



I M M U N O V A C C I N E

**ANNUAL INFORMATION FORM**

**FOR THE YEAR ENDED DECEMBER 31, 2017**

**March 20, 2018**

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## I. INTRODUCTION AND FORWARD LOOKING STATEMENTS

The information contained in this Annual Information Form is stated as at December 31, 2017, unless otherwise indicated. Unless otherwise indicated or if the context otherwise requires, “Immunovaccine”, “IMV”, “the Corporation”, “we”, “us” and “our” refer collectively to Immunovaccine Inc., #53-1344 Summer Street, Suite 412, Halifax, Nova Scotia, Canada, B3H 0A8 and to its subsidiary, ImmunoVaccine Technologies Inc. (“IVT”).

Unless specified otherwise, all amounts are presented in 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 AIF, such statements use such words as “will”, “may”, “could”, “intends”, “potential”, “plans”, “believes”, “expects”, “projects”, “estimates”, “anticipates”, “continue”, “potential”, “predicts” or “should” and other similar terminology. These statements reflect current expectations of management regarding future events and operating performance and speak only as of the date of this AIF. Forward looking statements include, among others:

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

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

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

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

These statements reflect management’s current beliefs and are based on information currently available to management. A more detailed assessment of the risks that could cause actual results to materially differ from current expectations is contained in the section entitled “Risk Factors and Uncertainties” of this AIF.

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.

## **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 #53-1344 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 the Province of Nova Scotia.

## **III. GENERAL DEVELOPMENT OF THE BUSINESS**

### ***Overview***

Immunovaccine is a clinical-stage company that develops products based on its proprietary platform and products with a primary focus on T cell activating therapies for cancer. The Corporation intends to capitalize on licensing opportunities of its platform for other applications such as infectious diseases. The Corporation’s proprietary DepoVax™ delivery platform is believed to produce a strong, high-quality immune response that has a specific and sustained immune effect with potential applications in multiple markets in cancer, infectious diseases and other therapeutic areas.

The Corporation’s cancer immunotherapy, DPX-Survivac, is currently being tested in a co-funded Phase 1b trial with Incyte Corporation (“Incyte”), which evaluates the combination of DPX-Survivac with Incyte’s investigational oral indoleamine 2,3-dioxygenase 1 (“IDO1”) inhibitor, epacadostat, in ovarian cancer patients. DPX-Survivac is also being tested in two investigator-sponsored Phase 2 clinical trials in

combination with checkpoint inhibitor pembrolizumab of Merck (“Merck”) in patients with recurrent, platinum-resistant ovarian cancer and in patients with measurable or recurrent diffuse large B cell lymphoma (“DLBCL”). In infectious disease vaccine applications, the Corporation’s has completed a demonstration Phase 1 clinical trial with a target against the respiratory syncytial virus (“RSV”). The Corporation has a commercial licencing agreement with Zoetis, Inc. (“Zoetis”) for the development of two cattle vaccines and is also conducting several research and clinical collaborations, including a collaboration with the Dana-Farber Cancer Institute (“Dana-Farber”) for Human Papillomavirus (“HPV”) related cancers and with Leidos, Inc. (“Leidos”) in the United States for the development of vaccine candidates for malaria and the Zika virus.

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

### ***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 Inc. (“Pfizer”). The Pfizer Animal Health division was later spun out into Zoetis. 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™ platform, an improvement on the Corporation’s original VacciMax® platform. The patented DepoVax™ platform is a combination of antigens plus adjuvanting immune enhancers formulated in lipid nanoparticles, and then in oil. The DepoVax™ platform creates a unique “depot effect” that holds the vaccine components at the site of injection, prolonging the immune system’s interaction with them and resulting in rapid, potent and long-lasting cellular and/or antibody immune responses.

The DepoVax™ platform is easy to use, chemically stable, scalable and is very versatile. The Corporation demonstrated the applicability of the DepoVax™ in pre-clinical studies using antigens for H5N1 pandemic influenza, hepatitis B, melioidosis, cocaine, anthrax, and Ebola virus. The pre-clinical studies in animals demonstrated significantly higher immune responses after a single dose with the DepoVax™ platform when compared to two or three doses of a control vaccine.

### ***Recent Developments***

Since January 1, 2018, the Corporation has announced:

- On February 15, 2018, that it has closed the previously announced bought deal public offering (the “February 2018 Public Offering”) of common shares of the Corporation (the “Common Shares”), including exercise of the over-allotment option in full, raising gross proceeds of \$14.375 million.

- On January 31, 2018, the publication of a preclinical study using magnetic resource imaging (“MRI”) to follow cancer peptide uptake in tumour models, and to correlate this immune activation to the resulting anti-cancer T cell activity. The *Journal of Biomedical Science* study, titled “Unique Depot Formed by an Oil Based Vaccine Facilitates Active Antigen Uptake and Provides Effective Tumour Control,” compared the mechanism of action (“MOA”) of Immunovaccine’s platform for immunotherapeutic stimulation with other technologies.<sup>1</sup>

In the study, published on January 27, 2018, researchers tracked how the cancer peptides were trafficked from the injection site to immunogenic activation in the lymph nodes. Researchers correlated this to both activation of T cells and the ensuing efficacy to control tumour progression. They concluded that Immunovaccine’s delivery technology had a fundamentally unique MOA. This MOA enabled active and prolonged immune stimulation, as well as better tumour control, as compared to other technologies examined in the study.

- On January 18, 2018, the appointment of Joseph Sullivan to the newly created role of Senior Vice President, Business Development, effective January 22, 2018. Mr. Sullivan will be responsible for providing strategic and operational leadership for the Corporation’s business development efforts. This includes expanding late-stage candidate development and preparation for commercialization, as well as forging strategic commercial partnerships to support further advancement of the company's clinical assets and platform.

### ***Overview of the Last 3 Years***

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

#### ***Year ended December 31, 2017***

During the year ended December 31, 2017, the Corporation announced:

- On December 7, 2017, an expansion of its continuing collaboration with UConn Health. The collaboration is part of Immunovaccine’s DPX-NEO program, which is evaluating the anti-cancer activity of proprietary patient-specific epitopes developed at UConn Health and formulated in the company’s DepoVax-based vaccine formulation. Based on prior preclinical and manufacturing milestones achieved in evaluating cancer neoepitopes formulated in Immunovaccine’s proprietary delivery formulation, Immunovaccine and UConn Health will begin working toward DPX-NEO’s first clinical trial;
- On December 5, 2017, positive top-line clinical data from its continuing phase 1b trial evaluating the safety and efficacy of Immunovaccine’s lead immuno-oncology candidate, DPX-Survivac, in combination with Incyte’s IDO1 enzyme inhibitor epacadostat, and low-dose cyclophosphamide in patients with advanced ovarian cancer. Immunovaccine is conducting the trial in a collaboration with Incyte;

Initial results from 10 evaluable patients in the DPX-Survivac plus-100 milligrams epacadostat dosing cohort demonstrate a disease control rate of 70 per cent, including partial responses (PR, defined as equal to 30-per-cent decrease in tumour lesion size) in 30 per cent of the patients (three out of 10). To date, the combination also exhibited a well-tolerated safety profile, with the

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<sup>1</sup> Published online, January 27, 2018. DOI: 10.1186/s12929-018-0413-9

majority of adverse events (“AEs”) reported as Grade 1 and Grade 2, and only one potential treatment-related AE;

- On November 21, 2017 an expansion of its collaboration with Leidos to develop preventative, peptide-based malaria vaccine candidates. The U.S. Agency for International Development (“USAID”) supported an initial collaboration via a Leidos Malaria Vaccine Development Program (MVDP) subcontract. Following the achievement of several preclinical milestones in this initial collaboration, Leidos and USAID selected the DepoVax-based platform as one of the preferred formulations for further development under a new contract extension. Under the new subcontract, the collaborators will conduct additional research that focuses on identifying the most promising target-formulation combinations;
- On November 8, 2017, that Health Canada has granted Sunnybrook Research Institute regulatory clearance to begin recruiting patients for its Phase 2 clinical study of a triple-combination immunotherapy in patients with measurable or recurrent DLBCL. This investigator-sponsored Phase 2 trial, designed to evaluate the safety and efficacy of Immunovaccine’s lead product candidate, DPX-Survivac, along with Merck’s pembrolizumab and low-dose cyclophosphamide, will evaluate the use of a triple-combination immunotherapy in patients with measurable or recurrent DLBCL. Investigators will assess the efficacy and safety of DPX-Survivac, along with a checkpoint inhibitor drug currently marketed by a large pharmaceutical company, and low-dose cyclophosphamide. The Corporation has elected to conclude operations on its initial Phase 2 DLBCL study, opting to replace it with this triple-combination trial;
- On October 17, 2017, that it has received a two-year extension of the maturity of its \$5M Province of Nova Scotia loan authorized in 2013. The original maturity date of the loan was August 9, 2018 and is now August 9, 2020;
- On August 31, 2017, the achievement of several milestones in its ongoing collaboration with global animal health company Zoetis to develop cattle vaccines. In recent controlled studies, the Immunovaccine formulations met efficacy and duration of immunity end-points against two disease targets. These results will enable Zoetis to advance two Immunovaccine-formulated vaccine candidates into late-stage testing;
- On July 12, 2017, a significant achievement in its personalized cancer medicine program. Immunovaccine scientists have successfully formulated 14 neoepitope cancer peptides into one single DepoVax formulation. In preclinical testing, the resulting personalized cancer vaccine demonstrated the ability to generate specific killer T-cell responses against cancer peptides. Immunovaccine has filed a patent application covering this novel DepoVax-based rapid formulation process. The supporting data for the patent include what the Corporation believes to be one of the first documented reports of 14 different neoepitope peptides synthesized into a single formulation.
- On June 21, 2017, that the Corporation completed a bought deal public offering (the “June 2017 Public Offering”) of Common Shares, raising gross proceeds of approximately \$10 million. The Corporation intends to use the net proceeds of the June 2017 Public Offering for the research and development and clinical advancement of its cancer and infectious disease vaccine candidates and for working capital and general corporate purposes;



- On April 18, 2017, that the first study participant has been treated in a Phase 1b/2 clinical study lead by Dana-Farber evaluating Immunovaccine’s investigational cancer vaccine, DPX-E7, in combination with low-dose cyclophosphamide in patients with incurable oropharyngeal, cervical and anal cancers related to HPV;
- On April 12, 2017, updated data on its investigator-sponsored Phase 1 clinical trial testing the safety and immunogenicity of its DepoVax-based, small B-cell epitope peptide vaccine candidate for RSV. In the 25µg dose cohort, which was the only dose tested out to one year, 100 percent of older adults (7/7 immune responders) vaccinated with Immunovaccine’s DepoVax™-based small B cell epitope peptide vaccine candidate for RSV (“DPX-RSV”) maintained the antigen-specific immune responses one year after receiving the booster dose. At one year, the antibody levels measured were still at peak with no sign of decrease. The 25µg dose was delivered in a volume of 50 microliters. A standard flu vaccine is typically 60µg delivered in 10 times this volume;
- On April 11, 2017, that University Health Network’s (“UHN”) Princess Margaret Cancer Centre has received Health Canada clearance to initiate the Phase 2 non-randomized, open-label trial designed to evaluate the potential anti-tumour activity of the combination of Merck’s pembrolizumab, Immunovaccine’s DPX-Survivac, and low-dose cyclophosphamide;
- On April 5, 2017, that new preclinical data presented at the 2017 American Association for Cancer Research (“AACR”) Annual Meeting demonstrated that phosphatidylserine targeting antibodies can enhance the anti-cancer activity of its DepoVax-based therapeutic vaccine platform;
- On March 2017, the first interim data analysis from the triple combination Phase 1b clinical trial in ovarian cancer, in combination with Incyte’s epacadostat and low-dose cyclophosphamide. The analysis included the results of blood tests, tumour biopsies and CT scans to assess safety, disease progression and T-cell response for the first four evaluable patients in the trial. All patients enrolled in the trial have recurrent ovarian cancer with evidence of progressive disease. Based on the interim analysis, the combination therapy appears to have an acceptable tolerable safety profile, with a single grade 3 and single grade 4 event reported and no serious adverse events (“SAEs”). At the time of the interim analysis, three of four patients exhibited stable disease, while a fourth patient progressed and exited the trial. In addition, researchers observed an increased T-cell activity in tumours in three of the four patients based on RNA sequencing and indications of early tumour shrinkage in the patient who has been in trial for the longest duration thus far (based on CT scan at day 140);
- On February 2017, an investigator-sponsored Phase 2 clinical trial in ovarian cancer in combination with Merck’s checkpoint inhibitor Pembrolizumab in patients with recurrent, platinum-resistant ovarian cancer. UHN Princess Margaret Cancer Centre will conduct the Phase 2 non-randomized, open-label trial designed to evaluate the potential anti-tumour activity of the combination of Pembrolizumab, DPX-Survivac, and low-dose cyclophosphamide; and
- On February 2017, appointed Pierre Labbé as Chief Financial Officer replacing Kimberly Stephens. In this role, Mr. Labbé will be responsible for leading the Corporation’s financial strategy and operations, with an emphasis on expanding financing and business development operations.

## *Year ended December 31, 2016*

During the year ended December 31, 2016, the Corporation announced:

- In December 2016, that it had completed a bought-deal private placement (the “December 2016 Private Placement”) of Common Shares, for gross proceeds of approximately \$8 million, to be used for general corporate and working capital purposes;
- In November 2016, that it had been granted “Orphan Drug Designation” status by the European Medicines Agency (“EMA”) for the use of DPX-Survivac for the treatment of ovarian cancer in the European Union;
- In November 2016, that it had received positive results from preclinical studies completed in collaboration with UConn Health for Immunovaccine’s DPX-NEO program, which is designed to develop patient-specific neoepitope immunotherapies to further expand the immuno-oncology applications for its DepoVax™-based vaccines. Results from the first study in mouse tumour models have shown positive anti-cancer activity;
- In November 2016, the appointment of Gabriela Rosu, M.D. as the Corporation’s first Chief Medical Officer. In this newly created executive role, Dr. Rosu will oversee the strategy and execution of the Corporation’s expanding clinical portfolio of programs;
- In October 2016, positive topline results from its Phase 1 trial evaluating the safety and immunogenicity of DPX-RSV. The results, six months after vaccination, confirmed earlier-reported interim data on the ability of DepoVax™-formulated antigens to generate a relevant, durable immune response, that the vaccine had a positive safety profile and was well tolerated with no SAEs among all study participants. Also, antigen-specific immune responses were detected at least six months after the last vaccination in 93 percent (15/16) of patients receiving DPX-RSV, in both low-dose (8/8 participants) and high-dose (7/8 participants) cohorts;
- In October 2016, the presentation by malarial researcher J. Alexandra Rowe, D Phil, of The University of Edinburgh, of topline preclinical data for Immunovaccine’s DepoVax™-based malarial vaccine which was presented at the World Vaccine Congress Europe in Barcelona, Spain on October 10, 2016. Results from studies in mice, conducted in collaboration with the University of Edinburgh’s Centre for Immunity, Infection and Evolution (“CIIE”) as part of a preclinical collaboration announced in June 2016, indicated that the novel CIIE-identified targets, when formulated in the DepoVax™ targeting platform, generated strong, sustained, antibody responses that could prevent, after a single injection, a process in severe malaria known as ‘rosetting’;
- In September 2016, the beginning of the treatment of the first patient with recurrent ovarian cancer in a Phase 1b clinical study of Immunovaccine’s novel T cell activating therapy, DPX-Survivac, in combination with epacadostat and low-dose cyclophosphamide. This triple combination study is the result of collaboration between Immunovaccine and Incyte to assess the safety and effectiveness of DPX-Survivac, along with Incyte’s investigational oral indoleamine IDO1 inhibitor, epacadostat, and low-dose cyclophosphamide in patients with recurrent ovarian cancer who have measurable disease;
- In August 2016, the obtention of new data from its Phase 1/1b trial in ovarian cancer, which reinforced previously reported results showing that DPX-Survivac was well tolerated, with no unexpected treatment-related SAEs and that it demonstrated the ability to generate a relevant, sustained immune response. New data from the Phase 1/1b trial yielded positive findings on tumour clinical response, including the presence of relevant circulating T cells and increased expression of several checkpoint inhibitor molecules;

- In July 2016, that it had received results from an interim analysis of the safety and immunogenicity of DPX-RSV in a Phase 1 clinical trial in healthy older adult volunteers completed by a team of investigators. The safety analysis indicates that the DPX-RSV was well tolerated among all study participants, with no SAEs recorded. Furthermore, immunogenicity data supported DPX-RSV's ability to generate a relevant immune response; the vaccine candidate obtained antigen-specific antibody responses in 75 percent (%) of subjects vaccinated with the lower dose, and 100 percent (%) of those vaccinated with the higher dose;
- In June 2016, that it had been awarded a subcontract by Leidos to evaluate Immunovaccine's DepoVax™ platform for the development of peptide based malaria vaccine targets. The subcontract is funded through Leidos' prime contract from the USAID to provide vaccine evaluations in the preclinical, clinical and field stages of malaria vaccine development. Leidos and Immunovaccine will work together to identify adjuvant and antigen combinations that can be used to protect against malaria and with the DepoVax™ delivery system, formulate promising vaccine candidates for potential clinical testing;
- In June 2016, that it had completed a bought deal private placement (the "June 2016 Private Placement") of units, for gross proceeds of approximately \$8 million used to advance the research and development and clinical advancement of the Corporation's cancer and infectious vaccine candidates and for general corporate and working capital purposes. Each unit was comprised of one Common Share and one-half of one common share purchase warrant (each whole common share purchase warrant, a "Warrant"). Each Warrant entitles its holder to acquire one additional Common Share at a price of \$0.72 per Common Share until June 8, 2018;
- In June 2016, the appointment of Shermaine Tilley, PhD, Managing Partner of CTI Life Sciences Fund, to its board of directors;
- In April 2016, new preclinical data at the AACR Annual Meeting 2016. The investigators' findings showed that a combination immunotherapy using a DepoVax™-based vaccine could enhance the anti-tumour effects of a PD-1 blockade, controlling growth in advanced HPV-expressing tumours in animal models;
- In April 2016, the appointment of Andrew Sheldon to the board of directors,. Mr. Sheldon was also appointed Chairman of the Board of Directors following the annual meeting of shareholders of the Corporation held on April 14, 2016;
- In April 2016, the appointment of Frederic Ors as Chief Executive Officer, replacing Marc Mansour, Ph.D., who, prior to stepping down in March 2016, was Chief Executive Officer since June 2014, and a member of the Board of directors since December 2013. Mr. Ors had been with the Corporation since April 2015 as Chief Business Officer;
- In April 2016, a collaboration with Leidos on developing a vaccine against the mosquito-borne Zika virus and infection, which may be linked to neurological birth defects. This collaboration is the first to expand on Immunovaccine's previously announced research project in which the Corporation will apply its DepoVax™ platform to development of a Zika virus vaccine candidate. The project builds upon earlier promising results with DepoVax™ vaccines targeting the Ebola virus, anthrax and RSV; and
- In January 2016, the obtention of clearance from the U.S. Food and Drug Administration ("FDA") and Health Canada to initiate a clinical study of DPX-Survivac in combination with low-dose cyclophosphamide and epacadostat. The Phase 1b clinical trial will assess the safety and effectiveness of Immunovaccine's novel T cell activating therapy, DPX-Survivac, along with Incyte's IDO1 inhibitor, epacadostat (INCB24360), and low-dose cyclophosphamide in patients with recurrent ovarian cancer who have measurable disease.

*Year ended December 31, 2015*

During the year ended December 31, 2015, the Corporation announced:

- In December 2015, the publication of research that used MRI to predict and optimize the efficacy of its cancer vaccines by measuring size changes in vaccine-draining lymph nodes. The preclinical study demonstrated that the increase in size of lymph nodes after vaccination with DepoVax™ technology indicated the strength of the immune response to the vaccine, and could help monitor and predict therapy success;
- In November 2015, initial results from a Phase 2 study demonstrated that DPX-Survivac can induce a strong immune response in DLBCL tumours. This early result demonstrates that DPX-Survivac, Immunovaccine's lead cancer immune therapy, can induce immune responses in hematologic cancers, such as DLBCL. Researchers observed changes in tumour-infiltrating T cells following administration of the DPX-Survivac therapy, which correlated with an immune response produced by DPX-Survivac and detected in the blood;
- In October 2015, safety data from a Phase 1 clinical study, which showed that DPX-RSV was well tolerated in the Phase 1 study's first 20 volunteers, of whom 8 subjects received the DPX-RSV vaccine. This data marks an important milestone for Immunovaccine as it provides the first safety profile of the DepoVax™-based vaccines for infectious diseases in healthy adults. Based on the vaccine candidate's safety and immunogenicity demonstrated in the study, the independent Safety Review Committee (SRC) has allowed the study to proceed to its next step, which includes vaccinating volunteers with DPX-RSV at a higher dose;
- In July 2015, having obtained approval from the FDA for orphan drug status to DPX-Survivac for the treatment of ovarian cancer. This designation is valid for all applications of DPX-Survivac in ovarian cancer without restriction to a specific stage of disease;
- In July 2015, entering into an exclusive worldwide license agreement with PharmAthene, Inc. ("PharmAthene") to develop and commercialize a Recombinant Protective Antigen Anthrax vaccine ("rPA") candidate utilizing Immunovaccine's proprietary DepoVax™ vaccine platform. Under the terms of this agreement, PharmAthene would work exclusively with Immunovaccine to develop an adjuvanted non-alum based rPA vaccine. In return, Immunovaccine granted PharmAthene exclusive worldwide rights to use DepoVax™ for the development and commercialization of the novel single-dose anthrax vaccine. This agreement was subsequently terminated in August 2016;
- In July 2015, data from its completed Phase 1 clinical trial with lead cancer immunotherapy candidate, DPX-Survivac, was published in the peer-reviewed journal *Oncoimmunology*. The manuscript "Survivin targeted immunotherapy drives robust polyfunctional T cell generation and differentiation in advanced ovarian cancer patients," which was published in the June 26, 2015, edition of the journal, outlines the safety and immunogenicity of DPX-Survivac when combined with a low dose of cyclophosphamide taken orally by patients;
- In June 2015, the enrollment of the first healthy adult volunteer in a Phase 1 clinical study of its RSV vaccine. The Phase 1 study, for which the Corporation received Health Canada clearance in January 2015, will evaluate the safety and immune response profile of the DPX-RSV vaccine candidate in healthy adults. The study, conducted at the Canadian Center for Vaccinology ("CCfV") in Halifax and led by Joanne Langley, M.D., will enroll 40 healthy adults who are 50 to 64 years of age. The vaccine will be tested at two different vaccine dose levels and study investigators will assess the vaccine's safety and immune response profile following one or two immunizations of each dose level. Immunovaccine and the Canadian Institutes of Health Research ("CIHR") are co-funding the trial;

- In June 2015, entering into a non-exclusive clinical trial collaboration with Incyte Corporation to evaluate the combination of Immunovaccine’s novel T cell activating immunotherapy, DPX-Survivac, with Incyte’s investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360). Immunovaccine and Incyte will co-fund and conduct a multicenter, open-label Phase 1B study to evaluate the safety, tolerability and efficacy of the novel combination in platinum-sensitive ovarian cancer patients who are at high risk of recurrence;
- In April 2015, having received approval to trade its common shares on the OTCQX® Best Marketplace in the United States under the symbol “IMMVF”;
- In March 2015, that it had treated the first patient with DLBCL in a Phase 2 clinical study of its lead cancer immunotherapy DPX-Survivac. The Corporation-sponsored trial is evaluating DPX-Survivac in combination with oral cyclophosphamide, an immune modulating agent, in patients with recurrent DLBCL. DPX-Survivac is designed to activate killer T cells of the immune system against the survivin antigen found in a wide variety of solid tumours and blood cancers; and
- In March 2015, results that three different rPA vaccines formulated with its novel DepoVax™ enhancement technology protected animals against a lethal anthrax challenge after a single vaccination. The National Institute of Health (“NIH”) led study demonstrates the potential of DepoVax™ as a universal enabler of single dose rPA-based anthrax vaccines. The anthrax challenge study was designed to evaluate the early protection potential of single dose DepoVax™/rPA vaccines. A very low dose of rPA that is known to provide partial protection in the rabbit model was used. This allowed a comparison of the potency of the various rPA vaccines formulated in DepoVax™.

#### **IV. DESCRIPTION OF THE BUSINESS**

##### ***Business Model and Strategy***

##### ***Operating Strategy***

Immunovaccine is dedicated to making immunotherapy more effective, more broadly applicable and more widely available to people facing cancer. The Corporation’s lead product, DPX-Survivac has demonstrated the ability to induce T cell activation with the potential of tumour shrinkage in advanced ovarian cancer and is currently being used in clinical trials in combination with checkpoint inhibitors from the Corporation’s collaborators, Incyte and Merck. The target of this T cell stimulating therapy is broadly applicable to many different cancers. The novel mechanism of action of the underlying delivery platform, DepoVax, is to promote uptake and extend exposure of antigens to cells of the immune system, which enhances and sustains immune responses. This allows Immunovaccine to leverage this technology to become a preferred partner in combination trials in hard to treat cancers, and to explore additional immuno-oncology targets, such as HPV related cancers and neopeptides. In addition, this platform is being used in other market indications, such as infectious disease vaccines, where the Corporation has demonstrated safety and immunogenicity with a novel proprietary vaccine to prevent RSV infections. The Corporation is currently collaborating with partners such as Incyte, Merck, Leidos and Dana-Farber to explore novel applications for the DepoVax platform.

The Corporation has a clinical-stage cancer immunotherapy, DPX-Survivac. Immunovaccine believes the principles behind a successful cancer immunotherapy should include a targeted antigen and an effective formulation and delivery technology, combined with a complementary therapeutic strategy. Antigens used in DPX-Survivac are believed to specifically target tumour cells without harming normal, healthy cells. These antigens are combined with the Corporation’s DepoVax platform in an effort to optimize the

presentation of these antigens to the immune system, resulting in an enhanced immune response. To be successful against cancer, the Corporation believes antigens must be administered in the right therapeutic setting, which includes a combination of therapies that help target various aspects of cancer. Immunovaccine believes that the effect of the therapy may be enhanced if an immune modulator is used simultaneously to prevent a patient's immune system from overriding the positive response to the antigen. The Corporation's goal in immuno-oncology is to advance its proprietary therapies in combination trials with pharmaceutical and large biotechnology companies to establish strategic partnerships and support further development and commercialization.

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

#### *Financing and Partnering Strategy*

Immunovaccine relies on equity financing and non-dilutive private and public partnerships to fund its development programs. Applying this strategy, over the years the Corporation has obtained more than \$15 million in government funding, including interest-free loans and government grants, from both the Province of Nova Scotia and from the Federal government through the Atlantic Canada Opportunities Agency (ACOA). To date, the Corporation has raised more than \$87 million in equity through prospectus and private placement offerings. In 2017, the Corporation completed a bought deal public offering for an aggregate of approximately \$10 million and in February 2018 the Corporation completed a bought deal public offering for an aggregate of approximately \$14.4 million.

In addition to using its own resources to develop its products through clinical trials, the Corporation is also involved in various collaborations and licensing deals to accelerate the development of its DepoVax™ platform and immuno-oncology products. The Corporation is conducting a collaboration with Incyte, to evaluate the combination of the Corporation's lead cancer immunotherapy, DPX-Survivac, with their IDO1 inhibitor epacadostat in a co-funded Phase 1b clinical trial in ovarian cancer patients. Results from this study may lead to an expansion of the clinical collaboration to investigate other cancers. In February 2017, the Corporation announced an Investigator-Sponsored Phase 2 Clinical Trial in Ovarian Cancer in combination with Merck's checkpoint inhibitor Pembrolizumab in patients with recurrent, platinum-resistant ovarian cancer. UHN's Princess Margaret Cancer Centre is conducting the Phase 2 non-randomized, open-label trial designed to evaluate the potential anti-tumour activity of the combination of Pembrolizumab, DPX-Survivac, and low-dose cyclophosphamide. In May 2017, the Corporation also announced an investigator sponsored Phase 2 clinical trial which will evaluate the use of a triple combination immunotherapy in patients with measurable or recurrent DLBCL also with checkpoint inhibitor pembrolizumab of Merck. Sunnybrook Research Institute is conducting the Phase 2 non-randomized, open-label trial designed to evaluate the potential anti-tumour activity of the combination of Pembrolizumab, DPX-Survivac, and low-dose cyclophosphamide.

Other programs include: a collaboration with Dana-Farber funded by Stand Up 2 Cancer-Farah Fawcett Foundation for producing a DepoVax™-based vaccine for HPV related cancers; and a collaboration with UConn Health on a clinical study to evaluate the immunologic and anti-tumour activity of patient-specific neoepitopes. The underlying goal of these types of partnerships is to produce pre-clinical and clinical data that could lead to licensing agreements, either to allow the use of the Corporation's DepoVax™ platform by others or provide access to specific pipeline product candidates.

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

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

## **PLATFORM AND PRODUCTS IN DEVELOPMENT**

### ***Delivery Platform***

The DepoVax platform is a unique and patented formulation providing a new way to deliver active ingredients to the immune system. Active ingredients are formulated in lipid nanoparticles and, after freeze drying, suspended directly into oil. DepoVax has a novel mechanism of action whereby it promotes uptake and extends delivery to the immune system. The DepoVax platform forms the basis of all Immunovaccine's product development programs.

The Corporation believes the novel mechanism of action of DepoVax makes the platform uniquely suitable for cancer immunotherapies, which are designed to target tumour cells. DepoVax can induce prolonged target-specific and polyfunctional cellular responses, which are postulated to be required for effective tumour control.







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

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

The ongoing clinical studies with DepoVax-based therapies for cancer and for protection from infectious diseases are expected by the Corporation to demonstrate the competitive advantages of this platform.

## IMMUNO-ONCOLOGY

### Pipeline

Indication	Product	Trials	Timing	Partners
Ovarian	DPX Survivac + mCPA + IDO1	Phase 1b	Ongoing	
	DPX Survivac + mCPA + PD-1	Phase 2	Ongoing	
DLBCL	DPX Survivac + mCPA + PD-1	Phase 2	Ongoing	
HPV cervical cancer	DPX E7 + mPCA	Phase 2	Ongoing	  

### *DPX- Survivac*

#### *Product Overview*

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

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

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

#### *Clinical Trial Development – Current and Planned Trials*

##### *Phase 1b Clinical trial in ovarian cancer with Incyte*

In June 2015, the Corporation announced it had entered into a non-exclusive clinical trial collaboration with Incyte to evaluate the combination of Immunovaccine's novel T cell activating immunotherapy, DPX-Survivac, with Incyte's investigational oral IDO1 inhibitor, epacadostat. Immunovaccine and Incyte are co-funding and conducting a multicenter, open-label, phase 1b study to evaluate the safety, tolerability



and efficacy of the novel combination in platinum resistant or sensitive ovarian cancer patients who are at high risk of recurrence. All patients enrolled in the trial have recurrent ovarian cancer with evidence of progressive disease. The investigational new drug (“IND”) application for the study, which will test the triple combination of DPX-Survivac, epacadostat and low dose oral cyclophosphamide, was approved by the FDA and Health Canada in January 2016. The study was initiated on September 8, 2016 and is anticipated to enroll up to 40 patients. The Corporation announced in March 2017 the first interim data analysis from this clinical study. The analysis included the results of blood tests, tumour biopsies and CT scans to assess safety, disease progression and T cell response for the first four evaluable patients in the trial. Based on the interim analysis, the combination therapy appears to have an acceptable tolerable safety profile, with a single grade 3 and single grade 4 event reported and no SAEs. At the time of the interim analysis, three of four patients exhibited stable disease, while a fourth patient progressed and exited the trial. In addition, researchers observed an increased T cell activity in tumours in three of the four patients based on RNA sequencing and indications of early tumour shrinkage in the patient who has been in trial for the longest duration thus far (based on CT scan at day 140).

In December 2017, the Corporation provided positive top-line clinical data. Initial results from 10 evaluable patients in the DPX-Survivac plus-100 milligrams epacadostat dosing cohort demonstrate a disease control rate of 70 per cent, including partial responses (PR, defined as equal to 30-per-cent decrease in tumour lesion size) in 30 per cent of the patients (three out of 10). To date, the combination also exhibited a well-tolerated safety profile, with the majority of adverse events (AEs) reported as Grade 1 and Grade 2AE.

Blood tests indicated that the majority of treated patients exhibited targeted T cell activation. Tumour biopsies and analyses thus far have supported the reported MOA of this immunotherapy combination, with DPX-Survivac triggering T cell infiltration into the tumour. This T cell activation was also correlated with tumour regression.

Investigators completed enrolment of 10 evaluable patients for the study's first dosing cohort, which consists of 100 mg epacadostat twice daily (BID), DPX-Survivac, and low-dose cyclophosphamide.

In the first dosing cohort, investigators observed:

- A 30-per-cent overall response rate, with three out of 10 PRs;
- Two of the patients exhibiting PRs have completed one year of treatment with responses continuing at 12 and 14 months, respectively;
- Four patients (40 per cent) had stable disease;
- Two of the patients exhibiting stable disease are still enrolled in the trial, with one of those patients showing a 21-per-cent tumour reduction; and
- A 70-per-cent disease control rate (defined as the total number of patients achieving complete response, partial response and stable disease).

At the time of data cut-off, there were also preliminary data on the first three evaluable patients in the second dosing cohort evaluating the combination of 300 mg BID epacadostat, DPX-Survivac, and low-dose cyclophosphamide. From the first three evaluable patients, two showed stable disease, with one patient showing tumour regression of approximately 25 per cent. The second dosing cohort is continuing and is expected to enroll 16 to 40 patients in total.

Immunovaccine expects to provide a clinical update on the second dosing cohort in the first half of 2018 and investigators are also planning to submit the study findings for scientific publication. If the results of this study are positive and if Incyte is in agreement, the Corporation would request a type C meeting with the FDA to discuss the possibility to conduct a registration trial for this combination. At this stage it is not possible to determine if the FDA would agree and if they agree, what type of clinical trial design would be requested and what would be the cost of this clinical trial.

The Corporation currently anticipates that, in addition to general clinical expenses which are distributed amongst the various clinical projects, its share of the cost (50%) to complete the Phase 1b clinical trial with Incyte will be approximately \$700,000 of which \$500,000 is expected to occur in 2018.

#### *Phase 2 clinical trial in ovarian cancer with Merck*

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

The Corporation expects to disclose preliminary results around mid-2018 once provided by UHN's Princess Margaret Cancer Centre and currently anticipates that, in addition to general clinical expenses which are distributed amongst the various clinical projects, its share of the cost to complete this study will be of approximately \$400,000 that are expected to occur in 2018..

#### *Phase 2 clinical trial in DLBCL with Merck*

On November 8, 2017, the Corporation announced that Health Canada has granted Sunnybrook Research Institute regulatory clearance to begin recruiting patients for its Phase 2 clinical study of a triple-combination immunotherapy in patients with measurable or recurrent diffuse large B-cell lymphoma. This trial, announced initially in May 2017, is designed to evaluate the safety and efficacy of Immunovaccine's lead product candidate, DPX-Survivac, along with Merck's pembrolizumab and low-dose cyclophosphamide in this patient population.

Researchers conducting the investigator sponsored study will test the novel immunotherapy combination in patients whose DLBCL expresses survivin, a tumour antigen highly expressed in 60 percent of DLBCL patients. DPX Survivac stimulates the immune system to produce T cell responses targeting survivin. The non-randomized, open label study is expected to enroll 25 evaluable participants at five centers in Canada.

The Corporation expects to disclose preliminary results around mid-2018 once provided by the Investigator and currently anticipates that, in addition to general clinical expenses which are distributed amongst the various clinical projects, its share of the cost to complete this study will be approximately \$2,400,000 of which \$1,000,000 is expected to occur in 2018. The Corporation is pursuing opportunities for additional trials with biotechnology and pharmaceutical companies, including combination therapies with DPX-Survivac as well as other applications of the DepoVax™ platform.

### ***Clinical Trial Development – Completed Trials***

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

The Corporation released interim results in October 2012, further interim results in January 2013 and final detailed positive results in June 2013 on the Phase 1 clinical trial. The analysis, which included all 18 patients enrolled in the study, confirmed that 12 of the 18 patients who received the DPX-Survivac combination therapy demonstrated antigen-specific immune responses. They were measured by at least one of the study's three immune monitoring assays (ELISpot, tetramer analysis and multi-parametric intracellular cell staining). In 11 of 12 patients, the immune responses were confirmed by two of the assays (five patients) or three of the 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, poly-functional 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 tumours and killing cancer targets.

Also, in the Phase 1 clinical trial, DPX-Survivac was deemed well-tolerated with no significant systemic adverse events reported in any patients recruited in this study. Reported adverse events were related primarily to grade 1-2 injection site reactions, which were experienced by the majority of patients after repeated vaccinations. Those patients presenting the strongest immune responses were more likely to exhibit more pronounced injection site reactions. Grade 3 injection site ulcerations, which were an expected adverse event with this vaccine, were experienced by three patients during the trial. Upon a six-month follow-up for the majority of patients, a trend of delayed progression was observed in patients who had strong immune responses to DPX-Survivac. The trend of delayed cancer progression, which was not statistically significant, may be attributed to the therapy or may be attributed to other unrelated factors. The results from this clinical trial were published in the peer-reviewed scientific journal *Oncoimmunology* in May 2015.

Immunovaccine highlighted results demonstrating that metronomic cyclophosphamide (“mCPA”), an immune modulating agent, enhanced the immunogenicity of DepoVax™-based vaccines in preclinical cancer models consistent with previously reported Phase 1 data showing a similar enhancement of DPX-Survivac in patients. Importantly, the animal studies demonstrated the combination therapy's ability to eliminate advanced tumours that could not be treated with vaccine or mCPA alone. Tumors exposed to the combination therapy specifically exhibited an increase in T cell activation markers, suggesting increased immune-mediated anti-tumour activity at the tumour site with the vaccine/mCPA therapy and further supporting the use of the combination therapy in clinical trials. This work was published in the peer reviewed scientific journal *Oncoimmunology* in November 2014.

In August 2016, the Corporation announced additional positive topline results from 54 evaluable patients treated in a Phase 1 and Phase 1b clinical trial program with DPX-Survivac in ovarian cancer. The data reinforced previously reported results showing that DPX-Survivac was well tolerated, with no unexpected treatment-related SAEs and that it demonstrated the ability to generate a relevant, sustained immune response. Researchers concluded an optimal dosing schedule for upcoming clinical studies involving DPX-Survivac in ovarian cancer, consisting of two “priming” injections with a booster administered every eight weeks over the duration of up to one year of treatments.

## ***Orphan Drug Status and Fast Track Designation***

The Corporation announced in November 2016 that the EMA granted orphan drug designation status to Immunovaccine's DPX-Survivac in ovarian cancer and in July 2015 the FDA also granted orphan drug status to DPX-Survivac for the treatment of ovarian cancer. This designation is valid for all applications of DPX-Survivac in ovarian cancer without restriction to a specific stage of disease.

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

## ***DPX-E7***

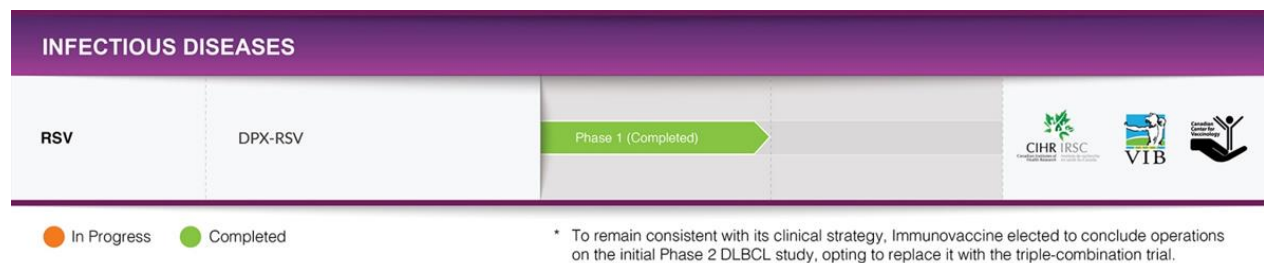
On April 17, 2017, the Corporation announced that the first study participant has been treated in a Phase 1b/2 clinical study evaluating Immunovaccine's investigational cancer vaccine, DPX-E7, in combination with low-dose cyclophosphamide in patients with incurable oropharyngeal, cervical and anal cancers related to HPV.

Dana-Farber is leading the DPX-E7 study through a \$1.5 million research grant from Stand Up To Cancer and the Farrah Fawcett Foundation to clinically evaluate collaborative translational research that addresses critical problems in HPV-related cancers.

The Dana-Farber study is a single center, open label, non-randomized clinical trial that will investigate the safety and clinical efficacy of DPX-E7 in combination with low-dose metronomic oral cyclophosphamide in a total of 44 treated participants. Its primary objectives are to evaluate changes in CD8+ T cells in peripheral blood and tumour tissue, and to evaluate the safety of DPX-E7 vaccination in HLA-A2 positive patients with incurable HPV-related head and neck, cervical or anal cancers. DPX-E7 targets an HPV viral protein known as E7. Immunovaccine has the option to produce the DPX-E7 vaccine if it proves successful in the clinical trials.

The Corporation expects to disclose preliminary results around mid-2018 once provided by Dana-Farber.

## **INFECTIOUS DISEASES**



## **DPX- RSV**

### *Product Overview*

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

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

#### *Phase 1 clinical trial in RSV*

A Phase 1 clinical study has been conducted in Canada with the Corporation's RSV vaccine in healthy adults. The RSV vaccine is formulated in Immunovaccine's proprietary DepoVax platform and is initially being developed to protect the elderly population from infection. The Phase 1 study, which was the first clinical trial of a DepoVax-based vaccine in an infectious disease indication, has evaluated the safety and immune response profile of the RSV vaccine candidate in 40 healthy older adult volunteers (age 50-64 years) and two dose cohorts, with 20 subjects in each cohort.




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

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

On April 12, 2017, the Corporation announced additional positive data from an extended evaluation of patients in this trial. An amendment had been submitted to Health Canada to test subjects who received the higher dose of vaccine out to one year after the booster vaccination. In the 25 µg dose cohort, which was the only dose tested out to one year, 100 percent of older adults (7/7 immune responders) vaccinated with DPX-RSV maintained the antigen-specific immune responses one year after receiving the booster dose. At one year, the antibody levels measured were still at peak with no sign of decrease.

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

## Platform collaboration

DEPOVAX PARTNERSHIPS			
Indication	Candidate	Progress	Partners
Malaria	Multiple antigens in DepoVax	Preclinical Ongoing	
		Preclinical Ongoing	
Zika	Peptides in DepoVax	Preclinical Ongoing	
BVDV	Antigens in DepoVax	Animal trials	
Contraceptive	Antigens in DepoVax	Animal trials	

### Malaria

In 2016, Immunovaccine Inc. was awarded a subcontract by Leidos, a health, national security, and infrastructure solutions company, to evaluate Immunovaccine's DepoVax™ platform for the development of peptide based malaria vaccine targets. The subcontract is funded through Leidos' prime contract from the USAID to provide vaccine evaluations in the preclinical, clinical and field stages of malaria vaccine development. Leidos and Immunovaccine are working together to identify adjuvant and antigen combinations that can be used to protect against malaria and, with the DepoVax™ delivery system, formulate promising vaccine candidates for potential clinical testing.

On November 21, 2017, an expansion of this collaboration was announced. Following the achievement of several preclinical milestones in the collaboration with USAID, Leidos and USAID selected the DepoVax-based platform as one of the preferred formulations for further development under a new contract extension. Under the new subcontract, the collaborators will conduct additional research that focuses on identifying the most promising target-formulation combinations.

### Zika Virus Vaccine Antigen

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

### Zoetis collaboration

On August 31, 2017, the Corporation announced the achievement of several milestones in its ongoing collaboration with global animal health company Zoetis to develop cattle vaccines. In recent controlled studies, the Immunovaccine formulations met efficacy and duration of immunity end-points against two disease targets. These results will enable Zoetis to advance two Immunovaccine-formulated vaccine candidates into late-stage testing.

### **Licensing Agreements**

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

### ***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 relating to its vaccine platform technology includes fourteen patent families, the first of which contains eight patents issued in five jurisdictions (United States, Europe, Canada, Japan and Australia). The thirteen other families collectively contain twenty-six patents issued in nine jurisdictions (United States, Europe, Canada, Australia, Japan, India, Singapore, China and separately Hong Kong) and thirty-seven pending patent applications in eleven jurisdictions. Taking into account the validations of the European patents, the Corporation's intellectual property portfolio includes sixty-six patents.

U.S. Patent 6,793,923, issued in 2004, contains claims to the Corporation's platform, covering "any antigen, any adjuvant in any liposome and any oil". The platform name, and other marks, are protected by trademarks in the United States, Canada and Europe.

Additional granted patents include:

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

- Chinese Patent 200880110239.7, granted March 9, 2016;
- Chinese Patent 200980120883.7, granted April 6, 2016;
- European Patent 2,197,497, granted June 1, 2016;
- Japanese Patent 6016970, granted October 7, 2016;
- United States Patent 9,498,493, granted November 22, 2016;
- Canadian Patent 2,700,828, granted January 24, 2017;
- Japanese Patent 6143731, granted May 19, 2017;
- Australian Patent 2012321022, granted July 6, 2017;
- Japanese Patent 6240077, granted November 10, 2017;
- Canadian Patent 2,700,808, granted November 14, 2017;
- Japanese Patent 6254351, granted December 8, 2017; and
- Canadian Patent 2,723,918, granted January 9, 2018.

Since 2008, the Corporation has filed twelve Patent Cooperation Treaty (“PCT”) applications relating to the Corporation’s technologies, some or all of which have now been filed in the United States, Europe, Japan, Canada, Australia, China, India, Brazil, Israel, Hong Kong and Singapore. These PCT applications cover specific DepoVax™ compositions with broad utility for infectious diseases and cancer applications, as well as methods of manufacture and other applications of the platform technology. Some of these applications have issued to patent as listed above. These patents, together with the other pending applications if allowed, extend patent protection for some or all DepoVax™-based compositions, and/or uses thereof, approximately up to the year 2037. The latest published PCT application covers DepoVax™ compositions comprising neoantigens, methods for their preparation and uses thereof in the treatment of cancer.

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

## ***Markets and Competition***

### ***Cancer Immunotherapies***

Cancer is considered one of the most widespread and prevalent diseases globally. According to Global Cancer Facts & Figures, 3rd edition (released February 2015 by the American Cancer Society), it is predicted that new cancer cases will rise to 21.7 million and the number of cancer deaths to 13 million by 2030. Conventional cancer treatment involves surgery to remove the tumour when possible, as well as chemotherapy and radiation. Chemotherapies are widely used despite their associated toxicities because they interfere with the ability of cancer cells to grow and spread. However, tumours often develop resistance to chemotherapies, limiting their efficacy in preventing tumour recurrence. Despite recent advances, independent sources note a high unmet medical need in cancer therapy, noting the median survival rate remains poor. Cancer immunotherapies, including therapeutic cancer vaccines, may provide a new and effective treatment. According to a Market & Markets report released in January 2017, the global immunotherapy drugs market is projected to reach USD\$201.52 Billion by 2021 from USD\$108.41 Billion in 2016, growing at a compound annual growth rate (“CAGR”) of 13.5% during the forecast period of 2016 to 2021. The major players operating in the immunotherapy drugs market include



F. Hoffmann-La Roche AG (Switzerland), GlaxoSmithKline (U.K.), AbbVie, Inc. (U.S.), Amgen, Inc. (U.S.), Merck & Co., Inc. (U.S.), Bristol-Myers Squibb (U.S.), Novartis International AG (Switzerland), Eli Lilly and Corporation (U.S.), Johnson & Johnson (U.S.), and AstraZeneca plc (U.K.).

Cancer immunotherapy seeks to harness the immune system to assist in the destruction of tumours and to prevent their recurrence. There has been significant interest in the field of cancer immunotherapy stemming from recent clinical success in prolonging patient survival with novel compounds. The ability to apply these appropriately has resulted from a greater understanding of the immune dysfunction that is characteristic of cancer. One area in which there have been breakthroughs has been in the area of checkpoint inhibitors, compounds that target key regulatory molecules of the immune system. Yervoy (anti-CTLA-4, or ipilimumab, developed by Bristol-Myers Squibb) was the first compound in this class to be approved for use in advanced metastatic melanoma. In cancer, these regulators (CTLA-4, PD-1 and its ligand PD-L1) act to inhibit CD8 T cell mediated anti-tumour immune responses that are crucial for tumour control. Monoclonal antibodies that target PD-1 and PD-L1 have shown unusual efficacy in cancer patients, with a significant percentage of patients experiencing durable response to these therapies. Several of these compounds are in advanced clinical trials, with one compound, Merck's Keytruda (pembrolizumab), having received FDA approval in September of 2014 for advanced melanoma patients who have stopped responding to other therapies. Bristol-Myers Squibb's compound nivolumab (Opdivo) has also been approved in the United States and Japan. These therapies have recently been approved for use in other advanced cancers including bladder cancer, non-small cell lung cancer, Hodgkin's Lymphoma, squamous cell carcinoma of the head and neck and stomach cancer. In addition, Keytruda in particular has been approved for use in cancers with a specific molecular indication irrelevant of cancer type, having been approved in May for use to treat solid tumours having a biomarker for microsatellite instability (MSI-H), which is a defect in the DNA repair pathway. This represents about 5% of a number of different tumour types, including colorectal, breast, prostate and thyroid cancers. Key opinion leaders in the field have indicated that the ideal combination, with checkpoint inhibitors, is likely to be a therapy that drives tumour specific immune responses. These include novel cancer vaccines and T cell based therapies. These therapies fit well with checkpoint inhibition therapy because they simultaneously activate strong tumour specific immune responses, while releasing the brakes on immune suppression. The success of such combinations should allow pharmaceutical companies to significantly expand the market of their checkpoint inhibitors, which are currently effective in approximately 10% to 30% of patients.

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

### *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, ten infectious diseases have been at least 90% eradicated in the United States thanks to vaccines.

However, during the past decade, diseases thought to be under control or retreating, such as measles, mumps and pertussis have re-emerged, mostly due to decline in childhood vaccination rates. In addition, infectious diseases such as influenza, meningitis and yellow fever continue to be a significant public health concern, despite the availability of vaccines. Other diseases without a suitable vaccine, such as dengue and malaria have extended their geographical reach, due to expansion of the insects which carry them. While the effort to control these known infectious diseases continues, more than 30 additional

emerging diseases have been identified in humans for the first time over the past two decades, such as severe acute respiratory syndrome (SARS) and Middle East respiratory virus (MERS) coronaviruses.

There is an increased awareness of the impact of current and emerging infectious diseases. Demand for newer treatments and vaccines are growing globally. The global market for infectious diseases treatment was valued in January 2016 by analyst Peggy Lehr of BCC Research at USD\$108.4 billion in 2015, should reach USD\$126.2 billion in 2016 and USD\$183.2 billion in 2021, demonstrating a CAGR of 7.7% from 2016 to 2021. According to TechNavio's analysts, the global human vaccines market is expected to grow at a CAGR of 11.69% during the period 2016-2020.

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

#### *Respiratory Syncytial Virus (RSV)*

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

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

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

A vaccine would likely provide patients with a stronger efficacy profile and a more sustained immune response. The Corporation expects that the development of a vaccine with these improved characteristics could expand the market potential, adding the elderly and immunocompromised patients. With these patient populations, the Corporation believes that the market has a multibillion-dollar revenue potential.

Although there have been relatively few developments related to RSV over the past decade, a renewed interest in the area due to new technologies and early research into new methods of addressing immunity,

such as maternal immunity transfer for pediatric RSV, could result in new transactions or alliances over the next several years. Most transactions and alliances that have taken place in this sector have minimized the risk with a relatively modest upfront payment, followed by larger milestone payments subject to successful progression through clinical development and commercialization.

### ***Manufacturing and Scalability***

The Corporation has developed and implemented the commercial scale manufacturing process for the DepoVax™ 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 lipid nanoparticles 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 (freeze-drying) 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 DPX-Survivac and DPX-0907 was successfully implemented at a GMP contract manufacturing facility in the United States. In preparing for Phase 1 and 2 clinical trials, the Corporation has successfully produced clinical batches for both therapeutic cancer vaccine candidates as well as producing the first clinical batch of an infectious disease candidate. The Corporation is also ready to develop and implement manufacturing processes for other DepoVax™-based vaccine products.

### ***Facilities***

The Corporation's laboratory is actually located at 1344 Summer Street, Suites 411 and 309, Halifax, Nova Scotia where the Corporation is currently renting premises of approximately 4,200 sq. ft. The Corporation is also renting an administrative office in Quebec City of approximately 1,176 sq. ft. located at 2875 Boulevard Laurier, Suite 430, Quebec.

Considering the growing number of employees, consequence of the increase number of clinical studies conducted by the Corporation, there was a requirement to increase the laboratory space. In February 2018, the Corporation signed a lease beginning on June 1<sup>st</sup>, 2018 for approximately 14,941 sq. ft. located at 130 Eileen Stubbs Avenue, Suite 19, Dartmouth, Nova Scotia. The Corporation believes that this new facility will be satisfactory given its current state of development.

### ***Regulatory Process***

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 United States 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 1 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 1 clinical trial, an IND application in the United States 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 regulatory authorities, clinicians, etc. At the conclusion of a successful Phase 1 clinical trial, a compound is shown safe in humans and further studies are warranted to show its efficacy to treat an illness;
- Phase 2 clinical trial: in a Phase 2 clinical trial, a larger population is used in order to establish appropriate dosing for the compound. This and any other clinical studies are also approved by the regulatory agencies. At the end of a successful Phase 2 clinical trial, the compound is shown to be active in the correct population and a relevant dose is chosen to continue its development;
- Phase 3 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 3 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) or biologics licence application (“BLA”) 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 for a different segment of 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™ 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 1 and 2 trials. However, the Corporation utilizes the services of consultants and internal resources, such as a Chief Medical Officer, Vice President of Clinical Research, Clinical and Regulatory Affairs Manager(s) and Clinical Research Associate, 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 and Clinical Advisory Committee***

The Corporation has retained experienced academic and industry experts 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 and Clinical Advisory Committee consists of the following members:

#### ***Barney Graham, PhD, MD***

Senior Investigator, Viral Pathogenesis Laboratory, National Institute of Allergy and Infectious Diseases Vaccine Research Center  
National Institutes of Health

#### ***Scott Halperin, MD***

Director  
Canadian Centre for Vaccinology

#### ***Ramy Ibrahim, MD***

Vice President, Clinical Development  
Parker Institute for Cancer Immunotherapy

#### ***James Johnston, MB, BCh, FRCPC***

Senior Scientist, Research Institute in Oncology and Hematology  
Cancer Care Manitoba

#### ***Grant McFadden, PhD***

Director, Biodesign Center for Immunotherapy, Vaccines and Virotherapy  
Arizona State University

#### ***Michael Aaron Morse, MD***

Professor of Medicine and Professor in the Department of Surgery  
Duke University Medical Center

#### ***Brad Nelson, PhD***

Director and Distinguished Scientist, Deeley Research Centre  
BC Cancer Agency

***Kunle Odunsi, PhD, MD, FRCOG, FACOG***

Cancer Center Deputy Director; Chair of the Department of Gynecologic Oncology; and Executive Director, Center for Immunotherapy  
Roswell Park Cancer Institute

***David Spaner, PhD, MD***

Senior Scientist, Biological Sciences, Odette Cancer Research Program  
Sunnybrook Research Institute

***Pramod Srivastava, PhD, MD***

Director, Center for Immunotherapy of Cancer and Infectious Diseases  
Eversource Energy Chair in Experimental Oncology  
Director of The Carole and Ray Neag Comprehensive Cancer Center  
University of Connecticut School of Medicine

***Regulatory Affairs Advisor***

***Irene Clement, Senior Regulatory Advisor:*** Ms. Clement is a founding partner of Clement Strategies Inc., a regulatory and biotechnology business consulting company. She has more than 30 years' experience in regulatory affairs in the biologics industry, including work with Health Canada, FDA, and European and WHO agencies. Ms. Clement's previous positions include Vice President Regulatory Affairs for ID Biomedical (subsequently part of GSK), Vice President of Regulatory Affairs at Shire Biologics, and Director Regulatory Affairs at Aventis Pasteur Ltd (now Sanofi Pasteur Ltd). She has been responsible for numerous successful clinical trial applications (CTA & IND) and has also obtained numerous license approvals in Canada, the United States, European Union, Japan, Australia and other countries. For more than ten years, Ms. Clement has provided consulting services to a number of biotechnology companies.

***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 companies active 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 impact 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, 2017, the Corporation had 33 full-time and part-time, including six employees holding PhD degrees, including one MD, 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".

## **V. 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, the Corporation has incurred significant operating losses. The net loss was \$12.0 million for the year ended December 31, 2017, \$8.9 million for the year ended December 31, 2016 and \$8.8 million for the year ended December 31, 2015. As of December 31, 2017, the Corporation had an accumulated deficit of \$70.8 million. 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 and 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 Corporation 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 ongoing and planned 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 ongoing and planned clinical trials of DPX-Survivac.

As of December 31, 2017, the Corporation had cash and cash equivalents of \$14.9 million and working capital of \$13.6 million.

The Corporation will need to obtain significant financing prior to the commercialization of DPX-Survivac, including funding to complete all of the required clinical trials of DPX-Survivac. The Corporation does not currently have funds available to enable the Corporation to complete all of the required clinical trials for the commercialization of DPX-Survivac and to fund operating expenses through the completion of these trials. The Corporation expects that it will require more than \$50 million or more to conduct the clinical trials and fund operating expenses through the completion of these trials.

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

- the progress and results of the 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, Health Canada or a similar regulatory authority outside the United States and Canada;
- 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 on acceptable terms to the Corporation, or at all.

***Raising additional capital may cause dilution to existing shareholders, 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 ongoing and planned clinical trials of DPX-Survivac and to fund 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 may be materially harmed.***

All of the product candidates of the Corporation are still in preclinical or clinical development. The Corporation may never be able to obtain regulatory approval for any of its product candidates. The Corporation has committed significant human and financial resources to the development of DPX-Survivac, and the DepoVax™ 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, Health Canada and similar regulatory authorities outside the United States and Canada;
- 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 third-party 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 ongoing and planned clinical trials of DPX-Survivac, fail to demonstrate safety and efficacy to the satisfaction of the FDA, Health Canada or similar regulatory authorities outside the United States and Canada 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 what 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 contemplated, 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 could also 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 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, 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, Health Canada or similar regulatory authorities outside the United States and Canada. 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 ongoing and planned 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 Corporation to decline and limit the Corporation's ability to obtain additional financing, including financing needed to complete the ongoing and planned trials of DPX-Survivac. The Corporation's inability to enroll a sufficient number of patients for these 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 undesirable 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.

***The design or the Corporation's execution of clinical trials may not support regulatory approval.***

The design or execution of a clinical trial can determine whether its results will support regulatory approval and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. The Corporation does not know whether any Phase 2, Phase 3 or other clinical trials the Corporation may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market the Corporation's product candidates.

Further, the FDA, Health Canada and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of the Corporation's product candidates. The Corporation's product candidates may not be approved even if they achieve their primary endpoints in future Phase 3 clinical trials or registration trials. The FDA, Health Canada or other regulatory authorities may disagree with the Corporation's trial design and the Corporation's interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial that has the potential to result in FDA, Health Canada or other agencies' approval. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than the Corporation requests or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA, Health Canada or other regulatory authorities may not approve the labeling claims that the Corporation believes would be necessary or desirable for the successful commercialization of its product candidates.

***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™-based products may be particularly difficult as, to date, the FDA has only approved a limited number of cancer immunotherapies and the DepoVax™-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 of its product that would be approved in the future, 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 approaches, 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™ 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 that may provide equivalent or better efficacy compared to DPX-Survivac.

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.

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, Health Canada 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 United States 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, Health Canada or similar regulatory authorities outside the United States or Canada. 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 \$15 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 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 maintains a clinical trial liability insurance coverage in the amount of \$10 million, 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. 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™ platform. Notwithstanding the large investment to date and anticipated future expenditures in its DepoVax™ 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™ 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™-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™ 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, Health Canada or similar regulatory authorities outside the United States and Canada, 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 and intermediate drug substances, 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, including raw ingredients, the Corporation has so far identified only one supplier which is qualified for the Corporation's GMP process. In the event that a supplier stops supplying the required ingredient(s), the Corporation may need to identify an alternative source of such components and may need to wait until it is qualified for the Corporation's GMP process before procuring the components, which may cause substantial delays to one 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.

Currently the Corporation is utilizing the GMP services of a contract manufacturing organization ("CMO") located in the United States for its clinical drug product manufacturing 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 products require 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 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 the Corporation 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 itself 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™ platform's manufacturing capabilities, which involve significant unpatented know-how. The Corporation seeks to protect these trade secrets, in part, by entering into non-disclosure 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.

***Cyber security incidents and privacy breaches could result in important remediation costs, increased cyber security costs, litigation and reputational harm.***

Cyber security incidents can result from deliberate attacks or unintentional events. Cyber-attacks and security breaches could include unauthorized attempts to access, disable, improperly modify or degrade the Corporation's information, systems and networks, the introduction of computer viruses and other malicious codes and fraudulent "phishing" emails that seek to misappropriate data and information or install malware onto users' computers. Cyber-attacks in particular vary in technique and sources, are persistent, frequently change and are increasingly more targeted and difficult to detect and prevent against.

Disruptions due to cyber security incidents could adversely affect the Corporation's business. In particular, a cyber security incident could result in the loss or corruption of data from the Corporation's research and development activities, including clinical trials, which may cause significant delays to some or all of the Corporation's clinical programs. Also, the Corporation's trade secrets, including unpatented know-how, technology and other proprietary information could be disclosed to competitors further to a breach, which would harm the Corporation's business and competitive position. If the Corporation is



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

The Corporation is subject to privacy and security regulations with respect to the use and disclosure of protected health information. Subject to limited exceptions, the regulations restrict the Corporation's ability to use or disclose patient identifiable information without patient consent for purposes other than treatment or health-care operations. Any breach of the Corporation's systems that results in personal information being obtained by unauthorized persons could adversely affect the reputation of the Corporation and lead to litigation, fines and liability for failure to comply with privacy and information security laws.

The Corporation relies on a third-party for its information technology ("IT") function. The Corporation meets with its third-party IT experts on a bi-annual basis to discuss matters related to cyber security. An IT risk assessment is performed on an annual basis with oversight by the Audit Committee and the functionality of internal controls established as a result of this risk assessment are confirmed with the Corporation's third-party IT experts on a quarterly basis.

***The Corporation must successfully upgrade and maintain its information technology systems.***

The Corporation relies on various information technology systems to manage its operations. There are inherent costs and risks associated with maintaining, modifying and/or changing these systems and implementing new systems, including potential disruption of the Corporation's internal control structure, substantial capital expenditures, additional administration and operating expenses, retention of sufficiently skilled personnel to implement and operate its systems, demands on management time and other risks and costs of delays or difficulties in transitioning to new systems or of integrating new systems into the Corporation's current systems. In addition, the Corporation's information technology system implementations may not result in productivity improvements at a level that outweighs the costs of implementation, or at all. The implementation of new information technology systems may also cause disruptions in the Corporation's business operations and have an adverse effect on its business, prospects, financial condition and operating results.

**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 may not be able to commercialize its product candidates, and its ability to generate revenue may be materially impaired.***

The Corporation's product candidates, including DPX-Survivac and DPX-RSV, 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, Health Canada 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 Corporation'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 future 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 United States federal and state healthcare laws and regulations that may impact the Corporation's activities, 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 in each jurisdiction when the Corporation products will eventually be offered 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 in the United States, 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.

***Contemporary 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* ("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.

In March 2010, President Obama signed into law the *Health Care Reform Law*, a 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, this 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Health Care Reform Law. The Corporation expects that the current Presidential Administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Health Care Reform Law. The Corporation cannot be sure whether 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.

With the enactment of the *Biologics Price Competition and Innovation Act of 2009* ("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 BPCIA 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 United States Congress could amend the BPCIA to significantly shorten these exclusivity periods, 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.

### **General Company-Related Risks**

***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 may be unable to obtain scientific research and experimental development tax incentive credits.***

The Corporation is eligible for scientific research and experimental development tax incentive credits in Canada. There is a risk that a Canadian federal or provincial governmental agency could conclude that: (i) some or all of the expenditures were not incurred on scientific research and experimental development activities (ii) the rate applicable to such credit is different from the rate claimed by the Corporation, and (iii) the related entity does not meet specified criteria for refundable tax credits, and therefore the governmental agency could reduce or disallow claims for such credits, including refundable credits previously funded. Furthermore, if the Canadian taxation authorities reduce the tax credit either by reducing the rate of the credit or the eligibility of some research and development expenses in the future, our operating results will be materially adversely affected.

***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, 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.

***The Corporation may acquire businesses or products, or form strategic alliances, in the future, and the Corporation may not realize the benefits of such acquisitions.***

The Corporation may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that the Corporation believes will complement or augment its existing business. If the Corporation acquires businesses with promising products or technologies, the Corporation may not be able to realize the benefit of acquiring such businesses if the Corporation is unable to successfully integrate them with its existing operations and company culture. The Corporation may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent it from realizing their expected benefits or enhancing the Corporation's business. The Corporation cannot assure investors that, following any such acquisition, it will achieve the expected synergies to justify the transaction.

*The Corporation has limited experience operating internationally, is subject to a number of risks associated with its international activities and operations, and may not be successful in its efforts to expand internationally.*

The Corporation currently has very limited operations outside of Canada. In order to meet the Corporation's long-term goals, the Corporation would need to grow its international operations significantly. Consequently, the Corporation is and will continue to be subject to additional risks related to operating in foreign countries, including:

- the fact that the Corporation has limited experience operating its business internationally;
- local, economic and political conditions, including inflation, geopolitical events, such as war and terrorism, foreign currency fluctuations and exchange risks, which could result in increased or unpredictable operating expenses and reduced revenues and other obligations incident to doing business in, or with a company located in, another country;
- the Corporation's customers' ability to obtain reimbursement for any product candidate in foreign markets, and unexpected changes in reimbursement and pricing requirements, tariffs, trade barriers and regulatory requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- longer lead times for shipping and longer accounts receivable collection times;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- reduced protection of intellectual property rights in some foreign countries or the existence of additional potentially relevant third party intellectual property rights; and
- compliance with foreign laws, rules and regulations, including data privacy requirements, labor relations laws, tax laws, accounting requirements, anti-competition regulations, import, export and trade restrictions, anti-bribery/anti-corruption laws, regulations or rules, which could lead to actions by the Corporation or its licensees, distributors, manufacturers, other third parties who act on its behalf or with whom the Corporation does business in foreign countries or the Corporation's employees who are working abroad that could subject the Corporation to investigation or prosecution under such foreign laws.

## **VI. 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.

## **VII. 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 20, 2018, 137,106,558 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.

## VIII. MARKET FOR SECURITIES

### *Trading Price and Volume*

The Common Shares are currently listed and posted for trading on the TSX and are traded under the symbol “IMV” and trade on the OTCQX under the symbol “IMMVF”.

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

	Price Range		Average Trading Volumes	Total Cumulative Volume
	High (\$)	Low (\$)		
January 2017	0.77	0.66	89,974	1,889,446
February 2017	1.400	0.740	395,358	7,511,801
March 2017	1.350	1.040	161,664	3,718,261
April 2017	1.530	1.000	257,902	4,900,132
May 2017	1.700	1.250	168,664	3,710,612
June 2017	1.330	1.120	62,472	1,374,379
July 2017	1.400	1.080	99,484	1,989,681
August 2017	1.230	1.110	53,950	1,186,895
September 2017	1.210	1.050	84,492	1,689,842
October 2017	1.550	1.040	204,516	4,294,842
November 2017	1.680	1.350	146,663	3,225,925
December 2017	2.550	1.580	255,061	4,846,152

### *Prior Sales*

The only securities of Immunovaccine that are outstanding but not listed or quoted on a marketplace are stock options, the Warrants and compensation options.

### *Stock Options*

During the year ended December 31, 2017, the Corporation issued 853,800 stock options, which have an exercise period of 5 years from the date of grant:

Date	Number	Exercise Price
January 19, 2017	453,800	\$0.75
January 31, 2017	400,000	\$0.75

### *Warrants and Compensation Options*

The Corporation issued on June 21, 2017, as consideration to the underwriters of the June 2017 Public Offering, 461,538 non-transferable compensation options exercisable at a price of \$1.32 per Common Share until June 21, 2019.

In connection with the June 2016 Private Placement, the Corporation issued on June 8, 2016 7,275,000 Warrants entitling the holder thereof to purchase one Common Share at a price of \$0.72 per Common Share until June 8, 2018. The Corporation also issued as consideration to the underwriters of the June 2016 Private Placement 871,908 non-transferable compensation options exercisable at a price of \$0.60 per Common Share until June 8, 2018.

The Corporation issued on December 9, 2016, as consideration to the underwriters of the December 2016 Private Placement, 640,000 non-transferable compensation options exercisable at a price of \$0.792 per Common Share until December 9, 2018.

## **IX. DIRECTORS AND OFFICERS**

### *Directors*

As at March 20, 2018, as a group, the Corporation's directors and executive officers beneficially owned, directly or indirectly, or exercised control of over an aggregate of 15,852,880 Common Shares representing 11.56% 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 20, 2018.

The following table sets forth the name, province or state and country of residence of each director 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.

<b>Name and Municipality of Residence</b>	<b>Position Held with the Corporation</b>	<b>Principal Occupation during Past Five Years</b>	<b>Director Since</b>
Andrew Sheldon <sup>(1)</sup> (Québec, Québec, Canada)	Chairman of the Board and Director	Head of Medicago New Ventures and Board Chairman of Quebec International. Former Chief Executive Officer of Medicago Inc (Biotech company) Former Vice -president of Shire Biochem Canada (Vaccine Manufacturer) Former General Manager of Rhône Merieux Canada (Vaccine Manufacturer)	April 14, 2016
Wade K. Dawe <sup>(2)</sup> (Halifax, Nova Scotia, Canada)	Director	Chairman and Chief Executive Officer of Fortune Bay Corp. Former President, Chief Executive Officer and Chairman of Brigus Gold Corp. (formerly Linear Gold Corp.) and Chairman of Stockport Exploration Inc. (formerly Linear Metals Corporation) (mining)	September 25, 2014 <sup>(4)</sup>

Name and Municipality of Residence	Position Held with the Corporation	Principal Occupation during Past Five Years	Director Since
		companies)	
James Hall <sup>(3)</sup> (Toronto, Ontario, Canada)	Director	President of James Hall Advisors Inc. (advisory firm) Former Vice President of Callidus Capital Corporation (specialized asset-based lender to companies in Canada and the United States)	February 22, 2010
Frederic Ors (Québec, Québec, Canada)	Director	Chief Executive Officer of Immunovaccine Inc. Former Chief Business Officer of Immunovaccine Inc. Former Vice President of Business development and Strategic Planning of Medicago Inc. (biotech company)	April 14, 2016
Wayne Pisano <sup>(2)</sup> <sup>(3)</sup> (Asbury, New Jersey, United States)	Director	Former President and Chief Executive Officer of VaxInnate (pandemic and influenza vaccine company) and Former President and Chief Executive Officer of Sanofi Pasteur (pediatric and adult vaccine manufacturing company)	October 17, 2011
Albert Scardino <sup>(2)</sup> (London, United Kingdom)	Director	Technology and Media investor and public affairs commentator	July 29, 2010
Alfred Smithers (Halifax, Nova Scotia, Canada)	Director	President and Chief Executive Officer of Iona Resources Holdings Limited (investment company)	September 25, 2014
Shermaine Tilley <sup>(3)</sup> (Toronto, Ontario, Canada)	Director	Managing Partner of CTI Life Sciences Fund (venture capital fund)	June 8, 2016

(1) Mr. Sheldon is a non-voting member of the Compensation and Corporate Governance Committee and the Audit Committee.

(2) Member of the Compensation and Corporate Governance Committee.

(3) Member of the Audit Committee.

(4) Mr. Dawe was first elected as director of the Corporation on May 18, 2007. Mr. Dawe did not stand for re-election at the 2014 annual general meeting of the Shareholders of the Corporation. However, he was reappointed as director on September 25, 2014.

*Biographies Andrew (Andy) Sheldon, Chairman of the Board and Director*

Mr. Sheldon has thirty years of experience in the pharmaceutical industry and was named CEO of the Year by the Vaccine Industry Excellence awards at the World Vaccine Congress in April 2012. He is the head of Medicago New Ventures and was formerly President and Chief Executive Officer of Medicago Inc. Before joining Medicago Inc. in 2003, Mr. Sheldon served as Vice President, Sales and Marketing, of Shire Biologics and as General Manager of Rhône Merieux Canada. Mr. Sheldon is also the Board Chairman of Quebec International in the Quebec City region. Mr. Sheldon has a Bachelors degree in agricultural sciences from the Université Laval, Québec City, and a bachelor's of science degree with honors in biological sciences from the University of East Anglia, in Norwich, England.

*Wade K. Dawe, Director*

Mr. Dawe is an accomplished entrepreneur, financier and investor based in Halifax, Nova Scotia, Canada. He currently serves as Chairman of Pivot Technology Solutions Inc., a TSX listed company and Chairman and CEO of Fortune Bay Corp., a TSX listed company formed in 2014. Mr. Dawe has founded or co-founded a number of successful companies. He was recently Chairman & Chief Executive Officer of Brigus Gold Corp., a NYSE and TSX publically listed gold production company. Mr. Dawe holds a Bachelor of Commerce degree from Memorial University of Newfoundland (MUN), where he currently serves on the Advisory board to the Faculty of Business Administration. Mr. Dawe, a native of Newfoundland and Labrador, also serves on the Queen Elizabeth II Hospital Foundation and is a member of the Young Presidents' Organization (YPO), an international organization for business leaders. He established and personally funds the annual James R. Pearcey Entrepreneurial Scholarship at MUN and recently funded DC Makes, a new entrepreneurship-based program at the Discovery Centre in Halifax, Nova Scotia.

*James W. Hall, Director*

Mr. Hall is an experienced, knowledgeable and versatile entrepreneur, business operator, corporate investor, director and advisor with expertise in finance (accounting/restructurings/special investigations), private equity, banking and media. He is currently President of James Hall Advisors Inc. – financial and management consultants - and was formerly Vice President of Callidus Capital Corporation (a stressed asset-based lender operating in Canada and the United States). Prior to Callidus, he served as Chairman and CEO of Journal Register Company (Philadelphia-based newspaper company), and was Senior Vice President and Chief Investment Officer of Working Ventures Canadian Fund Inc. from 1990 to 2002. Past corporate directorships include Indigo Books & Music Inc., Atomic Energy of Canada Limited, TerraVest Income Fund, General Donlee Income Fund and International Datacasting Corporation. A Chartered Professional Accountant, Mr. Hall is a graduate of the Richard Ivey School of Business at Western University in London, Ontario..

*Frederic Ors, Chief Executive Officer and Director*

Mr. Frederic Ors has served as our Chief Executive Officer since April 2016. He brings over 19 years of experience in the biopharmaceutical industry, having served in a number of management roles encompassing business development, intellectual property, strategic planning, pre-marketing and communication. Before joining Immunovaccine, Mr. Ors spent 14 years at Medicago Inc. serving in many roles of increasing responsibility and most recently as Vice President of Business development and Strategic Planning. He also has served as second Vice-Chair of the Vaccine Industry Committee of Biotech Canada for five years between 2012 and 2016. Prior to Medicago Inc., he was licensing manager at the University Paris VII-Denis Diderot, one of the largest science and medical university in France. He has a B.Sc. degree in Biology and a Master degree in Management from the University of Angers (France).

*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 has a depth of experience across the spectrum of commercial operations, public immunization policies and pipeline development. Mr. Pisano is a former president and CEO of Sanofi Pasteur, one of the largest vaccine companies in the world. He joined Sanofi Pasteur in 1997 and was promoted to President and CEO in 2007, the position he successfully held until his retirement in 2011. Post his retirement from Sanofi Pasteur, Mr. Pisano joined VaxInnate, a privately held biotech company, from January 2012 until November 2016 serving as president and CEO. 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.

*Albert Scardino, Director*

Mr. Scardino is a technology and media investor. 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 was a correspondent, commentator and editor for The New York Times, The Guardian, The Independent, the BBC and Sky News. He has served as a communications director in political campaigns and government. He earned his bachelor's degree at Columbia University and his master's at the University of California, Berkeley.

*Alfred (Fred) Smithers, Director*

Mr. Smithers is the President and Chief Executive Officer of Iona Resources Holdings Limited. He was founder and former President and Chief Executive Officer of the Secunda Group of Companies. In 2003 Mr. Smithers was named one of the "Top 50 CEOs of Atlantic Canada", and is a member of the Nova Scotia Business Hall of Fame. He received an Honorary Diploma from the Nova Scotia Community College and holds an Honorary Doctorate in Commerce from Saint Mary's University. Mr. Smithers currently sits on the Board of Directors of the Dartmouth General Hospital, and is on the Advisory Board of Atlantic Signature Mortgage & Loan. He is a recipient of the Canadian Red Cross Humanitarian Award, an Officer of the Order of Canada, and the Honorary British Consul for the Maritimes.

*Dr. Shermaine Tilley, Director*

Shermaine Tilley is a Managing Partner at CTI Life Sciences Fund, a Montreal-based venture capital fund investing across Canada as well as in the U.S. Prior to joining CTI Life Sciences Fund in 2006, Dr. Tilley was Senior VP at DRI Capital Inc. (formerly Drug Royalty Corporation), the world's first private equity firm doing royalty transactions in the biotech/pharma space. Before DRI Capital Inc., Dr. Tilley ran and managed a research laboratory, holding faculty positions at the NYU School of Medicine and Public Health Research Institute ("PHRI"), NY, and on the PHRI Board of Directors. Concomitantly with her tenure at NYU School of Medicine and PHRI, she consulted for the NIH Small Business Innovation Research ("SBIR") program in immunology and infectious disease for 10 years. Dr. Tilley holds a Ph.D. in biochemistry from the Johns Hopkins University School of Medicine, an MBA from the University of Toronto, and is a member of the CFA Society of Toronto. She currently sits on the boards of CellAegis Devices and BIOTEC Canada.

## *Executive Officers*

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

<b>Name and Municipality of Residence</b>	<b>Position held with the Corporation</b>	<b>Principal Occupation during Past Five Years</b>
Pierre Labbé (Quebec City, Quebec, Canada)	Chief Financial Officer	Vice President and Chief Financial Officer of Leddartech Inc. Vice President and Chief Financial Officer of the Québec Port Authority Vice-president and Chief Financial Officer of Medicago Inc.
Gabriela Rosu (Vancouver, British Columbia, Canada)	Chief Medical Officer	Medical Science Liaison, Oncology for Janssen Inc. Global Medical Advisor, Hematology for Novo Nordisk Health Care AG Medical Science Liaison, Oncology for Lundbeck Canada
Joseph Sullivan (Wyndmoor, Pennsylvania, United States of America)	Senior Vice President, Business Development	Executive Director, Merck & Company, Inc.

### *Pierre Labbé, CPA, CA, Chief Financial Officer*

Prior to joining Immunovaccine Mr. Pierre Labbé was Vice President and Chief Financial Officer of Leddartech Inc. (April 2015 to February 2017), Vice President and Chief Financial Officer of the Québec Port Authority (October 2013 to April 2015), and has experience in the life science sector, having served as Chief Financial Officer and Secretary of Medicago Inc. (2008-2013 and 2004-2007). Mr. Labbé is also a Director of Osisko Gold Royalties Ltd and Agility Health Inc. Mr. Labbé holds a Bachelor's Degree in Business Administration and a license in accounting from Université Laval, Québec City. He is a member of Ordre des comptables professionnels agréés du Québec, the Chartered Professional Accountants of Canada and the Institute of Corporate Directors.

### *Gabriela Rosu, MD, Chief Medical Officer*

Ms. Gabriela Rosu has as a Master's Degree from the University of Medicine and Pharmacy Gr.T. Popa in Romania. Most recently Dr. Rosu was Medical Science Liaison, Oncology for Janssen Canada. Prior to this, she served as a Global Medical Advisor, Hematology for Novo Nordisk Health Care AG (from August 2013 to April 2016). From April 2011 to August 2013, Dr. Rosu was Medical Science Liaison, Oncology of Lundbeck Canada.

### *Joseph Sullivan, Senior Vice President, Business Development*

Prior to joining Immunovaccine in January 2018, Mr. Joseph Sullivan worked at Merck & Company, Inc., launching new products and indications, evaluating business development opportunities, and forming external collaborations. Most recently, Mr. Sullivan led cross-functional efforts to identify, negotiate, and operationalize global vaccine partnerships to expand market access. Preceding this position, he led the New Vaccines Product Group, which was responsible for the commercial direction of new vaccine development, evaluation of Mr. Sullivan was an Associate in Venture Capital & Investment Banking with Allen & Company Inc. Mr. Sullivan holds an MBA from Cornell University and a BA from Hamilton College.

### ***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 U.S. Bankruptcy Code (pre-negotiated joint Chapter 11 plan of reorganization). Mr. Hall left JRC in March 2009.

Mr. Alfred Smithers was a director of Sportslick Inc. (“Sportslick”), a company listed on the TSX Venture Exchange, from October 20, 2008 to July 17, 2009. On July 14, 2009, an order appointing Ernst & Young Inc. as the interim receiver of Sportslick and Sun Vette Racing Inc. was issued by the Register of Bankruptcy under the *Bankruptcy and Insolvency Act* (Canada) and, in 2011, Sportslick exited from receivership.

### *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.

## **X. 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, including those related to cyber security, 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. 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, 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), Mr. Wayne Pisano and Dr. Shermaine Tilley, as well as Mr. Andrew Sheldon, as a non-voting member, all of whom are financially literate and independent directors within the meaning of National Instrument 52-110 – *Audit Committees*. The education and related experience of each current Audit Committee member is described below.

James Hall – Mr. Hall, a Chartered Professional Accountant, previously served as Chair of the audit committee of Atomic Energy of Canada Limited, International Datacasting Corporation, Terravest Income Fund and General Donlee Income Fund, and was a member of the audit committee of Journal Register Company and Indigo Books & Music Inc.

Wayne Pisano – Mr. Pisano holds an MBA and is the former Chief Executive Officer of VaxInnate and prior to that the Chief Executive Officer of Sanofi Pasteur.

Shermaine Tilley - Dr. Tilley holds a Ph.D. in biochemistry, an MBA and is a member of the CFA society of Toronto. She is currently a Managing Partner at CTI Life Sciences Fund and sits on the boards of CellAegis Devices, Phemi, Xagenic, Zymeworks, and BIOTECCanada.

Andrew Sheldon – Mr. Sheldon has thirty years of experience in the pharmaceutical industry and is the head of Medicago New Ventures and was formerly the President and Chief Executive Officer of Medicago Inc. since 2003. He was a member of Medicago’s board of directors until September 18, 2013 and has served on several other boards.

The Audit Committee is responsible for the integrity of the Corporation’s internal accounting and control systems, including controls over information technology. 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, Mr. Albert Scardino, as well as Mr. Andrew Sheldon, as a non-voting member. The education and related experience (as applicable) of each current member is described below:

Wayne Pisano – Mr. Pisano holds an MBA and is the former Chief Executive Officer of VaxInnate and prior to that the Chief Executive Officer of Sanofi Pasteur. He had direct responsibility in evaluating the compensation levels for other executive officers.

Wade Dawe – Mr. Dawe, as Chairman and Chief Executive Officer of Fortune Bay Corp, 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 and the former Chairman and Chief Executive Officer of Brigus Gold.

Albert Scardino – Mr. Scardino has extensive experience as a director of both for-profit and not-for-profit organizations, public and private, in the United States and United Kingdom.

Andrew Sheldon – Mr. Sheldon has thirty years of experience in the pharmaceutical industry and is the head of Medicago New Ventures and was formerly the President and Chief Executive Officer of Medicago Inc. since 2003. He was a member of Medicago’s board of directors until September 18, 2013

and has served on several other boards. As Chief Executive Officer of Medicago Inc., Mr. Sheldon is responsible for ensuring compensation levels are competitive and in line with the company's business strategy.

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.

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 a written code of business conduct for its directors, officers and employees.

#### *Assessment*

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

<b>Fees</b>	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Audit Fees <sup>(1)</sup>	\$86,850	\$86,000
Audit Related Fees <sup>(2)</sup>	\$44,600	\$4,500
Tax Fees <sup>(3)</sup>	\$41,200	\$37,740
All Other Fees <sup>(4)</sup>	\$12,000	-
<b>Total Fees</b>	<b>\$184,650</b>	<b>\$128,240</b>

(1) *Audit Fees* consist of the aggregate fees billed by the external auditor of the Corporation for audit services.

(2) *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.

(3) *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.

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

## **XI. 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, 2017. 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, 2017: (i) penalties or sanctions imposed by a court relating to 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.

## **XII. 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.

### **XIII. TRANSFER AGENT AND REGISTRAR**

The registrar and transfer agent for the Common Shares is Computershare Investor Services Inc. and for the warrants issued under the 2014 Public Offering and the June 2016 Private Placement is Computershare Trust Company of Canada, at their principal offices located at 100 University Avenue, 9<sup>th</sup> Floor, Toronto, Ontario, M5J 2Y1 and at 1500 Robert-Bourassa Boulevard, 7<sup>th</sup> Floor, Montréal, Québec, H3A 3S8.

### **XIV. MATERIAL CONTRACTS**

The following are the material contracts, other than contracts entered into in the ordinary course of business, that the Corporation has entered into since January 1, 2017 or prior thereto but which are still in effect:

- (i) an underwriting agreement entered into among Immunovaccine, Echelon Wealth Partners Inc., National Bank Financial Inc. and Bloom Burton Securities Inc. dated as of January 30, 2018 in connection with the February 2018 Public Offering;
- (ii) an underwriting agreement entered into among Immunovaccine, Echelon Wealth Partners Inc., National Bank Financial Inc. and Mackie Research Capital Corporation dated as of June 6, 2017 in connection with the June 2017 Public Offering;
- (iii) a loan agreement between Immunovaccine and the Province of Nova Scotia dated as of July 26, 2013 pursuant to which Immunovaccine received a loan of \$5 million, available in four equal instalments to be used to fund a portion of working capital through 2016; and
- (iv) a license agreement between Immunovaccine and Merck KGaA (MRCG.DE) dated as of July 12, 2010.

A copy of these contracts can be found under the profile of the Corporation on SEDAR at [www.sedar.com](http://www.sedar.com).

### **XV. 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.

### **XVI. 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 31, 2017 prepared in connection with the Corporation's most recent annual shareholders' meeting and is available on SEDAR at [www.sedar.com](http://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](http://www.sedar.com). All information incorporated by reference in this Annual Information Form is or will be 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](http://www.sedar.com).

All requests for the above-mentioned documents must be addressed to the Chief Financial Officer of Immunovaccine Inc., #53-1344 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: (i) the financial information that will be provided to the shareholders and others; (ii) the systems of internal controls which management and the Board of Directors have established; and (iii) the Corporation’s audit and financial reporting process. The external auditors’ ultimate responsibility is to the Board of Directors and the Committee, as representatives of the shareholders.

These representatives have the ultimate authority to evaluate and, where appropriate, recommend replacement of the external auditors. The Committee will primarily fulfill these responsibilities by carrying out the activities enumerated in Section 5 of this Mandate of the Committee (the “**Mandate**”). The 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

An “**affiliate**” of, or a person affiliated with, a specified person, means a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified, and includes, without limitation, (a) an executive officer of an affiliate; (b) a director who also is an employee of an affiliate; (c) a general partner of an affiliate; and (d) a managing member of an affiliate.

“**Board of Directors**” or “**Board**” means the Board of Directors of Immunovaccine Inc.

“**Chairman**” means the Chairman of the Committee.

“**Committee**” means the Audit Committee of Immunovaccine Inc.

“**Committees**” means the Committee and the Compensation and Corporate Governance Committee.

“**control**” (including the terms controlling, controlled by and under common control with) means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise.

“**Corporation**” means collectively, Immunovaccine Inc. and any subsidiary, including, without limitation, ImmunoVaccine Technologies Inc.

“**Financially Literate**” means the ability to read and understand a set of fundamental 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 (including, without limitation, a balance sheet, income statement, and cash flow statement).

**“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 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 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, all of which are Independent Directors. All members of the Committee shall be Financially Literate. The Committee shall also have at least one member who has past employment experience in finance or accounting, requisite professional certification in accounting, or any other comparable experience or background which results in the individual's financial sophistication, including being or having been a chief executive officer, chief financial officer or other senior officer with financial oversight responsibilities.
- 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 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 may but not required to be given 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 will receive meeting agendas in advance, along with appropriate briefing material.
- 3.7 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.
- 3.8 The Committee shall submit periodically a report to the Board on its activities, including the nature of its deliberations and the related recommendations.
- 3.9 The Committee, in the performance of its duties, may consult any relevant register or record of the Corporation.
- 3.10 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 auditors 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 (including, without limitation, the external auditors and independent counsel) employed by the audit committee and for ordinary administrative expenses of the Committee that are necessary or appropriate in carrying out its duties;
  - c) resolve any disagreements between the Corporation's senior management team and the external auditors regarding financial reporting;
  - d) pre-approve all auditing and non-audit services;
  - e) seek any information it requires from the Corporation's employees, all of whom are directed to cooperate with the Committee's requests, or external parties; and
  - f) to communicate directly with the Corporation's senior management team, external auditors, and outside counsel, as necessary, and separately, as necessary.



## **5. RESPONSIBILITIES AND DUTIES**

5.1 To fulfill its responsibilities and duties, the Committee shall:

### **Financial Statements**

- a) review the accounting principles, policies and practices followed by the Corporation 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, including complex or unusual transactions and highly judgmental areas, 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 draft press releases regarding the annual and interim financial statements and recommend to the Board for approval prior to publicly disclosing this information;
- d) 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;

### **Internal Control**

- e) consider the effectiveness of the Corporation's internal control system, including information technology security and control;
- f) understand the scope of external auditors' review of internal controls over financial reporting, and obtain reports on significant findings and recommendations, together with management's response;
- g) review the financial risk assessment and management policies followed by the Corporation in operating its business activities and the completeness and fairness of any disclosure thereof, including, without limitation, review of the use of derivative financial instruments by the Corporation;
- h) 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;
- i) establish procedures for (i) the receipt, retention and treatment of complaints received by the Corporation from employees regarding accounting, internal accounting controls, or auditing matters; and (ii) the confidential, anonymous submission by directors, officers and other employees of the Corporation of concerns regarding questionable accounting or auditing matters;

## **External Audit**

- j) appoint, compensate and retain the external auditors in connection with preparing or issuing an auditor's report or with performing other audit, review or attestation services for the Corporation;
- k) 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 attestation services for the Corporation, including the resolution of disagreements between management and the external auditors regarding financial reporting;
- l) obtain, on an annual, basis, a formal written statement from the external auditors delineating the relationship between the external auditors and the Corporation, actively engaging in a dialogue with the external auditors with respect to any disclosed relationships or services that may impact the objectivity and independence of the external auditors and for taking, or recommending that the full board take, appropriate action to oversee the independence of the external auditors under applicable securities laws and stock exchange rules;
- m) discuss with the external auditors their views about the quality of the implementation of International Financial Reporting Standards (or other generally accepted accounting principles used by the Corporation to report its financial statements), 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 and their views on the adequacy of the Corporation's financial personnel;
- n) review and provide direction regarding 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;
- o) 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 permitted non-audit services being provided;
- p) assess the effectiveness of the working relationship of the external auditors with management;
- q) determine the nature of non-audit services the external auditors are prohibited from providing to the Corporation, and pre-approve all permitted non-audit services provided by the external auditors to the Corporation;
- r) if appropriate, terminate the appointment of the external auditors;
- s) prepare the report required to be prepared by the Committee pursuant to applicable securities laws for inclusion with the annual financial statements;
- t) at least annually, obtain and review an appropriate report by the external auditors describing: (i) the external auditors' internal quality-control procedures; (ii) any material issues raised by the most recent internal quality-control review or peer

review of the external auditors, or any inquiry or investigation by governmental or professional authorities, within the preceding five years, respecting one or more independent audits carried out by the external auditors, and any steps taken to deal with such issues; and (iii) all relationships between the external auditors and the Corporation to enable the assessment of the external auditors;

### **Reporting Responsibility**

- u) review and reassess annually the Mandate of the Committee for adequacy and recommend any changes to the Board;
- v) 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;
- w) 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;

### **Compliance**

- x) review the effectiveness of the system for monitoring compliance with laws and regulations and the results of management's investigation and follow-up, including disciplinary action of any instances of noncompliance;
- v) review the findings of any examinations by regulatory agencies and any external auditors observations;
- w) review the process for communicating the code of conduct to the Corporation's employees and for monitoring compliance therewith; and
- x) obtain regular updates from management and Corporation's legal counsel regarding compliance matters.

Adopted by the Board on April 6, 2010 and amended on March 10, 2016 and November 16, 2017.