



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

**For the year ended December 31, 2013**

## LETTER TO SHAREHOLDERS

Dear fellow shareholder,

This past year, we saw the world of cancer therapy change.

Both the medical community and investors now know – thanks in part to two large studies in melanoma released in June – that the human immune system can be trained to destroy cancer cells. We have been pursuing this idea for some years now with our DPX-Survivac and DPX-0907 vaccines.

The two studies, released at the American Society of Clinical Oncology conference in Chicago, raise the possibility that cancer can be treated, at least in some cases, as a chronic long-term illness.

So far, our therapies have been tested in about 50 patients. The data from those tests have provided indications that our vaccines can indeed teach the immune system to manufacture cells that we believe will be able to recognize and kill cancer cells. We can confirm our early results only when we test the vaccines on many more cancer patients, which we are planning to do in 2014.

Our largest trial, on as many as 250 women with late-stage ovarian cancer, is sponsored by the Clinical Trials Group of the National Cancer Institute of Canada. We are currently conducting a dosing study on a small group of patients to determine the best course of treatment for the women in the larger study to come, particularly the spacing of time between vaccinations and the amount of vaccine to be given.

Another trial, for people suffering from a type of brain cancer known as Glioblastoma, is scheduled to begin in the first half of this year at the University of Rome. Fifty patients who will have already undergone surgery to remove the bulk of their tumor will receive a course of therapy that includes a drug designed to make their immune systems more active in combination with our vaccine. The vaccine will be delivered in multiple doses intended to stimulate the production of CD8 T cells, a type of blood cell that can search out and destroy cancer cells.

While we have been preparing for these two trials, cancer immunotherapy has become headline news in both the general press and among analysts. This past December, *Science* magazine named cancer immunotherapy as its “Breakthrough of the Year”. Citibank's health care analyst, Andrew Baum, suggested that within 10 years immunotherapy would account for 60% of all spending on cancer therapy in the US, and would represent a \$42 billion annual market. Major pharmaceutical companies rushed to license products in development at smaller companies.

The market moved further in our direction late in the year as several large companies with immunotherapy products in their pipelines announced that they would develop vaccine programs to help create combination therapies for cancer.

We believe the common thread connecting all of these developments is the fundamental idea that immunotherapies have the potential to shift cancer from a life threatening disease to a chronic and manageable condition.

This is all exciting news for Immunovaccine and our lead cancer vaccine programs, DPX-Survivac and DPX-0907. The programs made significant strides in 2013 and we expect this momentum to continue into 2014, as we initiate three separate Phase II clinical studies, in multiple cancer types. DPX-Survivac

and DPX-0907 are both wholly-owned Immunovaccine programs. In our view, this puts us in an enviable position, as drug developers, both large and small, seek out promising immunotherapy assets for their portfolios.

Here is a summary of our key developments during the year:

### ***Cancer***

- DPX-Survivac – Positive data from our completed Phase I study were presented at multiple venues during the year, including the 2013 ASCO annual meeting. We believe that these findings represent some of the strongest immune responses against a cancer target seen to date.

Based on these promising data, Canada's NCIC Clinical Trials Group (NCIC) agreed to sponsor and conduct a randomized Phase II study of DPX-Survivac in patients with advanced ovarian cancer. We expect this study to be initiated in 2014 with results available in 2017. Immunovaccine also signed an agreement with the University of Rome for a multicenter Phase II study of DPX-Survivac in Glioblastoma patients. The study is expected to begin in 2014, and its costs will be assumed by this university.

- DPX-0907 – Immunovaccine agreed to allow use of DPX-0907 in a Phase I/II study of breast and ovarian cancer patients at the Busto Arsizio Hospital in Italy. The study, which will be funded by Busto Arsizio, is expected to be initiated in 2014.

### ***Infectious Diseases***

- Anthrax – Positive –data from multiple studies of DepoVax™-based anthrax vaccines were presented in 2013. An immunogenicity study conducted as part of an ongoing bio-defense research program with the National Institutes of Health in the U.S. suggested that the DepoVax vaccine prompted a more rapid and long lasting immune response as compared to BioThrax™, the licensed anthrax vaccine that is currently in use. Additionally, studies in rabbits and non-human primates showed that a vaccine containing recombinant protective antigen (PA) formulated in DepoVax protected the animals against a lethal anthrax challenge. Additional studies are proposed.

- Respiratory syncytial virus – Immunovaccine received funding from the Canadian government's Industrial Research Assistance Program (IRAP) to develop a vaccine for this flu-like illness, a lung disease primarily in children, the elderly and patients with a compromised immune system.

- Leadership – Immunovaccine implemented changes to its management team and board of directors designed to strengthen the leadership of the company. Albert Scardino was appointed as Executive Chairman and Marc Mansour, Ph.D., was named Chief Operating Officer. Dr. Mansour was also appointed to the Board of Directors. Dr. Llew Keltner joined the board in early 2014.

- Financial Prudence – Consistent with the company's long-term corporate strategy of capital efficiency, Immunovaccine relied on various funding sources in 2013 to support its operations and ongoing clinical development programs. These included a \$5 million loan from the Province

of Nova Scotia announced in August 2013 and private placements raising gross proceeds of \$5.8 million.

Immunovaccine achieved these milestones in 2013 with broad support of investors, the government of Canada, the government of Nova Scotia, the international research community and a loyal and talented staff. Yet we believe we have only just begun to realize what can be accomplished with our underlying oil-based delivery system and broad vaccine product pipeline.

Our goals for the year ahead include:

- Initiate four clinical studies with DepoVax™-based vaccines:
  - o Phase II DPX-Survivac study in advanced ovarian cancer
  - o Phase II DPX-Survivac study in glioblastoma
  - o Phase I/II DPX-0907 study in breast and ovarian cancer
  - o Phase I study of DepoVax™-based candidate in RSV
  
- Advance our DepoVax™-based anthrax vaccine program with additional studies in collaboration with the National Institute for Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH) in the U.S.

We have entered 2014 with optimism for our DepoVax™ platform and vaccine pipeline, particularly DPX-Survivac. By the end of this year, we expect to be a different company, with three Phase II cancer vaccine clinical studies underway, our first clinical-stage infectious disease program and potential partners for one or more of these various products. The goals are ambitious, but we look forward to the challenge.

Thank you for your continuing support.



Albert Scardino  
Executive Chairman



Marc Mansour  
Chief Operating Officer

## **MANAGEMENT DISCUSSION AND ANALYSIS (“MD&A”)**

The following analysis provides a review of the audited annual consolidated results of operations, financial condition and cash flows for the year ended December 31, 2013 (“Fiscal 2013”), with information compared to the year ended December 31, 2012 (“Fiscal 2012”), for Immunovaccine Inc. (“Immunovaccine”, “IMV” or the “Corporation”).

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

Additional information regarding the business of the Corporation, including the Corporation’s Annual Information Form, is available on SEDAR at [www.sedar.com](http://www.sedar.com).

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

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

## **FORWARD-LOOKING STATEMENTS**

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

- statements with respect to the sufficiency of the Corporation’s financial resources to support 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 ongoing research and research collaborations;
- the Corporation’s business strategy;
- the Corporation’s exploration of opportunities to maximize shareholder value as part of the ordinary course of its business through collaborations, strategic partnerships and other transactions with third parties, which may or may not include plans for merger and acquisitions activities;
- the Corporation’s plans for the research and development of certain product candidates;
- the Corporation’s strategy for protecting its intellectual property;
- the Corporation’s ability to identify licensable products or research suitable for licensing and commercialization;
- the Corporation’s ability to obtain licences on commercially reasonable terms;
- the Corporation’s plans for generating revenue; and
- the Corporation’s plans for future clinical trials.

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 “Risk Factors”. Although the forward-looking statements contained in this MD&A are based upon what management of the Corporation believes

are reasonable assumptions, the Corporation cannot assure investors that actual results will be consistent with these forward-looking statements and should not be unduly relied upon by investors.

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

- obtaining additional funding on reasonable terms when necessary;
- positive results of pre-clinical and clinical tests;
- the Corporation's ability to successfully develop existing and new products;
- the Corporation's ability to attract 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 patents and proprietary rights;
- the Corporation's ability to manufacture its products and to meet demand; and
- regulatory approvals.

These statements reflect management's current beliefs and are based on information currently available to management. The information contained herein is dated as of March 14, 2014; the date of the Board's approval of the MD&A and the Fiscal 2013 audited annual consolidated financial statements. A more detailed assessment of the risks that could cause actual results to materially differ from current expectations is contained in the section entitled "Risk Assessment" of this MD&A.

## **CORPORATION OVERVIEW**

Immunovaccine is a clinical stage biopharmaceutical company that discovers and develops activators of the immune system to treat cancer and infectious diseases. Immunovaccine has built a proprietary product platform that is used to create immunogenic vaccines. The Corporation's proprietary DepoVax™ adjuvanting/delivery platform is believed to produce a strong, high-quality immune response that has a specific and sustained immune effect, and enables the Corporation to pursue vaccine candidates in cancer, infectious diseases and potentially other vaccine applications. The DepoVax™ platform is being used in multiple vaccine candidates, including two cancer vaccine candidates that are in or have completed Phase 1 clinical trials. One of the Corporation's cancer vaccine candidates is expected to enter large, randomized Phase 2 trials in 2014. The Corporation has research collaborations with several research organizations, including the National Institutes of Health ("NIH") in the U.S. The Corporation has licensed the delivery technology to Zoetis, formerly the animal health division of Pfizer, Inc. ("Pfizer"), for the development of vaccines for livestock. The common shares of the Corporation are listed on the TSX Venture Exchange ("TSX-V") under the symbol "IMV".

Based on reported pre-clinical and clinical data, the Corporation believes the DepoVax™ platform produces a strong, high-quality immune response that has a specific and sustained immune effect. The Corporation's adjuvanting technology platform has broad applications and is being evaluated in multiple vaccine candidates, including two cancer vaccine candidates that have completed or nearing completion of Phase I clinical trials. Immunovaccine is evaluating an infectious disease vaccine for respiratory syncytial virus (RSV). Immunovaccine also has research collaborations for various vaccines that could benefit from the DepoVax™ technology with commercial entities and academic institutions, including the US National Institutes of Health ("NIH"). In addition to the Corporation's strategy of developing a pipeline of differentiated vaccines, Immunovaccine is pursuing out-licensing opportunities for the DepoVax™ delivery platform on a product by product basis. Zoetis, formerly the animal health division of Pfizer, has licensed the Corporation's delivery technology to develop vaccines for livestock.

Based in Halifax, Nova Scotia, the Corporation had 20 full-time and part-time employees and three part-time consultants as at December 31, 2013. Being involved in a scientific and technical business, the Corporation requires staff with significant education, training and scientific knowledge that cannot be recruited or replaced easily. As a result, the Corporation recruits talented expertise locally, nationally and internationally. The business of the Corporation requires personnel with specialized skills and knowledge in the fields of basic and applied immunology, chemistry, formulation research and analytical chemistry method development. The Corporation has trained

scientists with broad experience in these fields including six employees holding PhD degrees and seven holding MSc or MBA degrees. In addition to the core team, the Corporation has also assembled a Scientific Advisory Board (“SAB”) of experienced and internationally recognized scientific advisors to assist management in dealing with industry-related issues and how these issues may affect the Corporation’s scientific research and product development.

## **BUSINESS STRATEGY**

### *Operating Strategy*

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

The Corporation has two clinical-stage cancer vaccines: DPX-Survivac; and DPX-0907. Immunovaccine believes the principles behind a successful therapeutic cancer vaccine should include a targeted antigen and an effective adjuvanting and vaccine delivery technology, combined with a complementary therapeutic strategy. Antigens used in both DPX-Survivac and DPX-0907 are believed to specifically target tumor cells without harming normal, healthy cells. These antigens are combined with the Corporation’s DepoVax™ platform in an effort to optimize the presentation of these antigens to the immune system, potentially resulting in an enhanced immune response. To be successful against cancer, the Corporation believes the vaccine must be administered in the right therapeutic setting, soon after a tumor has been identified and treated by surgery, chemotherapy and/ or other therapies that reduce tumor bulk. Immunovaccine also believes that the effect of the vaccine may be enhanced if an immune modulator is used simultaneously to prevent a patient’s immune system from overriding the positive response to the vaccine.

Using the same DepoVax™ adjuvanting platform and working with commercial and academic partners, the Corporation is also developing vaccines for infectious diseases, including a bio-defense vaccine that may protect against anthrax and a respiratory syncytial virus (“RSV”) vaccine. The Corporation engages in research collaborations which may lead to additional vaccine products. Pre-clinical studies have indicated that the platform may allow the development of enhanced vaccines for a wide range of cancer and infectious diseases by potentially generating a stronger and more durable immune response more quickly than is possible with existing delivery methods. For vaccines that are unusually non-immunogenic, the platform may significantly reduce the number of immunizations required. The Corporation’s goal is to advance additional vaccines that show promising results into human clinical trials.

### *Financing and Partnering Strategy*

Immunovaccine relies on equity financing and non-dilutive private and public partnerships to fund its development programs. Applying this strategy, the Corporation has obtained more than \$15 million in government funding, including interest-free loans and government grants. Most recently, the Corporation completed a \$4.2 million equity private placement in November 2013 and obtained a \$5 million secured loan from the Province of Nova Scotia in August 2013, available in four equal installments based on the Corporation meeting certain milestones, three of which have been met to date. The Corporation received the first installment of \$1.25 million on August 9, 2013.

While having used its own resources to initially bring its two cancer vaccines to human clinical trials, the Corporation is involved in various partnerships and collaborations to accelerate the development of its DepoVax™-based products. The Corporation announced the collaboration with Canada’s NCIC Clinical Trials Group (“NCIC CTG”), an organization supported by the Canadian Cancer Society, in which NCIC CTG will sponsor and conduct a Phase II study of the Corporation’s lead cancer vaccine, DPX-Survivac. The Corporation is currently in discussions with potential partners and may seek a co-development partnership arrangement to fund the balance of NCIC CTG-sponsored clinical trial costs. DPX-Survivac will also be tested in a fully funded investigator-initiated Phase II study in glioblastoma patients in Italy. Other programs include a clinical research collaboration with the Busto Arsizio Hospital in Italy to test DPX-0907 in ovarian and breast cancer patients, a research partnership with the NIH for vaccines against bio-terrorism threats, as well as other collaborations. The goal of these types of partnerships is to produce pre-clinical and clinical data that will lead to licensing agreements, either to allow the use of the Corporation’s DepoVax™ platform by others or to acquire antigens for use in new vaccines using DepoVax™.

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

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

## **PLATFORM AND PRODUCTS IN DEVELOPMENT**

### *DepoVax™ Vaccine Enhancement Platform*

DepoVax™ is a lipid depot-based vaccine delivery and enhancement platform that is believed to be easy to use, chemically stable and has the flexibility to incorporate a variety of antigens. The DepoVax™ platform forms the basis of Immunovaccine's therapeutic cancer and infectious diseases vaccine candidates.

The DepoVax™ platform is a combination of antigens, plus adjuvant (immune enhancers) formulated in liposomes and then suspended in oil. With the ability to retain the active components in the oil phase, the DepoVax™ platform creates a long-lasting "depot effect" that prolongs the exposure of vaccine ingredients to immune cells at the site of vaccination.

This unique formulation is expected to provide 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 Corporation believes one of the significant advantages of the DepoVax™ platform is its versatility. 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 the flexibility to develop many different vaccine products using a single platform.

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 potential single-dose capability is a key factor for developing rapid response vaccines for pandemics and disease outbreaks.

The Corporation believes the ability of DepoVax™ to induce robust cellular immune responses makes the platform uniquely suitable for therapeutic cancer vaccines, which are designed to specifically target tumor cells and to help patients remain in remission and combat the dissemination of micro-metastases. DepoVax™ can induce antigen-specific "poly-functional" cellular responses, which are postulated to be required for effective tumor control.

### *DPX-Survivac*

DPX-Survivac uses survivin-based antigens licensed from Merck KGaA, on a world-wide exclusive basis, and formulated in the DepoVax™ vaccine delivery platform. Survivin is a major tumor-associated antigen over-expressed in several cancers including ovarian cancer cells, making it a viable target for immunotherapy. DepoVax™ delivers the survivin-based antigens in a lipid depot-based format designed to generate a strong and prolonged immune response.

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

The Corporation believes DPX-Survivac could have broad commercial potential as a therapeutic cancer vaccine because it may be applicable for the treatment of multiple solid tumors and hematological cancers, including ovarian, glioblastoma, prostate, breast, pancreatic, multiple myeloma, B-cell lymphoma, and melanoma. The Corporation intends to proceed with pre-clinical testing of DPX-Survivac in a broader range of cancer indications to evaluate additional opportunities.

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

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

In the Phase I 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 primarily related to grade 1-2 injection site reactions, which were experienced by the majority of patients after repeated vaccinations. Those patients presenting the strongest immune responses were more likely to exhibit more pronounced injection site reactions. Grade 3 injection site ulcerations, which was an expected adverse event with this vaccine, was experienced by three patients during the trial. Upon a six month follow-up for the majority of patients, a trend of delayed progression was observed in patients who had strong immune responses to DPX-Survivac. The trend of delayed cancer progression, which was not statistically significant, may be attributed to the therapy or may be attributed to other unrelated factors.

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

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

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

The agreement between NCIC CTG and Immunovaccine will provide a framework for the NCIC CTG to sponsor the randomized Phase II trial and assume responsibility for conducting the trial in accordance with good clinical practice, in a significantly more capital efficient manner than if the trial was conducted by the Corporation as a sponsor. The Corporation is currently in discussions with potential partners and may seek a co-development

partnership arrangement to fund the balance of NCIC CTG-sponsored clinical trial costs. The trial is expected to get underway in 2014 with results expected in 2017.

A Phase Ib trial is currently underway to optimize and confirm the dose and schedule of vaccinations that will be employed in the randomized Phase II trial to be sponsored by the NCIC CTG.

The Corporation also recently announced it has signed an agreement with Professor Marianna Nuti, Ph.D., Department of Experimental Medicine at the University of Rome, to conduct an investigator-led trial on DPX-Survivac in patients with glioblastoma. This multicenter study based in Rome will be conducted in collaboration with neurosurgeons and oncologists coordinated by Professor Maurizio Salvati, M.D. The randomized, placebo-controlled study is expected to enroll up to 50 patients with newly diagnosed brain tumors that have been maximally resected. Testing DPX-Survivac in glioblastoma patients is expected to be initiated in 2014.

#### *DPX-0907*

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

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

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

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

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

The Corporation recently signed an Investigator-Initiated Study Agreement for the ongoing evaluation of its DPX-0907 cancer vaccine at the Busto Arsizio Hospital in Milan, Italy. Marco Bregni, M.D., head of the Oncology Unit of the Hospital of Busto Arsizio, will serve as the principal investigator for the Phase I/II DPX-0907 clinical trial in patients with breast and ovarian cancer. Immunovaccine expects the Phase I/II study to be initiated in 2014.

The Corporation is also exploring other opportunities for commercialization of DPX-0907 and is considering investigator funded trials, as recently announced, or partnership opportunities at various stages of clinical development, including at the Phase I and Phase II clinical trial stages.

## *Infectious Diseases*

The Corporation's business strategy includes leveraging the DepoVax™ platform within infectious and other diseases. The DepoVax™-adjuvanting platform has the potential to generate a rapid and robust immune response, often in a single dose. The unique vaccine enhancement and single-dose capability could prove to be beneficial in targeting difficult infectious and other disease candidates. Immunovaccine has conducted multiple proof of concept studies for DepoVax™ platform-based infectious diseases vaccines, including pandemic influenza, anthrax, pertussis, and hepatitis B vaccines.

The Corporation is performing pre-clinical research activities for a vaccine targeting respiratory syncytial virus ("RSV"), which is the second leading cause of respiratory illness in infants, the elderly and the immunosuppressed. Currently, there is no vaccine available for this virus and Immunovaccine is seeking to develop a novel vaccine formulation to be used in the elderly and healthy adults, including women of child-bearing age. The novel RSV antigen being evaluated in DepoVax™ is based on the short hydrophobic protein present on the surface of the RSV virion. This vaccine has a unique mechanism of action, in that the resultant antibodies bind to and destroy infected cells rather than directly bind and neutralize free virus. The Corporation is currently testing the immunogenicity and efficacy in appropriate RSV challenge models such as mice. The goal is to produce the pre-clinical data required to support a future potential IND filing leading to a Phase I clinical trial in Canada. Immunovaccine recently had a meeting with Health Canada to evaluate the requirements for filing a clinical trial application (CTA). Dr. Joanne Langley, professor of pediatrics and community health and epidemiology at Dalhousie Medical School and a recent recipient of the CIHR-GSK Chair in Pediatric Vaccinology, will be the principal investigator for a Phase I study to be conducted in Halifax, Canada.

## *Bio-terrorism*

The Corporation entered into a research collaboration to advance the development of next generation bio-defense vaccines against various biological agents. These novel vaccine candidates are being evaluated as part of a study funded by the NIH that was initiated in the first quarter of 2012.

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

Preliminary findings from the immunogenicity studies include:

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

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

Key study findings include:

- A single dose of DepoVax™ containing five micrograms of recombinant PA protected rabbits exposed to a lethal anthrax dose.
- In rabbit studies, DepoVax™ formulated vaccines began producing detectable and potentially protective toxin neutralizing antibodies in as little as 14 days, with maximal protective antibody levels achieved within 28 days following a single vaccination. The titers were sustained for at least 70 days at which time a lethal anthrax challenge was performed.
- In rabbit studies, neutralizing antibodies rose further in animals receiving a second dose of the DepoVax™ recombinant PA vaccine.
- In non-human primate studies, two doses containing recombinant PA formulated in DepoVax™ triggered sustained toxin neutralizing antibodies sufficient to protect them from lethal anthrax challenge. A single dose response was not evaluated in this model.

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

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

#### *Licensing opportunities*

While the Corporation is now focused on developing a pipeline of cancer immunotherapies as well as vaccines for infectious diseases and bioterrorism applications, it is also pursuing opportunities to license the Corporation's platform technology to other parties interested in creating enhanced vaccines on an application by application basis. In 2008, the Corporation signed a license agreement with Zoetis, formerly the animal health division of Pfizer, which represented the Corporation's first milestone in validating the DepoVax™ platform technology. The Corporation has multiple licensing agreements with Zoetis for the use of the Corporation's delivery technology in cattle and other livestock vaccine applications. These license agreements include upfront signing fees, milestone payments and royalties from future vaccine sales.

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

## **MARKET OVERVIEW**

#### *Therapeutic cancer vaccines*

Cancer is considered one of the most widespread and prevalent diseases globally. According to the US Centers for Disease Control and Prevention ("CDC"), 12.7 million individuals become victims of cancer and 7.6 million individuals die from the disease annually. Conventional cancer treatment involves surgery to remove the tumor when possible, as well as chemotherapy and radiation. Chemotherapies are widely used despite their associated toxicities because they interfere with the ability of cancer cells to grow and spread. Tumors often develop resistance to chemotherapies however, limiting their efficacy in preventing tumor recurrence. Despite recent advances, independent sources note a high unmet medical need in cancer therapy noting the median survival rate remains poor. Cancer immunotherapies, including therapeutic cancer vaccines, may potentially provide a new and effective treatment option.

A better understanding of cancer immunology has led to novel strategies for the therapy of cancer that are based on activating the immune system. Initially, the approval by the US FDA of Dendreon's Provenge® for prostate cancer and Bristol-Myers Squibb's ("Bristol-Myers") Yervoy™ (ipilimumab) for melanoma resulted in increased attention and support for immunotherapy and cancer vaccine companies. More recently, the reported clinical results achieved with other immunotherapies from Merck, Bristol-Myers and Roche, including monoclonal antibody therapies

targeting PD-1, led to increased interest in this class of therapeutics from the medical community. Because of the significant potential of immune based therapies, pharmaceutical companies have recently acquired a number of experimental cancer immunotherapy products, with some being in preclinical development. These transactions have served as transformational events for a number of companies, including Amplimmune, Compugen, Immunocore, and Okairos AG.

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

The global market for cancer vaccines, including both prophylactic and therapeutic vaccines, was USD\$1.6 billion in 2010. While the majority of this reflects sales of prophylactic vaccines, the area of therapeutic cancer vaccines is projected by some industry analysts to experience significant growth. Major pharmaceutical players, such as GSK and Merck KGaA, have therapeutic cancer vaccines currently advancing in Phase III clinical trials.

#### *Infectious Diseases*

Vaccines are credited with saving millions of lives since their introduction into medical practice and the healthcare system. The reduction in morbidity and mortality caused by many infectious diseases world-wide can be directly correlated to currently available vaccines. According to data from the U.S. Centers for Disease Control and Prevention (CDC), 10 infectious diseases have been at least 90% eradicated in the United States thanks to vaccines.

However, during the past decade, diseases thought to be under control or retreating, such as plague, diphtheria, yellow fever, dengue, meningitis, influenza and malaria, have re-emerged. While the effort to control these known infectious diseases continues, more than 30 emerging diseases have been identified in humans for the first time over the past two decades.

There is an increased awareness of the impact of current and emerging infectious diseases. Demand for newer treatments and vaccines is growing globally. Decision Resources reports that the world-wide market for vaccines against infectious diseases more than doubled between 2005 and 2011. The global market for infectious diseases treatment was valued at USD\$90.4 billion in 2009.

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

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

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

RSV is a respiratory virus that infects the lungs and breathing passages. It can be severe in infants, the elderly, and patients with compromised immune systems. RSV is the single most common cause of severe respiratory illness in

infants under the age of one and is more often being recognized as an important cause of respiratory illness in older adults. Globally, it is estimated that 64 million cases of RSV infection occur annually, with 160,000 deaths.

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

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

The World Health Organization (WHO) has designated RSV as a high-priority target for vaccine development. RSV is a significant problem in the elderly, particularly if they reside in a long-term care facility or participate in other senior day-care programs. RSV attack rates in nursing homes in the USA are approximately 5 to 10% per year with a 2 to 8% case fatality rate, amounting to approximately 10,000 deaths per year among persons greater than 64 years of age. Among elderly persons followed for 3 consecutive winters, RSV infection accounted for 10.6% of hospitalizations for pneumonia, 11.4% of hospitalizations for obstructive pulmonary disease, 5.4% for congestive heart failure and 7.2% for asthma.

#### *Bio-defense*

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

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

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

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

#### *Animal Health Market*

According to industry sources, the world animal health market, defined as a sector spanning veterinary pharmaceuticals, biologics and medicated feed additives, was approximately USD\$20 billion in 2008. The animal vaccine market subdivided into livestock, companion animal and other smaller segments including equine, poultry and aquatic, makes up approximately 20% of the total animal health market. Europe is the leading market for veterinary vaccines followed closely by North America. Asia-Pacific is the fastest growing market for veterinary vaccines.

The world-wide livestock vaccine market is comprised primarily of cattle and swine vaccines, along with, to a lesser extent, vaccines for sheep, poultry and other food animals. There are only a few players in the animal vaccine

market including Zoetis, Boehringer Ingelheim, Merial, Merck Animal Health, Novartis and AgriLabs. The majority of today's vaccines for the livestock market require a booster administration, which increases the handling. Therefore, a vaccine that requires fewer doses (one dose, in some cases) for efficacy could be a significant innovation and have the potential to replace existing products.

## RECENT AND ANNUAL DEVELOPMENTS

### *Key developments and achievements*

- On January 20, 2014, the Corporation appointed Llew Keltner, M.D., Ph.D. to its board of directors. Dr. Keltner, a consultant to IMV since early 2013, serves as chairman of Raptor Pharmaceuticals Corp (NASDAQ: RPTP), a commercial stage biotechnology company based in California.
- On January 17, 2014, the Corporation granted 1,731,500 stock options to employees, consultants, officers and directors, pursuant to terms and conditions of the Corporation's stock option plan. Employees and consultants were granted an aggregate of 457,500 options and officers and directors were granted an aggregate of 1,274,000 options. The options were granted at an exercise price of \$0.74. The options for the employees, consultants and directors will vest in three equal tranches at 6, 12, and 18 months from date of grant and the options for the officers will vest in three equal tranches, the first on the date of grant and the others on the first and second anniversary of the date of grant. All options are set to expire five years from the date of grant.
- On December 12, 2013, the Corporation appointed Marc Mansour, Ph.D., the Corporation's Chief Operating Officer (COO), to its board of directors. Since joining Immunovaccine in 2001, Dr. Mansour has led the development of Immunovaccine's DepoVax™ platform and the Corporation's lead therapeutic cancer vaccine DPX-Survivac. Previously serving as Chief Science Officer, he was appointed the Corporation's Chief Operating Officer in September 2013.
- On November 21, 2013, the Corporation completed the private placement of its common shares, raising gross proceeds of \$4.2 million. Through the issuance of 10,511,209 common shares at a price of \$0.40 per share. Net proceeds from the private placement are being used for general corporate purposes. This private placement enables the Corporation to draw down on the second disbursement of the \$5 million loan from the Province of Nova Scotia described below.
- On September 9, 2013, the Corporation announced positive results from anthrax challenge studies in rabbits and non-human primates using its DepoVax™ delivery system. The studies showed that all animals administered a vaccine containing recombinant protective antigen (PA) formulated in DepoVax™ were protected against a lethal anthrax challenge. Importantly, a single dose of DepoVax™ containing five micrograms of recombinant PA protected rabbits exposed to a lethal anthrax dose. Antibody titers plateaued in rabbits within 28 days highlighting the DepoVax™ platform's potential to enable a single-dose, rapid response anthrax vaccine. These studies, conducted under the National Institute of Allergy and Infectious Diseases' (NIAID's) preclinical services program, were intended to evaluate Immunovaccine's DepoVax™ adjuvanting technology and advance the development of next generation bio-defense vaccines.
- On September 3, 2013, the Corporation announced that Albert Scardino had been appointed Executive Chairman and Marc Mansour, Ph.D. became the Chief Operating Officer of the Corporation. Mr. Scardino has served as a director of the Corporation since 2010 and as Chairman since 2011. Dr. Mansour joined Immunovaccine's scientific team 12 years ago and has served as Chief Science Officer since 2007. The two appointments come after the employment of John Trizzino, Chief Executive Officer since 2011, came to an end on August 31, 2013. Mr. Trizzino is also no longer a director of Immunovaccine.
- On August 2, 2013, the Corporation obtained a loan of \$5 million from the Province of Nova Scotia, to be used to fund a portion of working capital through 2016. The secured loan is interest bearing and repayable in 2018. The loan will be made available in four equal installments. The Corporation received the first installment of \$1.25 million after meeting customary closing conditions. While the Corporation met the

milestones to draw down the second and third disbursements, the Corporation has not requested these funds from the Province of Nova Scotia. The remaining installment will be made available based on Immunovaccine meeting certain milestones.

- On July 15, 2013, the Corporation announced that Canada's NCIC Clinical Trials Group ("NCIC CTG"), an organization supported by the Canadian Cancer Society, will sponsor and conduct a randomized Phase II study of Immunovaccine's cancer vaccine, DPX-Survivac, in patients with advanced ovarian cancer. The study is designed to assess whether IMV's vaccine therapy can delay or prevent cancer recurrence. The Phase II trial is a randomized, blinded, placebo-controlled study with DPX-Survivac in combination with low dose oral cyclophosphamide as an immune modulator. The study will enroll approximately 250 patients with ovarian cancer at an estimated 20 clinical centers. The NCIC CTG is a Canadian-based academic clinical trials cooperative group conducting large multi-center clinical trials across Canada and internationally. The agreement between NCIC CTG and Immunovaccine will provide a framework for the NCIC CTG to sponsor the randomized Phase II trial and assume responsibility for conducting the trial in accordance with good clinical practice. The Corporation is in discussion with potential co-development partners to support the NCIC CTG-sponsored trial.
- On May 30, 2013, the Corporation announced it had agreed to use its lead cancer product, DPX-Survivac, in a study based in Rome designed to extend life for glioblastoma patients. The multicenter trial will be led by Professor Marianna Nuti, Ph.D., Department of Experimental Medicine at the University of Rome, and conducted in collaboration with neurosurgeons and oncologists coordinated by Professor Maurizio Salvati, M.D. Four major trial centers across Italy will be involved, with the cost of the trial being assumed by the University. The randomized, placebo-controlled study will enroll more than 50 patients with newly diagnosed brain tumors that have been maximally resected. The study is expected to start in 2014.
- On April 16, 2013, the National Research Council of Canada Industrial Research Assistance Program (NRC IRAP) entered into an agreement to provide a financial contribution of up to \$407,700 to Immunovaccine Inc. for development of a vaccine for respiratory syncytial virus (RSV), a common lung disease in children, the elderly and patients with a compromised immune system. The funding will be used to advance the RSV program, including the formulation of RSV antigens in IMV's patented DepoVax™ vaccine adjuvanting technology.
- On March 5, 2013, the Corporation closed the a non-brokered private placement of its securities, raising gross proceeds of \$1,603,880 by the issuance of 4,860,244 common shares at a price of \$0.33 per share. Net proceeds from the financing will be used to fund preclinical research and development efforts in the areas of infectious diseases, including respiratory syncytial virus ("RSV"), malaria and anthrax.
- On January 30, 2013, the Corporation announced the signing of an Investigator-Initiated Study Agreement for the ongoing evaluation of its DPX-0907 cancer vaccine at the Busto Arsizio Hospital in Italy. Marco Bregni, M.D., head of the Oncology Unit of the Hospital of Busto Arsizio, will serve as the principal investigator for the Phase I/II DPX-0907 clinical trial in patients with breast and ovarian cancer. Immunovaccine expects the Phase I/II study to be initiated during the fourth quarter of 2013.
- On January 7, 2013, the Corporation announced further detailed positive results from a Phase I clinical study of the Corporation's cancer vaccine, DPX-Survivac, for the treatment of ovarian cancer. The analysis, which now includes all 18 patients enrolled in the study, confirmed previously reported results and uncovered new findings.
- On January 3, 2013, the Corporation announced positive results from an immunogenicity study that evaluated anthrax vaccines formulated in the Corporation's DepoVax™ platform. This study is part of an ongoing bio-defense research program which was initiated in February 2012 to utilize Immunovaccine's DepoVax™ adjuvanting technology in advancing the development of next generation vaccines against the most threatening biological agents. Study findings suggested that the DepoVax™-based vaccines provided a more rapid and long lasting immune response as compared to the licensed anthrax vaccine BioThrax™. The study, which was conducted under the National Institute of Allergy and Infectious Diseases' (NIAID) Preclinical Services Program, was designed to test multiple DepoVax™-formulated anthrax vaccines in

non-human primates, specifically examining immunogenicity and safety after either one or two doses of the vaccine. Study investigators compared the DepoVax™-based vaccines to BioThrax™, the only commercially available anthrax vaccine. BioThrax™ requires at least two doses to produce immune responses in animal models.

## SELECTED ANNUAL INFORMATION

The following table summarizes selected financial data reported by the Corporation for the years ended December 31, 2013, 2012 and 2011. The information set forth should be read in conjunction with the respective audited financial statements.

	Year ended December 31, 2013	Year ended December 31, 2012	Year ended December 31, 2011
Net loss and comprehensive loss	(4,681,000)	(6,400,000)	(6,806,000)
Weighted-average shares outstanding	68,765,650	61,788,779	53,981,559
Basic and diluted loss per share	0.07	(0.10)	(0.13)
Total assets	5,096,000	3,850,000	7,142,000
Total long-term debt	1,331,000	991,000	918,000

### Results for Fiscal 2013, compared to Fiscal 2012.

#### Net loss and comprehensive loss

The net loss and comprehensive loss of \$4,681,000 for the year ended December 31, 2013 was \$1,719,000 lower than the net loss and comprehensive loss during the year ended December 31, 2012. This relates mainly to the \$792,000 decrease in research and development (R&D) costs, a \$470,000 decrease in accreted interest, an increase in income tax recovery of \$303,000, a decrease of \$160,000 in general and administration expenses, and a decrease of \$92,000 in business development costs.

#### Operating expenses

Overall operating expenses decreased by \$1,719,000 (27%), in Fiscal 2013 compared to Fiscal 2012. Explanations of the nature of costs incurred, along with explanations of changes in those costs are discussed below.

#### *Research and development expenses*

R&D expenses include salaries and benefits, expenses associated with the Phase I and Phase Ib clinical trials of DPX-Survivac, consulting fees paid to various independent contractors who possess specific expertise required by the Corporation, the cost of animal care facilities, lab supplies, peptides and other chemicals, rental of lab facilities, insurance, as well as other minor R&D related expenses. These R&D costs are offset by government loans and assistance and by investment tax credits received in relation to the R&D expenses incurred.

Research and development expenses consist of the following:

	Year ended December 31, 2013	Year ended December 31, 2012
	\$	\$
General research and development expenses	1,708,000	1,188,000
DPX-0907 clinical expenses	-	15,000
DPX-Survivac Phase I and Phase Ib clinical expenses	1,328,000	3,036,000
Share-based compensation	59,000	115,000
Depreciation of equipment and amortization of intangible	108,000	126,000
Government assistance	(358,000)	(922,000)
Investment tax credits	(303,000)	(224,000)
Total	2,542,000	3,334,000

The majority of the Corporation's R&D efforts and related expenses for both the year ended December 31, 2013 and the year ended December 31, 2012, were costs related to the Corporation's Phase I and Phase Ib clinical trials of DPX-Survivac, \$1,328,000 and \$3,036,000, respectively. As the Phase I clinical trial for DPX-Survivac is nearing completion, the expenses associated with the Phase I clinical trial were significantly reduced from the prior year. This reduction was offset by the \$194,000 of costs associated with the Phase Ib clinical trial.

The general research and development expenses increased by \$520,000 mainly due to the pre-clinical research expenses incurred in relation to the Corporation's RSV infectious disease program. The Corporation received a government grant from the National Research Council's Industrial Research Assistance Program (NRC-IRAP) towards reimbursement of the RSV pre-clinical costs, of which \$343,000 is recorded in Fiscal 2013.

The government assistance recorded for the year ended December 31, 2012 consisted mainly of amounts realized due to the initial valuation of the interest-free government loans. Under IFRS, the government interest-free repayable loans must be initially valued at fair value and the difference between the fair value of the loans and the contribution received must be treated as government assistance.

#### *General and administrative expenses*

General and administrative expenses of \$1,853,000 for the year ended December 31, 2013, decreased by \$160,000, compared to \$2,013,000 for the year ended December 31, 2012.

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

General and administrative expenses consist of the following:

	Year ended December 31, 2013	Year ended December 31, 2012
	\$	\$
General and administrative expenses, excluding salaries	1,367,000	901,000
Salaries and benefits	1,001,000	734,000
Government assistance	(497,000)	-
Share-based compensation	(25,000)	370,000
Depreciation of equipment	7,000	8,000
<b>Total</b>	<b>1,853,000</b>	<b>2,013,000</b>

General and administrative, excluding salaries, increased by \$466,000 in Fiscal 2013, due mainly to the increase in legal fees of \$260,000 and an increase in audit fees of \$32,000, which relate mainly to the costs surrounding the cancelled public offering, legal fees associated with obtaining the loan from the Province of Nova Scotia, as well as increased patent costs compared to Fiscal 2012. The increase also relates to an increase in consulting expenses of \$104,000, a \$31,000 increase in directors fees due to having an additional director in Fiscal 2013, a \$23,000 increase in foreign exchange loss, and a \$15,000 increase in interest due to the loan from the Province of Nova Scotia. These costs were offset by a decrease in travel of \$52,000, a decrease in office expenses of \$15,000 and a decrease in regulatory fees of \$12,000. During Fiscal 2013, the Corporation incurred increased consulting fees related to the completion of a valuation model.

Salary and benefits expense increased by \$267,000 due to the severance payment made to the former Chief Executive Officer who left the Corporation on August 31, 2013. The stock-based compensation expense decreased by \$25,000 due to the forfeiture of 620,000 stock options by the former Chief Executive Officer, as well as due to timing of stock option grants.

The government assistance of \$497,000 relates entirely to the initial valuation of the low-interest bearing government loans. Under IFRS, the \$1,250,000 low-interest bearing government loan from the Province of Nova

Scotia received in August 2013 must be initially valued at fair value and the difference between the fair value of the loans and the contribution received must be treated as government assistance.

#### *Business development expenses*

The Corporation's business development and investor relations activities decreased in Fiscal 2013 by \$92,000 compared Fiscal 2012 to a total of \$841,000. This is due mainly to the decrease in investor relations activity of \$128,000, a decrease in business development related travel of \$52,000, and a decrease in marketing and communications expense of \$26,000. These costs are offset by an increase in consulting fees of \$151,000, due mainly to a new business development consultant hired to assist with potential partnering activities.

### **SUMMARY OF QUARTERLY RESULTS**

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

<b>Quarter Ended In</b>	<b>Total Revenue \$</b>	<b>Total Expenses \$</b>	<b>Loss \$</b>	<b>Basic and Diluted Loss Per Share \$</b>
<i>Q4</i> - December 31, 2013	-	1,318,000	(1,370,000)	(0.02)
<i>Q3</i> - September 30, 2013*	-	1,041,000	(1,041,000)	(0.02)
<i>Q2</i> - June 30, 2013	-	965,000	(965,000)	(0.01)
<i>Q1</i> - March 31, 2013	-	1,585,000	(1,585,000)	(0.02)
<i>Q4</i> - December 31, 2012	-	1,712,000	(1,712,000)	(0.03)
<i>Q3</i> - September 30, 2012	-	1,728,000	(1,701,000)	(0.03)
<i>Q2</i> - June 30, 2012	-	1,583,000	(1,583,000)	(0.02)
<i>Q1</i> - March 31, 2012	-	1,404,000	(1,404,000)	(0.03)
<i>Q4</i> - December 31, 2011	-	1,387,000	(1,387,000)	(0.03)

\* Under IFRS, the \$1,250,000 low-bearing interest government loan from the Province of Nova Scotia received in August 2013 must be initially valued at fair value and the difference between the fair value of the loans and the contribution received must be treated as government assistance. The loan was originally recorded at book value and subsequently adjusted at year end.

### **Results for the three months ended December 31, 2013 (“Q4 Fiscal 2013”), compared to the three months ended December 31, 2012 (“Q4 Fiscal 2012”).**

#### **Net loss and comprehensive loss**

The net loss and comprehensive loss of \$1,318,000 for Q4 Fiscal 2013 was \$394,000 lower than the net loss and comprehensive loss for Q4 Fiscal 2012. This relates mainly to the \$309,000 decrease in research and development costs, a decrease of \$59,000 in general and administrative expenses and a decrease of \$45,000 in business development expenses, offset by a \$19,000 increase to accreted interest and adjustments.

#### **Operating expenses**

Overall operating expenses decreased by \$394,000 (23%) during Q4 Fiscal 2013 compared to Q4 Fiscal 2012. Explanations of the nature of costs incurred, along with explanations of changes in those costs are discussed below.

#### *Research and development expenses*

R&D expenses include salaries and benefits, expenses associated with the Phase I clinical trial of DPX-Survivac, consulting fees paid to various independent contractors who possess specific expertise required by the Corporation, the cost of animal care facilities, lab supplies, peptides and other chemicals, rental of lab facilities, insurance, as well as other minor R&D related expenses. These R&D costs are offset by government loans and assistance and by investment tax credits received in relation to the R&D expenses incurred.

The Corporation's R&D efforts and related expenses for Q3 Fiscal 2013 included costs surrounding the Corporation's Phase I clinical trial of DPX-Survivac and costs related to the Corporation's ongoing R&D activities associated with the investigation, analysis and evaluation of other potential vaccine candidates and technologies.

Research and development expenses consist of the following:

	Q4 Fiscal 2013	Q4 Fiscal 2012
	\$	\$
General research and development expenses	710,000	291,000
DPX-Survivac preclinical and clinical expenses	202,000	742,000
Stock-based compensation	(25,000)	17,000
Depreciation of equipment and amortization of intangible	26,000	32,000
Government loans and assistance	(99,000)	(62,000)
Investment tax credits	(117,000)	15,000
<b>Total</b>	<b>697,000</b>	<b>1,035,000</b>

The largest component of R&D expense for Q4 Fiscal 2013 was the preclinical work performed on the Corporation's RSV infectious disease program. As the DPX-Survivac Phase I clinical trial is nearing completion, the Corporation's resources were centered on supporting pre-clinical studies in infectious diseases and supporting the preparation of the Phase I/II clinical trials in Italy. The government loans and assistance recorded in Q4 Fiscal 2013 consists mainly of non-repayable government grants for the RSV pre-clinical studies, in comparison to amounts recorded in Q4 Fiscal 2012 which consisted mainly of the revaluation of the interest-free government loans. Under IFRS, the interest-free repayable government loans must be initially valued at fair value and the difference between the fair value of the loans and the contribution received must be treated as government assistance.

#### *General and administrative expenses*

General and administrative expenses of \$423,000 represented 31% of total expenses for Q4 Fiscal 2013 compared to \$482,000 (28% of total expenses) for Q4 Fiscal 2012, an overall decrease of \$59,000 (12%).

G&A expenses include salaries and benefits, directors' fees, legal fees, audit and taxation cost, consulting fees, travel, rental of office facilities, insurance, regulatory fees, stock-based compensation, depreciation of equipment and other minor office expenses.

General and administrative expenses consist of the following:

	Q4 Fiscal 2013	Q4 Fiscal 2012
	\$	\$
General and administrative expenses, excluding salaries	311,000	255,000
Salaries and benefits	63,000	176,000
Stock-based compensation	47,000	49,000
Depreciation of equipment	2,000	2,000
<b>Total</b>	<b>423,000</b>	<b>482,000</b>

G&A expenses, excluding salaries, increased by \$56,000 due mainly to the increase in legal fees of \$17,000 due to increased patent costs, the increase in directors' fees of \$13,000 due to the increased number of board meetings in Q4 Fiscal 2013 and the increase in interest charges of \$11,000 due to the interest on the loan from the Province of Nova Scotia. Salary and benefits expense decreased by \$113,000 due to the departure of the former Chief Executive Officer who left the Corporation on August 31, 2013.

#### *Business development expenses*

The Corporation's business development activities decreased in Q4 Fiscal 2013 by \$45,000, compared to Q4 Fiscal 2012, to a total of \$168,000. This is due mainly to the decrease in investor relations activity of \$66,000, a decrease of \$22,000 in legal fees, a decrease of \$15,000 in marketing and communications expense and a decrease of \$15,000

in travel costs. These costs are offset by an increase in consulting fees of \$69,000, due mainly to a new business development consultant hired to assist with potential partnering activities.

## **CASH FLOWS, LIQUIDITY AND CAPITAL RESOURCES**

At December 31, 2013, the Corporation had cash and cash equivalents of \$3,536,000 and working capital of \$3,317,000, compared to \$2,002,000 and \$2,064,000, respectively at December 31, 2012.

Since the Corporation's inception, the Corporation's operations have been financed through the issuance of shares, debt, revenue from animal health licenses, interest income on funds available for investment, government assistance and tax credits.

During the year ended December 31, 2013, cash of \$5,278,000 was used in operating activities. This included the reported net loss of \$4,681,000 prior to being decreased for non-cash amortization, non-cash depreciation, non-cash accretion of long-term debt, non-cash stock-based compensation, and fair value adjustment to long-term debt. The Corporation had a net source of cash of \$304,000 as a result of non-cash changes in working capital balances.

Sources of cash raised through financing activities were \$5,808,000 in two private placements, less share issuance costs of \$153,000 and \$1,250,000 through the drawdown of the first disbursement of the \$5,000,000 repayable loan from the Province of Nova Scotia, as described below. Use of cash through financing activities was \$90,000 in repayment of long-term debt.

During the year ended December 31, 2013, the Corporation purchased \$7,000 worth of equipment for ongoing research and operating activities.

On March 5, 2013, the Corporation completed a private placement of 4,860,244 shares at a price of \$0.33 per common share for aggregate gross proceeds of \$1,603,880. Total costs associated with the offering were \$50,881, including a finder's fee of 4% of a portion of the gross proceeds, totaling \$15,708, which was paid through the issuance of 47,600 common shares at a deemed price of \$0.33 per common share. The remaining costs were associated with professional fees and regulatory fees.

On August 2, 2013, the Corporation secured a \$5,000,000 repayable loan from the Province of Nova Scotia, through the Economic and Rural Development and Tourism ("ERDT") department. According to the terms of the agreement, the secured loan is interest bearing at a rate equal to ERDT's cost of funds plus 1%, compounded semi-annually and payable monthly. The loan will be made available in four equal installments based on the Corporation meeting certain milestones, and is repayable on the fifth anniversary of the date of the first disbursement. The Corporation received the first disbursement of \$1,250,000 on August 9, 2013.

On November 21, 2013, the Corporation completed a private placement of 10,511,209 shares at a price of \$0.40 per common share for aggregate gross proceeds of \$4,204,484. In connection with the private placement, the Corporation agreed to pay finders' fees representing an aggregate of \$82,562 in cash, along with 167,218 common shares and 50,925 compensation options, each compensation option entitling its holder to purchase one common share at a price of \$0.40 per share until May 21, 2015.

The Corporation aims to maintain adequate cash and cash resources to support the planned activities which include the completion of the Phase 1b DPX-Survivac clinical trial program, other research and development activities, business development efforts, administration costs and intellectual property maintenance and expansion. At December 31, 2013, the Corporation had approximately \$4.3 million of existing and identified potential sources of cash including:

- cash and equivalents of \$3.5 million; and
- amounts receivable and investment tax credits receivable of \$0.8 million.

For Fiscal 2013, the Corporation's quarterly "cash burn rate" (defined as net loss for the period adjusted for non-cash transactions including amortization, depreciation, accretion of long-term debt, and stock-based compensation) was approximately \$1.4 million. The Corporation forecasts the cash burn rate to be between \$1.3 million to \$1.4

million per quarter over the next twelve months, as it concludes the Phase Ib clinical trial for DPX-Survivac and pre-clinical studies on RSV.

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

While the Corporation has secured the \$5,000,000 loan from the Province of Nova Scotia and has recently raised \$4,200,000 in a private placement, management believes that its cash and cash resources may not be sufficient to fund operations for the next twelve months. Although the addition of the loan with the current existing and identified sources of cash appears to provide the Corporation with sufficient funding for the next twelve months, the Corporation must meet certain milestones to draw down on the loan and there is no certainty that the Corporation will be able to do so. The ability of the Corporation to continue as a going concern is dependent upon meeting the required milestones of the loan, and/or raising additional financing through equity and non-dilutive funding and partnerships. There can be no assurance that the Corporation will have sufficient capital to fund its ongoing operations, develop or commercialize any products without future financings. There can be no assurance that additional financing will be available on acceptable terms or at all. The Corporation is currently pursuing financing alternatives that may include equity, debt, and non-dilutive financing alternatives including co-development through potential collaborations, strategic partnerships or other transactions with third parties, that may or may not include merger and acquisitions activities. If the Corporation is unable to obtain additional financing when required, the Corporation may have to substantially reduce or eliminate planned expenditures or the Corporation may be unable to continue operations. These uncertainties cast doubt as to the ability of the Corporation to meet its obligations as they come due and, accordingly, the appropriateness of the use of accounting principles applicable to a going concern.

## **RELATED PARTY TRANSACTIONS**

During the year ended December 31, 2013, the Corporation paid a payroll liability on behalf of an officer. As at December 31, 2013, there are no related party receivables.

## **DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROLS OVER FINANCIAL REPORTING**

Disclosure controls and procedures ("DC&P") are intended to provide reasonable assurance that material information is gathered and reported to senior management to permit timely decisions regarding public disclosure. Internal controls over financial reporting ("ICFR") are intended to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with Canadian generally accepted accounting principles.

"Venture Issuers" as defined in National Instrument 52-109 – Certification of Disclosure in Issuers' Annual and Interim Filings ("NI 52-109") are not required to provide representations in their annual and interim filings relating to the establishment and maintenance of DC&P and ICFR, as defined in NI 52-109. In particular, the certifying officers do not make any representations relating to the establishment and maintenance of: (a) controls and other procedures designed to provide reasonable assurance that information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and (b) processes to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with the issuer's generally accepted accounting principles (IFRS).

## **SIGNIFICANT ESTIMATES**

The audited annual consolidated financial statements as at December 31, 2013 have been prepared in accordance with IFRS. Significant accounting estimates used in preparing the unaudited interim condensed consolidated financial statements include the initial fair valuation of long-term debt, the calculation of the carrying amount of long-term debt, the scientific research and experimental development (“SRED”) tax credits receivable, the fair value allocation of consideration for multiple element revenue arrangements, non-cash stock-based compensation expense, amortization and depreciation of intangibles and property and equipment, allocation of proceeds between common shares and warrants, and accrued liabilities.

Management has calculated the fair value of the interest-free government loans based on the forecast of the Corporation’s future revenue, discounted at an appropriate discount rate. The estimates and assumptions used in the valuation model were based on current information available to management and a degree of management’s judgment. A change in management’s assumptions used to forecast future revenue or a change in the discount rate could have a significant impact on the fair value of these interest-free government loans. Management has estimated the SRED receivable based on its assessment of tax credits receivable on eligible expenditures incurred during the period and its experience with claims filed with and collected from the Canada Revenue Agency. Management has analyzed the amounts receivable listing for potentially uncollectible amounts and has allowed for all balances which collection is doubtful. Management has made estimates regarding when stock options might be exercised and stock price volatility in calculating non-cash stock based compensation. The timing for exercise of options is out of the Corporation’s control and will depend on a variety of factors including the market value of the Corporation’s shares and the financial objectives of the stock-based instrument holders. Management has made estimates about the expected useful lives of long-lived assets, and the expected residual values of the assets. Management has determined the allocation of proceeds between common shares and warrants based on the relative values of the shares and warrants issued. Through knowledge of the Corporation’s activities in the year ended December 31, 2013, management has estimated the amount of accrued liabilities to be recorded.

## **OUTSTANDING SECURITIES**

The number of issued and outstanding common shares of the Corporation on March 14, 2014 is 79,258,923. The number of outstanding stock options on March 14, 2014 is 5,242,185. The outstanding stock options have a weighted average exercise price of \$0.71 per share and a weighted average remaining term of 3.14 years. The number of outstanding warrants on March 14, 2014 is 50,925. The outstanding warrants have a weighted average exercise price of \$0.40 per share and a weighted average remaining term of 1.14 years.

## **INTELLECTUAL PROPERTY RIGHTS**

The Corporation strives to protect its intellectual property in established, as well as emerging, markets around the world. The Corporation’s intellectual property portfolio for its vaccine platform technology includes five patent families, the first of which contains five patents issued in four jurisdictions (US, Europe, Japan and Australia) and two pending patent applications in the US and Canada. The four other families collectively contain 33 pending patent applications in eleven jurisdictions. US Patent 6,793,923, issued in 2004, contains claims to the Corporation’s platform, covering “any antigen, any adjuvant in any liposome and any oil”. An additional patent application for a DepoVax™ formulation was submitted in 2012. The Corporation’s platform name, DepoVax™, is protected by trademarks registered in the US, Canada and Europe.

Additional granted patents include:

- Europe patent 1,333,858, patent granted February 8, 2006;
- Japan patent 2002-540757, patent granted August 1, 2008;
- Australia patent, 202214861, patent granted January 11, 2007;
- Australia patent, 2006301891, patent granted December 20, 2012; and
- Chinese Patent No. ZL 2006 8 0036783.2, patent granted September 18, 2013.

Since 2008, Immunovaccine has filed five patent cooperation treaty (PCT) applications relating to the VacciMax® and DepoVax™ technologies, some or all of which have now been filed in the US, Europe, Japan, Canada, Australia, China, India, Brazil, Israel, Hong Kong and Singapore. These PCT applications cover specific

DepoVax™ compositions with broad utility for infectious diseases and cancer applications or a Survivin vaccine. If allowed, these patent applications may extend patent protection for some or all DepoVax™-based vaccines approximately up to the year 2033.

The licensing agreement between the Corporation and Immunotope for the seven antigens included in the DPX-0907 vaccine candidate stipulates that the Corporation will assume the cost of prosecuting and maintaining patent applications and issued patents relating to the peptide antigens under license. These antigens are protected by two issued patents in the US and pending patent applications in the US and Europe. A European patent application was recently refused by the European Patent Office. An appeal is underway and the outcome for this particular application in Europe remains uncertain. Additional divisional applications have been filed in Europe. The DPX-0907 vaccine candidate remains protected by granted patents and patent applications (Canada, US, Europe, Japan, Australia, China, India, Brazil, Israel, Hong Kong and Singapore) relating to the core vaccine delivery platform, as well as US patents (7,083,789 and allowed application 11/426,16) and patent applications in the US and Europe relating to the seven peptide antigens.

## **FINANCIAL INSTRUMENTS**

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

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

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

The Corporation has implemented the following classifications:

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

## **RISK ASSESSMENT**

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

- achieve or maintain profitability after incurring significant losses since inception and expect to incur losses for the foreseeable future;
- obtain substantial funding when needed before being forced to delay, reduce, terminate or eliminate product development programs;
- raise additional capital on reasonable terms without causing significant dilution to existing shareholders, restrict operations or require the Corporation to relinquish rights to its technologies or product candidates;
- obtain positive results of clinical trials, including clinical trials on DPX-Survivac and DPX-0907, as the Corporation depends heavily on their success;

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

The risks identified above do not include all possible risks as there may be other risks of which management is currently unaware. The above risks and other general risks and uncertainties relating to the Corporation and its activities are more fully described in the Annual Information Form of the Corporation for the year ended December 31, 2013, under the heading “Risk Factors and Uncertainties”.

#### **OFF BALANCE SHEET ARRANGEMENTS**

The Corporation was not party to any off balance sheet arrangements as of December 31, 2013.