ANNUAL INFORMATION FORM

FOR THE YEAR ENDED DECEMBER 31, 2019

March 30, 2020
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I. INTRODUCTION AND FORWARD-LOOKING STATEMENTS

The information contained in this Annual Information Form is stated as at December 31, 2019, unless otherwise indicated. Unless otherwise indicated or if the context otherwise requires, “IMV”, “the Corporation”, “we”, “us” and “our” refer collectively to IMV Inc., 130 Eileen Stubbs Avenue, Suite 19, Dartmouth, Nova Scotia, Canada, B3B 2C4 and to its subsidiary, Immunovaccine Technologies Inc. (“IVT”).

Unless specified otherwise, all amounts are presented in Canadian dollars.

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

- The Corporation’s business strategy;
- Statements with respect to the sufficiency of the Corporation’s financial resources to support its activities;
- Potential sources of funding;
- The Corporation’s ability to obtain necessary funding on favorable terms or at all;
- The Corporation’s expected expenditures and accumulated deficit level;
- The Corporation’s expected outcomes from its ongoing and future research and research collaborations;
- The Corporation’s ability to obtain necessary regulatory approvals;
- The Corporation’s expected outcomes from its pre-clinical studies and trials;
- The Corporation’s exploration of opportunities to maximize shareholder value as part of the ordinary course of its business through collaborations, strategic partnerships, and other transactions with third parties;
- The Corporation’s plans for the research and development of certain product candidates;
- The Corporation’s strategy for protecting its intellectual property;
- The Corporation’s ability to identify licensable products or research suitable for licensing and commercialization;
- The Corporation’s ability to obtain licences on commercially reasonable terms;
- The Corporation’s plans for generating revenue;
- The Corporation’s plans for future clinical trials; and
- The Corporation’s hiring and retention of skilled staff.
Forward-looking statements involve significant risks and uncertainties, should not be read as guarantees of future performance or results, and will not necessarily be accurate indications of whether or not such results will be achieved. A number of factors could cause actual results to differ materially from the results discussed in the forward-looking statements, including, but not limited to, the factors discussed under the heading “Risk Factors and Uncertainties”. Although the forward-looking statements contained in this AIF are based upon what management of the Corporation believes are reasonable assumptions, the Corporation cannot provide any assurance to investors that actual results will be consistent with these forward-looking statements and should not be unduly relied upon by investors.

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

- Obtaining additional funding on reasonable terms when necessary;
- Positive results of pre-clinical studies and clinical trials;
- The Corporation’s ability to successfully develop existing and new products;
- The Corporation’s ability to hire and retain skilled staff;
- The products and technology offered by the Corporation’s competitors;
- General business and economic conditions, including as a result of the pandemic outbreak of COVID-19
- The Corporation’s ability to protect its intellectual property;
- The Corporation’s ability to manufacture its products and to meet demand;
- The general regulatory environment in which the Corporation operates; and
- Obtaining necessary regulatory approvals and the timing in respect thereof.

These statements reflect management’s current views and beliefs and are based on estimates, assumptions, and information currently available to, and considered reasonable by, management. The forward looking information in this MD&A does not include a full assessment or reflection of the unprecedented impacts of the COVID-19 pandemic occurring in the first quarter of 2020 and the ongoing and developing resulting indirect global and regional economic impacts. The Corporation is currently experiencing uncertainty related to the rapidly developing COVID-19 situation. It is anticipated that the spread of COVID-19 and global measures to contain it, will have an impact on the Corporation, however it is challenging to quantify the potential magnitude of such impact at this time. The Corporation is regularly assessing the situation and remains in contact with its partners, clinical sites and investigators, and suppliers to assess any impacts and risks.

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

The Corporation was incorporated on May 18, 2007 under the name of Rhino Resources Inc. pursuant to the Canada Business Corporations Act. In September 2009, the Corporation changed its name to Immunovaccine Inc. and consolidated its outstanding share capital on a 5 to 1 basis. On May 2, 2018, the Corporation changed its name to IMV Inc. and consolidated its outstanding share capital on a 3.2 to 1 basis. The Corporation’s head and registered office is located at 130 Eileen Stubbs Avenue, Suite 19, Dartmouth, Nova Scotia, Canada, B3B 2C4.

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

III. GENERAL DEVELOPMENT OF THE BUSINESS

Overview

IMV is a clinical-stage biopharmaceutical company dedicated to making immunotherapy more effective, more broadly applicable, and more widely available to people facing cancer, infectious and other serious diseases. IMV is headquartered in Dartmouth, Nova Scotia and has an office in Quebec City, Quebec and as at December 31, 2019, had 62 full time employees. IMV is pioneering a new class of immunotherapies based on the Corporation’s proprietary drug delivery platform (“DPX”). This patented technology leverages a novel mechanism of action (“MOA”) discovered by the Corporation. This MOA does not release the active ingredients at the site of injection but forces an active uptake by immune cells (antigen-presenting cells) and delivery of active ingredients into lymph nodes. This unique MOA enables the programming of immune cells in vivo, which are aimed at generating powerful target-specific therapeutic capabilities. DPX’s no-release MOA can be leveraged to generate “first-in-class” T cell therapies with the potential, in the opinion of IMV, to be disruptive in the treatment of cancer. DPX also has multiple manufacturing advantages: it is fully synthetic; can accommodate hydrophilic and hydrophobic compounds; is amenable to a wide-range of applications (for example, peptides, small-molecules, RNA/DNA and antibodies); and provides long term stability as well as low cost of goods.

The Corporation’s first cancer immunotherapy uses survivin-based peptides licensed from Merck KGaA, on a world-wide exclusive basis, formulated in DPX (“DPX-Survivac”). Survivin is a well characterized and tumor-associated antigen known to be overexpressed in more than 20 different cancers. DPX-Survivac leverages the MOA of the DPX platform to generate a constant flow of killer T cells in the blood that are targeted against survivin expressed on cancer cells. It is comprised of five minimal MHC class I peptides to activate naïve T cells against survivin.

Survivin is a well characterized and recognized tumour associated antigen known to be expressed during fetal development and across most tumour cell types, but it is rarely present in normal, non-malignant adult cells. Survivin controls key cancer processes (apoptosis, cell division and metastasis) and has been associated with chemoresistance and cancer progression. It has been shown that survivin was expressed in all 60 different human tumour lines used in the National Cancer Institute’s cancer drug screening program and documented in the literature to be overexpressed in more than 20 indications.

Foremost, the Corporation’s clinical strategy is to target late stage unmet medical needs for a shorter path to clinical demonstration and first regulatory approval. In addition, the Corporation is evaluating combination with Merck’s Keytruda® checkpoint inhibitor in multiple solid tumor indications.
DPX-Survivac is currently being tested in:

- A phase 2 clinical trial that evaluates DPX-Survivac in an open label safety and efficacy study in ovarian cancer patients with advanced platinum-sensitive and resistant ovarian cancer;
- Two investigator-sponsored phase 2 clinical trials in combination with the checkpoint inhibitor Keytruda® (pembrolizumab) of Merck & Co Inc. (“Merck”) in patients with recurrent, platinum-resistant and sensitive ovarian cancer and in patients with measurable or recurrent diffuse large B cell lymphoma (“DLBCL”); and
- A phase 2 basket trial in combination with Merck’s Keytruda® (pembrolizumab) in patients with select advanced or recurrent solid tumors in bladder, liver (hepatocellular carcinoma), ovarian, or non-small-cell lung (“NSCLC”) cancers, as well as tumors shown to be positive for the microsatellite instability high (MSI-H) biomarker.

In infectious disease vaccine applications, the Corporation has completed a demonstration phase 1 clinical trial with a target against the respiratory syncytial virus (“RSV”). The Corporation also has a commercial licensing agreement with Zoetis for the development of two targeted therapies for cattle and is also conducting several research and clinical collaborations, including collaborations with:

- The Canadian Center for Vaccinology (“CCIV”) at Dalhousie University, the Izaak Walton Killam Health Center and the Nova Scotia Health Authority, the Canadian Immunization Research Network (“CIRN”); the Research Centre on Infectious Diseases at the University Laval in Quebec City and Global Urgent and Advanced Research and Development (“GUARD”) in Canada for the development of a vaccine candidate for coronavirus (“COVID-19”);
- The Wistar Institute to develop a targeted T cell therapy against the common BRAF cancer mutation;
- the Dana-Farber Cancer Institute (“Dana-Farber”) for Human Papillomavirus (“HPV”) related cancers; and
- Leidos, Inc. (“Leidos”) in the United States for the development of targeted therapies for malaria and the Zika virus.

The common shares of the Corporation (the “Common Shares”) are listed on the Nasdaq Stock Market LLC (“Nasdaq”) and on the Toronto Stock Exchange (“TSX”) under the symbol “IMV”.

History

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

From 2000 to 2008, the Corporation concentrated its research efforts on animal contraception for both wildlife and companion animals, while also working on vaccines for infectious diseases in livestock with CSL Animal Health, a division of CSL Limited, which was subsequently acquired by Pfizer Inc. (“Pfizer”). The Pfizer Animal Health division was later spun out into Zoetis.

Over those years the Corporation continued to develop its various technologies and began exploring potential new human applications. This research eventually led to acquiring survivin cancer targets from
Merck KGaA. Using traditional vaccine delivery technology, Merck had been unable to generate optimal T cell activation. Reformulating survivin cancer targets in its DPX delivery platform, IMV saw different results in preclinical research highlighting the potential for the treatment of human cancers. Thus, the Corporation’s first clinical candidate, DPX-Survivac, emerged. Since then, several clinical studies have demonstrated the potential of DPX-Survivac in cancer and today the corporation is continuing its development in 6 different cancer indications across multiple phase 2 studies.

Recent Developments

In March 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. We continue to monitor the COVID-19 situation, which is rapidly developing. In addition to adhering to directives from public health officials, we have implemented a pandemic contingency plan to guide our employees, contractors, visitors, facilities and operations. Our plan includes identifying essential business activities to help ensure continuity of business, restricting access to our offices and operation sites and encouraging all employees to work from home to the extent possible, asking business partners to engage us by telephone or video conference where possible, eliminating business travel and requiring self-isolation for employees travelling outside of Canada and increasing the frequency and emphasis on cleaning and sanitizing. As the COVID-19 health-crisis further develops, we will continue to rely on guidance and recommendations from local health authorities and the Centers for Disease Control and Prevention to update our policies.

Since January 1, 2020, the Corporation has announced:

- On March 30, 2020, that it has made significant progress on the development of DPX-COVID-19, a vaccine candidate against the novel coronavirus, including:
  - The Corporation has used sequences of the virus and immunoinformatics to predict and identify several hundred epitopes, of which 23 were selected for their biological relevance to the virus and potential to generate neutralizing antibodies against SARS-CoV-2;
  - Based on this analysis, IMV has begun manufacturing peptide candidates targeting these epitopes as well as planning with IMV’s suppliers and contract manufacturers to prepare for the cGMP batch required to support a clinical study in humans;
  - In collaboration with Gary Kobinger, Ph.D., Director of the Research Centre on Infectious Diseases at the University Laval in Quebec City, preclinical assays in animal models are also planned in April through May of this year to validate the safety and potency of the vaccine candidate before initiating the human clinical study;
  - In collaboration with Joanne Langley, M.D. at the Canadian Center for Vaccinology (CCfV) and the Canadian Immunization Research Network (CIRN) the design of a Phase 1 clinical study in 48 healthy subjects has been completed and clinical sites identified in both Nova Scotia and Quebec;
  - IMV has initiated discussions with Health Canada in preparation for a Clinical Trial Application (CTA). A meeting is being scheduled in the week of April 20, 2020 with the goal to initiate the clinical study in the summer of 2020; and
  - The company has submitted several grant applications in Canada in an effort to help support its clinical program.
On March 18, 2020, that it is advancing the clinical development of a DPX-based vaccine candidate against COVID-19. The goal of the development program, in collaboration with lead investigators for the phase 1 clinical study: Joanne Langley, M.D. and Scott Halperin, M.D., of the CCfV at Dalhousie University, the Izaak Walton Killam Health Center and the Nova Scotia Health Authority and the CIRN; along with Dr. Gary Kobinger, Ph.D., Director of the Research Centre on Infectious Diseases at the University Laval in Quebec City and GUARD in Canada, is to establish the clinical safety and immunogenicity of a vaccine candidate based on the Corporation’s DPX delivery technology and incorporating peptides targeting novel epitopes from the coronavirus strain.

On March 18, 2020, that is has entered into an equity distribution agreement with Piper Sandler & Co. (“Piper Sandler”), pursuant to which the Corporation may, from time to time sell, through “at-the-market” offerings with Piper Sandler acting as sales agent, on the Nasdaq such number of Common Shares as would have an aggregate offering price of up to US$30 million (the “ATM Distribution”). The Corporation plans to use the net proceeds from the ATM Distribution, if any, for general corporate purposes, including but not limited to working capital expenditures, capital expenditures, research and development expenditures, and clinical trial expenditures, including expenditures related to a COVID-19 vaccine candidate.

On February 25, 2020, that updated results from DeCidE1, an ongoing Phase 2 study of its lead candidate, DPX-Survivac, in patients with advanced recurrent ovarian cancer were reported during a conference call and webcast.

All 22 patients with advanced recurrent ovarian cancer enrolled in this arm of the study were heavily pre-treated, with the median number of therapies, prior to receiving DPX-Survivac, greater than three.

As of February 24, 2020, 19 patients were evaluable for efficacy with six patients (31%) still receiving treatment. Key preliminary findings are outlined below:

- 15 patients (79%) achieved disease control, defined as Stable Disease (“SD”) or Partial Response (“PR”) on target lesions:
  - Tumor shrinkage of target lesions was observed in 10 patients (53%).

- Durable clinical benefits lasting ≥ 6 months were observed in seven patients (37%) so far:
  - Four of these seven patients (21% of evaluable patients) achieved PR with tumor regression > 30% on target lesions;
  - Three stable diseases were ongoing for > 6 months (range 7-9) including -29.5% and -12% tumor regressions; and
  - Median duration not reached yet, with five of these seven (71%) patients still on treatment at > 6 months (range 7-10).

- Analysis of Baseline Tumor Burden (“BTB”) showed durable clinical benefits across a broad range of BTB (1.5-7.7 cm) with a higher number of patients achieving benefits in BTB < 5 cm as previously observed in other arms of the study:
  - Six out 11 with BTB < 5 cm (55%) achieved clinical benefits lasting > 6 months.

- Durable clinical benefits include platinum-resistant and refractory patients who previously received PARP inhibitors and bevacizumab; and
Treatment was well-tolerated, with most adverse events being Grade 1-2 reactions at the injection site.

- On February 14, 2020, that Albert Scardino was to retire from the IMV Board of Directors effective February 28th, 2020.
- On February 4, 2020, the presentation of clinical translational data supporting the mechanism of action of its lead compound, DPX-Survivac, during the 2020 ASCO-SITC Clinical Immuno-Oncology Symposium, being held in Orlando, FL.

As part of this analysis, the Corporation measured systemic immune responses, tumor immune infiltrates and clinical tumor response from pre- and post-treatment patient samples in connection with three Phase 1 and/or Phase 2 clinical studies, each evaluating DPX-Survivac alone or in a combination regimen in patients with platinum-sensitive or resistant, advanced ovarian cancer. Highlights from these translational data include:

- DPX-Survivac generated survivin-specific T cells in the blood of 80% of patients sampled;
- Clinical anti-tumor responses were correlated with increased infiltration of T cells into tumors following treatment with DPX-Survivac;
- DPX-Survivac induced enrichment in T cell, cytotoxic lymphocytes and B cell-specific signatures which correlate with clinical response; and
- Antigen-specific T cells retained their functionality throughout the duration of treatment.

**Overview of the Last 3 Years**

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

**Year ended December 31, 2019**

- On December 8, 2019, the Corporation announced updated results on the SPiReL study, an ongoing Phase 2 investigator-sponsored study of DPX-Survivac in combination with pembrolizumab in patients with recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL) that were presented in a poster session at the 61st American Society of Hematology (“ASH”) Annual Meeting in Orlando, FL.

In the poster presentation, Dr. Neil Berinstein reported updated clinical results from the ongoing Phase 2 SPiReL study. Highlights of this preliminary data are outlined below:

- 7/9 (77.8%) evaluable subjects exhibited clinical benefit, including three (33.3%) complete responses and two (22.2%) partial responses;
- Reproducible survivin-specific T cell responses observed in all subjects that achieved clinical responses on treatment;
- One subject, who received three prior lines of systemic therapies and failed autologous stem cell transplant, reached a complete response at the first on-study scan following treatment with the DPX-Survivac combination regimen and remains free of disease recurrence after completing the study; and
Clinical benefits and favorable toxicity profile observed in a heterogeneous population of r/r DLBCL patients, including patients of advanced age and/or with comorbidities, who are more susceptible to adverse effects and more difficult to treat.

- On October 30, 2019, the Corporation announced the appointment of Dr. Joanne Schindler, M.D., D.V.M. as its new Chief Medical Officer, effective November 4, 2019. Dr. Schindler brings over 15 years of experience in the biopharmaceutical industry, primarily in early-stage oncology drug development. Most recently, she had served as Vice President, Clinical Development and Executive Medical Director at H3 Biomedicine, overseeing the company’s clinical development efforts.

- On September 30, 2019, IMV presented preliminary results from its ongoing Phase 2 basket trial, during the Immunotherapy of Cancer poster session at the European Society for Medical Oncology (ESMO) 2019 Congress in Barcelona, Spain.

  Preliminary results from the phase 2 Basket Trial:

  o At the time of cut-off, 23 patients were enrolled across all five patient cohorts. This includes 19 patients across all cohorts who received DPX-Survivac in combination with pembrolizumab with CPA, and four patients from the ovarian cancer cohort receiving DPX-Survivac with only pembrolizumab;

  o Preliminary results from the first on-study scan showed tumor reduction in patients with ovarian cancer (with and without CPA), NSCLC and bladder cancer;

  o Partial responses observed at first scan in two subjects (bladder cancer, ovarian cancer); 19 out of 23 subjects are still active on study treatment;

  o T cell infiltration observed in biopsy samples from subjects who achieved tumor reduction on treatment;

  o Eight ovarian cancer patients were enrolled in the study, randomized 1:1 to treatment with and without CPA; Tumor control and tumor reductions were observed in both groups; and

  o Safety evaluation on all evaluable patients demonstrated that treatment was well-tolerated, with no related Grade 3-4 or immune-related adverse events (“AEs”) reported.

- On September 4, 2019, the Corporation announced a collaboration with The Wistar Institute and Meenhard Herlyn, D.V.M., D.Sc., professor in the Molecular and Cellular Oncogenesis Program and director of Wistar’s Melanoma Research Center.

Under this collaboration, IMV and The Wistar Institute will partner to develop a targeted T cell therapy against the common BRAF cancer mutation, based on peptides identified by the Herlyn lab. Mutations in this gene are the most frequently identified cancer-causing mutations in melanoma and have been identified in various other cancers, including non-Hodgkin lymphoma, colorectal cancer, thyroid cancer, and non-small cell lung and ovarian carcinomas.

The project scope includes optimizing the DPX formulation with the BRAF peptides and testing the investigational T cell therapy in the pioneering pre-clinical research models at Wistar. As part of the collaboration agreement, IMV holds an exclusive option to in-license intellectual property related to the program.
• On June 12, 2019, IMV provided updated data on the phase 2 combination trial with Merck’s Keytruda® (pembrolizumab) in DLBCL and at the first “on treatment” assessment, five of the first six patients demonstrated clinical benefit, including four patients with tumor regressions. Two patients reached a complete radiological response, one a partial response and two had stable disease while on study. In addition, the combination continued to demonstrate an acceptable safety profile.

Updated SPIReL data highlights:

At the time of data cut-off for this analysis, 11 patients were enrolled in the trial. Efficacy data from the first six evaluable patients are based on modified Cheson criteria:

- Two patients achieved a complete radiological response:
  - These patients have shown the best survivin specific T-cell responses to DPX-Survivac among the analyzed samples; and
  - One patient with a complete response (“CR”) has completed the one-year study period.

- One patient achieved a PR at first on treatment scan;

- Two patients have reached stable disease:
  - Each of these patients has remained progression free for six and eight months while on treatment.

- Objective response rate (“ORR”): 3/6 (50%);

- Disease Control Rate (DCR): 5/6 (83%);

- One patient with bulky disease progressed at first scan;

- Two subjects are not evaluable, coming off trial at day seven and day 28;

- The treatment combination appears to be well tolerated with only two serious adverse events related to treatment (low white blood count and low neutrophil count); and

- Radiological results from three additional patients are pending.

• On June 3, 2019, investigators shared new positive data for IMV’s DeCidE1 clinical trial at the 2019 American Society for Clinical Oncology (“ASCO”) annual meeting.

New data from evaluable patients from the phase 2 monotherapy arm of the trial indicated the potential for DPX-Survivac to impact solid tumor growth in hard-to-treat ovarian cancer patients. Longer-term follow-up from the phase 1b portion of the trial continued to demonstrate that the levels of survivin-specific T cells in the blood of patients – a measure of DPX-Survivac’s novel MOA – correlated with durable clinical benefits.

In a poster presentation, Dr. Janos L. Tanyi, MD, PhD, assistant professor of obstetrics and gynecology at the Hospital of the University of Pennsylvania, provided an update on the clinical
results from the first patients enrolled in the phase 2 monotherapy cohort. At the time of the presentation, researchers had enrolled 19 of 28 participants to date:

- Of seven patients evaluable at data cut-off in the monotherapy arm, five showed signs of treatment benefits, including reduction of target lesions in two patients, while two patients progressed;
- Within the group of four patients with low tumor burden – a potential predictor of response – three showed stable diseases including two reductions in tumor burden continuing the positive trend seen in earlier results;
- All subjects evaluable for T cell responses (five of five) showed survivin specific T cell activation in the blood, four of five showed a robust response. IHC analysis for tumor infiltration is continuing; and
- Treatments have been well tolerated.

The data also highlighted long-lasting responders from the phase 1b portion of the study with key takeaways as follows:

- Prolonged duration of clinical benefits reaching up to more than two years, surpassing the progression-free survival to previous treatments, including platinum-based chemotherapy;
- Long-lasting clinical benefits and high levels of survivin specific T cells are associated with long-term treatment;
- One subject has received DPX-Survivac for more than 21 months so far. This finding is the longest duration of treatment for DPX-Survivac on record to date; and
- It is supportive of DPX Survivac’s ability to maintain high levels of survivin-specific T cells in the blood over a prolonged period of time.

- On April 3, 2019, the Corporation announced that it presented preclinical research at the American Association for Cancer Research ("AACR") Annual Meeting 2019 that demonstrated how the MOA of IMV’s proprietary DPX technology can enhance a broad spectrum of immune cell infiltration into tumors, which included T cells, Natural Killer ("NK") cells, and macrophages. Analysis also revealed the differentiated characteristics of the immune cell responses and the potential implications for enhanced anti-tumor activity. In the poster titled, T-distributed stochastic neighbor embedding (t-SNE) analysis of tumor infiltrating lymphocytes after treatment with a T cell activating therapy identifies a unique population of recruited CD8+ T cells and novel options for combination immunotherapy, IMV researchers used specialized data analytics to examine how DPX-based agents, when combined with CPA, induced T cells to infiltrate tumors and attack cancerous cells. The study closely examined the types of immune cell responses and how and why they were able to affect disease. The data indicated that this approach stimulated the infiltration of a broad base of immune cells into tumors, including T cells, NK cells, and macrophages. The specific T cell population that moved into tumors could be grouped based on the co-expression of different checkpoint molecules such as PD-1 and Tim-3. However, those stimulated to infiltrate tumors generally did not express CTLA-4 (a protein found on T cells that inhibits the immune response).
On March 26, 2019, the Corporation announced preliminary data from the phase 2 cohort of the Decide clinical study. Six patients receiving DPX-Survivac monotherapy with intermittent low-dose cyclophosphamide (mCPA) have reached the first CT scan assessment with key related findings as follows:

- 83% of the subjects (5 of 6) show SD, including two tumor regressions
- 80% (4 of 5) with stable disease are in subjects with a lower BTB, which also includes the two tumor regressions

Importantly, in earlier stages of this trial, durable clinical responses occurred after 140 days, and have now lasted for 20 months or more. Additional data at the 140 days mark of this cohort will be available by the end of the first half of 2019.

This amended phase 2 study evaluates the safety and efficacy of DPX-Survivac monotherapy with mCPA in patients with advanced recurrent ovarian cancer. As of the March 25, 2019 data cut-off date, 13 patients have been enrolled in the phase 2 portion of the trial in addition to the 53 enrolled in the phase 1b cohort. Five patients were randomized into the DPX-Survivac monotherapy cohort. Seven patients had been randomized into DPX-Survivac/mCPA in combination with epacadostat before the phase 2 protocol was amended to stop enrollment in the combination arm. One of the patients in the combination arm elected to switch to the monotherapy arm of the trial. Positive data from the phase 1b portion of the trial led IMV to amend the study to monotherapy inpatients with lower tumor burden.

The amended phase 2 cohort of the DECIDE trial is targeting an enrollment of at least additional 16 patients in the population with a lower tumor burden. Enrollment is ongoing at multiple sites in the U.S. and Canada.

On March 18, 2019, that the Canadian bioresearch consortium CQDM has awarded a grant to a collaboration among IMV Inc., Centre de recherche du CHU de Quebec-Universite Laval and La Fondation du CHU de Quebec (“FCHUQc”).

Under the leadership of Dr. Yves Fradet, MD, professor of surgery and researcher in cancer immunotherapy, and his team, in collaboration with IMV’s team, this project will receive a grant of up to $1.2-million from CQDM and $300,000 from the FCHUQc, to develop a novel dual target T cell therapy for an initial clinical application in bladder cancer.

The work will target immunogenic peptides identified by Dr. Fradet’s team from the MAGE protein family member A9 (“MAGE-A9”). This protein is frequently expressed in various human cancers including bladder, lung and kidney (1). These peptides will be combined with selected immunogenic peptides from the survivin protein composing the DPX-Survivac T cell drug candidate.

The researchers believe that MAGE-A9 and survivin peptides presented on the surface of cancer cells can be used to program T cells to destroy tumours and may represent ideal targets for anti-cancer T cell immunotherapies. The collaborators will combine these peptides with IMV’s proprietary DPX technology to develop a first-in-class dual target T cell therapy (DPX-SurMAGE).
DPX-SurMAGE will be initially evaluated in preclinical studies. Upon successful completion of these preclinical evaluations, researchers are aiming to test the candidate in two clinical studies in patients with:

- Muscle invasive bladder cancer combined with an anti-PD-1 and intermittent low-dose cyclophosphamide (CPA) prior to cystectomy;
- Low-grade highly recurrent non muscle invasive bladder cancer combined with CPA prior to transurethral resection.

- On March 6, 2019, IMV completed a public offering of Common Shares. An aggregate of 4,900,000 Common Shares was issued at a price of $5.45 per Common Share, raising gross proceeds of $26.7 million (the **March 2019 Public Offering**”) and on March 11, 2019, the underwriters partially exercised their over-allotment option to purchase additional Common Shares, resulting in the issuance of an additional 504,855 Common Shares at a price of C$5.45 per Common Share for additional gross proceeds of approximately C$2.75 million. The Corporation raised total gross proceeds of approximately C$29.46 million under the March 2019 Public Offering. The Corporation intends to use the net proceeds of the Offering to accelerate the development of DPX-Survivac in combination with Keytruda as part of the phase 2 basket trial with Merck in patients with select advanced or recurrent solid tumours in bladder, liver (hepatocellular carcinoma), ovarian or non-small-cell lung cancers, as well as tumours shown to be positive for the microsatellite instability high biomarker and for general corporate purposes.

- On January 30, 2019, the Corporation announced an update on its clinical program for its lead investigational treatment, DPX-Survivac, as a potential monotherapy in advanced recurrent ovarian cancer. In December 2018, IMV met with the U.S. Food and Drug Administration (“FDA”) in a Type B meeting to discuss the results to date of its DeCidE1 (DPX-Survivac with low-dose cyclophosphamide and epacadostat) clinical trial and continuing development plan, as well as to obtain agency guidance on a potential accelerated regulatory pathway for DPX-Survivac as a T-cell immunotherapy for the treatment of advanced ovarian cancer in patients with progressing disease.

**FDA meeting highlights include:**

- The purpose of IMV’s Type B meeting with the FDA was to request feedback on the design of the clinical program for DPX-Survivac. This program includes the continuing DeCidE1 phase 2 clinical study and a potential future registration trial for accelerated approval in a subset of ovarian cancer patients.

- The FDA reviewed the Corporation’s proposed clinical development plan and acknowledged the potential for accelerated approvals in advanced ovarian cancer based on ORR according to Recist 1.1 criteria with reported median duration of response rate (“**DOR**”). In addition, the FDA provided important guidance on clinical design considerations for different lines of therapy and platinum-sensitive and resistant patient populations.

- In addition, IMV submitted a protocol amendment for a predictive enrichment approach to the phase 2 DeCidE1 trial, and further discussed those details with the FDA during the Type B meeting. The phase 2 primary end point, based on OOR per Recist 1.1 criteria, is intended to confirm the high response rate and duration of clinical benefits observed in previously announced results in a patient population defined by a clinical biomarker based BTB.
Multiple clinical sites are now open for enrolment in the DeCidE1 phase 2 trial. Subject to phase 2 results, IMV plans to schedule a follow-up meeting with the FDA to finalize the design of a potential pivotal trial based on ORR and DOR.

- On January 17, 2019, treatment of the first patient in its phase 1 trial evaluating neoepitopes formulated in the Corporation’s proprietary DPX delivery platform in patients with ovarian cancer. The study is part of the Corporation’s DPX-NEO program, which is a continuing collaboration between UConn Health and IMV to develop neoepitope-based anti-cancer therapies.

Investigators will assess the safety and efficacy of using patient-specific neoepitopes discovered at UConn Health and formulated in IMV’s proprietary DPX-based delivery technology in women with ovarian cancer. Investigators plan to enroll up to 15 patients in the phase 1 study. UConn Health is financing the trial with IMV providing materials and counsel.

Year ended December 31, 2018

- On December 13, 2018, investigators shared new positive data from IMV’s continuing DeCidE1 clinical trial at the 2018 ESMO Immuno-Oncology Congress. The phase 1b/2 study is evaluating the safety and efficacy of the combination of IMV’s lead candidate DPX-Survivac, low-dose cyclophosphamide, and 100 milligrams or 300 mg of Incyte Corporation’s (“Incyte”) IDO1 enzyme inhibitor epacadostat in patients with advanced recurrent ovarian cancer.

In a poster presentation, Dr. Oliver Dorigo, MD, PhD, associate professor of obstetrics and gynecology (oncology), Stanford University Medical Center, who served as the trial’s lead investigator and author on the poster, shared top-line safety results from 53 enrolled patients and efficacy data from the 32 participants evaluable for immune-related and clinical responses, as well as blood sample and tumour biopsy analyses;

Key findings included:

- Evidence of a clinical marker based on BTB, a measure of tumour size predictive of patient response to DPX-Survivac;
- 37.5 per cent (12/32) of evaluable study subjects began treatment with a non-bulky disease defined as BTB under five centimetres;
- 73 per cent (8/11) of tumour regressions and 80 per cent of clinical responses (4/5) observed in subset of patients with BTB less than five centimeters;
- Responders thus far showing prolonged duration of clinical benefits reaching up to more than two years, surpassing the progression-free interval from their previous chemotherapy treatment;
- Robust systemic survivin-specific T-cell responses and evidence of survivin-specific T cells tumour infiltration correlated with clinical benefits;
- 100 per cent of durable clinical responses correlated with T-cell infiltration;
- Epacadostat triggered inhibition of the conversion of tryptophan into kynurenine that was dose dependent; and
Cohort demographics were balanced and the combination yielded a tolerable safety profile.

At the time of data cut-off, 53 patients were enrolled in the phase 1b clinical trial, including 14 from the 100 mg epacadostat dosing cohort and 39 from 300 mg epacadostat cohort. Based on 300 mg cohort results, IMV and Incyte agreed to stop dosing patients with epacadostat before completion of the study. Patients who completed at least one CT scan, as required per the trial protocol, were evaluable for response analysis.

Seventy-one per cent of patients were evaluable for responses in the 100 mg cohort and 56 per cent in the 300 mg dose cohort. At time of data cut-off, eight participants remained on treatment and were being evaluated for clinical responses.

<table>
<thead>
<tr>
<th>Efficacy Parameter</th>
<th>Total target lesion size &lt; 5 cm</th>
<th>Total target lesion size ≥ 5 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100 mg (N=5)</td>
<td>300 mg (N=7)</td>
</tr>
<tr>
<td>Regression</td>
<td>5 (100)</td>
<td>3 (42.9)</td>
</tr>
<tr>
<td>PR (1)</td>
<td>3 (60.0)</td>
<td>1 (14.3)</td>
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<tr>
<td>SD (2)</td>
<td>2 (40.0)</td>
<td>4 (57.1)</td>
</tr>
<tr>
<td>DCR (3)</td>
<td>5 (100)</td>
<td>5 (71.4)</td>
</tr>
</tbody>
</table>

- On November 20, 2018, IMV announced an amendment of its phase 1b/2 clinical trial evaluating the safety and efficacy of IMV’s lead candidate, DPX-Survivac, in combination with either 100 milligrams or 300 mg of epacadostat in patients with recurrent ovarian cancer.

Review of new data from the phase 1b portion of the clinical trial demonstrate a high response rate and a durable clinical benefit in a subpopulation of patients with a clinical marker predictive of a response to DPX-Survivac and correlated to its novel MOA. New data included:

- Efficacy signals in the subpopulation of patients who received 100 mg dose epacadostat (n = 5) included 100 percent tumour regressions and 100 percent disease control rate; and 60 percent of these patients (3/5) reached a best response of a PR;

- Long duration of clinical benefit observed in responders with a median duration of 590 days, including one patient that has passed the two-year mark without disease progression;

- Clinical benefit correlated to DPX-Survivac’s MOA and clinical study primary end points: survivin-specific T cells in the blood and T cell infiltration into tumours; and

- The safety profile of DPX-Survivac is consistent with the profile observed in the Corporation’s previously reported studies.

Based on 300 mg cohort results, IMV and Incyte have agreed to stop dosing patients with epacadostat. IMV will continue the phase 1b/2 trial as a monotherapy study evaluating DPX-Survivac in the recurrent ovarian cancer subpopulation. IMV will inform and work with
investigators to appropriately modify the study in a manner consistent with the best interests of each patient;

IMV and Incyte will continue to explore the potential of additional combination studies.

- On November 6, 2018, the Corporation announced the appointment of Dr. Markus Warmuth, MD, a seasoned biopharmaceutical executive, to its board of directors. Dr. Warmuth currently serves as an entrepreneur in residence at the life science venture capital firm Third Rock Ventures. He brings more than 20 years of drug discovery experience and scientific acumen, with a strong focus on developing targeted therapy and immuno-oncology programs, to his role on IMV’s board.

- On September 27, 2018, the Corporation announced results of ongoing research to further explore the novel MOA of its RSV vaccine candidate. New data from a preclinical study highlighted the effects of two potential approaches to preventing RSV, comparing a single dose of the bovine version (“DPX-bRSV”) of IMV’s DPX™-based small B cell epitope peptide vaccine candidate for RSV (“DPX-RSV”) to a two-dose conventional investigational bovine RSV vaccine. Researchers found that IMV’s vaccine candidate yielded strong antigen-specific immune responses and a protective effect on disease pathology. The degree of protection was comparable between the two vaccine candidates.

  In this study, researchers compared the effects of both the IMV and conventional RSV vaccine approaches among bovines with known RSV infections (the bovine animal model is considered an optimal model of RSV infection). Researchers administered one dose of DPX-bRSV to one cohort; the second received two doses of a subunit RSV bovine vaccine. Researchers measured immune response with an antibody titer test and assessed disease pathology with a lung lesion score and other clinical parameters (such as body temperature changes).

  They found SH antibodies in 14 of the 15 animals that received DPX-bRSV, and the improvements observed in disease pathology were comparable between the two cohorts. These were the first bovine animal health data to directly correlate the vaccine-induced immune response against IMV’s novel RSV target - the SH viral protein– with measures of disease protection.

- On September 18, 2018, the Corporation announced details of the initial data from its ongoing investigator-sponsored phase 2 clinical trial in DLBCL. In the study, investigators are evaluating IMV’s lead candidate, DPX-Survivac, in combination with low dose cyclophosphamide and Merck’s checkpoint inhibitor Keytruda® (pembrolizumab), in patients with persistent or recurrent/refractory DLBCL.

  The preliminary data included assessments of safety and clinical activity (based on modified Cheson criteria) for the first four evaluable patients who have completed their first CT scan after the start of treatment. The data showed that:

  o Two of the first four evaluable participants showed tumour regressions at the first on-treatment CT scan:
    - The first enrolled participant demonstrated a tumour regression of 48% at first on-treatment scan; and
    - The second participant demonstrated a partial response (PR) via a tumour regression of 66% at first on-treatment scan.
Preliminary data from the third participant demonstrated stable disease;

- The other participant had early disease progression less than two months following treatment initiation and was discontinued from the study; and
- The combination therapy appears to demonstrate an acceptable safety profile, with no serious adverse events reported to date.


- On September 11, 2018, the Corporation announced an expansion of its clinical program with a phase 2 basket trial in collaboration with Merck evaluating its lead candidate, DPX-Survivac, in combination with low-dose cyclophosphamide and Merck’s anti-PD-1 therapy, Keytruda ® (pembrolizumab), in patients with select advanced or recurrent solid tumours across five indications.

The open-label, multicentre, phase 2 basket study will evaluate the safety and efficacy of the immunotherapeutic combination agents in patients with bladder, liver (hepatocellular carcinoma), ovarian or NSCLC cancers, as well as tumours shown to be positive for the microsatellite instability high (MSI-H) biomarker. Investigators plan to enroll a maximum of 184 patients across five indications at multiple medical centres in Canada and the United States.

- On August 9, 2018, IMV reached two important milestones in its continuing clinical trial collaboration with Incyte Investigators completed enrolment for both phase 1b dosing cohorts and treated the first patient in the phase 2 component of the combination trial, which was evaluating the safety and efficacy of IMV’s lead candidate, DPX-Survivac, and low-dose cyclophosphamide with (and without) epacadostat in patients with advanced ovarian cancer.

Investigators completed enrolment in the phase 1b cohorts of the study, with a total of 50 patients across the two dosing groups. The phase 1b study focused on evaluating the safety and efficacy of combining DPX-Survivac, 100 milligrams or 300 milligrams of epacadostat, and low-dose cyclophosphamide in individuals with advanced, platinum-sensitive and resistant ovarian cancer.

- On June 7, 2018, the Corporation announced the addition of Julia P. Gregory to the Board of Directors. Ms. Gregory is a seasoned biotechnology executive with chief executive officer, chief financial officer, board and investment banking experience. She recently served as Chief Executive Officer and board member of ContraFect Corporation, a public biotechnology company developing innovative anti-infectives. She also served as the chief executive officer and board member of the immuno-oncology company Five Prime Therapeutics.

- On June 3, 2018, that investigators shared new positive data in an oral presentation for its DeCidE1 (DPX-Survivac with low dose Cyclophosphamide and Epacadostat) clinical study at the 2018 ASCO annual meeting. This data from the ongoing phase 1b/2 trial evaluated the safety and efficacy of the combination of IMV’s lead candidate, DPX-Survivac, and low dose cyclophosphamide, with Incyte’s IDO1 enzyme inhibitor epacadostat, in patients with advanced recurrent ovarian cancer.

At the time of data cut-off, 39 patients were enrolled (including 25 new participants in the 300mg cohort with 8 evaluable from day 56 first CT scan). Data from the first 18 evaluable patients across both dosing cohorts showed:
7 tumour regressions, including 4 PR reported so far (PR, defined as ≥30% decrease in tumour lesion size); and

Study participants were generally tolerating treatments well, with no related serious adverse events (“SAEs”) reported.

Data from the first 8 evaluable participants in the 300mg epacadostat dosing cohort at first CT scan included:

- 6 patients demonstrated SD at day 56, with 4 of these SDs still on trial at data cut-off; and
- 2 patients with tumour regressions observed so far, including one PR with a tumour regression ongoing for more than 9 months.

Researchers also analyzed patient data to study the combination’s MOA. They examined blood samples and tumour biopsies for the 10 evaluable patients treated in the first dosing cohort. This data showed:

- Survivin-specific T cell responses detected in 100% (10/10) of patients;
- Increase in T cell infiltration post treatment in 37% (3/8) of the analyzable tumour biopsies based on two complementary testing methodologies (RNA sequencing and immunohistochemistry);
- 2 of the 3 patients with T cell infiltration showed PRs with significant and durable tumour regressions lasting more than one year; and
- The third patient with T cell infiltration exhibited Progressive Disease (PD) with evidence of down regulation of the major histocompatibility (MHC) presentation pathway and significant increases in suppressive markers, both indicative of mechanisms of resistance.

- On June 1, 2018, trading of the Common Shares began on Nasdaq under the symbol “IMV” and the Common Shares concurrently ceased to be traded on OTCQX.

- On May 2, 2018, the Corporation implemented a consolidation of its outstanding Common Shares on the basis of one new Common Share for every 3.2 outstanding Common Share and changed the Corporation name to IMV Inc. in an effort to ensure that its corporate denomination does not convey any ambiguities as to the nature of the activities and technologies of the Corporation, which are not limited to vaccines.

- On April 24, 2018, the Corporation announced that it entered into an agreement with Incyte to expand their ongoing clinical trial collaboration. The companies plan to add a phase 2 component to their ongoing phase 1b combination study evaluating the safety and efficacy of IMV’s lead candidate, DPX-Survivac, in combination with Incyte’s IDO1 enzyme inhibitor epacadostat and low dose cyclophosphamide in advanced ovarian cancer patients.

The phase 2 component is a randomized, open label, efficacy study that would include up to 32 additional evaluable subjects. It aimed to evaluate DPX-Survivac and low dose cyclophosphamide with, or without, epacadostat in patients with advanced recurrent ovarian cancer. In accordance
with regulatory guidelines for combination trials, the goal of this portion of the program would be to evaluate the clinical contribution of each investigational drug in the combination regimen.

- On April 16, 2018, the Corporation announced the presentation of new research on its T cell activating platform at the AACR annual meeting 2018. In collaboration with Incyte, researchers presented a poster supporting the enhanced anti-cancer immune responses from the combination of IMV’s proprietary T cell activating technology and Incyte’s IDO1 inhibitor program. A second poster analyzed the novel capability, as compared with other formulation technologies, of IMV’s delivery technology to combine a large range of anti-cancer peptides into a single formulation.

In the poster titled, “Combination of a T cell activating immunotherapy with immune modulators alters the tumour microenvironment and promotes more effective tumour control in preclinical models”, researchers presented new preclinical analysis on the combination of IMV’s DPX-based therapies, Incyte’s epacadostat and low-dose cyclophosphamide, in tumour models. As part of the analysis, researchers also examined the potential for heightened tumour response from T cell infiltration in the tumour microenvironment. The study indicated that the triple combination immunotherapy demonstrated a significant delay in tumour progression. Analysis of the T cells suggested that other immune modulating therapies, such as checkpoint inhibitors, could additionally enhance tumour control.

Related to IMV’s neoepitope program, researchers presented the poster, “A novel delivery platform containing up to 25 neoantigens can induce robust immune responses in a single formulation”. This study investigated the effects on immune response when formulating a broad range of peptides across multiple delivery technologies, including the Corporation’s proprietary formulation. The study indicated that IMV’s novel technology could incorporate at least 25 neoantigens into a single formulation, which generated strong CD8 and T cell responses, in excess of those induced by other formulations.

- On March 28, 2018, the Corporation announced that the first patient was treated in IMV’s phase 2 study combining DPX-Survivac with low-dose cyclophosphamide administered with pembrolizumab in patients with persistent or recurrent/refractory DLBCL.

- On February 15, 2018, IMV closed a bought deal public offering of Common Shares, raising gross proceeds of $14.375 million.

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

In the study, published on January 27, 2018, researchers tracked how the cancer peptides were trafficked from the injection site to immunogenic activation in the lymph nodes. Researchers correlated this to both activation of T cells and the ensuing efficacy to control tumour progression. They concluded that IMV’s delivery technology had a fundamentally unique MOA. This MOA

¹ Published online, January 27, 2018. DOI: 10.1186/s12929-018-0413-9
enabled active and prolonged immune stimulation, as well as better tumour control, as compared to other technologies examined in the study.

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

**Year ended December 31, 2017**

- On December 7, 2017, the Corporation announced an expansion of its continuing collaboration with UConn Health. The collaboration is part of IMV’s DPX-NEO program, which is evaluating the anti-cancer activity of proprietary patient-specific epitopes developed at UConn Health and formulated in the Corporation’s DPX-based vaccine formulation. Based on prior preclinical and manufacturing milestones achieved in evaluating cancer neoepitopes formulated in IMV’s proprietary delivery formulation, IMV and UConn Health will begin working toward DPX-NEO’s first clinical trial;

- On December 5, 2017, the Corporation announced positive top-line clinical data from its continuing phase 1b trial evaluating the safety and efficacy of IMV’s lead immuno-oncology candidate, DPX-Survivac, in combination with Incyte’s IDO1 enzyme inhibitor epacadostat, and low-dose cyclophosphamide in patients with advanced ovarian cancer. IMV is conducting the trial in a collaboration with Incyte;

  Initial results from 10 evaluable patients in the DPX-Survivac plus-100 milligrams epacadostat dosing cohort demonstrate a disease control rate of 70 per cent, including PR (defined as equal to 30-per-cent decrease in tumour lesion size) in 30 per cent of the patients (three out of 10). To date, the combination also exhibited a well-tolerated safety profile, with the majority of AEs reported as Grade 1 and Grade 2, and only one potential treatment-related AE;

- On November 21, 2017, an expansion of its collaboration with Leidos to develop preventative, peptide-based malaria vaccine candidates. The U.S. Agency for International Development ("USAID") supported an initial collaboration via a Leidos Malaria Vaccine Development Program (MVDP) subcontract. Following the achievement of several preclinical milestones in this initial collaboration, Leidos and USAID selected the DPX-based platform as one of the preferred formulations for further development under a new contract extension. Under the new subcontract, the collaborators will conduct additional research that focuses on identifying the most promising target-formulation combinations;

- On November 8, 2017, the Corporation announced that Health Canada has granted Sunnybrook Research Institute regulatory clearance to begin recruiting patients for its Phase 2 clinical study of a triple-combination immunotherapy in patients with measurable or recurrent DLBCL. This investigator-sponsored Phase 2 trial, designed to evaluate the safety and efficacy of IMV’s lead product candidate, DPX-Survivac, along with Merck’s pembrolizumab and low-dose cyclophosphamide, will evaluate the use of a triple-combination immunotherapy in patients with measurable or recurrent DLBCL. Investigators will assess the efficacy and safety of DPX-Survivac, along with a checkpoint inhibitor drug currently marketed by a large pharmaceutical company, and
low-dose cyclophosphamide. The Corporation has elected to conclude operations on its initial Phase 2 DLBCL study, opting to replace it with this triple-combination trial;

- On October 17, 2017, the Corporation announced that it has received a two-year extension of the maturity of its $5M Province of Nova Scotia loan authorized in 2013. The original maturity date of the loan was August 9, 2018 and is now August 9, 2020;

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

- On July 12, 2017, IMV scientists successfully formulated 14 neoepitope cancer peptides into one single DPX formulation. In preclinical testing, the resulting personalized cancer vaccine demonstrated the ability to generate specific killer T-cell responses against cancer peptides. IMV has filed a patent application covering this novel DPX-based rapid formulation process. The supporting data for the patent include what the Corporation believes to be one of the first documented reports of 14 different neoepitope peptides synthesized into a single formulation;

- On June 21, 2017, IMV completed a bought deal public offering (the “June 2017 Public Offering”) of Common Shares, raising gross proceeds of approximately $10 million. The Corporation intended to use the net proceeds of the June 2017 Public Offering for the research and development and clinical advancement of its cancer and infectious disease vaccine candidates and for working capital and general corporate purposes;

- On April 18, 2017, the Corporation announced that the first study participant has been treated in a Phase 1b/2 clinical study lead by Dana-Farber evaluating IMV’s investigational cancer vaccine, DPX-E7, in combination with low-dose cyclophosphamide in patients with incurable oropharyngeal, cervical and anal cancers related to HPV;

- On April 12, 2017, the Corporation announced updated data on its investigator-sponsored Phase 1 clinical trial testing the safety and immunogenicity of its DPX-based, small B-cell epitope peptide vaccine candidate for RSV. In the 25µg dose cohort, which was the only dose tested out to one year, 100 percent of older adults (7/7 immune responders) vaccinated with IMV’s DPX-RSV maintained the antigen-specific immune responses one year after receiving the booster dose. At one year, the antibody levels measured were still at peak with no sign of decrease. The 25µg dose was delivered in a volume of 50 microliters. A standard flu vaccine is typically 60µg delivered in 10 times this volume;

- On April 11, 2017, the Corporation announced that University Health Network’s (“UHN”) Princess Margaret Cancer Centre has received Health Canada clearance to initiate the Phase 2 non-randomized, open-label trial designed to evaluate the potential anti-tumour activity of the combination of Merck’s pembrolizumab, IMV’s DPX-Survivac, and low-dose cyclophosphamide;

- On April 5, 2017, the Corporation announced that new preclinical data presented at the 2017 AACR Annual Meeting demonstrated that phosphatidylserine targeting antibodies can enhance the anti-cancer activity of its DPX-based therapeutic vaccine platform;
• In March 2017, the Corporation announced the first interim data analysis from the triple combination Phase 1b clinical trial in ovarian cancer, in combination with Incyte’s epacadostat and low-dose cyclophosphamide. The analysis included the results of blood tests, tumour biopsies and CT scans to assess safety, disease progression and T-cell response for the first four evaluable patients in the trial. All patients enrolled in the trial have recurrent ovarian cancer with evidence of progressive disease. Based on the interim analysis, the combination therapy appears to have an acceptable tolerable safety profile, with a single grade 3 and single grade 4 event reported and no SAEs. At the time of the interim analysis, three of four patients exhibited stable disease, while a fourth patient progressed and exited the trial. In addition, researchers observed an increased T-cell activity in tumours in three of the four patients based on RNA sequencing and indications of early tumour shrinkage in the patient who has been in trial for the longest duration thus far (based on CT scan at day 140);

• On February 6, 2017, the Corporation announced an investigator-sponsored Phase 2 clinical trial in ovarian cancer in combination with Merck’s checkpoint inhibitor Pembrolizumab in patients with recurrent, platinum-resistant ovarian cancer. UHN Princess Margaret Cancer Centre will conduct the Phase 2 non-randomized, open-label trial designed to evaluate the potential anti-tumour activity of the combination of Pembrolizumab, DPX-Survivac, and low-dose cyclophosphamide; and

• On February 3, 2017, the Corporation announced that Pierre Labbé was appointed as Chief Financial Officer replacing Kimberly Stephens.

IV. DESCRIPTION OF THE BUSINESS

BUSINESS MODEL AND STRATEGY

IMV is dedicated to making immunotherapy more effective, more broadly applicable, and more widely available to people facing cancer and other serious diseases. The Corporation’s lead product candidate, DPX-Survivac, has demonstrated the ability to induce prolonged T cell activation leading to tumor regressions in advanced ovarian cancer and DLBCL.

Foremost, the Corporation’s clinical strategy is to target late stage unmet medical needs for a shorter path to clinical demonstration and first regulatory approval. In addition, the Corporation is evaluating combination with Merck’s Keytruda® checkpoint inhibitor in multiple solid tumor indications.

In collaboration with commercial and academic partners, the Corporation is also expanding the application of DPX as a delivery platform for other applications. Pre-clinical and clinical studies have indicated to date that the Corporation’s delivery platform may allow for the development of enhanced targeted therapies for a wide range of infectious diseases by generating a stronger and more durable immune response than with existing delivery methods.

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

Delivery Platform

The DPX platform is a unique and patented formulation discovered by the Corporation that provides a new way to deliver active ingredients to the immune system using a novel MOA. This MOA does not release the active ingredients at the site of injection but forces an active uptake by immune cells (antigen-presenting cells) and delivery of active ingredients into lymph nodes. IMV is exploiting this unique MOA to pioneer a new class of immunotherapies that represents a paradigm shift from current approaches. Thanks to its “no release” MOA, the DPX-based targeted therapies allow the programming of immune cells \textit{in-vivo} to generate new target-specific therapeutic capabilities. The DPX platform can be leveraged to generate “first-in-class” T cell therapies with the potential to be disruptive in the treatment of cancer. The Corporation believes that the novel MOA of DPX makes the platform uniquely suitable for cancer immunotherapies, which are designed to target tumor cells. DPX-based candidates can induce prolonged, target-specific, and polyfunctional T cell activation, which are postulated to be required for effective tumor control.

The DPX platform is based on active ingredients formulated in lipid nanoparticles and, after freeze drying, suspended directly into a lipiddic formulation. DPX-based products are stored in a dry format, which provides the added benefit of an extended shelf life. The formulation is designed to be easy to re-suspend and administer to patients.

DPX also has multiple manufacturing advantages: it is fully synthetic; can accommodate hydrophilic and hydrophobic compounds; is amenable to a wide-range of applications (for example, peptides, small-molecules, RNA/DNA, or antibodies); and provides long term stability as well as low cost of goods.

The DPX platform forms the basis of all IMV’s product development programs.

DPX-Survivac

Product Candidate Overview

DPX-Survivac, the Corporation’s first cancer immunotherapy candidate, uses survivin-based peptides licensed from Merck KGaA on a world-wide exclusive basis that are formulated in DPX. DPX-Survivac leverages the MOA of DPX to generate a constant flow of T cells in the blood that are targeted against survivin expressed on cancer cells and is comprised of five minimal MHC class I peptides to activate patients’ naïve T cells against survivin.

Survivin is a well characterized and recognized tumor associated antigen known to be expressed during fetal development and across most tumor cell types, but it is rarely present in normal non-malignant adult cells. Survivin controls key cancer processes (apoptosis, cell division, and metastasis) and has been associated with chemoresistance and cancer progression. It has been shown that survivin was expressed in all 60 different human tumor lines used in the National Cancer Institute’s cancer drug screening program and is documented in the literature to be overexpressed in more than 20 indications.

In clinical trials exploring the activity of DPX-Survivac, an intermittent low-dose oral regimen of cyclophosphamide is used as an immune-modulator. Conventional chemotherapeutic drugs are traditionally used for their cytotoxic effect on tumors but cyclophosphamide can also be used at lower doses to potentiate the activity of other immunotherapies without inducing significant cytotoxicity.

\begin{table}[h]
\centering
\begin{tabular}{|c|c|}
\hline
Cancer & Survivin % \\
\hline
Ovarian & 90 \\
Breast & 90 \\
Melanoma & 90 \\
Lung & 53 \\
Colorectal & 54 \\
Gastric & 94 \\
Kidney & 23-82 \\
Glioblastoma & 80 \\
ALL & 70 \\
CMML & 70 \\
MDS & 90 \\
DLBCL & 60 \\
\hline
\end{tabular}
\caption{Examples of % of patients with survivin expression in different indications}
\end{table}
Several studies have demonstrated that low-dose regimens of cyclophosphamide can have multiple beneficial effects for T cell therapies such as DPX-Survivac, including reduction of T regulatory cell numbers and increase in effector T cells (Hugues et al, Immunology, 2018). In Phase 1 clinical studies, IMV demonstrated that intermittent low-dose oral cyclophosphamide can act as an immune-modulator increasing the number of survivin-specific T cells generated by DPX-Survivac (Weir et al, AACR, 2016).

**IMMUNO-ONCOLOGY**

DPX-Survivac is being tested in 6 different cancer indications through multiple phase 2 clinical trials.

**Ongoing Clinical Trials**

<table>
<thead>
<tr>
<th>T cell therapy</th>
<th>Indication</th>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Sponsor</th>
<th>Collaborators</th>
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<tbody>
<tr>
<td>DPX-Survivac / CPA (Survivin)</td>
<td>Ovarian</td>
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<td>IMV</td>
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<td>DLBCL Combination with Keytruda®</td>
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<td>Lung (NSCLC) Combination with Keytruda®</td>
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<tr>
<td>Bladder Combination with Keytruda®</td>
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<td>MSI-H Combination with Keytruda®</td>
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<td>Liver (HCC) Combination with Keytruda®</td>
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<td>Ovarian Combination with Keytruda®</td>
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<td>Ovarian Combination with Keytruda®</td>
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<tr>
<td>DPX-MAGE / CPA (Survivin + MAGE A3)</td>
<td>Bladder</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>UHN</td>
<td></td>
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<tr>
<td>DPX-BRAF / CPA (BRAF)</td>
<td>Melanoma</td>
<td></td>
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<td>NYU</td>
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</tbody>
</table>

In all cases, intermittent low-dose CPA is abbreviated to CPA.

**COVID-19 Impact to Clinical Program**

It is anticipated that the COVID-19 pandemic crisis will impact ongoing trial activities across the industry due to the pressure placed on the healthcare system as well as governmental and institutional restrictions. IMV’s clinical team is working closely with each clinical site and our CRO on a contingency plan to ensure that patient safety and the integrity of data is maintained. IMV is following the FDA guidance issued for the COVID-19 pandemic: “FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic Guidance for Industry, Investigators, and Institutional Review Boards”. Additionally, the team continues to monitor updated institutional, regional and national guidance to fully comply with applicable guidelines as they are issued. It is noted that some clinical sites have paused or slowed enrollment in clinical trials, while other sites, less impacted, are continuing activities as planned. The overall enrollment rate may decrease, but clinical activities are continuing. Patients are encouraged to comply with directives from public health officials and, subject to such compliance, to attend visits as planned or to discuss alternatives with their physician. The current activities performed at central labs to assess the
eligibility of patients and the management of clinical samples is not impacted, and IMV is working with the vendors to ensure continuity of activities. Drug supply is not expected to be impacted at this time. As added precaution, IMV is working on a contingency plan to ensure proper provisioning of drugs to all clinical sites in the event of future transportation or other constraints.

**DPX-Survivac – Ongoing Clinical Trials**

*Ovarian subpopulation – DeCidE1 phase 1b/2*

The DeCidE1 phase 2 study is a multicenter, randomized, open-label study to evaluate the safety and effectiveness of DPX-Survivac with intermittent low dose cyclophosphamide (CPA). This phase 2 arm enrolled 22 patients with recurrent, advanced platinum-sensitive and resistant ovarian cancer. Patients received 2 subcutaneous injections of DPX-Survivac 3 weeks apart and every eight weeks thereafter, and intermittent low dose CPA one week on and one week off for up to 1 year. Paired tumor biopsies were performed prior to treatment and on treatment.

Primary endpoints of this study are overall response rate, disease control rate and safety. Secondary endpoints include cell mediated immunity, immune cell infiltration in paired biopsy samples, duration of response, time to progression, overall survival and biomarker analyses.

On June 3, 2019, investigators shared new positive data for IMV Inc.’s DeCidE1 clinical trial at the 2019 ASCO annual meeting.

New data from evaluable patients from the phase 2 DPX-Survivac/CPA arm of the trial indicated the potential for DPX-Survivac to impact solid tumor growth in hard-to-treat ovarian cancer patients. Longer-term follow-up from the phase 1b portion of the trial continued to demonstrate that the levels of survivin-specific T cells in the blood of patients; a measure of DPX-Survivac’s novel mechanism of action-correlated with durable clinical benefits.

On February 4, 2020, the Corporation presented clinical translational data supporting the mechanism of action of its lead compound, DPX-Survivac/CPA during the 2020 ASCO-SITC Clinical Immuno-Oncology Symposium. The Corporation measured systemic immune responses, tumor immune infiltrates and clinical tumor response from pre- and post-treatment patient samples in connection with three Phase 1 and/or Phase 2 clinical studies, each evaluating DPX-Survivac/CPA alone or in a combination regimen in patients with platinum-sensitive or resistant, advanced ovarian cancer. Highlights from these translational data include:

- DPX-Survivac generates robust, functional, targeted, and sustained survivin-specific T cell response in ovarian cancer subjects in the maintenance setting as well as with recurrent disease.

- DPX-Survivac induced activation of cytolytic T cell pathway is correlated with clinical response highlighting its unique mechanism of action.

- Enhanced number of unique survivin-specific T cell clones are detected in on-treatment tumor samples and the T cell infiltration on-treatment correlated with clinical responses.

- DPX-Survivac mechanism of action has been confirmed across multiple clinical trials and has shown to provide clinical benefit and long-term clinical response in some subjects with advanced recurrent ovarian cancer.
On February 25, 2020, the Corporation reported updated results from the ongoing DeCidE1 Phase 2 study of DPX-Survivac/CPA, in patients with advanced recurrent ovarian cancer. The new results show that DPX-Survivac immunotherapy is active and well-tolerated.

19 patients were evaluable for efficacy with six patients (31%) still receiving treatment. Key preliminary findings are outlined below:

- 15 patients (79%) achieved disease control, defined as SD or PR on target lesions:
  - Tumor shrinkage of target lesions was observed in 10 patients (53%).
- Durable clinical benefits lasting ≥ 6 months were observed in seven patients (37%) so far:
  - Four of these seven patients (21% of evaluable patients) achieved PR with tumor regression > 30% on target lesions;
  - Three stable diseases were ongoing for > 6 months (range 7-9) including -29.5% and -12% tumor regressions; and
  - Median duration not reached yet, with five of these seven (71%) patients still on treatment at > 6 months (range 7-10).
- Analysis of BTB showed durable clinical benefits across a broad range of BTB (1.5-7.7 cm) with a higher number of patients achieving benefits in BTB < 5 cm as previously observed in other arms of the study:
  - Six out 11 with BTB < 5 cm (55%) achieved clinical benefits lasting > 6 months.
- Durable clinical benefits include platinum-resistant and refractory patients who previously received PARP inhibitors and bevacizumab.
- Treatment was well-tolerated, with most adverse events being Grade 1-2 reactions at the injection site.

IMV plans to take these results to the FDA for a Type B meeting, to align on the design of a Phase 2b study with potential to support registration under accelerated approval in this indication.

In December 2018, IMV met with the FDA in a Type B meeting to discuss the results to date of its DeCidE1 clinical trial and continuing development plan, as well as to obtain agency guidance on a potential accelerated regulatory pathway for DPX-Survivac as a T cell immunotherapy for the treatment of advanced ovarian cancer in patients with progressing disease.

The purpose of IMV’s Type B meeting with the FDA was to request feedback on the design of the clinical program for DPX-Survivac. This program includes the continuing DeCidE1 phase 2 clinical study and a potential future registration trial for accelerated approval in a subset of ovarian cancer patients.

The FDA reviewed the Corporation’s proposed clinical development plan and acknowledged the potential for accelerated approval in advanced ovarian cancer based on ORR according to Recist 1.1 criteria with reported median DOR. In addition, the FDA provided important guidance on clinical design considerations for different lines of therapy and platinum-sensitive and resistant patient populations.
In addition, IMV submitted a protocol amendment for a predictive enrichment approach to the phase 2 DeCidE1 trial, and further discussed those details with the FDA during the Type B meeting. The phase 2 primary end point, based on ORR per Recist 1.1 criteria, is intended to confirm the high response rate and duration of clinical benefits observed in previously announced results in a patient population defined by a clinical biomarker based on baseline tumor burden.

The Corporation believes that there is still an urgent medical need in advanced recurrent ovarian cancer (Sources: 1. NCCN Guidelines Ovarian Cancer V2.2018; SEER Ovarian Cancer; JCO, vol 33; 32 Nov 2015, Gyn Onc 133(2014) 624-631):

- Nearly 70% of ovarian cancers are diagnosed in advanced stage;
- The overall 5-year survival rate is 46.5%, and only 29% for advanced disease;
- Most patients develop advanced, platinum-resistant, poor prognosis disease; and
- Limited options exist with current single-agents at 6-30% response rates and median progression free survival (mPFS) of 2.1 - 4.2 months.

The Corporation believes that it has the potential to be “best-class” in the competitive landscape of recurrent ovarian cancer as other immunotherapeutic treatments tested in this patient population (Merck’s Keytruda, and Pfizer/Merck KGaA’s Bavencio) are unlikely to proceed into registration trials based on the published results available:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Registralional Clinical Trials</th>
<th>Indication</th>
<th>Base for approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olaparib (Lynparza)</td>
<td>Single arm, open label, Phase 2 (Study 42)</td>
<td>Germline BRCA mutation ≥3 prior lines of chemotherapy</td>
<td>N=137 ORR: 34% - platinum-resistant: 30% mDoR: 7.9 mo</td>
</tr>
<tr>
<td>Rubraca (Rucaparib)</td>
<td>Single arm, open label, Phase 2 (Study 10 and ARIEL2)</td>
<td>Germline and/or somatic BRCA mutation ≥2 prior lines of chemotherapy</td>
<td>N=106 ORR: 42% platinum-resistant: 25% mDoR: 6.7 mo-9.2 mo</td>
</tr>
</tbody>
</table>

**Figure 2: Examples of previous US FDA accelerated approvals in ovarian cancer (source: FDA website)**

![Figure 3: Recurrent ovarian cancer immunotherapy competitive landscape](image-url)
Subject to phase 2 results, IMV plans to schedule a follow-up meeting with FDA to finalize the design of a potential pivotal trial based on ORR and DOR.

The Corporation’s clinical strategy with this trial is to establish the targeted T cell activity of its lead compound in order to increase value and de-risk clinical development, and to target late stage unmet medical needs for a shorter path to clinical demonstration and first regulatory approval.

The Corporation anticipates that, in addition to general clinical expenses which are distributed amongst the various clinical projects, the costs to complete this phase 2 clinical trial is currently estimated at $750,000 of which $750,000 is expected to occur in 2020.

**Combinations with Merck’s Keytruda® (pembrolizumab)**

**Phase 2 clinical trial in DLBCL – SPiReL Phase 2 (investigator-sponsored)**

This phase 2 study is a combination trial with Merck’s Keytruda® (pembrolizumab) in patients with measurable or recurrent DLBCL led by Sunnybrook Research Institute (investigator-sponsored). This investigator sponsored trial, announced initially in May 2017, is designed to evaluate the safety and efficacy of DPX-Survivac, Merck’s Keytruda® (pembrolizumab), and intermittent low-dose cyclophosphamide. IMV has provided an update on this trial at the ASH Annual meeting held in December 2019.

The primary objective of this study is to document the response rate to this treatment combination using modified Cheson criteria. Secondary objectives include duration of response and safety. Exploratory endpoints include T cell response, tumor immune cell infiltration, and gene expression analysis.

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**CR:** Nodal disease less than 1.5 cm, absence of extranodal disease, no new lesions and normal bone marrow (BM);

**PR:** ≥50% decrease in the sum of the product of the diameters (SPD), no new lesion;

**PD:** Longest diameter of node > 1.5 cm and ≥50% increase from Product of Perpendicular Diameter and increase in longest or smallest diameter from nadir (lowest value), unequivocal progression of non target, new lesions or BM involvement.

As of March 24, 2020, 19 subjects have been enrolled across five different clinical sites in Canada.

Researchers conducting the investigator sponsored study are testing the novel immunotherapy combination in patients whose DLBCL expresses survivin, a tumor antigen highly expressed in 60 percent of DLBCL patients. DPX Survivac stimulates the immune system to produce T cell responses targeting survivin. On December 8, 2019, IMV provided updated data on this study. Seven of the nine patients demonstrated clinical benefit, including three complete responses and two partial responses.

**Updated SPiReL data highlights:**

At the time of data cut-off for this analysis, efficacy data based on modified Chesoni criteria was available from nine evaluable patients:

- 7/9 (77.8%) evaluable subjects exhibited clinical benefit, including three (33.3%) complete responses and two (22.2%) partial responses;

- Reproducible survivin-specific T cell responses observed in all subjects that achieved clinical responses on treatment;
• One subject, who received three prior lines of systemic therapies and failed autologous stem cell transplant, reached a complete response at the first on-study scan following treatment with the DPX-Survivac combination regimen and remains free of disease recurrence after completing the study; and

• Clinical benefits and favorable toxicity profile observed in a heterogenous population of r/r DLBCL patients, including patients of advanced age and/or with comorbidities, who are more susceptible to adverse effects and more difficult to treat.

The Corporation anticipates that, in addition to general clinical expenses which are distributed amongst the various clinical projects, its share of the cost to complete this study is currently estimated at $600,000, of which $600,000 is expected to be spent in 2020.

Phase 2 basket trial in 5 solid tumor indications

In September 2018, the Corporation announced the expansion of its clinical program with a phase 2 basket trial in collaboration with Merck evaluating its lead candidate, DPX-Survivac/CPA, and Merck’s KEYTRUDA® (pembrolizumab), in patients with select advanced or recurrent solid tumors.

The open-label, multicenter, phase 2 basket study will evaluate the safety and efficacy of the immunotherapeutic combination in patients with bladder, liver (hepatocellular carcinoma), ovarian, or non-small cell lung NSCLC cancers, as well as tumors shown to be positive for the microsatellite instability high (MSI-H) biomarker. Investigators plan to enroll up to 184 patients across five indications in 20 medical centers in Canada and the United States.

The ASCO defines a basket clinical study as a trial that investigates the effects of a drug regimen in multiple tumor types that share a common molecular target, regardless of where the disease originated.

This is the third clinical trial evaluating the combination of DPX-Survivac/CPA and KEYTRUDA® (pembrolizumab) in advanced recurrent cancers.

On September 30, 2019, IMV presented preliminary results from its ongoing phase 2 basket trial, during the Immunotherapy of Cancer poster session at the European Society for Medical Oncology (ESMO) 2019 Congress in Barcelona, Spain.

Preliminary Results from the Phase 2 Basket Trial

At the time of cut-off, 23 patients were enrolled across all five patient cohorts. This includes 19 patients across all cohorts who received DPX-Survivac in combination with pembrolizumab with CPA, and four patients from the ovarian cancer cohort receiving DPX-Survivac with only pembrolizumab:

• Preliminary results from the first on-study scan showed tumor reduction in patients with ovarian cancer (with and without CPA), NSCLC and bladder cancer;

• Partial responses observed at first scan in two subjects (bladder cancer, ovarian cancer); 19/23 subjects are still active on study treatment;

• T cell infiltration observed in biopsy samples from subjects who achieved tumor reduction on treatment;
- Eight ovarian cancer patients were enrolled in the study, randomized 1:1 to treatment with and without CPA. Tumor control and tumor reductions were observed in both groups; and

- Safety evaluation on all evaluable patients demonstrated that treatment was well-tolerated, with no related Grade 3-4 or immune-related adverse events (AEs) reported.

As at March 24, 2020, 19 clinical sites were open, and 82 patients had been enrolled across the five indications. The Corporation expects to disclose updated patient data in the first half of 2020 and anticipates that, in addition to general clinical expenses, which are distributed amongst the various clinical projects, $22,400,000 is currently estimated to be spent for stage 1 for this trial, of which $6,500,000 is estimated to be spent in 2020.

**Phase 2 clinical trial in ovarian cancer (investigator-sponsored)**

In February 2017, the Corporation announced an investigator-sponsored phase 2 clinical trial in ovarian cancer in combination with Merck’s checkpoint inhibitor pembrolizumab in patients with recurrent, platinum-resistant ovarian cancer. UHN Princess Margaret Cancer Centre conducts the phase 2 non-randomized, open-label trial designed to evaluate the potential anti-tumor activity of the combination of pembrolizumab, DPX-Survivac, and intermittent low-dose cyclophosphamide. The trial is expected to enroll 42 subjects with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. The study’s primary objective is to assess overall response rate. Secondary study objectives include progression free survival rate, overall survival rate, and potential side effects, over a five-year period. At this stage, the Corporation has no specific plan on the next steps after this trial as it will have to be assessed with its partner based on the clinical trial results.

As of July 29, 2019, 13 patients were enrolled in the trial and the Corporation will disclose results once provided by the UHN Princess Margaret Cancer Centre and currently anticipates that, in addition to general clinical expenses, which are distributed amongst the various clinical projects, its share of the costs to complete this study, currently expected to be spent in 2020, are estimated at $100,000.

**DPX-SurMAGE**

In March 2019, IMV announced that CQDM, a Canadian bioresearch consortium, had awarded a grant for a collaboration among IMV Inc., Centre de recherche du CHU de Quebec-Universite Laval (“CHU”) and FCHUQc. The collaboration will receive a grant of up to $1,200,000 from the CQDM and $300,000 from the FCHUQc over three years, to develop a novel dual target T cell therapy for an initial clinical application in bladder cancer. IMV currently expects to contribute $2,800,000 over the next three years towards this project of which $1,600,000 has been contributed in 2019 and $500,000 is estimated to be contributed in 2020.

The work will target immunogenic peptides from the MAGE protein family member A9 (MAGE-A9). This protein is frequently expressed in various human cancers including bladder, lung and kidney. These peptides will be combined with selected immunogenic peptides from the survivin protein composing the DPX-Survivac T cell drug candidate.

The researchers believe that MAGE-A9 and survivin peptides presented on the surface of cancer cells can be used to program T cells to destroy tumors and may represent ideal targets for anti-cancer T cell immunotherapies. The collaborators will combine these peptides with IMV’s proprietary DPX technology to develop a first-in-class dual target T cell therapy.
DPX-SurMAGE will be initially evaluated in preclinical studies. Upon successful completion of these preclinical evaluations, researchers are aiming to test the candidate in two clinical studies in patients with:

- Muscle invasive bladder cancer combined with an anti-PD-1 and intermittent low-dose cyclophosphamide (CPA) prior to cystectomy; and
- Low-grade highly recurrent nonmuscle invasive bladder cancer combined with CPA prior to transurethral resection.

This collaboration is expected to span a three-year period and as part of the collaboration agreement, IMV holds an exclusive option to in-license intellectual property related to this collaboration.

In June 2019, IMV met with Health Canada for a pre-clinical trial application meeting. The objectives of this meeting were to present and discuss the strategy for the development (including pre-clinical and clinical plans) of DPX-SurMAGE, to the agency to ensure the strategy was aligned with the agency’s expectations. The agency agreed with the approach for pre-clinical, manufacturing and clinical development and made suggestions to facilitate its review by the agency.

Given the ongoing COVID-19 pandemic, the pressure placed on the healthcare system, as well as governmental and institutional restrictions, and the fact that IMV had not initiated a phase 1 trial of DPX-SurMAGE prior to the pandemic, IMV is uncertain of when it will initiate this trial. The Corporation intends to provide an update when more information is available.

**Clinical Trial Development – Completed Trials**

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

In June 2015, the Corporation announced it had entered into a non-exclusive clinical trial collaboration with Incyte to evaluate the combination of DPX-Survivac, with Incyte’s investigational oral IDO1 inhibitor, epacadostat. This trial was an open-label, phase 1b study to evaluate the safety, tolerability and efficacy of the combination in platinum resistant or sensitive ovarian cancer patients who are at high risk of recurrence. All patients enrolled in the trial had recurrent ovarian cancer with evidence of progressive disease. The investigational new drug (“IND”) application for the study was approved by the FDA and Health Canada in January 2016. The study was initiated on September 8, 2016 and the Corporation announced in March 2017 the first interim data analysis from this clinical study. Based on the interim analysis, the combination therapy appeared to have an acceptable safety profile with a single grade 3 and single grade 4 event reported and no SAEs. At the time of the interim analysis, three of four patients exhibited stable disease, while a fourth patient progressed and exited the trial. In addition, researchers observed increased T cell activity in tumours in three of the four patients based on RNA sequencing and indications of early tumour shrinkage in the patient who has been in trial for the longest duration thus far (based on CT scan at day 140).

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

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

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

In the first dosing cohort, investigators observed:

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

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

On April 24, 2018, the Corporation announced that it entered into an agreement with Incyte to expand the ongoing clinical trial collaboration. The Companies added a phase 2 component to their ongoing phase 1b combination study.

The phase 2 component was a randomized, open label, efficacy study that would include up to 32 additional evaluable subjects. It would evaluate DPX-Survivac and low dose cyclophosphamid with, or without, epacadostat in patients with advanced recurrent ovarian cancer. In accordance with regulatory guidelines for combination trials, the goal of this portion of the program was to evaluate the clinical contribution of each investigational drug in the combination regimen.

On November 20, 2018, the Corporation announced an amendment to its phase 1b/2 clinical trial evaluating the safety and efficacy of IMV’s lead candidate, DPX-Survivac, in combination with either 100 mg or 300 mg of epacadostat in patients with recurrent ovarian cancer.

Review of [new] data from the phase 1b portion of that clinical trial demonstrate a high response rate and a durable clinical benefit in a subpopulation of patients with a clinical marker predictive of a response to DPX-Survivac and correlated to its novel MOA. [New] data include:

- Efficacy signals in the subpopulation of patients who received 100 mg dose epacadostat (n=5) included 100% tumour regressions and 100% disease control rate; and 60% of these patients (3/5) reached a best response of a PR;
• Long duration of clinical benefit observed in responders that lasted beyond treatment duration (1 year), median duration of 590 days, including one patient that has passed the two-year mark without disease progression, and prolonged tumour control observed in 3 out 4 PRs in that subpopulation.

<table>
<thead>
<tr>
<th>Previous Chemotherapy treatment</th>
<th>PR1b study</th>
<th>Improvement over previous treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>601 PR – 4.6 months (Topotecan)</td>
<td>PR – 22 months</td>
<td>+ 17.4 months</td>
</tr>
<tr>
<td>606 CR – 15.8 months (Platinum)</td>
<td>PR – 25 months ongoing</td>
<td>+ 9.2 months ongoing</td>
</tr>
<tr>
<td>614 SD – 10 months (Platinum)</td>
<td>PR – 16 months ongoing</td>
<td>+ 6 months ongoing</td>
</tr>
<tr>
<td>611 CR – 33 months (Platinum)</td>
<td>PR – 5 months (non-target lesion – Pt decision)</td>
<td>na</td>
</tr>
</tbody>
</table>

Based on 300 mg cohort results, IMV and Incyte have agreed to stop dosing patients with epacadostat. IMV will continue the phase 1b/2 trial as a monotherapy study evaluating DPX-Survivac in the recurrent ovarian cancer subpopulation. IMV will inform and work with investigators to appropriately modify the study in a manner consistent with the best interests of each patient.

IMV and Incyte will continue to explore the potential of additional combination studies.

On December 13, 2018, the Corporation announced that investigators shared new positive data from the Corporation’s ongoing DeCidE1 clinical trial at the 2018 ESMO Immuno-Oncology Congress. The phase 1b/2 study was evaluating the safety and efficacy of the combination of IMV’s lead candidate DPX-Survivac, low dose cyclophosphamide, and 100 mg or 300 mg of Incyte’s IDO1 enzyme inhibitor epacadostat in patients with advanced recurrent ovarian cancer.

Key findings included:

• Evidence of a clinical marker based on BTB, a measure of tumour size predictive of patient response to DPX-Survivac:
37.5% (12/32) of evaluable study subjects began treatment with a non-bulky disease defined as BTB < 5 cm; and

73% (8/11) of tumour regressions and 80% of clinical responses (4/5) observed in subset of patients with BTB < 5 cm.

- Responders showing prolonged duration of clinical benefits reaching up to more than two years, surpassing the progression-free interval from their previous chemotherapy treatment;

- Robust systemic survivin-specific T cell responses and evidence of survivin-specific T cells tumour infiltration correlated with clinical benefits:
  - 100% of durable clinical responses correlated with T cell infiltration.

- Epacadostat triggered inhibition of the conversion of tryptophan into kynurenine that was dose dependent; and

- Cohort demographics were balanced and the combination yielded a tolerable safety profile.

At the time of data cut-off, 53 patients were enrolled in the phase 1b clinical trial, including 14 from the 100 mg epacadostat dosing cohort and 39 from 300 mg epacadostat cohort. Based on 300 mg cohort results, IMV and Incyte agreed to stop dosing patients with epacadostat before completion of the study. Patients who completed at least one CT scan, as required per the trial protocol, were evaluable for response analysis.

71% of patients were evaluable for responses in the 100 mg cohort and 56% in the 300mg dose cohort. At time of data cut-off, 8 participants remained on treatment and were being evaluated for clinical responses.

<table>
<thead>
<tr>
<th>Efficacy Parameter</th>
<th>Total target lesion size &lt; 5 cm</th>
<th>Total target lesion size ≥ 5 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mg (N=5)</td>
<td>300 mg (N=7)</td>
<td>All (N=12) N (%)</td>
</tr>
<tr>
<td>Regression</td>
<td>5 (100)</td>
<td>3 (42.9)</td>
</tr>
<tr>
<td>100 mg (N=5)</td>
<td>300 mg (N=16)</td>
<td>All (N=20) N (%)</td>
</tr>
<tr>
<td>PR<a href="1">^1</a></td>
<td>6 (14.3)</td>
<td>4 (33.3)</td>
</tr>
<tr>
<td>SD<a href="2">^2</a></td>
<td>2 (40.0)</td>
<td>4 (57.1)</td>
</tr>
<tr>
<td>DCR<a href="3">^3</a></td>
<td>5 (100)</td>
<td>5 (71.4)</td>
</tr>
</tbody>
</table>

[^1]: Partial Response (PR) is defined as ≥30% decrease in sum of target lesions
[^2]: Stable Disease (SD) is defined as < 30% decrease and ≥20% increase in sum of target tumour lesions
[^3]: Disease Control Rate (DCR) refers to the total number of patients achieving complete response, partial response, or stable disease.

First-in-human Phase 1 and 1b clinical trials in Ovarian cancer

DPX-Survivac was first tested in humans in maintenance therapy in subjects with advanced ovarian cancer who have no measurable disease following surgery and front-line platinum/taxane chemotherapy. Together, the completed phase 1 and phase 1b studies (n=56) identified a dose that was taken forward into the current phase 1b and 2 clinical studies.

Key findings from these clinical studies are summarized below:
• DPX-Survivac has been well tolerated, and the most frequent treatment related AEs in clinical studies conducted to date have been Grade 1 and Grade 2 injection site reactions;

• An active immune response was detected in > 92% of assayed subjects following treatment with DPX-Survivac and intermittent low dose CPA;

• There was an increase in systemic survivin-specific T cells on treatment and a measurable decrease in tumour burden (PR) in a subject with residual disease following treatment with DPX-Survivac in combination with intermittent low dose CPA; and

• DPX-Survivac in combination with the intermittent low dose CPA enhanced the systemic immune activation elicited by DPX-Survivac. Robust immune responses were generated after 1 to 2 doses, and these immune responses were maintained by subsequent dosing.

The results from these clinical trials were published in the peer-reviewed scientific journal *Oncoimmunology* in May 2015 at the ASCO 2015 conference.

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**Orphan Drug Status and Fast Track Designation**

The Corporation announced, in November 2016, that the European Medicines Agency (EMA) had granted orphan drug designation status to IMV’s DPX-Survivac in ovarian cancer. In July 2015, the FDA also granted orphan drug status to DPX-Survivac for the treatment of ovarian cancer. This designation is valid for all applications of DPX-Survivac in ovarian cancer without restriction to a specific stage of disease.

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

**OTHER PROGRAMS**

**Oncology**

**DPX-NEO**

On January 17, 2019, treatment of the first patient occurred in the phase 1 trial evaluating neoeptopes formulated in the Corporation’s proprietary DPX delivery platform in patients with ovarian cancer. The
study is part of the Corporation’s DPX-NEO program, which is a continuing collaboration between UConn Health and IMV to develop neoepitope-based anti-cancer therapies.

Investigators will assess the safety and efficacy of using patient-specific neoepitopes discovered at UConn Health and formulated in IMV’s proprietary DPX-based delivery technology in women with ovarian cancer. Investigators plan to enroll up to 15 patients in the phase 1 study. UConn Health is financing the trial with IMV providing materials and advice.

The Corporation expects to disclose results only when those are made available by UConn Health.

**DPX-E7**

Dana-Farber is leading the DPX-E7 study through a $1,500,000 research grant from Stand Up To Cancer and the Farrah Fawcett Foundation to clinically evaluate collaborative translational research that addresses critical problems in HPV-related cancers. The Dana-Farber study is a single center, open label, non-randomized clinical trial that will investigate the safety and clinical efficacy in a total of 44 treated participants. Its primary objectives are to evaluate changes in CD8+ T cells in peripheral blood and tumor tissue, and to evaluate the safety in HLA-A2 positive patients with incurable HPV-related head and neck, cervical, or anal cancers. The trial has pre-consented 76 patients so far, from which 11 patients have been treated.

The Corporation expects to disclose results only when those are made available by Dana-Farber.

**Other Applications**

**Product Overview**

A component of the Corporation’s business strategy is partnering the DPX platform for infectious and other disease applications. The DPX platform has the potential to generate a rapid and robust immune response, often in a single dose. The unique single-dose capability could prove to be beneficial in targeting difficult infectious and other disease candidates.

**DPX-COVID-19**

The ongoing pandemic outbreak of COVID-19 and its alarmingly quick transmission to over 125 countries across the world resulted in the World Health Organization (WHO) declaring a pandemic on March 11, 2020.

The outbreak is caused by a novel coronavirus, the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). There is an urgent need to develop vaccines to control its spread and help protect vulnerable populations. However, the bottleneck with current conventional vaccine approaches is the length of time required for vaccine development. The Corporation believes IMV’s DPX delivery technology offers the possibility of a fully synthetic epitope-based approach with the potential for accelerated development and rapid, large-scale production of a vaccine that would be compliant with current good manufacturing practice (cGMP).

Research in coronaviruses has identified the benefit of humoral and cellular (B and T cell) immune responses for treatment and protection from infection.

IMV believes that it has already demonstrated in multiple clinical trials in oncology and infectious diseases the potential of its technology for the induction of robust and sustained B and T cells. The Corporation
believes there is an opportunity to pursue a COVID-19 development program to establish the clinical safety and immunogenicity using a similar approach for COVID-19.

The Corporation intends to develop its vaccine candidate DPX-COVID-19 in collaboration with lead investigators for the phase 1 clinical study: Joanne Langley, M.D. and Scott Halperin, M.D., of the Canadian Center for Vaccinology (CCfV) at Dalhousie University, the Izaak Walton Killam Health Center and the Nova Scotia Health Authority and the Canadian Immunization Research Network (CIRN); along with Dr. Gary Kobinger, Ph.D., Director of the Research Centre on Infectious Diseases at the University Laval in Quebec City and Global Urgent and Advanced Research and Development (GUARD) in Canada. The investigators will assist with preclinical and clinical evaluation and with further development strategy in collaboration with the Canadian government and others.

Third-party research in related coronaviruses has identified the benefit of humoral and cellular (B and T cell) immune responses for protection and resolution of infection, and the Corporation believes the body of data it has produced to date supports its DPX platform for peptide-based induction of B cells and T cells. The Corporation is now designing a vaccine candidate against COVID-19 based on third-party immunological studies of SARS-CoV and third-party sequencing data available for SARS-CoV-2 with the goal of selecting potentially immunogenic epitopes within the virus that induce neutralizing antibody responses and protective T cell responses.

Through the Corporation’s other clinical studies, the Corporation believes its DPX technology has demonstrated a favorable safety profile and immunogenicity in both cancer and infectious disease settings, with sustained effect and potential for single-dose effectiveness as a prophylactic vaccine. Over 200 patients have been dosed with DPX-based immunotherapies and data from these studies suggest treatment is well-tolerated, including in heavily pre-treated cancer patients with advanced-stage disease. The Corporation has also applied this technology for the prevention of RSV, the second-leading cause of respiratory illness in infants, the elderly and the immunosuppressed. The Corporation reported its Phase 1 data from its clinical candidate, DPX-RSV, which demonstrated a favorable safety profile and immunogenicity in older adults (age 50-64), as well as preclinical data from research-stage candidates aimed at other infectious diseases, including malaria and anthrax.

RSV

The Corporation has performed preclinical research activities for an RSV targeted candidate, which is the second leading cause of respiratory illness in infants, the elderly, and the immunosuppressed. Currently, there is no preventive therapy available for this virus and IMV is seeking to develop a novel DPX-based formulation to be used in elderly and healthy adults, including women of child-bearing age. IMV has in-licensed the RSV antigen exclusively from VIB VZW, a non-profit life sciences research institute funded by the Flemish government, to expand its pipeline of DPX-based candidates. The novel RSV antigen being evaluated in the DPX platform is based on the short hydrophobic protein present at low levels on the surface of the RSV virion. But, more importantly, it is also present on the surface of RSV-infected cells. This DPX-based candidate has a unique mechanism of action in which the resultant antibodies bind to and destroy infected cells.

Phase 1 clinical trial in RSV

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

In October 2016 and April 2017, the Corporation announced positive topline results from this trial. The report outlined that more than nine months after the last vaccination, 15 of 16 participants (93%) who received DPX-RSV demonstrated antigen-specific immune responses. The candidate also continued to have a positive safety profile and was well tolerated with no SAEs among all study participants. Within the 25µg dose patient cohort, which was the only dose tested out to one year, 100 percent of older adults (7/7 immune responders) vaccinated with DPX-RSV maintained the antigen-specific immune responses one year after receiving the booster dose. After one year, the antibody levels measured were still at peak with no sign of decrease.

On September 27, 2018, IMV announced results of ongoing research to further explore the novel MOA of its candidate. New data from a preclinical study highlighted the effects of two potential approaches to preventing RSV, comparing a single dose bovine version of DPX-RSV to a two-dose conventional investigational bovine RSV (bRSV) preventive therapy. Researchers found that IMV’s targeted therapy yielded strong antigen-specific immune responses and a protective effect on disease pathology.

They found SH antibodies in 14 of the 15 animals that received DPX-bRSV, and the improvements observed in disease pathology were comparable between the two cohorts. These were the first bovine animal health data to directly correlate the induced immune response against IMV’s novel RSV target – the SH viral protein– with measures of disease protection.

Conventional RSV preventive therapies target either the F or G proteins of the virus and provide protection by neutralizing the RSV virus. Clinical measures of efficacy focus on the amount of neutralizing antibodies in the bloodstream. DPX-RSV works differently; it targets the SH viral ectodomain of the RSV virus and, instead of neutralizing the virus, it enables the immune system to recognize and destroy infected cells. Because there are no neutralizing antibodies resulting from the DPX-RSV MOA, a different clinical assessment is required to determine the candidate’s protective effect. IMV has exclusive worldwide licenses on applications that target the SH ectodomain antigen in RSV. The Corporation is exploring opportunities to out-license this product to potential partners.

**Leidos Collaboration**

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

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

On August 31, 2017, the Corporation announced the achievement of several milestones in its ongoing collaboration with global animal health company Zoetis to develop targeted T cell therapy for cattle. In recent controlled studies, the IMV formulations met efficacy and duration of immunity endpoints against two disease targets. These results will enable Zoetis to advance two DPX-formulation candidates into late-stage testing.

Licensing Agreements

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

In April 2018, IMV signed a licensing agreement and granted SpayVac-for-Wildlife (SFW Inc.) a license to two of its proprietary delivery platforms. SFW Inc. has global exclusive rights to use both of these platforms to develop humane, immune-contraceptive compounds for control of overabundant, feral and invasive wildlife populations against royalties on sales.

Intellectual Property

The Corporation strives to protect its intellectual property in established, as well as emerging, markets around the world. The Corporation’s intellectual property portfolio relating to its vaccine platform technology includes seventeen patent families, the first of which contains eight patents issued in five jurisdictions (United States, Europe, Canada, Japan, and Australia). The sixteen other families collectively contain forty-one patents issued in ten jurisdictions (United States, Europe, Canada, Australia, Japan, India, Israel, Singapore, China and separately Hong Kong) and sixty-one pending patent applications in nine jurisdictions. Taking into account the validations of the European patents, the Corporation’s intellectual property portfolio includes ninety-four patents.

U.S. Patent 6,793,923, issued in 2004, contains claims to the Corporation’s platform, covering a vaccine composition comprising any antigen other than a zona-pellucida-derived antigen, any adjuvant, any liposomes and a carrier, including any oil. Trademark protection is being and has been sought for the platform name, and other marks, in the United States and Canada.

Additional granted patents include:

- European Patent 1,333,858, granted February 8, 2006;
- Australian Patent 2002214861, granted January 11, 2007;
- Japanese Patent 4164361, granted August 1, 2008;
- United States Patent 7,824,686, granted November 2, 2010;
- Australian Patent 2006301891, granted December 20, 2012;
- Chinese Patent 101282742, granted September 18, 2013;
- European Patent 1,948,225, granted December 11, 2013;
- Australian Patent 2008303023, granted April 24, 2014;
- Australian Patent 2008307042, granted May 15, 2014;
- Singaporean Patent 166901, granted May 27, 2014;
- Japanese Patent 5591705, granted August 8, 2014;
- European Patent 2,296,696, granted August 27, 2014;
- Australian Patent 2009253780, granted November 27, 2014;
- Japanese Patent 5731198, granted April 17, 2015;
- Indian Patent 266563, granted May 18, 2015;
- Canadian Patent 2,428,103, granted June 9, 2015;
- Hong Kong Patent 1155642, granted July 24, 2015;
- Chinese Patent 200880110239.7, granted March 9, 2016;
- Chinese Patent 200980120883.7, granted April 6, 2016;
- European Patent 2,197,497, granted June 1, 2016;
- United States Patent 9,498,493, granted November 22, 2016;
- Canadian Patent 2,700,828, granted January 24, 2017;
- Australian Patent 2012321022, granted July 6, 2017;
- Canadian Patent 2,700,808, granted November 14, 2017;
- Japanese Patent 6254251, granted December 12, 2017;
• Canadian Patent 2,723,918, granted January 9, 2018;
• United States Patent 9,925,142, granted March 27, 2018;
• Israeli Patent 231888, granted May 29, 2018;
• United States Patent 10,022,441, granted July 17, 2018;
• Israeli Patent 209775, granted July 31, 2018;
• Singaporean Patent 11201401177W, granted October 10, 2018;
• United States Patent 10,105,435, granted October 23, 2018;
• European Patent 2978450, granted September 19, 2018;
• Australian Patent 2013384879, granted December 13, 2018;
• Japanese Patent 6448676, granted January 9, 2019;
• United States Patent 10,232,052, granted March 19, 2019;
• United States Patent 10,272,042, granted April 30, 2019
• Honk Kong Patent 1220914, granted September 6, 2019;
• Canadian Patent 2,622,464, granted September 9, 2019;
• Japanese Patent 6625587, granted December 25, 2019; and

Since 2008, the Corporation has filed 14 Patent Cooperation Treaty (“PCT”) applications relating to the Corporation’s technologies, some or all of which have now been filed in the United States, Europe, Japan, Canada, Australia, China, India, Brazil, Israel, Hong Kong and Singapore. These PCT applications cover specific DPX™ compositions with broad utility for infectious diseases and cancer applications, as well as methods of manufacture and other applications of the platform technology. Some of these applications have issued to patent as listed above. These patents, together with the other pending applications if allowed, extend patent protection for some or all DPX™ based compositions, and/or uses thereof, approximately up to the year 2040. The latest published PCT application covers methods of delivering active and immunomodulatory agents using DPX™.

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

Cancer Immunotherapies

Cancer is considered one of the most widespread and prevalent diseases globally. According to the 2019 Cancer Facts & Figures released by the American Cancer Society, it is predicted that the global cancer burden will rise to 27.5 million and the number of cancer deaths to 16.3 million by 2040 solely due to the growth of the aging population. However, these projections may be underestimates given the adoption of unhealthy behaviors and lifestyles associated with rapid income growth and changes in reproductive patterns in economically transitioning countries. According to the 2019 Cancer Facts & Figures, cancer usually develops in older people; 80% of all cancers in the United States are diagnosed in people 55 years of age or older. The “oldest old”, adults ages 85 and older are the fastest-growing population group in the US and women outnumber men in this age group because of a longer life expectancy.

Conventional cancer treatment involves surgery to remove the tumor whenever possible, as well as chemotherapy and radiation. Chemotherapies are widely used, despite their associated toxicities, because they interfere with the ability of cancer cells to grow and spread. However, studies have shown that older patients often receive little or no treatment because the benefit of prolonged survival does not outweigh potential adverse effects and impact on quality of life. Also, in all groups of patients, tumors often develop resistance to chemotherapies, thus 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 may provide new and effective treatments. According to a Market & Markets report released in September 2016, the global immunotherapy drug market is projected to reach USD$119.39 billion by 2021 from USD$61.97 billion in 2016, growing at a compound annual growth rate (CAGR) of 14% during the forecast period of 2016 to 2021. The major players operating in the immunotherapy drug market include F. Hoffmann-La Roche AG (Switzerland), GlaxoSmithKline (U.K.), AbbVie, Inc. (U.S.), Amgen, Inc. (U.S.), Merck. (U.S.), Bristol-Myers Squibb (U.S.), Novartis International AG (Switzerland), Eli Lilly and Corporation (U.S.), Johnson & Johnson (U.S.), and AstraZeneca plc (U.K.).

Cancer immunotherapy seeks to harness the immune system to assist in the destruction of tumors and to prevent their recurrence. There has been significant interest in the field of cancer immunotherapy stemming from recent clinical success in prolonging patient survival with novel compounds. The ability to apply these appropriately has resulted from a greater understanding of the immune dysfunction that is characteristic of cancer. One area in which there have been breakthroughs has been in the area of checkpoint inhibitors, which are compounds that target key regulatory molecules of the immune system. Yervoy® (anti CTLA 4, or ipilimumab, developed by Bristol Myers Squibb) was the first compound in this class to be approved for use in advanced metastatic melanoma. In cancer, these regulators (CTLA 4, PD 1 and its ligand PD L1) act to inhibit CD8 T cell-mediated anti-tumor immune responses that are crucial for tumor control. Monoclonal antibodies that target PD 1 and PD L1 have shown unusual efficacy in cancer patients, with a significant percentage of patients experiencing durable response to these therapies. Several of these compounds have been approved in multiple indications. Merck’s Keytruda® (pembrolizumab) and Bristol Myers Squibb’s Opdivo® (nivolumab) received FDA approval in 2014 for advanced melanoma patients who have stopped responding to other therapies. These therapies have subsequently been approved for use in other advanced cancers including bladder cancer, NSCLC, Hodgkin’s Lymphoma, squamous cell carcinoma of the head and neck and stomach cancer. In addition, Keytruda® in particular has been approved for use in cancers with a specific molecular indication irrelevant of cancer type, having been approved in May 2017 for use to treat solid tumors having a biomarker for microsatellite instability (MSI-H), which is a defect in the DNA repair pathway. This represents about 5% of a number of different tumor types, including colorectal, breast, prostate, and thyroid cancers.
These drugs have been shown to be helpful in treating several types of cancer but with success only in a limited percentage of patients. It is not yet known exactly why, though researchers have noticed that these drugs seem to work especially well for patients whose cancer cells have a higher number of mutations.

Key opinion leaders in the field have indicated that the solution lies in combining checkpoint inhibitors with other cancer treatments and that the ideal combination is likely to be a therapy that drives tumor specific immune responses. These include novel T cell-based therapies. These targeted therapies fit well with checkpoint inhibition therapy because they simultaneously activate strong tumor-specific T cell activation, while also releasing the brakes on immune suppression. The success of such combinations should allow pharmaceutical companies to significantly expand the market of their checkpoint inhibitors.

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

Manufacturing and Scalability

The Corporation has developed and implemented GMP (Good Manufacturing Practices) manufacturing process for DPX-Survivac. The scale-up methods have been transferred to, and manufacturing has been contracted out to reputable contract manufacturing organizations to manufacture sterile products for clinical purposes.

Facilities

The Corporation’s laboratory and head office is located at 130 Eileen Stubbs Avenue, Suite 19, Dartmouth, Nova Scotia where the Corporation is currently renting premises of approximately 14,941 sq. ft. The Corporation is also renting an administrative office in Quebec City of approximately 1,743 sq. ft. located at 2875 Boulevard Laurier, Suite 220, Quebec.

Regulatory Process

The FDA and Health Canada share similar processes by which new products are approved. In both cases, development and approval can be a lengthy process, in some cases over five to 10 years. The FDA approves products for the United States market and Health Canada does so for the Canadian market. Though the processes are generally similar, each regulatory body has its own unique requirements for a product. In order to sell a product in each market, it has to be approved by the appropriate governing body. In most cases, early studies conducted in one jurisdiction will be accepted in the other; however, further and somewhat modified studies may be required in order to have a product approved in another jurisdiction.

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

- discovery: early laboratory work to show that a compound can have unique chemical medicinal properties;
- pre-clinical proof-of-concept studies: studies usually conducted in laboratory animals (mice, etc.) to show that a compound is active in a living creature and retains its medicinal properties;
- Phase 1 clinical trial: a small study in human subjects which looks mainly at safety of the compound in humans. In order to be eligible to do a Phase 1 clinical trial, an IND application in the United States or a Clinical Trial Application (“CTA”) in Canada must be filed and approved by the
This application must contain information about the safety and efficacy of the compound in laboratory animals, any manufacturing information and chemical analysis. This is a lengthy process, requiring much involved research, conferences with regulatory authorities, clinicians, etc. At the conclusion of a successful Phase 1 clinical trial, a compound is shown safe in humans and further studies are warranted to show its efficacy to treat an illness;

- Phase 2 clinical trial: in a Phase 2 clinical trial, a larger population is used in order to establish appropriate dosing for the compound. This and any other clinical studies are also approved by the regulatory agencies. At the end of a successful Phase 2 clinical trial, the compound is shown to be active in the correct population and a relevant dose is chosen to continue its development;

- Phase 3 clinical trial: a large and sometimes multi-level trial, involving a statistically significant sample of the population for which the compound is designed. Stringent Chemistry, Manufacturing and Controls (CMC) are required which may delay the initiation of the trial. Phase 3 trials are designed to establish the efficacy of the compound and identify potential safety issues that may surface in the general population in order for the regulatory agency to better assess the risk/benefit of the compound when a registration application is made;

- registration application: a New Drug Application (“NDA”) or Biologics Licence Application (“BLA”) has to be filed with the regulatory body describing all of the clinical trials conducted to date, the relevant population, safety data, the label which will be placed on the pharmaceutical product, the sales/marketing information, etc. The regulatory body looks at the package and decides whether approval should be granted; and

- approval: once received, the pharmaceutical product may be sold to the target population. However, clinical studies may continue for the pharmaceutical product for a different segment of population (e.g. children vs. adults).

**Specialized Skill and Knowledge**

The business of the Corporation requires personnel with specialized skills and knowledge in the fields of basic and applied immunology. Researchers must be able to design and implement studies to assess the efficacy of DPX in generating humoral and cellular responses. Specialized knowledge and skills relating to chemistry and formulation process development are also needed. Such knowledge and skills are needed to develop product specific analytical methods and formulation processes. The Corporation has trained scientists with broad experience in these fields.

The Corporation has subcontracted out several key functions to conduct the clinical program for its clinical trials. However, the Corporation has internal resources, such as a Chief Medical Officer, Vice President of Clinical Research, Clinical and Regulatory Affairs Manager(s) and Clinical Research Associates and utilizes the services of consultants to ensure proper and timely completion of the required activities.

The Corporation also continues to conduct internal discovery and proof-of-concept work for other potential DPX applications, some of which is anticipated to be done with a partner organization.

**Scientific and Clinical Advisory Committee**

The Corporation has retained experienced academic and industry experts to assist its management in dealing with industry-related issues and how these issues may affect the Corporation’s scientific research and product development.
The Scientific and Clinical Advisory Committee consists of the following members:

**Ramy Ibrahim, MD**  
Vice President, Clinical Development  
Parker Institute for Cancer Immunotherapy

**James Johnston, MB, BCH, FRCPC**  
Senior Scientist, Research Institute in Oncology and Hematology  
Cancer Care Manitoba

**Grant McFadden, PhD**  
Director, Biodesign Center for Immunotherapy, Vaccines and Virotherapy  
Arizona State University

**Michael Aaron Morse, MD**  
Professor of Medicine and Professor in the Department of Surgery  
Duke University Medical Center

**Brad Nelson, PhD**  
Director and Distinguished Scientist, Deeley Research Centre  
BC Cancer Agency

**Kunle Odunsi, PhD, MD, FRCOG, FACOG**  
Cancer Center Deputy Director; Chair of the Department of Gynecologic Oncology; and Executive Director, Center for Immunotherapy  
Roswell Park Cancer Institute

**David Spaner, PhD, MD**  
Senior Scientist, Biological Sciences, Odette Cancer Research Program  
Sunnybrook Research Institute

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

**Equipment and components required to conduct activities**

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

The Corporation’s discovery and development processes involve the controlled use of hazardous and radioactive materials and, accordingly, the Corporation is subject to federal, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. To the knowledge of the Corporation, compliance with such environmental laws and regulations does not and will not have any significant impact on its capital spending, profits or competitive position within the normal course of its operating activities. There can be no assurance, however, that the Corporation will not be required to incur significant costs to comply with environmental laws and regulations in the future or that its operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations.

**Employees**

As at December 31, 2019, the Corporation had 62 full-time and part-time, including 12 employees holding PhD degrees, including one MD, and a number of other employees holding M.Sc. or MBA degrees. The Corporation’s employees are not governed by a collective bargaining agreement. The Corporation depends on certain key members of its management and scientific staff and the loss of services of one or more of these persons could adversely affect the Corporation. See “Risk Factors and Uncertainties”.

V. **RISK FACTORS AND UNCERTAINTIES**

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

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

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

Since inception, the Corporation has incurred significant operating losses. The net loss was $27.6 million for the year ended December 31, 2019, $21.9 million for the year ended December 31, 2018 and $12 million for the year ended December 31, 2017. As of December 31, 2019, the Corporation had an accumulated deficit of $120 million. To date, the Corporation has financed operations primarily through public offerings in Canada, private placements of securities, grants and license and collaboration agreements. The Corporation has devoted substantially all efforts to research and development, including clinical trials. IMV expects to continue to incur significant expenses and increasing operating losses for at least the next several years. The Corporation anticipates that the expenses will increase substantially if and as the Corporation:

- initiates or continues the clinical trials of DPX Survivac and other product candidates, such as DPX-SurMAGE, DPX-BRAF and DPX-COVID-19;
- seeks regulatory approvals for the product candidates that successfully complete clinical trials;
establishes a sales, marketing and distribution infrastructure to commercialize products for which the Corporation may obtain regulatory approval;

- maintains, expands and protects the Corporation’s intellectual property portfolio;
- continues other research and development efforts;
- hires additional clinical, quality control, scientific and management personnel; and
- adds operational, financial and management information systems and personnel, including personnel to support product development and planned commercialization efforts.

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

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

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

As of December 31, 2019, the Corporation had cash and cash equivalents of $14.1 million and working capital of $13.2 million.

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

The Corporation’s future capital requirements will depend on many factors, including:
• the progress and results of the clinical trials of DPX Survivac and other product candidates;

• the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for other product candidates;

• the costs, timing and outcome of regulatory review of any product candidate;

• the costs of commercialization activities, including product sales, marketing, manufacturing and distribution, for any of the product candidates for which regulatory approval is received;

• revenue, if any, received from commercial sales of the Corporation’s product candidates, should any of the product candidates be approved by the FDA, Health Canada or a similar regulatory authority outside the United States and Canada;

• the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing the Corporation’s intellectual property rights and defending intellectual property related claims;

• the extent to which the Corporation acquires or invests in other businesses, products and technologies;

• the Corporation’s ability to obtain government or other third party funding; and

• the Corporation’s ability to establish collaborations on favorable terms, if at all, particularly arrangements to market and distribute product candidates on a worldwide basis.

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

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

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

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

*The Corporation does not have governmental authorization to begin clinical testing of DPX-COVID-19, and the process of conducting necessary clinical studies, manufacturing and clinical organization, as well as obtaining such governmental authorization from Health Canada is not guaranteed.*

The Corporation is at the early stages of developing its proposed vaccine candidate DPX-COVID-19. Creating a new vaccine, testing it for toxicity and efficacy, securing clinical drug supply, scaling production and manufacturing, and establishing supply and distribution logistics are all steps that have significant natural time limitations. We have not received any authorization from Health Canada or any other governmental regulatory authority, to develop or initiate clinical trials for DPX-COVID-19, and although we have identified lead clinical investigators, the Corporation has not entered into any agreements for the establishment of clinical sites. Even if Health Canada were to accelerate the approval processes necessary to permit the Corporation to commence a phase 1 study and subsequent studies and trials to the maximum extent possible, the spread of the Coronavirus pandemic may be faster than its development efforts. There is no guarantee that even if the development of DPX-COVID-19 is successful, the Corporation will secure the necessary regulatory approval for its commercialization or that DPX-COVID-19 will receive market acceptance or reach the population in time. In addition, a number of other biotechnology companies, academic institutions and governmental entities are also researching and developing therapies and vaccines to address the COVID-19 pandemic, and many of these competitors have significantly greater financial and scientific resources than the Corporation. In light of the declaration by the World Health Organization of the pandemic, the third-party clinical investigators and clinical site operators that the Corporation may seek to collaborate with on the development of DPX-COVID-19, as well as governmental entities, may decide to prioritize or rationalize their resources in favor of competing therapies and vaccines. In such event, the Corporation’s efforts to develop DPX-COVID-19 could be delayed, which could harm the viability of this development program.

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

All of the product candidates of the Corporation are still in preclinical or clinical development. The Corporation may never be able to obtain regulatory approval for any of its product candidates. The Corporation has committed significant human and financial resources to the development of DPX Survivac, and the DPX Platform. The ability to generate product revenues, which is not expected to occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of these product candidates, especially DPX Survivac, the most advanced product candidate. The success of these product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- receipt of marketing approvals from the FDA, Health Canada and similar regulatory authorities outside the United States and Canada;
- establishing commercial manufacturing capabilities by identifying and making arrangements with third party manufacturers for the product candidates;
• maintaining patent and trade secret protection and regulatory exclusivity for the product candidates;

• launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;

• acceptance of the products, if and when approved, by patients, the medical community and third party payors;

• effectively competing with other therapies; and

• a continued acceptable safety profile of the products following approval.

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

If clinical trials of the product candidates, such as the ongoing and planned clinical trials of DPX Survivac or for DPX-SurMAGE, DPX-BRAF or DPX-COVID-19, fail to demonstrate safety and efficacy to the satisfaction of the FDA, Health Canada or similar regulatory authorities outside the United States and Canada or do not otherwise produce positive results, the Corporation may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of the product candidates.

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

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

• regulators or institutional review boards may not authorize the Corporation or its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

• the Corporation may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

• clinical trials of the product candidates may produce negative or inconclusive results, and the Corporation may decide, or regulators may require, additional clinical trials be conducted or product development programs be abandoned;

• the number of patients required for clinical trials of the product candidates may be larger than anticipated, enrollment in these clinical trials may be slower than anticipated or participants may drop out of these clinical trials at a higher rate than anticipated;
• the Corporation’s third party contractors may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all;

• the Corporation might have to suspend or terminate clinical trials of its product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;

• regulators or institutional review boards may require that the Corporation or its investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

• the cost of clinical trials of the product candidates may be greater than anticipated;

• the supply or quality of the product candidates or other materials necessary to conduct clinical trials of the product candidates may be insufficient or inadequate; and

• the Corporation’s product candidates may have undesirable side effects or other unexpected characteristics, causing the Corporation or its investigators, regulators or institutional review boards to suspend or terminate the trials.

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

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

• be delayed in obtaining marketing approval for its product candidates;

• not obtain marketing approval at all;

• obtain approval for indications or patient populations that are not as broad as intended or desired;

• obtain approval with labeling that includes significant use restrictions or safety warnings, including boxed warnings;

• have the product removed from the market after obtaining marketing approval;

• be subject to additional post marketing testing requirements; or

• be subject to restrictions on how the product is distributed or used.

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

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

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

Patient enrollment is affected by other factors including:

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

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

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

All of the Corporation’s product candidates are still in preclinical or clinical development and their risk of failure is high. It is impossible to predict when or if any of the Corporation’s product candidates will prove effective or safe in humans or will receive regulatory approval. If the Corporation’s product candidates are associated with undesirable side effects or have characteristics that are unexpected, the Corporation may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk benefit perspective.
The design or the Corporation’s execution of clinical trials may not support regulatory approval.

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

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

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

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

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

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

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

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

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

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

Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to the Corporation’s approaches, and others are based on entirely different approaches. Many marketed therapies for the indications that the Corporation is currently pursuing, or indications that it may in the future seek to address using the DPX platform, are widely accepted by physicians, patients and payors, which may make it difficult for the Corporation to replace with any products that the Corporation successfully develops and are permitted to market.

There are many FDA approved cancer therapies that may provide equivalent or better efficacy compared to DPX Survivac.

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

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

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

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

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

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

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

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

The Corporation has received significant funding from government organizations since its inception totaling over $15 million. There is no assurance the Corporation will continue to apply for and/or be awarded government funding in the future. If the Corporation is unable to obtain additional government funding, including as it relates to its DPX-COVID-19 program, it will have to either obtain funds through raising additional capital or arrangements with strategic partners or others, if available, that may require the Corporation to relinquish material rights to certain technologies or potential markets. There is no certainty that financing will be available in amounts the Corporation requires to pursue the planned activities or on acceptable terms, if at all.

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

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

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

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

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

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

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

The Corporation has based its research and development efforts on its DPX platform. Notwithstanding the large investment to date and anticipated future expenditures in its DPX platform, the Corporation has not yet developed, and may never successfully develop, any marketed drugs using this approach. As a result of pursuing the development of product candidates using the DPX platform, the Corporation may fail to develop product candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success.

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

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

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

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

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

The Corporation will need to raise capital or develop collaborations with third parties to commercialize its products. If the Corporation is not able to obtain such funding or enter into collaborations for any such product candidate, the Corporation may have to curtail the development of such product candidate, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase its expenditures and undertake development or commercialization activities at the Corporation’s own expense. If the Corporation elects to increase its expenditures to fund development or commercialization activities on its own, the Corporation may need to obtain additional capital, which may not be available to the Corporation on acceptable terms or at all. If the Corporation does not have sufficient funds, the Corporation may not be able to further develop these product candidates or bring these product candidates to market and generate product revenue.

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

- collaborators may not pursue development and commercialization of the Corporation’s product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator’s strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with the Corporation’s products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than the Corporation’s;

- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

- collaborators may not properly maintain or defend the Corporation’s intellectual property rights or may use the Corporation’s proprietary information in such a way as to invite litigation that could jeopardize or invalidate the Corporation’s proprietary information or expose the Corporation to potential litigation;

- disputes may arise between the collaborators and the Corporation that result in the delay or termination of the research, development or commercialization of the Corporation’s products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. For example, the Corporation could have to build a sales force.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future collaborator of the Corporation were to be involved in a business combination, the continued pursuit and emphasis on the Corporation’s product development or commercialization program could be delayed, diminished or terminated.
The Corporation relies on third parties to conduct its clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

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

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

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

The Corporation currently procures ingredients and intermediate drug substances for the manufacturing of the Corporation’s pipeline products from specialized suppliers. For some components, including raw ingredients, the Corporation has so far identified only one supplier which is qualified for the Corporation’s GMP process. In the event that a supplier stops supplying the required ingredient(s), the Corporation may need to identify an alternative source of such components and may need to wait until it is qualified for the Corporation’s GMP process before procuring the components, which may cause substantial delays to one or all of the Corporation’s clinical programs.

Risks Related to the Manufacturing of the Corporation’s Product Candidates

Natural disasters, public health crises, political crises, and other catastrophic events outside of our control may damage the facilities or disrupt the operations of our strategic partners, third party manufacturers, suppliers or other third parties upon which we rely, and could delay or impair our ability to initiate or complete our clinical trials or commercialize candidate product.

Our strategic partners, third-party manufacturers, suppliers and other third parties upon which we rely have operations around the world and are exposed to a number of global and regional risks outside of our control. These include, but are not limited to, natural disasters, such as earth quakes, tsunamis, power shortages or outages, floods or monsoons, public health crises, such as pandemics and epidemics, political crises, such as terrorism, war, political instability or other conflict, or other events outside of our control.
In December 2019, a novel strain of coronavirus (COVID-19) emerged in Wuhan, Hubei Province, China. While initially the outbreak was largely concentrated in China and caused significant disruptions to the economy, it has now spread to several other countries and infections have been reported around the world which resulted in the World Health Organization (WHO) declaring a pandemic on March 11, 2020 and have caused governmental authorities and non-governmental entities to introduce measures to try to limit this pandemic. The extent to which coronavirus (COVID-19) impacts our operations will depend on future developments which are highly uncertain and cannot be predicted with confidence. Some components of our products are manufactured by third parties located in other countries, including Germany, Japan and China. The continued spread of the coronavirus (COVID-19) globally could adversely impact our operations, including among others, our manufacturing supply chain, clinical trial operations and could have an adverse impact on our business and financial results.

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

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

Currently the Corporation is utilizing the GMP services of a contract manufacturing organization (“CMO”) located in the United States for its clinical drug product manufacturing and does not have a fully qualified and approved backup facility. The Corporation may need to approve an alternative CMO to avoid delays in planned clinical programs should there be any issues with the current CMO. The Corporation’s products require a unique manufacturing process and uses specialized equipment manufactured by another third party to manufacture the Corporation’s clinical candidate vaccines. The specialized equipment used during the manufacturing process is made by only one manufacturer. In the event of catastrophic equipment failure and in the event that this particular supplier of the equipment ceases its operations and/or replacement equipment cannot be procured, alternative suppliers of similar equipment may be sought and additional product development may be required, which may cause significant delays to some or all of the Corporation’s clinical programs.

Risks Related to the Corporation’s Intellectual Property

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

The Corporation is a party to a number of intellectual property license agreements with third parties and expects to enter into additional license agreements in the future. The Corporation’s existing license agreements impose, and the Corporation expects that future license agreements will impose, various diligences, milestone payment, royalty, insurance, indemnification and other obligations on the Corporation. If the Corporation fails to comply with its obligations under these licenses, its licensors may have the right to terminate these license agreements, in which event the Corporation might not be able to market any product that is covered by these agreements, or to convert the license to a non-exclusive license,
which could materially adversely affect the value of the product candidate being developed under the license agreement. Termination of these license agreements or reduction or elimination of the Corporation’s licensed rights may result in the Corporation having to negotiate new or reinstated licenses with less favorable terms.

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

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

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

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

Assuming the other requirements for patentability are met, in the United States, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is generally entitled to the patent. Under the America Invents Act, or AIA, enacted in September 2011, the United States moved to a first inventor to file system in March 2013. The Corporation may become involved in opposition or interference proceedings challenging its patent rights or the patent rights of others. An adverse determination in any such proceeding or litigation could reduce the scope of, or invalidate, the Corporation’s patent rights, allowing third parties to commercialize its technology or
products and compete directly with the Corporation, without payment to the Corporation, or result in its inability to manufacture or commercialize products without infringing third party patent rights. For example, Merck has to maintain patents on antigens licensed to the Corporation.

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

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

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

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

The Corporation’s commercial successes depends upon its ability and the ability of its collaborators to develop, manufacture, market and sell its product candidates and use its proprietary technologies without infringing the proprietary rights of third parties. The Corporation may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to its products and technology, including interference proceedings before the U.S. Patent and Trademark Office or other similar regulatory authorities. Third parties may assert infringement claims against the Corporation based on existing patents or patents that may be granted in the future. If the Corporation is found to infringe a third party’s intellectual property rights, it could be required to obtain a license from such third party to continue developing and marketing its products and technology. However, the Corporation may not be able to obtain any required license on commercially reasonable terms or at all. Even if the Corporation was able to obtain a license, it could be non-exclusive, thereby giving its competitors access to the same technologies licensed to the Corporation. The Corporation could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, the Corporation could be found liable
for monetary damages. A finding of infringement could prevent the Corporation from commercializing its product candidates or force the Corporation to cease some of its business operations, which could materially harm the Corporation’s business. Claims that the Corporation has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business.

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

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

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

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

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

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

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

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

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

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

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

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

_The Corporation must successfully upgrade and maintain its information technology systems._

The Corporation relies on various information technology systems to manage its operations. There are inherent costs and risks associated with maintaining, modifying and/or changing these systems and implementing new systems, including potential disruption of the Corporation’s internal control structure, substantial capital expenditures, additional administration and operating expenses, retention of sufficiently skilled personnel to implement and operate its systems, demands on management time and other risks and costs of delays or difficulties in transitioning to new systems or of integrating new systems into the

Corporation’s current systems. In addition, the Corporation’s information technology system implementations may not result in productivity improvements at a level that outweighs the costs of implementation, or at all. The implementation of new information technology systems may also cause disruptions in the Corporation’s business operations and have an adverse effect on its business, prospects, financial condition and operating results.

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

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

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

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. To date, the FDA has only approved one active cellular immunotherapy product. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA or Health Canada has substantial discretion in the approval process and may refuse to accept any application or may decide that the Corporation’s data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval the Corporation ultimately obtains may be limited or subject to restrictions or post approval commitments that render the approved product not commercially viable.

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

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

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

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

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

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

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

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that it submits;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of the Corporation’s products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

- the federal healthcare anti kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

- the federal False Claims Act imposes civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services;

- the federal transparency requirements under the Health Care Reform Law will require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

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

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

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

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

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

In March 2010, President Obama signed into law the Health Care Reform Law, a law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect the Corporation’s business practices with health care practitioners. The Corporation will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, this law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase the Corporation’s regulatory burdens and operating costs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Health Care Reform Law. The Corporation expects that the current Presidential Administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Health Care Reform Law. The Corporation cannot be sure whether legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of the Corporation’s product candidates, if any, may be.
With the enactment of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), as part of the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years, or approved by the FDA until 12 years, after the original brand product identified as the reference product was approved under a BLA. The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for the Corporation’s biological products.

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

**General Risks related to the Corporation**

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

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

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to the Corporation’s success. The Corporation may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. The Corporation also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, the Corporation relies on consultants and advisors, including scientific and clinical advisors, to assist it in formulating its research and development and commercialization strategy. The Corporation’s consultants and advisors may be employed by employers other than the Corporation and may have commitments under consulting or advisory contracts with other entities that may limit their availability to the Corporation.

*The Corporation may be unable to obtain scientific research and experimental development tax incentive credits in Canada.*

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

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

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

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

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

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

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

- the fact that the Corporation has limited experience operating its business internationally;
- local, economic and political conditions, including inflation, geopolitical events, such as war and terrorism, foreign currency fluctuations and exchange risks, which could result in increased or unpredictable operating expenses and reduced revenues and other obligations incident to doing business in, or with a company located in, another country;
- the Corporation’s customers’ ability to obtain reimbursement for any product candidate in foreign markets, and unexpected changes in reimbursement and pricing requirements, tariffs, trade barriers and regulatory requirements;
different medical practices and customs in foreign countries affecting acceptance in the marketplace;

longer lead times for shipping and longer accounts receivable collection times;

the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;

reduced protection of intellectual property rights in some foreign countries or the existence of additional potentially relevant third party intellectual property rights; and

compliance with foreign laws, rules and regulations, including data privacy requirements, labor relations laws, tax laws, accounting requirements, anti-competition regulations, import, export and trade restrictions, anti-bribery/anti-corruption laws, regulations or rules, which could lead to actions by the Corporation or its licensees, distributors, manufacturers, other third parties who act on its behalf or with whom the Corporation does business in foreign countries or the Corporation’s employees who are working abroad that could subject the Corporation to investigation or prosecution under such foreign laws.

As a passive foreign investment company (“PFIC”) for United States federal income tax purposes, certain adverse tax rules may apply to U.S. holders of the Common Shares.

Based on the composition of the Corporation’s income and the value of its assets, the Corporation believes that it is a PFIC for United States federal income tax purposes for the 2019 taxable year and, based on estimates of the Corporation’s income and assets for 2020, the Corporation believes that it is likely to be a PFIC for the 2020 taxable year.

The Corporation will be classified as a PFIC for any taxable year for United States federal income tax purposes if either (i) 75% or more of its gross income in that taxable year is passive income or (ii) the average percentage of its assets by value in that taxable year which produce or are held for the production of passive income (which includes cash) is at least 50%.

PFIC status is determined annually and depends upon the composition of a company’s income and assets and the market value of its stock from time to time. Therefore, there can be no assurance as to the Corporation’s PFIC status for future taxable years. The value of the Corporation’s assets will be based, in part, on the then market value of its Common Shares, which is subject to change.

If the Corporation is a PFIC for any taxable year during which a U.S. holder (as defined under “Certain U.S. Federal Income Tax Considerations” in this prospectus) holds Common Shares, such U.S. holders could be subject to adverse United States federal income tax consequences whether or not the Corporation continues to be a PFIC. For example, U.S. holders of Common Shares may become subject to increased tax liabilities under United States federal income tax laws and regulations, and will become subject to burdensome reporting requirements. If the Corporation is a PFIC during a taxable year in which a U.S. holder holds Common Shares, such U.S. holder may be able to make a “mark-to-market” election or a “qualified electing fund” election that could mitigate the adverse United States federal income tax consequences that would otherwise apply to such U.S. holder. Although upon request of a U.S. holder of Common Shares, the Corporation will provide the information necessary for a U.S. holder to make the qualified electing fund election with respect to the Corporation, no assurance can be given that such information will be available for any lower-tier PFIC that the Corporation does not control.
U.S. holders of Common Shares are urged to consult their own tax advisers as to the United State federal income tax consequences related to the Corporation’s expected classification as a PFIC.

**United States investors may not be able to obtain enforcement of civil liabilities against the Corporation.**

The enforcement by investors of civil liabilities under the United States federal or state securities laws may be affected adversely by the fact that the Corporation is governed by the Canada Business Corporations Act, that the majority of the Corporation officers and directors are residents of Canada, and that all, or a substantial portion of their assets and a substantial portion of the Corporation assets, are located outside the United States. It may not be possible for investors to effect service of process within the United States on certain of its directors and officers or enforce judgments obtained in the United States courts against the Corporation or certain of the Corporation directors and officers based upon the civil liability provisions of United States federal securities laws or the securities laws of any state of the United States.

**As a foreign private issuer, the Corporation is subject to different U.S. securities laws and rules than a domestic U.S. issuer, which may limit the information publicly available to its U.S. shareholders.**

The Corporation is a foreign private issuer under applicable U.S. federal securities laws and, therefore, is not required to comply with all of the periodic disclosure and current reporting requirements of the United States Securities Exchange Act of 1934, as amended (the “Exchange Act“) and related rules and regulations. As a result, the Corporation does not file the same reports that a U.S. domestic issuer would file with the United States Securities and Exchange Commission (the “SEC”), although it will be required to file with or furnish to the SEC the continuous disclosure documents that the Corporation is required to file in Canada under Canadian securities laws. In addition, the Corporation’s officers, directors and principal shareholders are exempt from the reporting and “short swing” profit recovery provisions of Section 16 of the Exchange Act. Therefore, the Corporation’s shareholders may not know on as timely a basis when its officers, directors and principal shareholders purchase or sell securities of IMV as the reporting periods under the corresponding Canadian insider reporting requirements are longer. In addition, as a foreign private issuer, the Corporation is exempt from the proxy rules under the Exchange Act.

**The Corporation may lose its foreign private issuer status in the future, which could result in significant additional costs and expenses to the Corporation.**

In order to maintain its current status as a foreign private issuer, a majority of the Corporation’s Common Shares must be either directly or indirectly owned of record by non-residents of the United States unless the Corporation also satisfies one of the additional requirements necessary to preserve this status. The Corporation may in the future lose its foreign private issuer status if a majority of the Common Shares are owned of record in the United States and the Corporation fails to meet the additional requirements necessary to avoid loss of foreign private issuer status. The regulatory and compliance costs to the Corporation under U.S. federal securities laws as a U.S. domestic issuer may be significantly more than the costs the Corporation incurs as a Canadian foreign private issuer eligible to use the multijurisdictional disclosure system (“MJDS”). If the Corporation is not a foreign private issuer, it would not be eligible to use the MJDS or other foreign issuer forms and would be required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. In addition, the Corporation may lose the ability to rely upon exemptions from Nasdaq corporate governance requirements that are available to foreign private issuers.
VI. DIVIDENDS

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

VII. DESCRIPTION OF CAPITAL STRUCTURE

The Corporation is authorized to issue an unlimited number of Common Shares, without nominal or par value of which, as at March 30, 2020, 51,028,180 Common Shares are issued and outstanding as fully-paid and non-assessable Common Shares. The holders of Common Shares are entitled to receive notice of, to attend and to vote at any meeting of the shareholders of the Corporation and each one Common Share shall carry the right to one vote. Subject to the prior rights of the holders of Preferred Shares (as defined hereinafter), the holders of Common Shares are entitled to receive dividends as and when declared by the Board of Directors of the Corporation. The holders of Common Shares have the right, subject to the rights, privileges, restrictions and conditions attaching to any other class of shares of the Corporation, to receive the remaining property of the Corporation upon dissolution, liquidation or winding-up thereof.

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

VIII. MARKET FOR SECURITIES

Trading Price and Volume

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

The following table provides the price ranges and trading volume of the Common Shares on the TSX for the periods indicated below:

<table>
<thead>
<tr>
<th>Date</th>
<th>High (C$)</th>
<th>Low (C$)</th>
<th>Total Cumulative Volume(1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2019</td>
<td>C$7.75</td>
<td>C$6.79</td>
<td>491,743</td>
</tr>
<tr>
<td>February 2019</td>
<td>C$7.44</td>
<td>C$6.30</td>
<td>547,500</td>
</tr>
<tr>
<td>March 2019</td>
<td>C$6.00</td>
<td>C$4.78</td>
<td>1,462,493</td>
</tr>
<tr>
<td>April 2019</td>
<td>C$5.53</td>
<td>C$3.95</td>
<td>1,207,785</td>
</tr>
<tr>
<td>May 2019</td>
<td>C$6.17</td>
<td>C$4.86</td>
<td>1,167,399</td>
</tr>
<tr>
<td>June 2019</td>
<td>C$5.91</td>
<td>C$3.58</td>
<td>1,446,270</td>
</tr>
<tr>
<td>July 2019</td>
<td>C$4.60</td>
<td>C$3.55</td>
<td>592,613</td>
</tr>
<tr>
<td>August 2019</td>
<td>C$4.20</td>
<td>C$3.06</td>
<td>593,529</td>
</tr>
<tr>
<td>September 2019</td>
<td>C$4.40</td>
<td>C$3.22</td>
<td>397,164</td>
</tr>
<tr>
<td>October 2019</td>
<td>C$4.10</td>
<td>C$3.01</td>
<td>689,477</td>
</tr>
<tr>
<td>November 2019</td>
<td>C$3.95</td>
<td>C$2.77</td>
<td>1,003,585</td>
</tr>
<tr>
<td>December 2019</td>
<td>C$4.10</td>
<td>C$3.30</td>
<td>748,590</td>
</tr>
</tbody>
</table>
The following table provides the price ranges and trading volume of the Common Shares on Nasdaq for the periods indicated below:

<table>
<thead>
<tr>
<th></th>
<th>Price Ranges</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High (US$)</td>
<td>Low (US$)</td>
<td>Total Cumulative Volume</td>
<td></td>
</tr>
<tr>
<td>January 2019</td>
<td>US$5.85</td>
<td>US$5.00</td>
<td>32,118</td>
<td></td>
</tr>
<tr>
<td>February 2019</td>
<td>US$5.67</td>
<td>US$4.80</td>
<td>175,377</td>
<td></td>
</tr>
<tr>
<td>March 2019</td>
<td>US$4.37</td>
<td>US$3.60</td>
<td>1,482,792</td>
<td></td>
</tr>
<tr>
<td>April 2019</td>
<td>US$4.06</td>
<td>US$2.90</td>
<td>480,834</td>
<td></td>
</tr>
<tr>
<td>May 2019</td>
<td>US$4.57</td>
<td>US$3.56</td>
<td>669,721</td>
<td></td>
</tr>
<tr>
<td>June 2019</td>
<td>US$4.50</td>
<td>US$2.69</td>
<td>703,778</td>
<td></td>
</tr>
<tr>
<td>July 2019</td>
<td>US$3.82</td>
<td>US$2.72</td>
<td>305,853</td>
<td></td>
</tr>
<tr>
<td>September 2019</td>
<td>US$3.31</td>
<td>US$2.48</td>
<td>121,673</td>
<td></td>
</tr>
<tr>
<td>October 2019</td>
<td>US$3.16</td>
<td>US$2.29</td>
<td>109,836</td>
<td></td>
</tr>
<tr>
<td>December 2019</td>
<td>US$3.11</td>
<td>US$2.52</td>
<td>534,473</td>
<td></td>
</tr>
</tbody>
</table>

**Prior Sales**

The only securities of IMV that are outstanding but not listed or quoted on a marketplace are stock options, compensation options and deferred stock units.

**Stock Options**

During the year ended December 31, 2019, the Corporation issued 343,100 stock options, which have an exercise period of 5 years from that date of grant:

<table>
<thead>
<tr>
<th>Date</th>
<th>Number</th>
<th>Exercise Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 15, 2019</td>
<td>243,100</td>
<td>$7.39</td>
</tr>
<tr>
<td>November 7, 2019</td>
<td>100,000</td>
<td>$3.95</td>
</tr>
</tbody>
</table>

**IX. DIRECTORS AND OFFICERS**

**Directors**

As at March 30, 2020, as a group, the Corporation’s directors and executive officers beneficially owned, directly or indirectly, or exercised control of over an aggregate of 557,651 Common Shares representing 1.10% of the issued and outstanding Common Shares as at such date. The information as to the number of Common Shares beneficially owned or over which control is exercised, not being within the knowledge of the Corporation, has been obtained from the System for Electronic Disclosure by Insiders (SEDI) and confirmed with each director or executive officer, as the case may be, individually as at March 30, 2020.

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

<table>
<thead>
<tr>
<th>Name and Municipality of Residence</th>
<th>Position Held with the Corporation</th>
<th>Principal Occupation during Past Five Years</th>
<th>Director Since</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andrew Sheldon (1) (Québec, Québec, Canada)</td>
<td>Chairman of the Board and Director</td>
<td>Chairman of Quebec International Former Chief Executive Officer of Medicago Inc. (Biotech company)</td>
<td>April 2016</td>
</tr>
<tr>
<td>Julia P. Gregory (2)(3) (Scarborough, New York, United States)</td>
<td>Director</td>
<td>Chair and CEO of Isometry Advisors Inc. (Management and financial consultants) CEO of ContraFect Corporation (Biotech company)</td>
<td>June 2018</td>
</tr>
<tr>
<td>James Hall (3) (Toronto, Ontario, Canada)</td>
<td>Director</td>
<td>President of James Hall Advisors Inc. (advisory firm) Senior Vice President of Callidus Capital Corporation (specialized asset-based lender to companies in Canada and the United States)</td>
<td>February 2010</td>
</tr>
<tr>
<td>Frederic Ors (Québec, Québec, Canada)</td>
<td>Director</td>
<td>Chief Executive Officer of IMV Inc. Former Chief Business Officer of IMV Inc. Former Vice President of Business development and Strategic Planning of Medicago Inc. (biotech company)</td>
<td>April 2016</td>
</tr>
<tr>
<td>Wayne Pisano (3)(4) (Asbury, New Jersey, United States)</td>
<td>Director</td>
<td>Former President and Chief Executive Officer of VaxInnate (pandemic and influenza vaccine company) and Former President and Chief Executive Officer of Sanofi Pasteur (pediatric and adult vaccine manufacturing company)</td>
<td>October 2011</td>
</tr>
<tr>
<td>Shermaine Tilley (2)(4) (Toronto, Ontario, Canada)</td>
<td>Director</td>
<td>Managing Partner of CTI Life Sciences Fund (venture capital fund)</td>
<td>June 2016</td>
</tr>
<tr>
<td>Markus Warmuth (4) (Boston, Massachusetts, United States)</td>
<td>Director</td>
<td>Entrepreneur in residence Third Rock Ventures (venture fund) CEO of H3 Biomedicine</td>
<td>November 2018</td>
</tr>
</tbody>
</table>

(1) Mr. Sheldon is a non-voting member of the Compensation Committee, Corporate Governance Committee and the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Audit Committee.
(4) Member of the Corporate Governance Committee.
Biographies

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

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

Julia P. Gregory

Ms. Gregory is a seasoned biotechnology executive with a proven track record for successfully growing, capitalizing and repositioning private and public biotechnology companies. She is well-versed in corporate governance and SEC issues and has extensive experience in recruiting outstanding management teams. As a biotechnology executive, she has raised more than $1.5 billion for biotechnology companies across all types of business cycles and structured creative strategic alliances and transactions for them with pharmaceutical companies including GlaxoSmithKline, Bristol-Myers Squibb Company, Takeda Pharmaceutical Company, Ltd., Genentech, Inc. (now Roche) and Human Genome Sciences (now GSK). Most recently, she was CEO and Board member of ContraFect (Nasdaq: CFRX), which focused on new biologics as an alternative to antibiotics. Prior to ContraFect, she was CEO and Board member of FivePrime Therapeutics (Nasdaq: FXRX), which discovered and developed innovative protein and antibody therapeutics in the fields of oncology and immunology. She was the EVP Corporate Development and Chief Financial Officer of Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX) during its $220 million initial public offering and was involved in the creation of Lexicon’s $500 million private equity investment plan. In addition to her deep experience in the biopharmaceutical industry, Ms. Gregory has twenty years of investment banking experience, starting at Dillon, Read & Co., Inc. and subsequently at Punk, Ziegel & Company, where she served as the head of investment banking and head of its life sciences practice. Ms. Gregory has also served on the Board of Directors at The Global TB Alliance for Drug Development, Clinipace Worldwide, and the Institute for the Study of Aging, a private foundation for Alzheimer’s. She was formerly the Executive Chair of Cavion, Inc.(sold to Jazz Pharmaceuticals), Director of the Sosei Group Corporation and currently is a Director at Iconic Therapeutics, Kuur Therapeutics (formerly Cell Medica, Ltd), Freeline Therapeutics Ltd, Nurix Therapeutics, Inc and Biohaven Pharmaceutical Holding Company Ltd. (NYSE: BHVN). Ms. Gregory attained a Masters of Business Administration from The Wharton School of The University of Pennsylvania and her B.A. in International Affairs from George Washington University’s Elliott School of International Affairs where she was elected to Phi Beta Kappa.

James W. Hall, Director

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

**Frederic Ors, Chief Executive Officer and Director**

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

**Wayne Pisano, Director**

Mr. Pisano has more than 30 years of experience as a pharmaceutical industry executive. He has a depth of experience across the spectrum of commercial operations, public immunization policies and pipeline development. Mr. Pisano is a former president and CEO of Sanofi Pasteur, one of the largest vaccine companies in the world. He joined Sanofi Pasteur in 1997 and was promoted to President and CEO in 2007, the position he successfully held until his retirement in 2011. Post his retirement from Sanofi Pasteur, Mr. Pisano joined VaxInnate, a privately held biotech company, from January 2012 until November 2016 serving as president and CEO. Prior to joining Sanofi Pasteur, he spent 11 years with Novartis (formerly Sandoz). He has a bachelor’s degree in biology from St. John Fisher College, New York and an MBA from the University of Dayton, Ohio. He has served as a Board director for AERAS a non-profit organization with a focus on TB vaccine development and is currently a board member of Oncolytics Biotech Inc, Provention Bio Inc. and AlImmune Inc.

**Dr. Shermaine Tilley, Director**

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

**Dr. Markus Warmuth, Director**

As a long-time advocate for industry collaboration and data-driven drug discovery, Dr. Warmuth brings over 20 years of immuno-oncology and precision medicine drug development expertise to IMV. He currently serves as an Entrepreneur in Residence at Third Rock Ventures, where he plays an integral role in the venture capital firm’s formation of new anti-cancer biotech companies. Prior to his role at Third Rock, Dr. Warmuth spent seven years as the Chief Executive Officer of H3 Biomedicine, a
biopharmaceutical company that specializes in the discovery and development of genomics-based precision oncology treatments. Dr. Warmuth has also previously served in multiple roles at the Novartis Institute for Biomedical Research (NIBR) and the Genomics Institute of the Novartis Research Foundation (GNF), including as the Director of Kinase Biology, Head of Oncology Pharmacology. He earned his MD from Ludwig Maximilian University in Munich, Germany.

**Executive Officers**

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

<table>
<thead>
<tr>
<th>Name and Municipality of Residence</th>
<th>Position held with the Corporation</th>
<th>Principal Occupation during Past Five Years</th>
</tr>
</thead>
</table>
| Pierre Labbé (Québec City, Québec, Canada) | Chief Financial Officer | Vice President and Chief Financial Officer of Leddartech Inc.  
Vice President and Chief Financial Officer of the Québec Port Authority |
| Joanne Schindler (Sherborn, Massachusetts, United States of America) | Chief Medical Officer | VP, Clinical Development, Executive Medical Director for H3 Biomedicine  
Clinical Program Lead for Agios Pharmaceuticals  
VP, Clinical Development for Constellation Pharmaceuticals, Inc.  
Senior Medical Oncology Consultant for Development Insights LLP, consulting group |
| Joseph Sullivan (Wyndmoor, Pennsylvania, United States of America) | Senior Vice President, Business Development | Executive Director, Merck & Company, Inc. |

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

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

**Joanne Schindler, MD, Chief Medical Officer**

Prior to joining IMV, Dr. Schindler served as Vice President, Clinical Development and Executive Medical Director at H3 Biomedicine, overseeing the company’s clinical development efforts. Previously, she worked as Vice President, Clinical Development at Constellation Pharmaceuticals, and earlier held various clinical development leadership roles at SynDevRx, ImmunoGen, Novartis, Fresenius Biotech and GlycoGenesys. Joanne holds an M.D. from the University of Connecticut School of Medicine, a D.V.M. from Tufts University School of Veterinary Medicine and a B.A. in biology from Brandeis University.

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

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

Shareholding, Cease Trade Orders, Bankruptcies, Penalties or Sanctions

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

a. a director, chief executive officer or chief financial officer of any corporation (including the Corporation) that:
   i. was subject to an order that was issued while the proposed director was acting in the capacity as director, chief executive officer or chief financial officer, or
   ii. was subject to an order that was issued after the proposed director ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

b. a director or executive officer of any corporation (including the Corporation) that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or

c. has become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromises with creditors, or had a receiver, manager or trustee appointed to hold the assets of the proposed director.

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

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

a. any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or

b. any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable security holder in deciding whether to vote for a proposed director.

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

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

X. CORPORATE GOVERNANCE

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

Board of Directors

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

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

As a practice, the Board approves significant corporate communications with shareholders. The Board currently consists of eight members. The Corporation has historically endeavoured to have a diverse Board with a sufficient number of directors to encourage a variety of opinions on matters which come before the Board, while at the same time limiting its membership to a number of directors that facilitates effective and efficient decision making. While there are no specific criteria for Board membership, the Corporation seeks to attract directors with a wealth of business knowledge and a diversity of business experience.

Board Functioning

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

Board Committees

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

The primary function of the Audit Committee is to assist the Board of Directors in fulfilling its oversight responsibilities by reviewing: (i) the financial information that will be provided to the shareholders and others; (ii) the systems of internal controls which management and the Board of Directors have established; and (iii) the Corporation’s audit and financial reporting process. The external auditors’ ultimate responsibility is to the Board of Directors and the Committee, as representatives of the shareholders. The text of the Audit Committee Mandate is set forth in Schedule A hereto.

The Audit Committee is currently composed of Mr. James Hall (Chairman), Mr. Wayne Pisano and Ms. Julia P. Gregory, as well as Mr. Andrew Sheldon, as a non-voting member, all of whom are financially literate and independent directors within the meaning of National Instrument 52-110 – *Audit Committees.* The education and related experience of each current Audit Committee member is described below.

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

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

Julia P. Gregory – Ms. Gregory has a MBA from The Wharton School of The University of Pennsylvania and is the former CEO of ContraFect (Nasdaq: CFRX) and prior to that she was CEO of FivePrime Therapeutics (Nasdaq: FXRX). She was the EVP Corporate Development and Chief Financial Officer of Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX). Ms. Gregory also has twenty years of investment banking experience.

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

**Compensation Committee**

The Committee’s primary duties and responsibilities are to review and make recommendations to the Board in respect of:

- the recruitment, hiring, evaluation, determination of terms of employment and the job description of the CEO;
- the Corporation’s compensation strategy, policies and guidelines, taking into account the proposals from the CEO, and to monitor their consistency with the Corporation’s goals and strategies;
- the CEO’s recommendations on the appointment and compensation of Executive Officers and other key employees of the Corporation;
- management incentive and perquisite plans and any non-standard remuneration plans;
- succession planning of the Corporation’s senior management; and
• Board compensation and training matters.

The Compensation Committee is currently composed of three independent board members: Dr. Shermaine Tilley (Chairman), Ms. Julia P. Gregory, and Mr. Andrew Sheldon, as a non-voting member. The education and related experience (as applicable) of each current member is described below:

Shermaine Tilley – Dr. Tilley is a Managing Partner at CTI Life Sciences Fund. Prior to joining CTI Life Sciences Fund in 2006, Dr. Tilley was Senior VP at DRI Capital Inc. (formerly Drug Royalty Corporation), the world’s first private equity firm doing royalty transactions in the biotech/pharma space. Before DRI Capital Inc., Dr. Tilley ran and managed a research laboratory, holding faculty positions at the NYU School of Medicine and Public Health Research Institute (“PHRI”), NY, and on the PHRI Board of Directors.

Julia P. Gregory – Ms. Gregory has an MBA from The Wharton School of The University of Pennsylvania and is the former CEO of ContraFect (Nasdaq: CFRX) and prior to that she was CEO of FivePrime Therapeutics (Nasdaq: FXRX). She was the EVP Corporate Development and Chief Financial Officer of Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX). Ms. Gregory also has twenty years of investment banking experience.

Andrew Sheldon – Mr. Sheldon has thirty years of experience in the pharmaceutical industry and is the head of Medicago New Ventures and was formerly the President and Chief Executive Officer of Medicago Inc. since 2003. He was a member of Medicago’s board of directors until September 18, 2013 and has served on several other boards. As Chief Executive Officer of Medicago Inc., Mr. Sheldon was responsible for ensuring compensation levels are competitive and in line with the company’s business strategy.

Corporate Governance Committee

The primary function of the Committee is to assist the Board of Directors in the exercise of certain duties regarding the corporate governance of the Corporation. Among others, the Committee develops policies regarding corporate governance for the Corporation, for internal governance as well as for the Corporation’s external communications.

The Corporate Governance Committee is currently composed of Mr. Wayne Pisano (Chairman), Dr. Shermaine Tilley, Mr. Markus Warmuth as well as Mr. Andrew Sheldon, as a non-voting member. The education and related experience (as applicable) of each current member is described below:

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

Shermaine Tilley – Dr. Tilley is a Managing Partner at CTI Life Sciences Fund. Prior to joining CTI Life Sciences Fund in 2006, Dr. Tilley was Senior VP at DRI Capital Inc. (formerly Drug Royalty Corporation), the world’s first private equity firm doing royalty transactions in the biotech/pharma space. Before DRI Capital Inc., Dr. Tilley ran and managed a research laboratory, holding faculty positions at the NYU School of Medicine and PHRI, NY, and on the PHRI Board of Directors.

Markus Warmuth – Mr. Warmuth currently serves as an Entrepreneur in Residence at Third Rock Ventures, a venture capital firm. Prior to that, he spent seven years as the Chief Executive Officer of H3 Biomedicine, a biopharmaceutical company that specializes in the discovery and development of genomics-based precision oncology treatments. Mr. Warmuth earned his MD from Ludwig Maximilian University in Munich, Germany.
Andrew Sheldon – Mr. Sheldon has thirty years of experience in the pharmaceutical industry and is the head of Medicago New Ventures and was formerly the President and Chief Executive Officer of Medicago Inc. since 2003. He was a member of Medicago’s board of directors until September 18, 2013 and has served on several other boards. As Chief Executive Officer of Medicago Inc., Mr. Sheldon was responsible for ensuring compensation levels are competitive and in line with the company’s business strategy.

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

*Orientation and Continuing Education*

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

*Ethical Business Conduct*

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

*Assessment*

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

*Compensation*

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

*External Auditor Service Fees*

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

<table>
<thead>
<tr>
<th>Fees</th>
<th>December 31, 2019</th>
<th>December 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit Fees[^1]</td>
<td>$95,500</td>
<td>$87,000</td>
</tr>
<tr>
<td>Audit Related Fees[^2]</td>
<td>$58,300</td>
<td>$89,350</td>
</tr>
<tr>
<td>Tax Fees[^3]</td>
<td>$63,012</td>
<td>$33,500</td>
</tr>
<tr>
<td>All Other Fees[^4]</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total Fees</td>
<td>$216,812</td>
<td>$209,850</td>
</tr>
</tbody>
</table>

(1) *Audit Fees* consist of the aggregate fees billed by the external auditor of the Corporation for audit services.
(2) *Audit Related Fees* consist of the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit or review of the issuer’s financial statements and are not reported under “Audit Fees” above and
include the provision of comfort letters and consents, the consultation concerning financial accounting and reporting of specific issues and the review of documents filed with regulatory authorities.

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

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

**XI. LEGAL PROCEEDINGS AND REGULATORY ACTIONS**

The Corporation is not a party to any legal proceeding, and its property is not and was not the subject of any material legal proceeding, during the year ended December 31, 2018. The Corporation is not aware of any legal proceeding outstanding, threatened or pending as of the date hereof by or against the Corporation.

The Corporation is not and was not subject to, during the year ended December 31, 2019: (i) penalties or sanctions imposed by a court relating to Canadian securities legislation or by a Canadian securities regulatory authority; (ii) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision; and (iii) settlement agreements entered into with a court relating to Canadian securities legislation or with a Canadian securities regulatory authority.

**XII. INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

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

**XIII. TRANSFER AGENT AND REGISTRAR**

The registrar and transfer agent for the Common Shares is Computershare Investor Services Inc., at their principal offices located at 100 University Avenue, 9th Floor, Toronto, Ontario, M5J 2Y1 and at 1500 Robert-Bourassa Boulevard, 7th Floor, Montréal, Québec, H3A 3S8.

**XIV. MATERIAL CONTRACTS**

The following are the material contracts, other than contracts entered into in the ordinary course of business, that the Corporation has entered into since January 1, 2019 or prior thereto but which are still in effect:

(i) an equity distribution agreement entered into between IMV and Piper Sandler dated March 18, 2020 in connection with the ATM Distribution;

(ii) an underwriting agreement entered into among IMV, Wells Fargo Securities Canada, Ltd., Raymond James Ltd. and a syndicate of underwriters dated as of March 1, 2019 in connection with the March 2019 Public Offering;

(iii) a loan agreement between IMV and the Province of Nova Scotia dated as of July 26, 2013 pursuant to which IMV received a loan of $5 million, available in four equal instalments to be used to fund a portion of working capital through 2016; and
(iv) a license agreement between IMV and Merck KGaA dated as of July 12, 2010 with regards to the world-wide exclusive licensing of survivin-based peptides.

A copy of these contracts can be found under the profile of the Corporation on SEDAR at www.sedar.com.

XV. INTERESTS OF EXPERTS

The Company’s independent auditors are PricewaterhouseCoopers LLP, Chartered Professional Accountants, who have issued an independent auditor’s report dated March 30, 2020 in respect of the Corporation’s consolidated financial statements as at December 31, 2019 and December 31, 2018 and for each of the years then ended. PricewaterhouseCoopers LLP has advised that they are independent with respect to the Corporation within the meaning of the Chartered Professional Accountants of Nova Scotia CPA Code of Professional Conduct and the rules of the U.S. Securities and Exchange Commission.

XVI. ADDITIONAL INFORMATION

Additional information, including directors’ and officers’ remuneration and indebtedness, principal holders of our securities, options and to purchase securities and interests of insiders in material transactions, if any, is contained in the Management Information Circular of the Corporation dated April 1, 2019 prepared in connection with the Corporation’s most recent annual shareholders’ meeting and is available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov. Additional financial information, including the Corporation’s audited financial statements and management’s discussion and analysis of financial condition and results of operations, is available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov. All information incorporated by reference in this Annual Information Form is or will within the prescribed delays be contained or included in one of the Corporation’s continuous disclosure documents filed with the Canadian securities regulatory authorities, which may be viewed on SEDAR at www.sedar.com, and with the SEC, which may be viewed on EDGAR at www.sec.gov.

All requests for the above-mentioned documents must be addressed to the Chief Financial Officer of IMV Inc., 130 Eileen Stubbs Avenue, Suite 19, Dartmouth, Nova Scotia, B3B 2C4, or by fax at (902) 492-0888.
1. PURPOSE

The primary function of the Audit Committee (the “Committee”) is to assist the Board of Directors in fulfilling its oversight responsibilities by reviewing: (i) the financial information that will be provided to the shareholders and others; (ii) the systems of internal controls which management and the Board of Directors have established; and (iii) the Corporation’s audit and financial reporting process. The external auditors’ ultimate responsibility is to the Board of Directors and the Committee, as representatives of the shareholders.

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

2. INTERPRETATION

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

An “Audit Committee Financial Expert” means a person who has the following attributes: (a) an understanding of generally accepted accounting principles and financial statements; (b) the ability to assess the general application of such principles in connection with the accounting for estimates, accruals and reserves; (c) experience preparing, auditing, analyzing or evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the Corporation’s financial statements, or experience actively supervising one or more persons engaged in such activities; (d) an understanding of internal controls over financial reporting; and (e) an understanding of audit committee functions. A person shall have acquired such attributes through: (a) education and experience as a principal financial officer, principal accounting officer, controller, public accountant or auditor or experience in one or more positions that involve the performance of similar functions; (b) experience actively supervising a principal financial officer, principal accounting officer, controller, public accountant, auditor or person performing similar functions; (c) experience overseeing or assessing the performance of companies or public accountants with respect to the preparation, auditing or evaluation of financial statements; or (d) other relevant experience.

“Board of Directors” or “Board” means the Board of Directors of IMV Inc.

“Chairman” means the Chairman of the Committee.

“Committee” means the Audit Committee of IMV Inc.
“Committees” means the Committee and the Compensation and Corporate Governance Committee.

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

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

“Executive Officer” means the president, principal financial officer, principal accounting officer (or, if there is no such accounting officer, the controller), any vice-president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the issuer.

“Family Member” means a person’s spouse, parents, children and siblings, whether by blood, marriage or adoption, or anyone residing in such person’s home.

“Financially Literate” means the ability to read and understand a set of fundamental financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the consolidated financial statements of the Corporation (including, without limitation, a balance sheet, income statement, and cash flow statement).

“Independent Director” means a director who is not an Executive Officer or employee of the Corporation or any other individual who has a direct or indirect relationship with the Corporation, which would interfere with the exercise of an independent judgment regarding the best interests of the Corporation or in carrying out the responsibilities of a director. An individual is not an Independent Director if such individual:

(a) is, or has been within the last three years, an employee or Executive Officer of the Corporation;

(b) is a Family Member of an individual who is or has been, within the last three years, an Executive Officer of the Corporation;

(c) is or has been (or whose Family Member is or has been), within the last three years, an Executive Officer, a partner or an employee of a material service provider of the Corporation (including the external auditors);

(d) participated in the preparation of the financial statements of the Corporation at any time during the past three years;

(e) is or has been (or whose Family Member is or has been), within the last three years, an Executive Officer of another entity where at any time within the last three years any of the Executive Officer’s of the Corporation served on the entity’s Compensation Committee;
has a relationship with the Corporation under which he or she may directly or indirectly accept any consulting, advisory or other fees from the Corporation or a related entity, except for any compensation as a member of the Board or as a member of a Committee;

received (or whose Family Member received) more than C$75,000 in compensation from the Corporation (excluding (A) fees as a director or Committee member, (B) compensation paid to a Family Member who is an employee (other than an Executive Officer) of the Corporation, or (C) benefits under a tax-qualified retirement plan or non-discretionary compensation) during any consecutive 12 month period within the last three years;

is, or has a Family Member who is, a partner in, or a controlling shareholder or an Executive Officer of, any organization to which the Corporation made, or from which the Corporation received, payments for property or services in the current or any of the past three fiscal years that exceed 5% of the recipient’s consolidated gross revenues for that year, or US$200,000, whichever is more, other than the following: (i) payments arising solely from investments in the Corporation’s securities; or (ii) payments under non-discretionary charitable contribution matching programs;

is a natural person who controls the Corporation; or

is an affiliate of the Corporation (or any subsidiary of the Corporation).

3. COMPOSITION OF COMMITTEE AND COMMITTEE MEETINGS

3.1 The Committee shall be comprised of at least three Directors, all of which are Independent Directors. All members of the Committee shall be Financially Literate. The Committee shall also have at least one member who has past employment experience in finance or accounting, requisite professional certification in accounting, or any other comparable experience or background which results in the individual’s financial sophistication, including being or having been a chief executive officer, chief financial officer or other senior officer with financial oversight responsibilities. Additionally, the Committee shall have at least one member who is an Audit Committee Financial Expert.

3.2 The Committee will meet on a quarterly basis and will hold special meetings as circumstances require. The timing of the meetings shall be determined by the Committee. At all Committee meetings a majority of the members shall constitute a quorum. The Board shall appoint the Chairman. If the Chairman is not present at a Committee meeting, the members present shall choose one of their number to act as Chairman for the purposes of this specific meeting.

3.3 Notice of each meeting shall be given to each Committee member and may but not required to be given to the other directors and to the Corporation’s senior management. Unless they are expressly called to the meeting, the latter only receive the notice for information purposes.

3.4 The Committee may invite the persons it considers useful to invite, including the Corporation’s senior management, to attend the meetings and participate in the discussions concerning the Committee’s business.
3.5 The Committee members, whenever possible, shall take all necessary steps to attend Committee meetings and to prepare themselves with respect to the matters and documents to be discussed thereat.

3.6 The Committee will receive meeting agendas in advance, along with appropriate briefing material.

3.7 The Committee shall appoint a secretary. The secretary shall attend the meetings, during which he or she shall take minutes. The minutes shall be made available to the directors for consultation and are approved by the Board before being included in the Corporation’s registers or records.

3.8 The Committee shall submit periodically a report to the Board on its activities, including the nature of its deliberations and the related recommendations.

3.9 The Committee, in the performance of its duties, may consult any relevant register or record of the Corporation.

3.10 The Committee members shall receive, in this capacity, the compensation that the Board establishes from time to time.

4. COMMITTEE AUTHORITY AND RELATIONSHIP WITH EXTERNAL AUDITORS

4.1 The external auditors shall report directly to the Committee.

4.2 The Committee reports to the Board of Directors and has the authority:
   a) to engage independent counsel and other advisors as it determines necessary to carry out its duties;
   b) to set and pay the compensation for any advisors (including, without limitation, the external auditors and independent counsel) employed by the audit committee and for ordinary administrative expenses of the Committee that are necessary or appropriate in carrying out its duties;
   c) resolve any disagreements between the Corporation’s senior management team and the external auditors regarding financial reporting;
   d) pre-approve all auditing and non-audit services;
   e) seek any information it requires from the Corporation’s employees, all of whom are directed to cooperate with the Committee’s requests, or external parties; and
   f) to communicate directly with the Corporation’s senior management team, external auditors, and outside counsel, as necessary, and separately, as necessary.
5. RESPONSIBILITIES AND DUTIES

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

Financial Statements

a) review the accounting principles, policies and practices followed by the Corporation in accounting for and reporting its financial results of operations;

b) review the Corporation’s audited annual consolidated financial statements and the unaudited quarterly financial statements, including complex or unusual transactions and highly judgmental areas, and recommend to the Board for approval prior to publicly disclosing this information. Also review and recommend to the Board for approval any accompanying related documents such as the Annual Information Form or equivalent filings and the Management’s Discussion and Analysis prior to publicly disclosing this information;

c) review the draft press releases regarding the annual and interim financial statements and recommend to the Board for approval prior to publicly disclosing this information;

d) satisfy itself that adequate procedures are in place for the review of the Corporation’s public disclosure of financial information extracted or derived from the Corporation’s financial statements and periodically assess the adequacy of those procedures;

Internal Control

e) consider the effectiveness of the Corporation’s internal control system, including information technology security and control;

f) understand the scope of external auditors’ review of internal controls over financial reporting, and obtain reports on significant findings and recommendations, together with management’s response;

g) review the financial risk assessment and management policies followed by the Corporation in operating its business activities and the completeness and fairness of any disclosure thereof, including, without limitation, review of the use of derivative financial instruments by the Corporation;

h) review and approve any management decision relating to any potential need for internal auditing, including whether this function should be outsourced and if such function is outsourced, approve the supplier of such service;

i) establish procedures for (i) the receipt, retention and treatment of complaints received by the Corporation from employees regarding accounting, internal accounting controls, or auditing matters; and (ii) the confidential, anonymous submission by directors, officers and other employees of the Corporation of concerns regarding questionable accounting or auditing matters;
External Audit

j) appoint, compensate and retain the external auditors in connection with preparing or issuing an auditor’s report or with performing other audit, review or attestation services for the Corporation;

k) oversee the work of the external auditors engaged for the purpose of preparing or issuing an auditor’s report or performing other audit, review or attestation services for the Corporation, including the resolution of disagreements between management and the external auditors regarding financial reporting;

l) obtain, on an annual, basis, a formal written statement from the external auditors delineating the relationship between the external auditors and the Corporation, actively engaging in a dialogue with the external auditors with respect to any disclosed relationships or services that may impact the objectivity and independence of the external auditors and for taking, or recommending that the full board take, appropriate action to oversee the independence of the external auditors under applicable securities laws and stock exchange rules;

m) discuss with the external auditors their views about the quality of the implementation of International Financial Reporting Standards (or other generally accepted accounting principles used by the Corporation to report its financial statements), with a particular focus on the accounting estimates and judgments made by management and management’s selection of accounting principles. Meet in private with appropriate members of management and separately with the external auditors on a regular basis to share perceptions on these with the external auditors and their views on the adequacy of the Corporation’s financial personnel;

n) review and provide direction regarding the scope of the annual audit, the audit plan, the access granted to the Corporation’s records and the co-operation of management in any audit and review function;

o) review the effectiveness of the independent audit effort, including approval of the fees charged in connection with the annual audit, any quarterly reviews and any permitted non-audit services being provided;

p) assess the effectiveness of the working relationship of the external auditors with management;

q) determine the nature of non-audit services the external auditors are prohibited from providing to the Corporation, and pre-approve all permitted non-audit services provided by the external auditors to the Corporation;

r) if appropriate, terminate the appointment of the external auditors;

s) prepare the report required to be prepared by the Committee pursuant to applicable securities laws for inclusion with the annual financial statements;

t) at least annually, obtain and review an appropriate report by the external auditors describing: (i) the external auditors’ internal quality-control procedures; (ii) any
material issues raised by the most recent internal quality-control review or peer review of the external auditors, or any inquiry or investigation by governmental or professional authorities, within the preceding five years, respecting one or more independent audits carried out by the external auditors, and any steps taken to deal with such issues; and (iii) all relationships between the external auditors and the Corporation to enable the assessment of the external auditors;

**Reporting Responsibility**

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

v) report to the Board on the major items covered at each Committee meeting and make recommendations to the Board and management concerning these matters. Annually report to the Board on the effectiveness of the Committee;

w) perform any other activities consistent with this Mandate, the Corporation’s bylaws and governing law as the Committee or the Board deems necessary or appropriate;

**Compliance**

x) review the effectiveness of the system for monitoring compliance with laws and regulations and the results of management’s investigation and follow-up, including disciplinary action of any instances of noncompliance;

y) review the findings of any examinations by regulatory agencies and any external auditors observations;

z) review the process for communicating the code of conduct to the Corporation’s employees and for monitoring compliance therewith; and

aa) obtain regular updates from management and Corporation’s legal counsel regarding compliance matters.

Adopted by the Board on April 6, 2010 and amended on March 10, 2016 and May 30, 2018