigens.

#### Markets and Competition

#### Therapeutic cancer vaccines

Cancer is considered one of the most widespread and prevalent diseases globally. According to the US Centers for Disease Control and Prevention ("CDC"), 12.7 million individuals become victims of cancer and 7.6 million individuals die from the disease annually. 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. Tumors often develop resistance to chemotherapies however, 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 potentially provide a new and effective treatment.

A better understanding of cancer immunology has led to novel strategies for the therapy of cancer that are based on activating the immune system. Initially, the approval by the US FDA of Dendreon's Provenge® for prostate cancer and Bristol-Myers Squibb's ("Bristol-Myers") Yervoy<sup>TM</sup> (ipilimumab) for melanoma resulted in increased attention and support for immunotherapy and cancer vaccine companies. More recently, the reported clinical results achieved with other immunotherapies from Merck, Bristol-Myers and Roche, including monoclonal antibody therapies targeting PD-1, led to increased interest in this class of therapeutics from the medical community. Because of the significant potential of immune based therapies, pharmaceutical companies have recently acquired a number of experimental cancer immunotherapy products, with some being in preclinical development. These transactions have served as transformational events for a number of companies, including Amplimmune, Compugen, Immunocore, and Okairos AG.

It is generally recognized that cancer vaccines are best administered after surgery and chemotherapy when tumor burden is low. The goal is to train the body's immune system to target and kill remaining cancer cells and maintain patients in remission. Cancer vaccines have potential to be used in combination with chemotherapy, radiation and/or surgery to significantly improve outcomes for cancer patients. Cancer vaccines may also become an important component of novel combination immunotherapies which may offer synergistic benefits. The Corporation believes that cancer vaccines will become part of a multipronged approach for the treatment of cancer. Recently, the pharmaceutical industry has recognized the therapeutic potential of cancer vaccines. Pharmaceutical companies with active cancer vaccine programs in various stages of development (pre-clinical to Phase III) include Roche, Merck KGaA, Pfizer, and GlaxoSmithKline ("GSK").

The global market for cancer vaccines, including both prophylactic and therapeutic vaccines, was USD\$1.6 billion in 2010. 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 III 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 worldwide can be directly correlated to currently available vaccines. According to data from the U.S. Centers for Disease Control and Prevention (CDC), 10 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 plague, diphtheria, yellow fever, dengue, meningitis, influenza and malaria, have re-emerged. While the effort to control these known infectious diseases continues, more than 30 emerging diseases have been identified in humans for the first time over the past two decades.

There is an increased awareness of the impact of current and emerging infectious diseases. Demand for newer treatments and vaccines is 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\$90.4 billion in 2009.

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 diseases 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.

In North America, RSV is the most frequent cause of hospitalization in the first two years of life. Specifically in Canada, RSV-associated lower respiratory tract illness (LRTI) in young children accounts for over 12,000 hospitalizations annually in up to 2% of the birth cohort. In Canadian adults, 2 to 3% of all respiratory admissions annually can be attributed to RSV infection.

There is currently no vaccine available for the prevention of RSV. The only product available today to help protect against severe RSV disease is Synagis, a monthly injection given during peak RSV season and indicated only for specific groups of infants at high risk. No cost-effective, feasible, effective treatment has been found which alters the natural history of RSV infection. Systematic meta-analyses of inhaled bronchodilators, glucocorticoids, antibiotics, inhaled heliox, nebulized deoxyribonuclease and epinephrine do not demonstrate any significant clinical benefit. The mainstay of care for most patients remains supportive.

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. Among elderly persons followed for 3 consecutive winters, RSV infection accounted for 10.6% of hospitalizations for pneumonia, 11.4% of hospitalizations for obstructive pulmonary disease, 5.4% for congestive heart failure and 7.2% for asthma.

#### Bio-defense

According to the US Center for Bio-security's review of the US government's federal budget for fiscal 2012, funds for civilian bio-defense total USD\$6.4 billion. Of that total, USD\$5.8 billion (90%) is budgeted for programs that have both bio-defense and non bio-defense goals and applications, and USD\$637.6 million (10%) is budgeted for programs that have objectives solely related to bio-defense.

US government-funding programs for civilian bio-defense are intended to address a range of scientific, public health, healthcare, national security, and international security issues in addition to bio-defense. Programs with both bio-defense and non bio-defense goals and applications include those that fund basic scientific research in infectious diseases pathogenesis and immunology, programs to improve planning and operations related to public health preparedness, and programs to improve preparedness and response for a range of other disasters.

An example of programs with both bio-defense and non bio-defense goals includes NIAID Bio-defense Research Program, which, in addition to funding pre-clinical and clinical research toward bio-defense countermeasures, funds basic infectious diseases pathogenesis and immunology research with implications for a multitude of other diseases. Immunovaccine's platform technology and products have application to many of these programs.

A recent report by GBI Research states that as the potential threat of biological terrorist attacks continue to command the attention of governments around the globe, anthrax and smallpox remain amongst the most researched diseases in the bio-defense industry.

#### 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\$20 billion in 2008. The animal vaccine market subdivided into livestock, companion animal and other 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.

#### Safety Profile

The Corporation has demonstrated the safety and immunogenicity potential of the DepoVax<sup>TM</sup> platform in humans by completing the Phase I clinical trial of DPX-0907. In the Phase I clinical trial, 23 patients were vaccinated with DPX-0907, with no dose limiting toxicities. The most common adverse events were grades 1 and 2 injection site reactions. A grade 3 local site reaction was reported after repeat injections of 1 mL of the vaccine. Such local site reactions are expected and the severity of the injection site reactions were related to the volume of vaccine administered.

In the Phase I clinical trials with DPX-Survivac, 18 patients were vaccinated with 3 doses of the vaccine, with or without low dose oral cyclophosphamide, with no vaccine-related systemic adverse events reported. The most common adverse events were grades 1 and 2 injection site reactions. Grade 3 local site reactions were reported in three patients receiving the combination therapy after repeat injections of the vaccine, with resolution over time. Such local site reactions were expected and the severity of the injection site reactions were related to the volume of vaccine administered. The vaccine, therefore, was considered well- tolerated. An ongoing Phase Ib study will continue to assess the safety profile of DPx-Survivac.

Extensive pre-clinical safety testing for both DPX-0907 and DPX-Survivac has also been conducted. The results show that both vaccine candidates were well-tolerated by the animal models. In addition, survivin antigens used in DPX-Survivac have already been tested in Phase I human clinical trials with encouraging safety results.

Studies conducted by the NIH in monkeys demonstrated that one or two doses of a Depovax vaccine designed for infectious diseases applications was well-tolerated with visible site reactions observed and no microscopic finding of major concern. The further testing of this formulation remains in progress at the NIH.

Also, the Corporation's contraceptive vaccine has been safely used in at least 8 different mammals for almost 10 years. For example, multi-year trials with macaque monkeys in Hong Kong demonstrate the efficacy and safety of the Corporation's technology in a non-human primate.

The Corporation has conducted a progressive series of safety studies in-house using some of the most common animal models including mice, rabbits, rats and ferrets. Extensive evaluation of the platform in these animal models and comparisons with other commonly used delivery technologies such as a combination of Granulocyte–Macrophase Colony Stimulating Factor and mineral oil suggests a good safety profile for the Corporation's technology.

#### Manufacturing and Scalability

The Corporation has developed and implemented the commercial scale manufacturing process for the DepoVax<sup>TM</sup> platform, which is applicable to all of the Corporation's subsequent human health vaccines. The scale-up methods have been transferred to, and manufacturing has been contracted out to, a reputable contract GMP development and manufacturing facility licensed from Health Canada to manufacture sterile products for clinical and commercial purposes. The Corporation has purchased and installed dedicated equipment at the site.

Historically, large-scale production of liposomes has been a challenge. Therefore, the Corporation manufactured commercial scale pilot vaccine batches, including 50 liters (200,000 doses) of a hepatitis B vaccine as a test basis at the contract manufacturing facility. The Corporation has confirmed the stability of the vaccine manufactured there and also confirmed that the biological activity of the batch is equivalent to the Corporation's laboratory batches.

Immunovaccine has also completed the lyophilization process for its vaccines. Lyophilization (freezedrying) is the final step in manufacturing of the product, making it easily reconstituted for injection. The lyophilization parameters have been established and transferred to a GMP filling and lyophilization facility.

The product-specific manufacturing process for both DPX-Survivac and DPX-0907 was successfully implemented at a GMP contract manufacturing facility in the US. In preparing for Phase I clinical trials, the Corporation has successfully produced clinical batches for both therapeutic cancer vaccine candidates. The Corporation is also ready to develop and implement manufacturing processes for other DepoVax<sup>TM</sup>-based vaccine products.

#### **Facilities**

The Corporation's laboratory is located at 1344 Summer Street, Suite 411, Halifax, Nova Scotia where the Corporation is currently renting premises of approximately 3,900 sq. ft. The Corporation believes that its facilities are satisfactory given its current state of development.

#### Regulatory Process

The Food and Drug Administration (USA) (the "FDA") and Health Canada share similar processes by which new products are approved. In both cases, development and approval can be a lengthy process, in some cases over five to 10 years. The FDA approves products for the US market and Health Canada does so for the Canadian market. Though the processes are generally similar, each regulatory body has its own unique requirements for a product. In order to sell a product in each market, it has to be approved by the appropriate governing body. In most cases, early studies conducted in one jurisdiction will be accepted in

the other; however, further and somewhat modified studies may be required in order to have a product approved in another jurisdiction.

All products typically go through the following steps in order to be approved:

- discovery: early laboratory work to show that a compound can have unique chemical medicinal properties;
- pre-clinical proof-of-concept studies: studies usually conducted in laboratory animals (mice, etc.) to show that a compound is active in a living creature and retains its medicinal properties;
- Phase I clinical trial: a small study in human subjects which looks mainly at safety of the compound in humans. In order to be eligible to do a Phase I clinical trial, an Investigational New Drug (IND) application in the US or a Clinical Trial Application ("CTA") in Canada must be filed and approved by the regulatory body. This application must contain information about the safety and efficacy of the compound in laboratory animals, any manufacturing information and chemical analysis. This is a lengthy process, requiring much involved research, conferences with the regulatory authorities, clinicians, etc. At the conclusion of a successful Phase I clinical trial, a compound is shown safe in humans and further studies are warranted to show its efficacy to treat an illness;
- Phase II clinical trial: in a Phase II clinical trial, a larger population is used in order to establish
  appropriate dosing for the compound. This and any other clinical studies also need to be approved
  by the regulatory agencies. At the end of a successful Phase II clinical trial, the compound is
  shown to be active in the correct population and a relevant dose is chosen to continue with the
  development;
- Phase III clinical trial: a large and sometimes multi-level trial, involving a statistically significant sample of the population for which the compound is designed. Stringent Chemistry, Manufacturing and Controls (CMC) are required which may delay the initiation of the trial. Phase III trials are designed to establish the efficacy of the compound and identify potential safety issues that may surface in the general population in order for the regulatory agency to better assess the risk/benefit of the compound when a registration application is made;
- registration application: a New Drug Application ("NDA") has to be filed with the regulatory body describing all of the clinical trials conducted to date, the relevant population, safety data, the label which will be placed on the pharmaceutical product, the sales/marketing information, etc. The regulatory body looks at the package and decides whether approval should be granted; and
- approval: once received, the pharmaceutical product may be sold to the target population; however, clinical studies may continue for the pharmaceutical product to be approved for a different population (e.g. children vs. adults).

#### Specialized Skill and Knowledge

The business of the Corporation requires personnel with specialized skills and knowledge in the fields of basic and applied immunology. Researchers must be able to design and implement studies to assess the efficacy of DepoVax<sup>TM</sup> in generating humoral and cellular responses. Specialized knowledge and skills relating to chemistry and formulation process development are also needed. Such knowledge and skills

are needed to develop product specific analytical methods and formulation processes. The Corporation has trained scientists with broad experience in these fields.

Clinical and regulatory expertise and knowledge is currently accessed by the Corporation through arrangements with well-respected consultants with experience in regulatory affairs or clinical research relating specifically to vaccines.

The Corporation has subcontracted out several key functions to conduct the clinical program for its Phase I trials. However, the Corporation utilizes the services of consultants and internal resources, such as a clinical trial manager, to ensure proper and timely completion of the required activities. The Corporation also continues to conduct internal discovery and proof-of-concept work for the other potential vaccine indications, some of which is anticipated to be done with a partner organization.

#### Scientific Advisory Board

The Corporation has retained experienced scientific advisors to assist its management in dealing with industry-related issues and how these issues may affect the Corporation's scientific research and product development.

The Scientific Advisory Board consists of the following members:

Neil Berinstein, M.D.: Dr. Berinstein obtained his Medical Doctoral Degree at the University of Manitoba and completed training programs at the University of Toronto in Internal Medicine and Medical Oncology and at Stanford University in the area of Immunotherapy for cancer. Dr. Berinstein was a founding director of the Advanced Therapeutics Program at the Toronto-Sunnybrook Regional Cancer Centre with a long track record in fundamental research and a significant publication record in the area of normal and malignant B cell biology and cancer immunotherapy. Dr. Berinstein was Global Program Head of Sanofi Pasteur's cancer vaccine program from 1998-2009. He is a Full Professor in the Department of Medicine at the University of Toronto. He currently is Chief Scientific Officer at IRX Therapeutics. He is a member of the Executive Committee of the Cancer Research Institute Cancer Immunotherapy Consortium. He has published over 100 research papers and a similar number of research abstracts.

Scott Halperin, M.D.: Dr. Halperin's numerous professional positions include: professor of pediatrics and microbiology and immunology at Dalhousie University; head of infectious diseases at the IWK Health Centre in Halifax, Nova Scotia; and, director of the Canadian Center for Vaccinology, a joint collaboration of the IWK Health Centre, Capital Health, and Dalhousie University. As one of the world's leading authorities on the development of vaccines, his research focuses on the diagnosis, treatment, and prevention of pertussis (whooping cough) and other vaccine-preventable diseases such as influenza. His research in the area of pertussis has sparked improved diagnosis, treatment and prevention of this lifethreatening disease and his team is credited with developing one of the pertussis vaccines that is now used Dr. Halperin is also principal investigator of the Public Health Agency of around the world. Canada/Canadian Institutes of Health Research Influenza Research Network (PCIRN). This group connects most of the major medical research institutions and universities across Canada, in an effort to ensure the safety and effectiveness of influenza vaccines and vaccination programs and to train the next generation of clinical vaccine researchers. He earned his undergraduate degree in biology from Stanford University and his medical degree from Cornell University. He conducted his postgraduate residency training in pediatrics at the University of Virginia and his fellowship in pediatric infectious diseases at the University of Virginia and the University of Minnesota.

W. Martin Kast, Ph.D.: Dr. Kast holds a number of prestigious positions including: the Walter A. Richter Cancer Research Chair, Professor of Molecular Microbiology & Immunology, Obstetrics & Gynecology and Urology, Director Beckman Center for Immune Monitoring, Director Medical Biology Graduate Program and Co-Leader Tumor Microenvironment Program at the Norris Comprehensive Cancer Center, University of Southern California, Los Angeles, CA. In 2010 he was named Eminent Scientist and North American Immunologist of the Year and in 2012 he won the Landsteiner Prize. He currently serves as the Secretary/Treasurer of the International Papillomavirus Society.

*Michel Klein*, Ph.D.: Dr. Klein currently is Chairman of VaxiBio Inc., a new vaccine biotechnology company recently registered in Canada with a subsidiary in Taiwan. His experience includes Vice President Biotechnology Research – Pasteur Mérieux Connaught Canada, Professor of Immunology – University of Toronto, Corporate Vice President, Science and Technology – Aventis Pasteur Group and Chief Executive Officer, CANVAC – Canadian Network for Vaccines and Immunotherapeutics.

*Walter Storkus*, Ph.D.: Dr. Storkus currently is a Professor (Tenure) with Departments of Dermatology & Immunology at the University of Pittsburgh. Past positions include Head of Research – Division of Surgical Oncology, Department of Surgery and Professor (Tenure) for Departments of Surgery & Pathology, as well as Departments of Surgery, Dermatology and Immunology at the University of Pittsburgh. Dr. Storkus has memberships in professional and societies throughout the United States..

#### Regulatory Affairs Advisor

Irene Clement, Regulatory Consultant B.Sc., MLT: Ms. Clement is a founding partner of Clement Strategies Inc., a regulatory and biotechnology business consulting company. She is an accomplished Senior Regulatory Professional with over 25 years experience in Regulatory Affairs in the Biologics industry. She has a proven track record in dealing with regulatory authorities worldwide, including Health Canada, US FDA, European and WHO agencies. Ms. Clement's previous positions include Vice President Regulatory Affairs for ID Biomedical (subsequently became GSK), Vice President of Regulatory Affairs at Shire Biologics, and Director Regulatory Affairs at Aventis Pasteur Ltd (now Sanofi Pasteur Ltd). Ms. Clement has been responsible for numerous successful Clinical trial applications (CTA &IND) as she assisted companies in attaining product development goals as well as global license maintenance activities. She has also obtained numerous license approvals in Canada, the US, EU, Japan, Australia and other countries.

#### Equipment and components required to conduct activities

Standard raw materials, component parts, and products required by the Corporation in pursuing its research and development activities are supplied from reputable supply companies in the biotechnology industry. Pricing is predictable as there are many alternatives of such supplies that are readily available. In the event where a custom product is required, such materials are obtained from custom synthesis and/or purification manufacturers which operate in accordance with their respective regulations (ISO). These manufacturers are reputable and have been supplying such materials for the biotechnology/ pharmaceutical industry for a long time. There may be a lead time of weeks/months for such custom materials which is known and anticipated. The Corporation has identified the necessary providers of raw materials and services required for producing clinical grade vaccine for its clinical trial activities.

#### **Environmental Protection**

The Corporation's discovery and development processes involve the controlled use of hazardous and radioactive materials and, accordingly, the Corporation is subject to federal, provincial and local laws and

regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. To the knowledge of the Corporation, compliance with such environmental laws and regulations does not and will not have any significant on its capital spending, profits or competitive position within the normal course of its operating activities. There can be no assurance, however, that the Corporation will not be required to incur significant costs to comply with environmental laws and regulations in the future or that its operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations.

#### **Employees**

As at December 31, 2013, the Corporation had 20 full-time and part-time employees, including 6 employees holding PhD degrees and a number of other employees holding M.Sc. or MBA degrees. The Corporation's employees are not governed by a collective bargaining agreement. The Corporation depends on certain key members of its management and scientific staff and the loss of services of one or more of these persons could adversely affect the Corporation. See "Risk Factors and Uncertainties".

#### Risk Factors and Uncertainties

Investing in the Corporation's securities involves a high degree of risk. Prospective investors should carefully consider the risks described below, together with all of the other information included or referred to in this Annual Information Form. There are numerous and varied risks, known and unknown, that may prevent the Corporation from achieving its goals. The risks described below are not the only ones that the Corporation will face. If any of these risks actually occur, the Corporation's business, financial condition or results of operations may be materially adversely affected. In that case, the trading price of the Corporation's securities could decline and investors in the Corporation's securities could lose all or part of their investment.

#### Risks Related to the Financial Position and Need for Additional Capital

The Corporation has incurred significant losses since inception and expects to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, IMV has incurred significant operating losses. The net loss was \$5.2 million for the year ended December 31, 2013, \$6.4 million for the year ended December 31, 2012 and \$6.8 million for the year ended December 31, 2011. As of December 31, 2013, the Corporation had an accumulated deficit of \$35 million. As a result of the operating losses and negative cash flows from operations since inception, the 2013 financial statements includes an explanatory paragraph indicating that there is substantial doubt about the Corporation's ability to continue as a going concern.

To date, the Corporation has financed operations primarily through public offerings in Canada, private placements of securities, grants and license and collaboration agreements. The Corporation has devoted substantially all efforts to research and development, including clinical trials. IMV expects to continue to incur significant expenses and increasing operating losses for at least the next several years. The Corporation anticipates that the expenses will increase substantially if and as the Corporation:

- initiates or continues the clinical trials of DPX-Survivac and other product candidates;
- seeks regulatory approvals for the product candidates that successfully complete clinical trials;

- establishes a sales, marketing and distribution infrastructure to commercialize products for which the Corporation may obtain regulatory approval;
- maintains, expands and protects the Corporation's intellectual property portfolio;
- continues other research and development efforts;
- hires additional clinical, quality control, scientific and management personnel; and
- adds operational, financial and management information systems and personnel, including personnel to support product development and planned commercialization efforts.

To become and remain profitable, the Corporation must develop and eventually commercialize a product or products with significant market potential. This development and commercialization will require the Corporation to be successful in a range of challenging activities, including successfully completing preclinical testing and clinical trials of the product candidates, obtaining regulatory approval for these product candidates, marketing and selling those products that obtain regulatory approval. The Corporation is only in the preliminary stages of some of these activities. The Corporation may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability. Even if profitability is achieved, the Corporation may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable would decrease the value of the Corporation and could impair the Corporation's ability to raise capital, expand the business, maintain research and development efforts or continue operations. A decline in the value of the company could also cause shareholders to lose all or part of their investment.

The Corporation will need substantial additional funding. If the Corporation is unable to raise capital when needed, the Corporation would be forced to delay, reduce, terminate or eliminate product development programs, potentially including the planned Phase II clinical trials of DPX-Survivac or commercialization efforts.

The Corporation expects expenses to increase in connection with the ongoing activities, particularly as the Corporation continues the research, development and clinical trials of, and seeks regulatory approval for, the product candidates. In addition, if the Corporation obtains regulatory approval of any of the product candidates, the Corporation expects to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. Furthermore, the Corporation will need to obtain additional funding in connection with continuing operations. If the Corporation is unable to raise capital when needed or on attractive terms, the Corporation would be forced to delay, reduce, terminate or eliminate the product development programs, potentially including the planned Phase II clinical trials of DPX-Survivac.

As of December 31, 2013, the Corporation had cash, cash equivalents and short-term investments of \$3.5 million and working capital of \$3.2 million.

The Corporation will need to obtain significant financing prior to the commercialization of DPX-Survivac, including funding to complete the planned Phase II clinical trial of DPX-Survivac. The Corporation does not currently have funds available enable the Corporation to complete the planned Phase II clinical trial of DPX-Survivac and to fund operating expenses through the completion of the trials. The Corporation expects that in addition to the NCIC sponsoring the Phase II clinical trials, the Corporation will require up to \$30 million or more to conduct the Phase II trials and fund the operating expenses through the completion of the trial.

The Corporation's future capital requirements will depend on many factors, including:

- the progress and results of the planned Phase II clinical trials of DPX-Survivac;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for other product candidates;
- the costs, timing and outcome of regulatory review of the product candidates;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution, for any of the product candidates for which regulatory approval is received;
- revenue, if any, received from commercial sales of the Corporation's product candidates, should any of the product candidates be approved by the FDA or a similar regulatory authority outside the United States;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing the Corporation's intellectual property rights and defending intellectual property-related claims;
- the extent to which the Corporation acquires or invests in other businesses, products and technologies;
- the Corporation's ability to obtain government or other third-party funding; and
- the Corporation's ability to establish collaborations on favorable terms, if at all, particularly arrangements to market and distribute product candidates on a worldwide basis.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and the Corporation may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, the Corporation's product candidates, if approved, may not achieve commercial success. The Corporation's commercial revenues, if any, will be derived from sales of products that the Corporation does not expect to be commercially available for several years, if at all. Accordingly, the Corporation will need to continue to rely on additional financing to achieve the Corporation's business objectives. Additional financing may not be available to the Corporation on acceptable terms, or at all.

## Raising additional capital may cause dilution to existing stockholders, restrict operations or require the Corporation to relinquish rights to its technologies or product candidates.

Until such time, if ever, as the Corporation can generate substantial product revenues, the Corporation expects to finance the cash needs through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Currently, the Corporation does not have any committed external source of funds. The Corporation will require substantial funding to complete the planned Phase II clinical trials of DPX-Survivac and to fund the operating expenses and other activities. To the extent that the Corporation raises additional capital through the sale of equity or convertible debt securities, the shareholders ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the shareholders rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting the Corporation's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring

dividends. If the Corporation raises additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, the Corporation may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable.

#### Risks Related to the Development and Commercialization of the Corporation's Product Candidates

The Corporation depends heavily on the success of DPX-Survivac and other product candidates. All of the product candidates are still in preclinical or clinical development. Clinical trials of the product candidates may not be successful. If the Corporation is unable to commercialize the product candidates or experiences significant delays in doing so, the business will be materially harmed.

The Corporation has invested a significant portion of efforts and financial resources in the development of DPX-Survivac, DPX-0907, and the DepoVax<sup>TM</sup> Platform. The ability to generate product revenues, which is not expected to occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of these product candidates, especially DPX-Survivac, the most advanced product candidate. The success of these product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States:
- establishing commercial manufacturing capabilities by identifying and making arrangements with third-party manufacturers for the product candidates;
- maintaining patent and trade secret protection and regulatory exclusivity for the product candidates;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- acceptance of the products, if and when approved, by patients, the medical community and thirdparty payors;
- effectively competing with other therapies; and
- a continued acceptable safety profile of the products following approval.

If the Corporation does not achieve one or more of these factors in a timely manner or at all, the Corporation could experience significant delays or an inability to successfully commercialize its product candidates, which would materially harm its business.

If clinical trials of the product candidates, such as the planned Phase II clinical trials of DPX-Survivac, fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, the Corporation may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of the product candidates.

Before obtaining regulatory approval for the sale of the product candidates, the Corporation must conduct extensive clinical trials to demonstrate the safety, purity and potency, or efficacy, of the product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of the Corporation's clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

The Corporation may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent the Corporation's ability to receive regulatory approval or commercialize its product candidates. Unforeseen events that could delay or prevent the Corporation's ability to receive regulatory approval or commercialize its product candidates include:

- regulators or institutional review boards may not authorize the Corporation or its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the Corporation may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of the product candidates may produce negative or inconclusive results, and the Corporation may decide, or regulators may require, additional clinical trials be conducted or product development programs be abandoned;
- the number of patients required for clinical trials of the product candidates may be larger than anticipated, enrollment in these clinical trials may be slower than anticipated or participants may drop out of these clinical trials at a higher rate than anticipated;
- the Corporation's third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all;
- the Corporation might have to suspend or terminate clinical trials of its product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks:
- regulators or institutional review boards may require that the Corporation or its investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of the product candidates may be greater than anticipated;

- the supply or quality of the product candidates or other materials necessary to conduct clinical trials of the product candidates may be insufficient or inadequate; and
- the Corporation's product candidates may have undesirable side effects or other unexpected characteristics, causing the Corporation or its investigators, regulators or institutional review boards to suspend or terminate the trials.

In addition, the patients recruited for clinical trials of the product candidates may have a disease profile or other characteristics that are different than expected and different than the clinical trials were designed for, which could adversely impact the results of the clinical trials.

If the Corporation is required to conduct additional clinical trials or other testing of its product candidates beyond those that are currently contemplate, if the Corporation is unable to successfully complete clinical trials of its product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, the Corporation may:

- be delayed in obtaining marketing approval for its product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use restrictions or safety warnings, including boxed warnings;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed or used.

The Corporation's product development costs will also increase if delays in testing or approvals are experienced. The Corporation does not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which the Corporation may have the exclusive right to commercialize its product candidates or allow the Corporation's competitors to bring products to market before the Corporation does and impair the Corporation's ability to commercialize its product candidates and may harm the business and results of operations.

## If the Corporation experiences delays or difficulties in the enrollment of patients in the clinical trials, receipt of necessary regulatory approvals could be delayed or prevented.

The Corporation may not be able to initiate or continue clinical trials for its product candidates, including the planned Phase II clinical trial of DPX-Survivac, if the Corporation is unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, many of the Corporation's competitors have ongoing clinical trials for product candidates that could be competitive with the Corporation's product candidates, and patients who would otherwise be eligible for the Corporation's clinical trials may instead enroll in clinical trials of the Corporation's competitors' product candidates.

Patient enrollment is affected by other factors including:

- severity of the disease under investigation;
- eligibility criteria for the study in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

The actual amount of time for full enrollment could be longer than planned. Enrollment delays in these planned Phase II trials or any of the Corporation's other clinical trials may result in increased development costs for its product candidates, which would cause the value of the company to decline and limit the Corporation's ability to obtain additional financing, including financing needed to complete the planned Phase II trials of DPX-Survivac. The Corporation's inability to enroll a sufficient number of patients for these planned Phase II clinical trials or any of the other clinical trials would result in significant delays or may require the Corporation to abandon one or more clinical trials altogether.

If serious adverse or inappropriate side effects are identified during the development of the product candidates, the Corporation may need to abandon or limit the development of some of its product candidates.

All of the Corporation's product candidates are still in preclinical or clinical development and their risk of failure is high. It is impossible to predict when or if any of the Corporation's product candidates will prove effective or safe in humans or will receive regulatory approval. If the Corporation's product candidates are associated with undesirable side effects or have characteristics that are unexpected, the Corporation may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Even if any of the Corporation's product candidates, including DPX-Survivac, receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

If DPX-Survivac or any other product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. Gaining market acceptance for the DepoVax<sup>TM</sup>-based products may be particularly difficult as, to date, the FDA has only approved a limited number of cancer immunotherapies and the DepoVax<sup>TM</sup>-based products are based on a novel technology. If these products do not achieve an adequate level of acceptance, the Corporation may not generate significant product revenues and may not become profitable. The degree of market acceptance of the Corporation's product candidates, if approved for commercial sale, will depend on a number of factors, including:

• efficacy and potential advantages compared to alternative treatments;

- the ability to offer its product candidates for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

If the Corporation is unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market its product candidates, the Corporation may not be successful in commercializing its product candidates if and when they are approved.

The Corporation does not have a sales or marketing infrastructure and has no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, the Corporation must either develop a sales and marketing organization or outsource these functions to third parties. The Corporation currently intends to establish commercialization arrangements with third parties.

There are risks involved with entering into arrangements with third parties to perform these services. If the Corporation enters into arrangements with third parties to perform sales, marketing and distribution services, its product revenues or the profitability of these product revenues are likely to be lower than if the Corporation were to market and sell any products that it develops. In addition, the Corporation may not be successful in entering into arrangements with third parties to sell and market its product candidates or doing so on terms that are favorable to the Corporation. The Corporation likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market its products effectively. If the Corporation does not establish sales and marketing capabilities successfully, either on its own or in collaboration with third parties, it will not be successful in commercializing its product candidates.

# The Corporation faces substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than it may.

The development and commercialization of new drug products is highly competitive. The Corporation faces competition with respect to its current product candidates, and will face competition with respect to any products that it may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which the Corporation is developing its product candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to the Corporation's approach, and others are based on entirely different approaches. Many

marketed therapies for the indications that the Corporation is currently pursuing, or indications that it may in the future seek to address using the DepoVax<sup>TM</sup> platform, are widely accepted by physicians, patients and payors, which may make it difficult for the Corporation to replace with any products that the Corporation successfully develops and are permitted to market.

There are many FDA-approved cancer therapies for cancer that may provide equivalent or better efficacy compared to DPX-Survivac. In glioblastoma, for example, the currently approved standard of care using radiation and temozolomide therapy followed by temozolomide maintenance provides a clinical benefit that may not be surpassed by therapy with DPX-Survivac in the same patient population.

In addition, the Corporation estimates that there are numerous cancer immunotherapy products in clinical development by many public and private biotechnology and pharmaceutical companies targeting numerous different cancer types. A number of these are in late stage development. For example Stimuvax (Merck KgaA), a cancer vaccine in late stage clinical development for the treatment of non-small lung cancer (NSLC) may successfully improve overall survival to a better extent than DPX-Survivac in the same patient population.

DPX-0907, similar to DPX-Survivac, is designed to produce T cells specific for antigens believed to be associated with cancer. As with DPX-Survivac, approved therapies and therapies in development may provide equivalent or better efficacy compared to DPX-0907.

The Corporation's competitors may develop products that are more effective, safer, more convenient or less costly than any that the Corporation is developing or that would render its product candidates obsolete or non-competitive. The Corporation's competitors may also obtain FDA or other regulatory approval for their products more rapidly than the Corporation.

Many of the Corporation's competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than the Corporation. Mergers and acquisitions in the pharmaceutical, biotechnology and device industries may result in even more resources being concentrated among a smaller number of the Corporation's competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with the Corporation in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the Corporation's programs.

Even if the Corporation is able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm the business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, recently passed legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, the Corporation might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay the commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues

the Corporation is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder the Corporation's ability to recoup its investment in one or more product candidates, even if its product candidates obtain regulatory approval.

The Corporation's ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. The Corporation cannot be sure that reimbursement will be available for any product that it commercializes and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which the Corporation obtains marketing approval. Obtaining reimbursement for the Corporation's products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, the Corporation may not be able to successfully commercialize any product candidate for which the Corporation obtained marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers the Corporation's costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover the Corporation's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in Canada or the United States. Third party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. The Corporation's inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that the Corporation develops could have a material adverse effect on the Corporation's operating results, the Corporation's ability to raise capital needed to commercialize products and the Corporation's overall financial condition.

# The Corporation's reliance on government funding adds uncertainty to the Corporation's research and commercialization efforts of its government-funded product candidates.

The Corporation has received significant funding from government organizations since its inception totaling over \$10 million. There is no assurance the Corporation will continue to apply for and/or be awarded government funding in the future. If the Corporation is unable to obtain additional government funding, it will have to either obtain funds through raising additional capital or arrangements with strategic partners or others, if available, that may require the Corporation to relinquish material rights to certain technologies or potential markets. There is no certainty that financing will be available in amounts the Corporation requires for to pursue the planned activities or on acceptable terms, if at all.

Product liability lawsuits against the Corporation could cause the Corporation to incur substantial liabilities and to limit commercialization of any products that the Corporation may develop.

The Corporation faces an inherent risk of product liability exposure related to the testing of its product candidates in human clinical trials and will face an even greater risk if the Corporation commercially sells any products that it may develop. None of the Corporation's product candidates have been widely used over an extended period of time, and therefore, safety data is limited.

If the Corporation cannot successfully defend itself against claims that its product candidates or products caused injuries, it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that it may develop;
- injury to the Corporation's reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that the Corporation may develop.

The Corporation currently holds \$10 million in clinical trial liability insurance coverage, which may not be adequate to cover all liabilities that it may incur. The Corporation will need to increase its insurance coverage when it begins commercializing its product candidates, if ever. Insurance coverage is increasingly expensive. The Corporation may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

The Corporation may expend its limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because the Corporation has limited financial and managerial resources, the Corporation focuses on research programs and product candidates for specific indications. As a result, the Corporation may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. The Corporation's resource allocation decisions may cause the Corporation to fail to capitalize on viable commercial products or profitable market opportunities. The Corporation's spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

The Corporation has based its research and development efforts on its DepoVax<sup>TM</sup> platform. Notwithstanding the large investment to date and anticipated future expenditures in its DepoVax<sup>TM</sup> platform, the Corporation has not yet developed, and may never successfully develop, any marketed drugs using this approach. As a result of pursuing the development of product candidates using the DepoVax<sup>TM</sup> platform, the Corporation may fail to develop product candidates or address indications based on other

scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success.

The Corporation's long-term business plan is to develop DepoVax<sup>TM</sup>-based products for the treatment of various cancers and infectious diseases. The Corporation may not be successful in its efforts to identify or discover additional product candidates that may be manufactured using its DepoVax<sup>TM</sup> platform. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development.

If the Corporation does not accurately evaluate the commercial potential or target market for a particular product candidate, the Corporation may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for the Corporation to retain sole development and commercialization rights to such product candidate.

### Risks Related to the Corporation's Dependence on Third Parties

If the Corporation is not able to establish collaborations, the Corporation may have to alter its development and commercialization plans.

The Corporation's drug development programs and the potential commercialization of its product candidates will require substantial additional cash to fund expenses. For some of the Corporation's product candidates, the Corporation plans to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

The Corporation faces significant competition in seeking appropriate collaborators. Whether the Corporation reaches a definitive agreement for a collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to the Corporation's ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with the Corporation for its product candidate. The Corporation may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. The Corporation may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

The Corporation will need to raise capital or develop collaborations with third parties to commercialize its products. If the Corporation is not able to obtain such funding or enter into collaborations for any such product candidate, the Corporation may have to curtail the development of such product candidate, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase its expenditures and undertake development or commercialization activities at the Corporation's own expense. If the Corporation elects to increase its expenditures to fund development or commercialization activities on its

own, the Corporation may need to obtain additional capital, which may not be available to the Corporation on acceptable terms or at all. If the Corporation does not have sufficient funds, the Corporation may not be able to further develop these product candidates or bring these product candidates to market and generate product revenue.

The Corporation expects to depend on collaborations with third parties for the development and commercialization of its product candidates. If those collaborations are not successful, the Corporation may not be able to capitalize on the market potential of these product candidates.

The Corporation intends to establish commercialization arrangements with third-parties. The Corporation's likely collaborators for any development, distribution, marketing, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

Potential delays include delays in manufacture or clinical trials, failure to produce sufficient quantities of product to conduct trials, or failure to complete trials. The Corporation's collaborators may fail to meet contractual obligations. They could also pursue other technologies or develop alternative products that could compete with the products the Corporation is developing. If the Corporation does enter into any such arrangements with any third parties, the Corporation will likely have limited control over the amount and timing of resources that its collaborators dedicate to the development or commercialization of its product candidates. The Corporation's ability to generate revenues from these arrangements will depend on its collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving the Corporation's product candidates would pose the following risks to the Corporation:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of the Corporation's product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with the Corporation's products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than the Corporation's;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend the Corporation's intellectual property rights or may use the Corporation's proprietary information in such a way as to invite litigation that

could jeopardize or invalidate the Corporation's proprietary information or expose the Corporation to potential litigation;

- disputes may arise between the collaborators and the Corporation that result in the delay or termination of the research, development or commercialization of the Corporation's products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. For example, the Corporation could have to build a sales force.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future collaborator of the Corporation were to be involved in a business combination, the continued pursuit and emphasis on the Corporation's product development or commercialization program could be delayed, diminished or terminated.

# The Corporation relies on third parties to conduct its clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

The Corporation does not independently conduct clinical trials of its product candidates. The Corporation relies on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. The Corporation's reliance on these third parties for clinical development activities reduces its control over these activities but does not relieve the Corporation of its responsibilities. The Corporation remains responsible for ensuring that each of its clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires the Corporation to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The Corporation is also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Furthermore, these third parties may also have relationships with other entities, some of which may be the Corporation's competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct the Corporation's clinical trials in accordance with regulatory requirements or the Corporation's stated protocols, the Corporation will not be able to obtain, or may be delayed in obtaining, regulatory approvals for its product candidates and will not be able to, or may be delayed in its efforts to, successfully commercialize its product candidates.

The Corporation also relies on other third parties to store and distribute drug supplies for its clinical trials. Any performance failure on the part of the Corporation's existing or future distributors could delay clinical development or regulatory approval of its product candidates or commercialization of its products, producing additional losses and depriving the Corporation of potential product revenue.

The Corporation depends on third-party suppliers to obtain the Corporation's raw ingredients, intermediate drug substances and specialized equipment, which are necessary for the production of the Corporation's products.

The Corporation currently procures ingredients and intermediate drug substances for the manufacturing of the Corporation's pipeline products, from specialized suppliers. For some components, the Corporation has so far identified only one supplier. In the unlikely event that a supplier may stop supplying the required ingredient(s), the Corporation may need to identify an alternative source of such ingredient(s) which may cause substantial delays to one or all of the Corporation's clinical programs. Currently the Corporation is utilizing the GMP services of a contract manufacturing organization (CMO) located in the United States for its clinical drug product manufacture and does not have a fully qualified and approved backup facility. The Corporation may need to approve an alternative CMO to avoid delays in planned clinical programs should there be any issues with the current CMO. The Corporation's product(s) requires a unique manufacturing process and uses specialized equipment manufactured by another third party to manufacture the Corporation's clinical candidate vaccines. The specialized equipment used during the manufacturing process is made by only one manufacturer. In the event of catastrophic equipment failure and in the event that this particular supplier of the equipment ceases its operations and/or replacement equipment cannot be procured, alternative suppliers of similar equipment may be sought and additional product development may be required, which may cause significant delays to some or all of the Corporation's clinical programs.

# Risks Related to the Manufacturing of the Corporation's Product Candidates

If the Corporation is unable to commercially manufacture its products, the Corporation could face delayed trial approvals or sales.

The Corporation has no experience manufacturing commercial quantities of products and does not currently have the resources to commercially manufacture any products that the Corporation may develop. Accordingly, if the Corporation becomes successful in developing any product with commercial potential, the Corporation would either be required to develop the facilities to manufacture independently or secure a contract manufacturer or enter into another arrangement with third parties to manufacture such products. If the Corporation is unable to develop such capabilities or enter into any such arrangement on favourable terms, the Corporation may be unable to compete effectively in the marketplace. If the Corporation is unable to manufacture or contract for a sufficient supply of product on acceptable terms, or if the Corporation encounters delays or difficulties in its relationships with manufacturers or collaborators, its preclinical, clinical testing and/or product sales could be delayed, thereby delaying the submission of products for regulatory approval and/or market introduction and subsequent sales of such products.

# Risks Related to the Corporation's Intellectual Property

If the Corporation fails to comply with its obligations under its intellectual property licenses with third parties, the Corporation could lose license rights that are important to its business.

The Corporation is a party to a number of intellectual property license agreements with third parties and expects to enter into additional license agreements in the future. The Corporation's existing license agreements impose, and the Corporation expects that future license agreements will impose, various diligences, milestone payment, royalty, insurance, indemnification and other obligations on the Corporation. For example, the Corporation's agreement with Immunotope requires it to maintain its patents and patent applications with respect to the antigens it licenses from them. If the Corporation fails

to comply with its obligations under these licenses, its licensors may have the right to terminate these license agreements, in which event the Corporation might not be able to market any product that is covered by these agreements, or to convert the license to a non-exclusive license, which could materially adversely affect the value of the product candidate being developed under the license agreement. Termination of these license agreements or reduction or elimination of the Corporation's licensed rights may result in the Corporation having to negotiate new or reinstated licenses with less favorable terms.

If the Corporation is unable to obtain and maintain patent protection for its technology and products, or if the Corporation's licensors are unable to obtain and maintain patent protection for the technology or products that it licenses from them, or if the scope of the patent protection obtained is not sufficiently broad, the Corporation's competitors could develop and commercialize technology and products similar or identical to that of the Corporation's, and its ability to successfully commercialize its technology and products may be adversely affected.

The Corporation's success depends in large part on its and its licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to its proprietary technology and products. The Corporation and its licensors have sought to protect the Corporation's proprietary position by filing patent applications in the United States and abroad related to its novel technologies and products that are important to its business. This process is expensive and time-consuming, and the Corporation may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that the Corporation will fail to identify patentable aspects of its research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, the Corporation does not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that it licenses from third parties and are reliant on its licensors. Therefore, the Corporation cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of its business. If such licensors fail to maintain such patents, or lose rights to those patents, the rights the Corporation has licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of the Corporation's and its licensors' patent rights are highly uncertain. The Corporation and its licensors' pending and future patent applications may not result in patents being issued which protect its technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the Corporation's patents or narrow the scope of its patent protection.

The laws of foreign countries may not protect the Corporation's rights to the same extent as the laws of Canada and the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in Canada and the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore the Corporation cannot be certain that its or its licensors were the first to make the inventions claimed in its owned or licensed patents or pending patent applications, or that the Corporation or its licensors were the first to file for patent protection of such inventions.

Assuming the other requirements for patentability are met, in the United States, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is generally entitled to the patent. Under the America Invents Act, or AIA, enacted in September 2011, the United States moved to a first inventor to file system in March 2013. The

Corporation may become involved in opposition or interference proceedings challenging its patent rights or the patent rights of others. An adverse determination in any such proceeding or litigation could reduce the scope of, or invalidate, the Corporation's patent rights, allowing third parties to commercialize its technology or products and compete directly with the Corporation, without payment to the Corporation, or result in its inability to manufacture or commercialize products without infringing third-party patent rights. For example, Merck has to maintain patents on antigens licensed to the Corporation.

Even if the Corporation's owned and licensed patent applications issue as patents, they may not issue in a form that will provide the Corporation with any meaningful protection, prevent competitors from competing with the Corporation or otherwise provide the Corporation with any competitive advantage. The Corporation's competitors may be able to circumvent its owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the Corporation's owned and licensed patents may be challenged in the courts or patent offices in Canada, the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit the Corporation's ability to or stop or prevent the Corporation from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of its technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, the Corporation's owned and licensed patent portfolio may not provide it with sufficient rights to exclude others from commercializing products similar or identical to the Corporation's.

# The Corporation may become involved in lawsuits to protect or enforce its patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe the Corporation's patents. To counter infringement or unauthorized use, the Corporation may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of the Corporation's is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that its patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of the Corporation's patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of the Corporation's confidential information could be compromised by disclosure during this type of litigation. In addition, the Corporation's licensors may have rights to file and prosecute such claims and it is reliant on them.

# Third parties may initiate legal proceedings alleging that the Corporation is infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of the Corporation's business.

The Corporation's commercial successes depends upon its ability and the ability of its collaborators to develop, manufacture, market and sell its product candidates and use its proprietary technologies without infringing the proprietary rights of third parties. The Corporation may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to its products and technology, including interference proceedings before the U.S. Patent and Trademark Office or other similar regulatory authorities. Third parties may assert infringement claims against the Corporation based on existing patents or patents that may be granted in the future. If the Corporation is found to infringe a third party's intellectual property rights, it could be required to obtain a license from such third party to continue developing and marketing its products and technology. However, the

Corporation may not be able to obtain any required license on commercially reasonable terms or at all. Even if the Corporation was able to obtain a license, it could be non-exclusive, thereby giving its competitors access to the same technologies licensed to the Corporation. The Corporation could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, the Corporation could be found liable for monetary damages. A finding of infringement could prevent the Corporation from commercializing its product candidates or force the Corporation to cease some of its business operations, which could materially harm the Corporation's business. Claims that the Corporation has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business.

The Corporation has research licenses to certain reagents and their use in the development of its product candidates. The Corporation would need commercial licenses to these reagents for any of the Corporation's product candidates that receive approval for sale in the United States or Canada. The Corporation believes that commercial licenses to these reagents will be available. If the Corporation is unable to obtain any such commercial licenses, it may be unable to commercialize its product candidates without infringing the patent rights of third parties. If the Corporation did seek to commercialize its product candidates without a license, these third parties could initiate legal proceedings against the Corporation.

# The Corporation may be subject to claims that its employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of the Corporation's employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although the Corporation tries to ensure that its employees do not use the proprietary information or know-how of others in their work for the Corporation, the Corporation may be subject to claims that it or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If the Corporation fails in defending any such claims, in addition to paying monetary damages, it may lose valuable intellectual property rights or personnel. Even if the Corporation is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

# Intellectual property litigation could cause the Corporation to spend substantial resources and distract its personnel from their normal responsibilities.

Even if resolved in the Corporation's favor, litigation or other legal proceedings relating to intellectual property claims may cause the Corporation to incur significant expenses, and could distract the Corporation's technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of the Corporation's common shares. Such litigation or proceedings could substantially increase the Corporation's operating losses and reduce the resources available for development activities. The Corporation may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of the Corporation's competitors may be able to sustain the costs of such litigation or proceedings more effectively than it can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on the Corporation's ability to compete in the marketplace.

# If the Corporation is unable to protect the confidentiality of its trade secrets, the Corporation's business and competitive position would be harmed.

In addition to seeking patents for some of the Corporation's technology and products, it also relies on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain its competitive position. The types of protections available for trade secrets are particularly important with respect to the DepoVax<sup>TM</sup> platform's manufacturing capabilities, which involve significant unpatented know-how. The Corporation seeks to protect these trade secrets, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as the Corporation's employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. The Corporation also enters into confidentiality and invention or patent assignment agreements with its employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose the Corporation's proprietary information, including its trade secrets, and the Corporation may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, courts in certain jurisdictions are less willing or unwilling to protect trade secrets. If any of the Corporation's trade secrets were to be lawfully obtained or independently developed by a competitor, it would have no right to prevent them from using that technology or information to compete with the Corporation. If any of the Corporation's trade secrets were to be disclosed to or independently developed by a competitor, its competitive position would be harmed.

# Risks Related to Regulatory Approval of the Corporation's Product Candidates and Other Legal Compliance Matters

If the Corporation is not able to obtain, or if there are delays in obtaining, required regulatory approvals, the Corporation will not be able to commercialize its product candidates, and its ability to generate revenue will be materially impaired.

The Corporation's product candidates, including DPX-Survivac and DPX-0907, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent the Corporation from commercializing the product candidate. The Corporation has not received regulatory approval to market any of its product candidates in any jurisdiction. The Corporation has only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations to assist it in this process. Securing FDA or Health Canada approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA or Health Canada for each therapeutic indication to establish the product candidate's safety and efficacy. Securing FDA or Health Canada approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA or Health Canada. The Corporation's product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude the Corporation from obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product

candidates involved. To date, the FDA has only approved one active cellular immunotherapy product. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA or Health Canada has substantial discretion in the approval process and may refuse to accept any application or may decide that the Corporation's data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval the Corporation ultimately obtains may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If the Corporation experiences delays in obtaining approval or if it fails to obtain approval of its product candidates, the commercial prospects for the Corporation's product candidates may be harmed and its ability to generate revenues will be materially impaired.

# Failure to obtain regulatory approval in international jurisdictions would prevent the Corporation's product candidates from being marketed abroad.

The Corporation intends to enter into arrangements with third parties under which they would market its products outside Canada or the United States. In order to market and sell the Corporation's products in the European Union and many other jurisdictions, the Corporation or such third parties must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA or Health Canada approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA or Health Canada approval. In addition, in many countries outside the United States or Canada, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. The Corporation or these third parties may not obtain approvals from regulatory authorities outside the United States or Canada on a timely basis, if at all. Approval by the FDA or Health Canada does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States or Canada does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The Corporation may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize its products in any market.

# If the Corporation fails to comply with environmental, health and safety laws and regulations, it could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of the Corporation's business.

The Corporation is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. The Corporation's operations involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. The Corporation's operations also produce hazardous waste products. The Corporation generally contract with third parties for the disposal of these materials and wastes. The Corporation cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from the Corporation's use of hazardous materials, it could be held liable for any resulting damages, and any liability could exceed its resources. The Corporation also could incur significant costs associated with civil or criminal fines and penalties.

Although the Corporation maintains workers' compensation insurance to cover it for costs and expenses it may incur due to injuries to its employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. The Corporation does not maintain insurance for environmental liability or toxic tort claims that may be asserted against the Corporation in connection with its storage or disposal of biological, hazardous or radioactive materials.

In addition, the Corporation may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair the Corporation's research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Any product candidate for which the Corporation obtains marketing approval could be subject to restrictions or withdrawal from the market and the Corporation may be subject to penalties if it fails to comply with regulatory requirements or if it experiences unanticipated problems with its products, when and if any of them are approved.

Any product candidate for which the Corporation obtains marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, among others, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, cGTP requirements, requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved label. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if the Corporation does not market its products for their approved indications, the Corporation may be subject to enforcement action for off-label marketing.

In addition, later discovery of previously unknown problems with the Corporaiton's products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that it submits;

- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of the Corporation's products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The Corporation's relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose the Corporation to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which the Corporation obtains marketing approval. The Corporation's future arrangements with third-party payors and customers may expose the Corporation to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which it markets, sells and distributes its products for which it obtains marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Health Care Reform Law will require
  manufacturers of drugs, devices, biologics and medical supplies to report to the Department of
  Health and Human Services information related to physician payments and other transfers of
  value and physician ownership and investment interests; and

analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply
to sales or marketing arrangements and claims involving healthcare items or services reimbursed
by non-governmental third-party payors, including private insurers, and some state laws require
pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance
guidelines and the relevant compliance guidance promulgated by the federal government in
addition to requiring drug manufacturers to report information related to payments to physicians
and other health care providers or marketing expenditures.

Efforts to ensure that the Corporation's business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that the Corporation's business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If the Corporation's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, it may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of the Corporation's operations. If any of the physicians or other providers or entities with whom the Corporation expects to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Recently enacted and future legislation may increase the difficulty and cost for the Corporation to obtain marketing approval of and commercialize its product candidates and affect the prices it may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of the Corporation's product candidates, restrict or regulate post-approval activities and affect its ability to profitably sell any product candidates for which it obtains marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class in certain cases. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement that is provided for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect the Corporation's business practices with health care practitioners. The

Corporation will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase the Corporation's regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. The Corporation cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of the Corporation's product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject the Corporation to more stringent product labeling and post-marketing testing and other requirements.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years, or approved by the FDA until 12 years, after the original brand product identified as the reference product was approved under a BLA. The new law is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for the Corporation's biological products.

The Corporation believes that if any of its product candidates were to be approved as biological products under a BLA, such approved products should qualify for the four-year and 12-year periods of exclusivity. However, there is a risk that the U.S. Congress could amend the BPCIA to significantly shorten these exclusivity periods as proposed by President Obama, or that the FDA will not consider the Corporation's product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the Corporation's reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

# Risks Related to Employee Matters and Managing Growth

# The Corporation's future success depends on its ability to retain its key executives and to attract, retain and motivate qualified personnel.

The corporation is highly dependent on its executive officers. Although the Corporation has formal employment agreements with each of its executive officers, these agreements do not prevent the Corporation's executives from terminating their employment with the Corporation at any time. The loss of the services of any of these persons could impede the achievement of the Corporation's research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to the Corporation's success. The Corporation may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and

biotechnology companies for similar personnel. The Corporation also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, the Corporation relies on consultants and advisors, including scientific and clinical advisors, to assist it in formulating its research and development and commercialization strategy. The Corporation's consultants and advisors may be employed by employers other than the Corporation and may have commitments under consulting or advisory contracts with other entities that may limit their availability to the Corporation.

The Corporation expects to expand its development, regulatory, manufacturing and sales and marketing capabilities, and as a result, the Corporation may encounter difficulties in managing its growth, which could disrupt the Corporation's operations.

The Corporation expects to experience significant growth in the number of its employees and the scope of its operations, particularly in the areas of drug development, regulatory affairs, manufacturing and sales and marketing. To manage the Corporation's anticipated future growth, it must continue to implement and improve its managerial, operational and financial systems, expand its facilities and continue to recruit and train additional qualified personnel. Due to the Corporation's limited financial resources and the limited experience of its management team in managing a company with such anticipated growth, the Corporation may not be able to effectively manage the expansion of its operations or recruit and train additional qualified personnel. The physical expansion of the Corporation's operations may lead to significant costs and may divert its management and business development resources. Any inability to manage growth could delay the execution of the Corporation's business plans or disrupt the Corporation's operations.

# V. DIVIDENDS

The Corporation has not declared or paid any dividends on its Common Shares to date. The payment of dividends in the future will be dependent on the Corporation's earnings, financial condition and such other factors as the Corporation's Board of Directors considers appropriate. However, the Corporation's current policy is to reinvest future earnings in order to finance its growth and the development of its business. As a result, the Corporation does not intend to pay dividends in the foreseeable future.

#### VI. DESCRIPTION OF CAPITAL STRUCTURE

The Corporation is authorized to issue an unlimited number of Common Shares, without nominal or par value of which, as at March 14, 2014, 79,258,923 are issued and outstanding as fully-paid and non-assessable Common Shares. The holders of Common Shares are entitled to receive notice of, to attend and to vote at any meeting of the shareholders of the Corporation and each one Common Share shall carry the right to one vote. Subject to the prior rights of the holders of Preferred Shares (as defined hereinafter), the holders of Common Shares are entitled to receive dividends as and when declared by the Board of Directors of the Corporation. The holders of Common Shares have the right, subject to the rights, privileges, restrictions and conditions attaching to any other class of shares of the Corporation, to receive the remaining property of the Corporation upon dissolution, liquidation or winding-up thereof.

The Corporation is also authorized to issue an unlimited number of preferred shares (the "**Preferred Shares**") without nominal or per value in one or more series of which, as of the date hereof, none are issued and outstanding. The Board of Directors of the Corporation may determine, before issuance, the designation, rights, privileges and restrictions attached to each series of Preferred Shares provided that the Preferred Shares shall rank senior to the Common Shares.

# VII. MARKET FOR SECURITIES

### Trading Price and Volume

The Common Shares are listed and posted for trading on the TSX-V and are traded under the symbol "IMV".

The following table sets forth the reported high and low trade prices in Canadian dollars and the cumulative volume of trading of the Common Shares for the periods indicated below:

	Price Range		Average Trading Volumes	Total Cumulative Volume
	High (\$)	Low (\$)		
January 2013	0.400	0.320	46,563	838,140
February 2013	0.370	0.285	18,387	330,971
March 2013	0.330	0.280	11,555	150,222
April 2013	0.340	0.255	12,394	223,094
May 2013	0.350	0.220	33,859	609,476
June 2013	0.400	0.310	39,435	473,230
July 2013	0.315	0.260	13,184	197,764
August 2013	0.360	0.240	20,556	431,683
September 2013	0.390	0.280	43,527	870,557
October 2013	0.470	0.350	100,352	2,207,763
November 2013	0.550	0.400	27,737	582,491
December 2013	0.530	0.350	24,379	487,599

# Stock options

During the year ended December 31, 2013, the Corporation issued 514,070 stock options, which have an exercise period of 5 years from the date of grant:

Date	Number	Exercise Price
April 30, 2013	514,070	\$0.28

#### VIII. DIRECTORS AND OFFICERS

#### **Directors**

As at March 14, 2014, as a group, the Corporation's directors and executive officers beneficially owned, directly or indirectly, or exercised control of over an aggregate of 7,427,818 Common Shares representing 10% of the issued and outstanding Common Shares as at such date. The information as to the number of Common Shares beneficially owned or over which control is exercised, not being within the knowledge

of the Corporation, has been furnished by SEDI and confirmed with each director or executive officer, as the case may be, individually as of March 14, 2014.

The following table sets forth the name, province or state and country of residence of each director and executive officer of the Corporation and states the respective positions and offices held with the Corporation, their principal occupations during the last five years and the periods during which each director has served as a director of the Corporation. Each director will hold office until the next annual meeting of shareholders or until his successor is duly elected, unless prior thereto the director resigns or the director's office becomes vacant by reason of death or other cause.

Name and Municipality of Residence	Position Held with the Corporation	Principal Occupation during Past Five Years	Director Since (3)
Albert Scardino (London, United Kingdom)	Executive Chairman of the Board and Director	Chairman of Auctionair Limited (on-line auction services for airline and media industries)	July 29, 2010
Wade K. Dawe (1) (2) (4) (Halifax, Nova Scotia, Canada)	Director	Former President, Chief Executive Officer and Chairman of Brigus Gold Corp. (formerly Linear Gold Corp.) and Chairman of Linear Metals Corporation (mining companies)	May 18, 2007
James Hall <sup>(2) (3)</sup> (Toronto, Ontario, Canada)	Director	President and Chief Executive Officer, James Hall Advisors Inc. (advisory firm)	February 22, 2010
Llew Keltner (Portland, Oregon, United States)	Director	Chief Executive Officer of EPISTAT (international healthcare technology transfer, corporate risk management and healthcare strategy company), former Chief Executive Officer of AgonOx, Inc (a biotechnology company) and former Managing Partner of i.Investment Advisory Pte. Ltd Singapore	January 17, 2014
Stephanie Leouzon (2) (3) (London, United Kingdom)	Director	Partner at Torreya Partners (life sciences advisory firm)	May 24, 2012
Wayne Pisano (2)(3) (Asbury, New Jersey, USA)	Director	President of Pirus Biological & Vaccine Consulting (vaccine and venture capitalist industry consulting company) and Chief Executive Officer of VaxInnate (pandemic and influenza vaccine company) Former Chief Executive of Sanofi Pasteur (pediatric and adult vaccine manufacturing company)	October 17, 2011
Bradley Thompson <sup>(2)</sup> (Calgary, Alberta, Canada)	Director	Executive Chairman, Chief Executive Officer and President of Oncolytics Biotech Inc. (biotech company)	June 22, 2011
Marc Mansour (Halifax, Nova Scotia, Canada)	Director	Chief Operating Officer, Immunovaccine Inc.	December 12, 2013

- (1) Member of the Compensation and Corporate Governance Committee
- (2) Member of the Finance Committee
- (3) Member of the Audit Committee
- (4) Mr. Dawe is not standing for re-election.

# **Biographies**

### Albert Scardino, Chairman of the Board and Director

Mr. Scardino is a journalist, media investor and communications strategist. He has extensive experience as a director of both for-profit and not-for-profit organizations, public and private, in the US and the UK. He has written for his own newspaper, The Georgia Gazette (where he won a Pulitzer Prize), as well as for The New York Times and The Guardian. He has served as a communications director in political campaigns and government and as a commentator and media critic for national and international news organizations. He is also chairman of Auctionair, an on-line auction site. He was educated at Columbia University and the University of California, Berkeley. He has been an investor in Immunovaccine since 2005 and a director since 2010.

### Wade K. Dawe, Director

Mr. Dawe has been an entrepreneur in Canadian mining and venture capital industries since 1994. He has significant experience in public markets and finance and has served on the Board of Immunovaccine Inc. since 2005. Mr. Dawe is the former Chairman and Chief Executive Officer of Brigus Gold, a Toronto Stock Exchange (TSX) and New York Stock Exchange (NYSE Amex) listed company. Mr. Dawe has a Bachelor of Commerce degree from Memorial University of Newfoundland (MUN) 1992. He is a member of the Young Presidents' Organization (YPO), an international organization for business leaders. A native of Newfoundland and Labrador, he now resides in Halifax, Nova Scotia.

#### James Hall, Director

Mr. Hall is President & CEO of James Hall Advisors Inc. which provides financial and management advisory services to both private and publicly-held companies principally in the financial services, media and entertainment sectors. Prior to Advisors, Mr. Hall was Chairman and Chief Executive Officer of Philadelphia-based pure-play newspaper company Journal Register Company, and served as Senior Vice President & Chief Investment Officer of private equity investment fund Working Ventures Canadian Fund Inc. from 1990 to 2002. Mr. Hall is a director of Indigo Books & Music Inc., Atomic Energy of Canada Limited, Adventus Intellectual Property Inc., and a trustee of Omers Trust. A Chartered Accountant (CPA, CA), Mr. Hall is a graduate of the Richard Ivey School of Business at Western University in London, Ontario.

#### Llew Keltner, Director

Dr. Keltner, has a 30 year career in biopharma drug and business development. He is Chief Executive Officer of EPISTAT, an international healthcare technology transfer, corporate risk management and healthcare strategy company that he founded in 1972. Dr. Keltner was the Chief Executive Officer of AgonOx, a biotech company developing OX40 agonists for use in cancer therapy, from 2011 to 2013. He was the President of Novici Biotech, a privately-held gene and protein optimization firm in 2010 and 2011. Dr. Keltner was Chief Executive Officer and President of Light Sciences Oncology, a privately-held biotechnology company developing a late stage, light-activated therapy for hepatocellular cancer and other solid tumors from 2001 to 2010. From 1997 to 2004, Dr. Keltner was Chief Executive Officer of Metastat, a development-stage biotech company focused on cancer metastasis. Dr. Keltner holds positions on the boards of Raptor Pharmaceuticals, where he serves as Chairman (NASDAQ:RPTP), Infostat, BioQuiddity, Oregon Life Sciences, and Goodwell Technologies. He is a previous Director of Light Sciences Corporation, Vital Choice, Thesis Technologies, Oread Companies, and MannKind Corporation (NASDAQ:MNKD). He has also been a scientific advisory board member at Lifetime

Corporation, ASB Meditest, Oread Laboratories, Hall-Kimbrell, and aai Pharma. Dr. Keltner is an Associate Professor at Case Western Reserve School of Medicine, and a Guest Lecturer and Director in the Bioethics Program at Columbia University School of Medicine. He is currently a member of the American Society of Clinical Oncology, American Medical Association, International Association of Tumor Marker Oncology, American Association of Clinical Chemistry, and Drug Information Association. Dr. Keltner received an M.S. in Epidemiology and Biostatistics, a Ph.D. in Biomedical Informatics and an M.D. from Case Western Reserve University in Cleveland, Ohio. Dr. Keltner has also authored many research publications.

# Stephanie Léouzon, Director

Stephanie Léouzon is a Partner at Torreya Partners, a life sciences advisory firm she joined in 2012. She was formerly with Credit Suisse in London from 1998 to 2010, her most recent positions being Senior Advisor and Managing Director in Health Care Investment Banking. She has advised on more than 20 strategic transactions, and been involved in over 45 financing transactions for health care clients. Mrs. Léouzon earned an MBA degree from the Darden Graduate School of Business Administration at the University of Virginia, and a BA degree from Mount Holyoke College.

# Wayne Pisano, Director

Mr. Pisano has more than 30 years of experience as a pharmaceutical industry executive and was recognized in 2010 as Pharma Executive of the Year by the World Vaccine Congress. He is currently the president and CEO of VaxInnate a privately held biotech company. He joined Immunovaccine's Board in October 2011. Mr. Pisano is the former president and CEO of Sanofi Pasteur, one of the largest vaccine companies in the world. He joined Sanofi Pasteur in 1997, assuming increasing levels of responsibility. He was promoted to President and CEO in 2007, the position he successfully held until his retirement in 2011. Prior to joining Sanofi Pasteur, he spent 11 years with Novartis (formerly Sandoz). He has a bachelor's degree in biology from St. John Fisher College, New York and an MBA from the University of Dayton, Ohio.

#### Bradley Thompson, Director

Dr. Thompson is Executive Chairman, Chief Executive Officer and President of Oncolytics Biotech Inc. Prior to joining Oncolytics, he served as Chief Executive Officer of SYNSORB Biotech Inc. from May 1994 to February 1999, and was Head of Biotechnology at The Alberta Research Council. Dr. Thompson received his Ph.D. from the University of Western Ontario in the Department of Microbiology and Immunology.

# Marc Mansour, Chief Operating Officer, Director

Dr. Marc Mansour holds a PhD in biology and has completed a Master of Business Administration. He is an expert in vaccinology and cancer immunotherapy. Since he joined Immunovaccine, Dr. Mansour led the clinical development of the DepoVax<sup>TM</sup> platform and the Corporation's lead therapeutic cancer vaccine DPX-Survivac, soon entering randomized Phase II trials in ovarian cancer and glioblastoma. He represents the Corporation to the investor and scientific communities. He continues to lead the internal development of vaccines based on the DepoVax<sup>TM</sup> platform, and externally with collaborators and commercial partners.

# **Executive Officers**

The following table sets forth the name, province or state and country of residence of the other non-director executive officers:

Name and Municipality of Residence	Position held with the Corporation	Principal Occupation during Past Five Years
Kimberly Stephens (Halifax, Nova Scotia, Canada)	Chief Financial Officer	Chief Financial Officer for the Corporation; Director of Finance for the Corporation; Director of Finance for GL Noble Denton Canada; Director of Finance for SolutionInc.

# Kimberly Stephens, Director

Ms. Kimberly Stephens is a Chartered Accountant with more than 13 years of financial management experience across several industries, including her position as Director of Finance for a Canadian subsidiary of an international company, Germanischer Lloyd. Ms. Stephens gained public company experience with her role as the Director of Finance for SolutionInc, and was an Audit Manager in the Assurance and Advisory group of PricewaterhouseCoopers. She is also a director and treasurer of BioNova, Nova Scotia Life Sciences Association and a director of Habitat for Humanity Nova Scotia, holding positions on both the Finance Committee and the Family Services Committee. Ms. Stephens is also a volunteer with the Big Brothers Big Sisters of Greater Halifax.

### Shareholding, Cease Trade Orders, Bankruptcies, Penalties or Sanctions

Except as disclosed below and to the knowledge of the Corporation, none of the current executive officers or directors of the Corporation or shareholders holding a sufficient number of securities of the Corporation to affect materially the control thereof is, or within 10 years before the date hereof, has been:

- a. a director, chief executive officer or chief financial officer of any corporation (including the Corporation) that:
  - (i) was subject to an order that was issued while the proposed director was acting in the capacity as director, chief executive officer or chief financial officer, or
  - (ii) was subject to an order that was issued after the proposed director ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.
- b. a director or executive officer of any corporation (including the Corporation) that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or
- c. has become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromises with creditors, or had a receiver, manager or trustee appointed to hold the assets of the proposed director.

For the purposes of (a) above, "order" means a cease trade order, an order similar to a cease trade order or an order that denied the relevant Corporation access to any exemption under securities legislation, in each case that was in effect for a period of more than 30 consecutive days.

Except as disclosed below and to the knowledge of the Corporation, none of the current executive officers or directors of the Corporation has been subject to:

- a. any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or
- b. any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable security holder in deciding whether to vote for a proposed director.

Mr. James Hall was the Chairman and Chief Executive Officer of Journal Register Corporation ("JRC") on February 21, 2009 when JRC filed a voluntary petition for relief under the US Bankruptcy Code (pre-negotiated joint Chapter 11 plan of reorganization). Mr. Hall left the company in March 2009.

# **Conflicts of Interest**

There are no existing or potential material conflicts of interest between the Corporation or its subsidiary and any director or officer of the Corporation or its subsidiary.

#### IX. CORPORATE GOVERNANCE

The Board of Directors is committed to developing, implementing and monitoring good corporate governance practices, and providing full and complete disclosure of its systems of corporate governance. The following describes the Corporation's approach to corporate governance.

# **Board of Directors**

The Board is responsible for the supervision of management and for approving the overall direction in a manner which is in the best interests of the Corporation. In order to provide guidance and advise, the Board participates fully in assessing and approving strategic plans and prospective decisions proposed by management. To ensure that the principal business risks that are borne by the Corporation are appropriately managed, the Board:

- receives periodic reports from management of its assessment and management of such risks;
- monitors financial and operating performance. This ongoing regular monitoring function often entails review and comment by the Board on various management reports; and
- monitors through the Audit Committee, internal accounting and control procedures and reviews detailed financial information contained in management reports and acts upon the recommendations of the Corporation's auditors.

As a practice, the Board approves significant corporate communications with shareholders. The Board currently consists of eight members, of whom seven will be seeking re-election at the annual meeting of shareholders to be held on April 23, 2014. The Corporation has historically endeavoured to have a

diverse Board with a sufficient number of directors to encourage a variety of opinions on matters which come before the Board, while at the same time limiting its membership to a number of directors that facilitates effective and efficient decision making. While there are no specific criteria for Board membership, the Corporation seeks to attract directors with a wealth of business knowledge and a diversity of business experience.

# **Board Functioning**

The Board adopted a corporate governance policy which, among other things, sets out those matters, in addition to those required by statute, which must be brought by the Chief Executive Officer or other senior management to the Board for approval. The Corporate Governance Policy ensures that all major strategic decisions, including any change in our strategic direction and acquisitions or divestitures of a material nature, will be presented by management to the Board for approval. As part of its ongoing activity, the Board regularly receives and comments upon reports of management as to the performance of the Corporation's business and management's expectations and planned actions in respect thereto.

#### **Board Committees**

The Board has an Audit Committee, a Finance Committee, and a Compensation and Corporate Governance Committee. Each committee has a formal mandate outlining its responsibilities and its obligations to report its recommendations and decisions to the Board.

The Audit Committee is currently composed of Mr. James Hall (Chairman), Mrs. Stephanie Léouzon and Mr. Wayne Pisano, all of whom are financially literate and independent directors within the meaning of NI 52-100. The education and related experience of each current Audit Committee member is described below.

James Hall – Mr. Hall, a Chartered Accountant, presently serves on the audit committee of Indigo Books & Music Inc. He previously served as Chair of the audit committees of International Datacasting Corporation, Terravest Income Fund and General Donlee Income Fund, and was a member of the audit committee of Journal Register Company.

Stephanie Léouzon - Mrs. Léouzon is a Partner at Torreya Partners, a life sciences advisory firm and formerly a Senior Advisor and Managing Director in Health Care Investment Banking at Credit Suisse in London. She has advised on more than 20 strategic transactions, and been involved in over 45 financing transactions for health care clients. Mrs. Léouzon earned an MBA degree from the Darden Graduate School of Business Administration at the University of Virginia, and a BA degree from Mount Holyoke College.

Wayne Pisano – Mr. Pisano holds an MBA and is currently the Chief Executive Officer of VaxInnate, a pandemic and influenza vaccine company.

The Audit Committee is responsible for the integrity of the Corporation's internal accounting and control systems. It receives and reviews the financial statements, annual and special meeting materials and other disclosure documents of the Corporation and makes recommendations thereon to the Board before such statements, materials and documents are approved by the Board. The Audit Committee communicates directly with the Corporation's auditors in order to discuss audit and related matters whenever appropriate. The text of the Audit Committee Mandate is set forth in Schedule "A" hereto.

The Compensation and Corporate Governance Committee is currently composed of Mr. Wayne Pisano (Chairman), Mr. Wade Dawe and Mr. Bradley Thompson. The education and related experience (as applicable) of each current member is described below:

Wayne Pisano – Mr. Pisano is currently the Chief Executive Officer of VaxInnate, a pandemic and influenza vaccine company. He also was the Chief Executive Officer of Sanofi Pasteur for over 3.5 years and had direct responsibility in evaluating the compensation levels for other executive officers.

Wade Dawe – Mr. Dawe is the former Chairman and Chief Executive Officer of Brigus Gold and is responsible for ensuring compensation levels are competitive and in line with the company's business strategy. He is also the Chairman and Director of Linear Metals Corporation.

Bradley Thompson – Mr. Thompson is currently the Executive Chairman and Chief Executive Officer of Oncolytics Biotech Inc. and is responsible for reviewing the compensation levels for other executive officers and corporate governance responsibilities.

The Compensation and Corporate Governance Committee is comprised of independent directors and has been charged by the Board with the responsibility of:

- reviewing and making recommendations to the Board regarding compensation policies and practices. The Committee shall: obtain appropriate information about compensation policies and payments by Canadian companies of a comparable size to the Corporation; establish objectives, evaluate performance, recommend compensation, and develop a process for succession planning; review and approve appointments, promotions, terminations of senior management; and recommend grants of stock options subject to the Board's subsequent ratification;
- proposing to the full Board of Directors new nominees to the Board and for assessing directors on an ongoing basis. The Committee evaluates qualifications for proposed new directors. This Committee performs the role which might otherwise be served by a nominating committee; and
- periodically assessing the performance, effectiveness, and compensation of the Board as a whole and its committees and is responsible for making recommendations to the Board on any proposed changes.

The Finance Committee is responsible for assisting the Board with respect to the Corporation's financial policies and strategies, financial risk management practices and financing activities. The Finance Committee assists the Board to monitor and review the financial structure and investment strategies of the Corporation generally and makes recommendations to the Board as appropriate. The Finance Committee also assists the Board in the development of financing, investment and corporate development strategies and provides input on the execution of Board-approved strategies.

The Finance Committee is currently composed of Mrs. Stephanie Léouzon (Chairman), Mr. Wade Dawe and Mr. James Hall.

Committees are empowered to engage, or to request that management engage, outside advisors at the Corporation's expense. The Board would consider any such request by an individual member of the Board on its merits at the time it was made.

# Orientation and Continuing Education

The Board does not have a formal orientation program for new directors, and does not have any formal continuing education for its members.

#### Ethical Business Conduct

The Board has not adopted a written code of business conduct for its directors, officers and employees.

#### Assessment

The Board, the Board Committees and the Directors will be subject to an annual assessment. Each Director will be required to complete a self-evaluation and an evaluation of the performance of the Board, the Board Committees and their respective chairpersons. These evaluations will then be reviewed by the Compensation and Corporate Governance Committee, which will present its recommendations to the Board. The evaluation of the Compensation and Corporate Governance Committee and its Chairperson will be reviewed by the Chairman of the Board who will present his recommendations to the Board.

# Compensation

The Compensation and Corporate Governance Committee is responsible for determining appropriate compensation for directors in light of the nature of activities and size of the Corporation, and making recommendations to the Board of Directors in that respect.

# *Pre-Approval Policies and Procedures*

All Audit Committee decisions regarding the engagement of the Corporation's auditors for the provision of non-audit services are approved by the Board.

### External Auditor Service Fees

The following table summarizes the Audit, Audit Related, Tax Related and Other Fees (excluding expenses and taxes) billed by the Corporation's auditor, PricewaterhouseCoopers LLP to the Corporation and its subsidiary Immunovaccine Technologies Inc. for the two most recently completed fiscal years.

Fees	December 31, 2013	December 31, 2012
Audit Fees (1)	\$56,300	\$72,500
Audit Related Fees (2)	\$40,950	\$6,220
Tax Fees (3)	\$47,685	\$14,913
All Other Fees (4)	\$-	\$-
Total Fees	\$144,935	\$93,633

<sup>(1)</sup> Audit Fees consist of the aggregate fees billed by the external auditor of the Corporation for audit services.

<sup>(2)</sup> Audited Related Fees consist of the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit or review of the issuer's financial statements and are not reported under "Audit Fees" above and include the provision of comfort letters and consents, the consultation concerning financial accounting and reporting of specific issues and the review of documents filed with regulatory authorities.

<sup>(3)</sup> Tax Fees include fees billed for tax compliance, tax advice and tax planning services, including the preparation of original tax returns and claims for refund; tax consultations, such as assistance and representation in connection with tax audits and appeals, tax advice related to mergers and acquisitions, and requests for rulings or technical advice from taxing authorities; tax planning services; and consultation and planning services.

<sup>(4)</sup> All Other Fees include the aggregate fees billed for products and services provided by the auditors, other than the services reported above.

# X. LEGAL PROCEEDINGS AND REGULATORY ACTIONS

The Corporation is not a party to any legal proceeding, and its property is not and was not the subject of any material legal proceeding, during the year ended December 31, 2013. The Corporation is not aware of any legal proceeding outstanding, threatened or pending as of the date hereof by or against the Corporation.

The Corporation is not and was not subject to, during the year ended December 31, 2013: (i) penalties or sanctions imposed by a court relating to Canadian securities legislation or by a Canadian securities legislation or by a Canadian securities regulatory authority; (ii) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision; and (iii) settlement agreements entered into with a court relating to Canadian securities legislation or with a Canadian securities regulatory authority.

#### XI. INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

There are no material interests, direct or indirect, of directors, executive officers, any shareholder who beneficially owns, directly or indirectly, more than 10% of the outstanding Common Shares, or any known associates or affiliates of such persons, in any transaction within the last three years or in any proposed transaction which has materially affected or would materially affect the Corporation.

Directors or executive officers subscribed for securities of the Corporation, directly or indirectly, as follows:

On March 5, 2013, the Corporation raised approximately \$1.6 million through the private placement of common shares of the Corporation at the price of \$0.33 per common share. Wade K. Dawe invested \$150,000, Stephanie Léouzon invested \$50,000 and Albert Scardino invested \$572,500.

On November 21, 2013, the Corporation raised approximately \$4.2 million through the private placement of common shares of the Corporation at the price of \$0.40 per common share. Albert Scardino invested \$500,000 in this private placement.

### XII. TRANSFER AGENT AND REGISTRAR

The registrar and transfer agent for the Common Shares is Computershare Investor Services Inc., at its principal offices located at 100 University Avenue, 9<sup>th</sup> Floor, Toronto, Ontario, M5J 2Y1 and at Suite 2008, Purdy's Wharf Tower II, 1969 Upper Water Street, Halifax, Nova Scotia, B3J 3R7.

# XIII. MATERIAL CONTRACTS

The Corporation has not entered into any material contracts, other than contracts entered in the ordinary course of business, during 2013 except for the loan agreement from the Province of Nova Scotia pursuant to which the Corporation received a loan of \$5 million available in four equal instalments to be used to fund a portion of working capital through 2016. The Corporation also entered into a contract on July 2010 with Merck KGaA (MRCG.DE) that is still effect. A copy of these agreements can be found under the profile of the Corporation on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>.

#### XIV. INTEREST OF EXPERTS

PricewaterhouseCoopers LLP, the auditor of the Corporation, is the only person, company or partnership which is named as having prepared or certified a statement, report or valuation described, included or referred to in a filing made by the Corporation during or relating to the Corporation's most recently completed financial year and whose profession or business gives authority to a statement, report or valuation made. The partners and associates of PricewaterhouseCoopers LLP do not hold any of the issued and outstanding Common Shares.

#### XV. ADDITIONAL INFORMATION

Additional information, including directors' and officers' remuneration and indebtedness, principal holders of our securities, options and to purchase securities and interests of insiders in material transactions, if any, is contained in the Management Information Circular of the Corporation dated March 14, 2014 prepared in connection with the Corporation's most recent annual shareholders' meeting and is available on SEDAR at www.sedar.com. Additional financial information, including the Corporation's audited financial statements and management's discussion and analysis of financial condition and results of operations, is available on SEDAR at www.sedar.com. All information incorporated by reference in this Annual Information Form is or will within the prescribed delays be contained or included in one of the Corporation's continuous disclosure documents filed with the Canadian securities regulatory authorities, which may be viewed on SEDAR at www.sedar.com.

All requests for the above-mentioned documents must be addressed to the Chief Financial Officer of Immunovaccine Inc., 1344 Summer Street, Suite 412, Halifax, Nova Scotia, B3H 0A8, or by fax at (902) 492-0888.

#### **SCHEDULE A**

# MANDATE OF THE AUDIT COMMITTEE

#### 1. PURPOSE

The primary function of the Audit Committee (the "Committee") is to assist the Board of Directors in fulfilling its oversight responsibilities by reviewing: the financial information that will be provided to the shareholders and others; the systems of internal controls which management and the Board of Directors have established; and the Corporation's and its subsidiaries' audit and financial reporting process. The independent accountants' ultimate responsibility is to the Board of Directors and the Audit Committee, as representatives of the shareholders.

These representatives have the ultimate authority to evaluate and, where appropriate, recommend replacement of the external auditors. The Audit Committee will primarily fulfill these responsibilities by carrying out the activities enumerated in Section 5 of this Mandate. The Audit Committee will, at all times, be given full access to the Corporation's management and records and to the external auditors as necessary to carry out these responsibilities.

#### 2. INTERPRETATION

- "Board of Directors" or "Board" means the Board of Directors of the Corporation.
- "Chairman" means the Chairman of the Committee.
- "Committee" means the Audit Committee of the Corporation.
- "Committees" means the Audit Committee of the Corporation and the Corporate Governance Committee.
- "Corporation" means collectively, Immunovaccine Inc. and its subsidiary, ImmunoVaccine Technologies Inc.
- "Financially Literate" means the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the consolidated financial statements of the Corporation.
- "Independent Director" means a director who has no direct or indirect relationship with the Corporation, which could be reasonably expected to interfere with the exercise of an independent judgment regarding the best interests of the Corporation. Save exceptions, is not an Independent Director the person who:
- (a) is or has been within the last three years, an employee or executive officer of the Corporation;
- (b) is a member of the immediate family of an individual who is or has been, within the last three years, an executive officer of the Corporation;

- (c) is or has been (or whose immediate family member is or has been), within the last three years, an executive officer, a partner or an employee of a material service provider of the Corporation (including the external auditors);
- (d) is or has been (or whose immediate family member is or has been), within the last three years, an executive officer of an entity if any of the current executive officers of the Corporation serves or served at the same time on the entity's Compensation and Corporate Governance Committee;
- (e) has a relationship with the Corporation under which he or she may directly or indirectly accept any consulting, advisory or other fees from the Corporation, except for any compensation as a member of the Board of Directors or as a member of a committee of the Board of Directors of the Corporation;
- (f) received (or whose immediate family member received) more than \$75,000 in direct compensation from the Corporation during any 12 month period within the last three years;
- (g) is a natural person who controls the Corporation;
- (h) is an affiliate of the Corporation; or
- (i) is a natural person who is both a director and an employee of the Corporation.

### 3. COMPOSITION OF COMMITTEE AND COMMITTEE MEETINGS

- 3.1 The Committee shall be comprised of at least three Directors, of which the majority of the Directors are Independent Directors. All members of the Committee shall be Financially Literate.
- 3.2 The Committee will meet on a quarterly basis and will hold special meetings as circumstances require. The timing of the meetings shall be determined by the Audit Committee. At all Committee meetings a majority of the members shall constitute a quorum. The Board shall appoint the Chairman. If the Chairman is not present at a Committee meeting, the members present shall choose one of their number to act as Chairman for the purposes of this specific meeting.
- 3.3 Notice of each meeting shall be given to each Committee member and to the other directors and to the Corporation's senior management. Unless they are expressly called to the meeting, the latter only receive the notice for information purposes.
- 3.4 The Committee may invite the persons it considers useful to invite, including the Corporation's senior management, to attend the meetings and participate in the discussions concerning the Committee's business.
- 3.5 The Committee members, whenever possible, shall take all necessary steps to attend Committee meetings and to prepare themselves with respect to the matters and documents to be discussed thereat.

- 3.6 The Committee shall appoint a secretary. The secretary shall attend the meetings, during which he or she shall take minutes. The minutes shall be made available to the directors for consultation and are approved by the Board before being included in the Corporation's registers or records.
- 3.7 The Committee shall submit periodically a report to the Board on its activities, including the nature of its deliberations and the related recommendations.
- 3.8 The Committee, in the performance of its duties, may consult any relevant register or record of the Corporation.
- 3.9 The Committee members shall receive, in this capacity, the compensation that the Board establishes from time to time.

#### 4. COMMITTEE AUTHORITY AND RELATIONSHIP WITH EXTERNAL AUDITORS

- 4.1 The external auditor shall report directly to the Committee.
- 4.2 The Committee reports to the Board of Directors and has the authority:
  - a) to engage independent counsel and other advisors as it determines necessary to carry out its duties;
  - b) to set and pay the compensation for any advisors employed by the audit committee; and
  - c) to communicate directly with the internal and external auditors.

### 5. RESPONSIBILITIES AND DUTIES

- 5.1 To fulfill its responsibilities and duties, the Committee shall:
  - a) review the accounting principles, policies and practices followed by the Corporation and its subsidiaries in accounting for and reporting its financial results of operations;
  - b) review the Corporation's audited annual consolidated financial statements and the unaudited quarterly financial statements and recommend to the Board for approval prior to publicly disclosing this information. Also review and recommend to the Board for approval any accompanying related documents such as the Annual Information Form or equivalent filings and the Management's Discussion and Analysis prior to publicly disclosing this information;
  - c) review the annual and interim draft press releases quarterly and recommend to the Board for approval prior to publicly disclosing this information;
  - satisfy itself that adequate procedures are in place for the review of the Corporation's public disclosure of financial information extracted or derived from the Corporation's financial statements and periodically assess the adequacy of those procedures;

- e) recommend to the Board of Directors the selection of the external auditors in connection with preparing or issuing an auditor's report or with performing other audit, review or attesting services for the Corporation;
- f) recommend to the Board of Directors the compensation of the external auditors;
- g) oversee the work of the external auditors engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Corporation, including the resolution of disagreements between management and the external auditors regarding financial reporting;
- h) obtain, on an annual, basis, a formal written statement from the external auditors delineating the relationship between the audit firm and the Corporation, and review and discuss with the external auditors such relationship to determine the "independence" of the auditors;
- i) review any management letter prepared by the external auditors concerning the Corporation's internal financial controls, record keeping and other matters and management's response thereto;
- j) discuss with the external auditors their views about the quality of the implementation of Canadian Generally Accepted Accounting Principles, with a particular focus on the accounting estimates and judgments made by management and management's selection of accounting principles. Meet in private with appropriate members of management and separately with the external auditors on a regular basis to share perceptions on these with the external auditors their views on the adequacy of the Corporation's financial personnel;
- k) approve the scope of the annual audit, the audit plan, the access granted to the Corporation's records and the co-operation of management in any audit and review function;
- review the effectiveness of the independent audit effort, including approval of the fees charged in connection with, the annual audit, any quarterly reviews and any non-audit services being provided;
- m) assess the effectiveness of the working relationship of the external auditors with management;
- n) review the financial risk management policies followed by the Corporation in operating its business activities and the completeness and fairness of any disclosure thereof. Review the use of derivative financial instruments by the Corporation;
- o) review and approve any management decision relating to any potential need for internal auditing, including whether this function should be outsourced and if such function is outsourced, approve the supplier of such service;

- p) establish procedures for (i) the receipt, retention and treatment of complaints received by the Corporation regarding accounting, internal accounting controls, or auditing matters; and (ii) the confidential, anonymous submission by employees of the Corporation of concerns regarding questionable accounting or auditing matters;
- q) the Committee will determine the nature of non-audit services the external auditors are prohibited from providing to the Corporation. The Committee will pre-approve all non-audit services provided by the external auditors to the Corporation;
- r) review annually the mandate of the Committee for adequacy and recommend any changes to the Board;
- s) report to the Board on the major items covered at each Committee meeting and make recommendations to the Board and management concerning these matters. Annually report to the Board on the effectiveness of the Committee; and
- t) perform any other activities consistent with this Mandate, the Corporation's Bylaws and governing law as the Committee or the Board deems necessary or appropriate.

# 5.2 Pre-Approval Policies and Procedures

All Audit Committee decisions regarding the engagement of the auditor of the Corporation for the provision of non-audit services are to be ratified by the Board of Directors.

Adopted by the Board on April 6, 2010