

## **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2014**

This management's discussion and analysis has been prepared as of April 27, 2015 and should be read in conjunction with the financial statements of iCo Therapeutics Inc. ("iCo" or the "Company") for the year ended December 31, 2014 and the related notes thereto. Our financial statements are prepared in accordance with International Financial Reporting Standards ("IFRS") and all dollar amounts are expressed in Canadian dollars unless otherwise noted. In this discussion, unless the context requires otherwise, references to "we" or "our" are references to iCo Therapeutics Inc. Additional information relating to our Company, including our annual information form, is available by accessing the SEDAR website at [www.sedar.com](http://www.sedar.com).

### **Forward Looking Statements**

This Management's Discussion and Analysis ("MD&A") contains certain statements, other than statements of historical fact, that are forward-looking statements which reflect the current view of the Company with respect to future events including corporate developments, financial performance and general economic conditions which may affect the Company. The forward-looking statements in this MD&A include, but are not limited to, statements regarding: the status of our research and development programs; iCo-007, iCo-008 and the Oral AmpB Delivery System; our expectations regarding future research and development expenses; and the sufficiency of the Company's financial resources to fund operations for the remainder of 2015. Forward-looking statements include, but are not limited to, those statements set out in this MD&A under Business Overview and Strategy, iCo-007, iCo-008, Oral AmpB Delivery System, research and development, Liquidity, Capital resources and Outlook, Comparison of Cash Flows, Long term Obligations and Commitments, Critical Accounting Estimates, Financial Instruments and Risks and Uncertainties. We have based these forward-looking statements largely on our current expectations, projections and assumptions made based on our experience, perception of historical trends, the current business and financial environment. Key assumptions upon which the forward-looking statements are based include the following:

- a) The Company's Oral AmpB Delivery System program will not be unreasonably delayed and expenses will not increase substantially;
- b) The Company will be able to secure additional financial resources to continue our research and development activities;
- c) Key personnel will continue their employment with the Company;
- d) The Company will successfully maintain all necessary commitments to product licences and other agreements and maintain regulatory approvals in good standing;
- e) The Company will be able to maintain and enforce its intellectual property rights and otherwise protect its proprietary technologies.

Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Risks that could cause actual results to differ from current expectations include: reliance on collaborative partners; changes in government and government agency policies and regulations; general economic and financial market conditions; failure to retain key employees; performance failure of third parties and/or sub-contractors; potential for clinical trial delays and/or adverse events leading to clinical trial liability; inadequate protection of intellectual

property rights; the impact of US/Canadian exchange rates; inability to raise sufficient capital to fund research and development activities; inability to identify new assets for our therapeutic pipeline; the development and adoption of competitive technologies; and general risks inherent to the biotechnology industry.

Except as may be required by applicable law or stock exchange regulation, we undertake no obligation to update publicly or release any revisions to these forward looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events. Accordingly, readers should not place undue reliance on forward-looking statements. If we do update one or more forward-looking statements, no inference should be drawn that additional updates will be made with respect to those or other forward-looking statements.

## **Business Overview and Strategy**

We are a Canadian biotechnology company principally focused on the identification, development and commercialization of drug candidates to treat sight- and life-threatening diseases.

We principally focus on in-licensing drug candidates with a clinical history and re-dose, reformulate and develop drug candidates for the treatment of sight- and life-threatening diseases. We assume the clinical, regulatory and commercial development activities for our product candidates and advance them along the regulatory and clinical pathway toward commercial approval. We believe that our approach may reduce the risk, time and cost of developing therapeutics by avoiding the uncertainty associated with certain research and pre-clinical stages of drug development. We use our expertise to manage and perform what we believe are the critical aspects of the drug development process, including the design and conduct of clinical trials, the development and execution of strategies for the protection and maintenance of intellectual property rights and interaction with drug regulatory authorities. The main elements of our strategy are as follows:

### Identification of Product Candidates

We directly perform scientific evaluation and market assessment of pharmaceutical products and research developed by other biopharmaceutical companies. As part of this process, we evaluate the related scientific research and pre-clinical and clinical research, if any, and the intellectual property rights in such products and research, with a view to determining the therapeutic and commercial potential of the applicable product candidates. We intend to mitigate the risks associated with our development and commercialization efforts by targeting drug candidates that:

- have an established clinical history or are in late-stage pre-clinical trials;
- have well-established safety profiles;
- may be well-suited to reformulation as a means of expanding use indications or altering the route of administration;
- have been successfully manufactured on a clinical grade basis in quantities sufficient for clinical trials; and
- has data suggestive of potential efficacy as treatments for sight- or life-threatening diseases.

Our initial focus was on sight threatening diseases because we believe that there is an unmet need for new and effective therapeutics in this field. In addition, several members of our management team and key

advisors have considerable expertise in ophthalmology. Subsequently, we have also focused on certain life-threatening diseases, through the advancement of our Oral AmpB Delivery System and the expertise that has been gained through its development.

In addition to continued efforts involving other potential indications for our current assets, Management is also actively engaging in a review of certain complimentary assets that the company may consider in-licensing or acquiring.

### In-Licensing

Upon identifying a promising biopharmaceutical product, we seek to negotiate a license to the rights for the product from the holder of those rights. The terms of such licenses vary, but generally our goal is to secure licenses that permit us to engage in further development, reformulation, clinical trials, intellectual property protection (on behalf of the licensor or otherwise) and further licensing of manufacturing and marketing rights to any resulting products. This process of securing license rights to products is commonly known as “in-licensing”. In certain instances, we have taken the “option” approach, whereby we gain an exclusive right to in-license a drug candidate for a defined period of time before we have to actually make a commitment to do so. This approach allows us to review additional data before making a decision to in-license a particular drug candidate.

### Product Advancement

Upon in-licensing a product candidate, our strategy is to apply our skills and expertise to advance the product toward regulatory approval and commercial production and sale in major markets. These activities include implementing intellectual property protection and registration strategies, formulating or reformulating existing drug products, making regulatory submissions, performing or managing clinical trials in target jurisdictions, and undertaking or managing the collection, collation and interpretation of clinical and field data and the submission of such data to the relevant regulatory authorities in compliance with applicable protocols and standards.

### Developing Partnerships with Biopharmaceutical Companies

In order to augment our ability to develop our product candidates and effectively market any products in respect of which we obtain regulatory approval, we may enter into an agreement or partnership with a biopharmaceutical company that has drug development or sales and marketing capabilities, or both. Entering into an agreement or partnership with a pharmaceutical or biotechnology company that has these capabilities may enable us to increase our returns from our product candidates by utilizing that company’s development or sales and marketing capabilities, or both, to further accelerate development of our product candidates or enable us to develop the candidate in more than one indication simultaneously.

### Outsourcing

In order to optimize the development of our product candidates, we outsource certain of our product development activities. Factors that we consider in determining which activities to outsource include cost, relative expertise, capacity and quality assurance. The product development functions that we have chosen to outsource include pre-clinical activities in support of regulatory filings, clinical trials and manufacturing. We believe that our relationships with external laboratories enable us to complete pre-clinical testing faster and more efficiently than if we performed these activities ourselves. Additionally, there are many independent contract research organizations that are specifically equipped and set up to manage clinical trial projects, thus alleviating the need for iCo to commit internal resources to do so.

Because our manufacturing needs are currently sporadic, we believe that it is more efficient to outsource manufacturing.

## **Products**

We have in-licensed three product candidates (iCo-007, iCo-008 and an Oral AmpB Delivery System (previously known as iCo-009) for potential use in sight- and life- threatening diseases.

### ***iCo-007***

In August 2011, we initiated a US physician sponsored Phase 2 clinical trial involving iCo-007, titled the iDEAL study (“iDEAL Study”).

On June, 9, 2014, we announced top-line results related to the eight month visual acuity (VA) primary endpoint for subjects enrolled in the iDEAL Study,

Statistical methods employed included both Last Observation Carry Forward (“LOCF”) and Multiple Imputation (“MI”) analyses given the departure of patients from the study prior to their eight month visit. Using both statistical methods, mean changes in visual acuity measures in all four groups at both month four and month eight were negative. Using the LOCF method, mean change in VA at eight months was approximately minus 11 letters (350 µg monotherapy), minus 21 letters (700 µg monotherapy), minus 14 letters (350 µg + laser arm) and minus 14 letters (350 µg + Lucentis). Some patients in each cohort did show improvements in mean change in VA. At eight months using the LOCF analysis, roughly 20% of patients in the 350 µg monotherapy arm gained five letters or greater of vision versus 13% in the 700 µg monotherapy arm, 12% in the 350 µg + laser arm and 11% in the 350 µg + Lucentis arm. At four months, patients gaining five letters or more for the 350 µg, 700 µg, 350 µg + laser and 350 µg + Lucentis arms were approximately 24%, 18%, 21% and 30%, respectively.

Using the LOCF method, it was observed that at month eight there was an inverse statistically significant difference in mean VA change from baseline between 350 µg monotherapy and 700 µg monotherapy arms, meaning there was greater loss of VA in the 700 µg monotherapy cohort. There was no statistically significant difference in mean VA between the 350 µg monotherapy and either 350 µg + laser or 350 µg + Lucentis arms. When using MI analysis there was no statistically significant difference observed between 350 µg monotherapy and each of the 700 µg monotherapy, 350 µg + laser and 350 µg + Lucentis arms.

At eight months, in the 700 µg monotherapy arm, 64% of patients experienced a 15 letter or greater loss of vision, compared to 33% in the 350 µg monotherapy arm, 33% in the 350 µg + laser arm, and 41% in the 350 µg + Lucentis arm. At four months the corresponding numbers were 29%, 9%, 9%, and 14%, respectively.

Management has determined that the Phase 2 iCo-007 diabetic macular edema (DME) data that has been presented, along with our internal analysis, has not demonstrated to date any subgroup response rates that warrant further financial investment by iCo in the DME program at this time. Management will, however, continue to investigate other potential use indications for its licensed technology which targets the C-Raf kinase pathway. Use indications may include certain oncology applications as a number of approved drugs currently target Raf kinase isoforms.

### ***iCo-008 (Bertilimumab)***

iCo-008 is a human monoclonal antibody that we believe may treat sight threatening forms of allergic conjunctivitis by neutralizing eotaxin-1, a ligand to the chemokine receptor CCR3. It is our view that iCo-008 neutralizes eotaxin-1 by binding to it and, as a consequence, preventing it from binding to CCR3. We believe that iCo-008 has the potential to inhibit intracellular signaling associated with mast cell degranulation and the recruitment of eosinophils to the site of allergic reactions and, as a result, potentially inhibit both early stage and late stage development of severe allergic conjunctivitis. We also believe that iCo-008 could also be used to treat a variety of systemic disease indications which involve eosinophils including severe asthma, food allergies, and inflammatory bowel disease.

Published scientific literature has also indicated that iCo-008 may have utility to potentially treat age related macular degeneration (“AMD”), a severe ophthalmic disease which effects elderly patients and can lead to blindness in just a few years. In light of this new information, we are currently exploring AMD as a possible therapeutic indication for iCo-008. We will only undertake a clinical trial program for iCo-008 in the event we are able to obtain sufficient financial resources to do so.

Before we licensed iCo-008 from Medimmune Limited (“MedImmune”), MedImmune (then known as Cambridge Antibody Technology) conducted Phase I clinical trials testing the safety, tolerability and pharmacokinetics of iCo-008 and Phase 2 clinical trials testing the efficacy of iCo-008 as a treatment for allergic rhinitis and allergic conjunctivitis. To date, we have developed a clinical plan for iCo-008 and assembled a key opinion leader advisory group. While it was our intention to run a Phase 2 clinical trial to test the efficacy and safety of iCo-008 in individuals with a serious sight threatening form of allergic conjunctivitis known as vernal keratoconjunctivitis, the global credit crisis which began in 2008 severely restricted our ability to raise equity capital. In response to the crisis we made the strategic decision to reserve our cash resources for developing iCo-007 and explore strategic initiatives to fund further development of iCo-008.

In December 2010, we granted IMMUNE Pharmaceuticals Corp. (“IMMUNE”), based in Israel and the United States, an option to an exclusive license for the development and commercialization rights to the systemic uses of iCo-008. The license option is for systemic uses including inflammatory bowel disease and severe asthma. iCo retained worldwide exclusive rights to all uses and applications in the ocular field. Under the terms of the agreement, IMMUNE paid the Company a non-refundable option fee creditable upon conversion against an upfront license fee payment of US\$1 million. iCo may receive up to an additional US\$32 million in milestone payments as well as royalties on net sales of licensed products. On June 24, 2011, the option was converted to an exclusive sub-licence agreement. The upfront consideration was amended such that iCo received: US\$500,000 in cash, 600,000 common shares of IMMUNE and 200,000 IMMUNE warrants.

On August 26, 2013, IMMUNE completed a merger with Epicept Corporation, a company publicly traded on the NASDAQ OTCQX. The combined company changed its name to Immune Pharmaceuticals Inc. (“Immune Pharmaceuticals”) and currently trades on the NASDAQ under the symbol IMNP and Stockholm Exchange under the symbol IMNP.

Following authorization from Israeli health authorities, Immune Pharmaceuticals has initiated a Phase 2 double-blind placebo controlled study with its lead drug, Bertilimumab (iCo-008), in patients with moderate-to-severe ulcerative colitis. The clinical trial is a randomized, double-blind, placebo-controlled parallel group study that will evaluate the safety, clinical efficacy, and pharmacokinetic profile of Bertilimumab in subjects with active moderate-to-severe ulcerative colitis. Ninety patients are expected to be enrolled into the study, sixty of whom will be treated with Bertilimumab 7mg/kg and thirty of whom will be treated with placebo every two weeks, at days 0, 14, and 28. These patients are being evaluated for

clinical response after 6 weeks to determine the decrease if any in the full Mayo Clinic Ulcerative Colitis Score. Secondary and exploratory end points will include clinical remission defined as symptom free, fecal calprotectin, a recognized marker of gastro-intestinal inflammation, histopathology improvement and degree of mucosal injury. Patient follow-up will continue up to day 90. Patients will be enrolled initially from up to ten hospitals in Israel and later in other countries pending approval of local health authorities. Immune Pharmaceuticals also announced that it expected to expand the Phase 2 program to the treatment of bullous pemphigoid (BP), a rare auto-immune condition that affects the skin and causes the formation of blisters. Subsequently, it was announced that patient screening initiation for its both its bullous pemphigoid and ulcerative colitis studies. Completion of patient enrollment and clinical results for the ulcerative study are anticipated in 2016. Initial clinical data from the BP trial may be available by the end of 2015. On March 31 2015, Immune Pharmaceuticals announced that it intends to expand its planned BP clinical development for bertilimumab to include US centers in the trial and also intends to initiate studies to further investigate the relationship between eotaxin-1 levels and the Bullous Pemphigoid Disease Area Activity Index (BPDAI) and to assess the burden of illness from a medical and economic standpoint. On April 15, 2015, Immune Pharmaceuticals announced initiation of Bertilimumab development in Liver diseases including NASH. The development program will include pre-clinical studies and initiation of a pilot Phase II clinical trial expected before the end of 2015. It was also announced that subsequent to initiating in 2014 an enhanced GMP Manufacturing process of Bertilimumab, the new process had demonstrated by end of first quarter 2015 a higher comparable performance and improved productivity than the previous process. Immune may bridge to the new process before initiation of Phase III trials.

#### ***Oral AmpB Delivery System, formerly known as iCo-009 (and related derivatives)***

iCo's experimental oral formulations of Amphotericin B ("AmpB") began development at the University of British Columbia ("UBC"), and are now continuing at the University of Saskatchewan. Dr. Kishor Wasan has recently moved from the University of British Columbia to the University of Saskatchewan to become Professor and Dean, College of Pharmacy and Nutrition. Although AmpB has been used to treat systemic fungal infections intravenously for approximately 50 years, an oral formulation of AmpB has yet to be developed. Historically, Amphotericin B was shown to have a limited oral bioavailability due to its low aqueous solubility and membrane permeability" (Menez et al, 2007). Intravenous AmpB has historically been a potent but toxic option for the treatment of serious systemic fungal infections. Systemic fungal infections are fungal infections that affect the entire body and are particularly prevalent among people whose immune systems have been weakened by certain treatments, such as organ transplant recipients, or certain conditions, such as cancer, diabetes or AIDS. Although a number of drugs have been developed for the treatment of systemic fungal infections, nonetheless systemic fungal infections remain a leading cause of death for organ transplant recipients and other patients with compromised immune systems. Further, in developing nations, oral therapy is in need for a disease called Visceral Leishmaniasis ("VL"), known for its high mortality rates. Current AmpB therapy requires repeated infusions in the hospital setting and is often associated with infusion-related adverse events, such as renal toxicity. Successful oral formulation could resolve the safety issues associated with parenteral application and enable a much broader patient access to this highly effective treatment option.

We have completed a number of pre-clinical studies with iCo's Oral AmpB Delivery System which have shown promising pharmacokinetic and tissue distribution results in two anti-fungal animal models. We are currently generating additional pre-clinical data to further demonstrate oral bioavailability, safety and efficacy prior to commencing a clinical program with iCo's Oral AmpB formulations to support an Investigational New Drug application ("IND") to the US Food and Drug Administration ("FDA") prior to commencing a Phase I clinical trial in humans. iCo's Oral AmpB formulations have also demonstrated

promising results in animal models for VL conducted at independent laboratories in the United States. Based on these studies, the Oral AmpB Delivery System received Orphan Drug Status from the FDA for the treatment of VL. Formal GLP toxicology studies, manufacturing of drug product under GMP standards and other pre-clinical studies will also be required to support a Phase I clinical trial. To this end we have been working in cooperation with UBC to obtain third party financing, primarily through government and private granting agencies such as the Canadian Institute of Health Research (“CIHR”) to fund certain pre-clinical studies. UBC, with assistance from iCo, has been awarded a number of grants including: CIHR POP I and POP II grants and National Research Council Funding through the Industrial Research Assistance Program. This support included certain matching funding requirements from iCo. We also completed a collaboration development agreement with the Consortium for Parasitic Drug Development (“CPDD”) for up to USD \$182,930 for the research and development of our Oral AmpB Delivery System for the treatment of neglected diseases such as Leishmaniasis and Trypanosomiasis.

On May 31, 2012, we announced that the company had been awarded a \$1.1million non-repayable financial contribution from the National Research Council of Canada to support iCo’s Oral AmpB Delivery System as a novel treatment for patients with Human Immunodeficiency Virus (HIV). The funding will support feasibility testing and pre-clinical toxicology studies, as well as human safety and efficacy clinical trials to examine the role of the AmpB Delivery System in potentially treating patients with latent HIV reservoirs. The funding for the 3-year project comes from the NRC Industrial Research Assistance Program (NRC-IRAP) under the CHTD Program, which aims to encourage and support the participation of small and medium-sized enterprises in the development of an HIV vaccine and other technologies related to the prevention, treatment, and diagnosis of HIV. The program is part of the Canadian HIV Vaccine Initiative (CHVI), a collaboration between the Government of Canada and the Bill & Melinda Gates Foundation. The Company submits monthly expenditure claims that are subject to NRC-IRAP approval and subsequent reimbursement.

On December 12, 2013, we announced that the Oral AmpB Delivery System had been moved into in-vitro testing with study partner, ImmuneCarta®, (the immune monitoring business unit of Caprion a proteomics service provider based in Montreal). The deliverables associated with this project include the recruitment of eight HIV-infected subjects successfully treated with HAART with detectable latent viral reservoir. Leukapheresis and tissue samples (when available) collected from these subjects were used in several assays in order define the subsets of the cells (CD4+ T cells and monocytes) where HIV frequently hides and to test the effect of Oral AmpB on the reactivation and the elimination of HIV reservoirs. Recruitment of the eight HIV-infected subjects has been completed and on August 19, 2014, we reported the results of the study.

Memory cells, or white blood cells, from eight HIV-infected subjects with a durable viral suppression using antiretroviral therapy (HAART) were obtained and exposed *in vitro* to various concentrations of Oral AmpB. Samples from one patient were determined not to be susceptible to reactivation. In the remaining subjects, Oral Amp B demonstrated a reactivation response of HIV viral production in six out of seven *in vitro* cultures with detectable HIV reservoir. Some HIV reservoirs are not possible to reactivate and this may explain why one culture did not show reactivation response.

On October 22, 2014, we announced next steps for our Oral AmpB Delivery System, having previously announced positive findings from its *in vitro* work involving samples from HIV/AIDS patients exposed to HAART therapy. iCo now plans to complete pre clinical studies and regulatory filings to move forward with an initial Phase 1A clinical trial, utilizing approximately \$700,000 remaining of the aggregate \$1.1m funding and technological advice from NRC-IRAP under CHTD Program. The preparation and regulatory filings are expected to be underway in the second half of 2015, with initiation of a Phase 1A study early in the first quarter of 2016.

iCo continues to work towards obtaining additional non-dilutive sources of capital for its Oral AmpB Delivery System.

## 2014 Corporate Highlights

In 2014, we accomplished the following milestones:

### iCo-007

- On March 5, 2014, we announced the final month eight patient visit in the iDEAL Study. This US Phase 2 investigator-sponsored study is evaluating the efficacy and safety of iCo-007 after repeated injections in patients with Diabetic Macular Edema (DME). The study's primary endpoint was change in visual acuity from baseline to month eight, followed by secondary endpoints at month twelve.
- On April 29, 2014, we announced that research collaborators made a poster presentation at the Association for Research in Vision and Ophthalmology 2014 Annual Meeting. The Meeting was held from May 4<sup>th</sup> - 8<sup>th</sup>, 2014 in Orlando, Florida. The poster, titled "Demographics and Baseline Characteristics of the iDEAL Study: A Randomized, Multi-center, Phase II Study of the safety, Tolerability, and Bioactivity of Repeated Intravitreal Injections of iCo-007 as Monotherapy or in Combination with Ranibizumab or Laser Photocoagulation in the Treatment of Diabetic Macular Edema with Involvement of the FoveAL Center" was presented by Dr. Quan Dong Nguyen et al. The poster presented the design, demographics, and baseline characteristics of the iDEAL Study, as well as the inclusion/exclusion criteria and characteristics by randomized treatment group.
- On June, 9, 2014, we announced top-line results related to the eight month visual acuity (VA) primary endpoint for subjects enrolled in the Phase 2 iDEAL Study, conducted in collaboration with JDRF, evaluating the efficacy and safety after repeated injections of iCo-007 in patients with Diabetic Macular Edema (DME).

Statistical methods employed included both Last Observation Carry Forward ("LOCF") and Multiple Imputation ("MI") analyses given the departure of patients from the study prior to their eight month visit. Using both statistical methods, mean changes in visual acuity measures in all four groups at both month four and month eight were negative. Using the LOCF method, mean change in VA at eight months was approximately minus 11 letters (350 µg monotherapy), minus 21 letters (700 µg monotherapy), minus 14 letters (350 µg + laser arm) and minus 14 letters (350 µg + Lucentis).

Some patients in each cohort did show improvements in mean change in VA. At eight months using the LOCF analysis, roughly 20% of patients in the 350 µg monotherapy arm gained five letters or greater of vision versus 13% in the 700 µg monotherapy arm, 12% in the 350 µg + laser arm and 11% in the 350 µg + Lucentis arm. At four months, patients gaining five letters or more for the 350 µg, 700 µg, 350 µg + laser and 350 µg + Lucentis arms were approximately 24%, 18%, 21% and 30%, respectively.

Using the LOCF method it was observed that at month eight there was an inverse statistically significant difference in mean VA change from baseline between 350 µg monotherapy and 700 µg monotherapy arms, meaning there was greater loss of VA in the 700 µg monotherapy cohort. There was no statistically significant difference in mean VA between the 350 µg



monotherapy and either 350 µg + laser or 350 µg + Lucentis arms. When using MI analysis there was no statistically significant difference observed between 350 µg monotherapy and each of the 700 µg monotherapy, 350 µg + laser and 350 µg + Lucentis arms.

At eight months, in the 700 µg monotherapy arm, 64% of patients experienced a 15 letter or greater loss of vision, compared to 33% in the 350 µg monotherapy arm, 33% in the 350 µg + laser arm, and 41% in the 350 µg + Lucentis arm. At four months the corresponding numbers were 29%, 9%, 9%, and 14%, respectively.

- Eight month iDEAL study data, previously reported in June 2014, was presented at the American Academy of Ophthalmology on October 17, 2014 by the iDEAL Study Chairman.
- Management has determined that the Phase 2 iCo-007 diabetic macular edema (DME) data that has been presented, along with our internal analysis, has not demonstrated to date any subgroup response rates that warrant further financial investment by iCo in the DME program at this time. Management will, however, continue to investigate other potential use indications for its licensed technology which targets the C-Raf kinase pathway. Use indications may include certain oncology applications as a number of approved drugs currently target Raf kinase isoforms.

### **iCo-008**

- On March 10, 2014, Immune Pharmaceuticals announced that it had entered into a definitive agreement with investors for the sale of \$11.7 million of preferred stock and warrants in a private placement transaction (expected to result in approximately \$11 million in net proceeds to Immune, after the subtraction of transaction fees and expenses). The purchasers in the offering include biotech specialist institutional investors, existing Immune investors and members of Immune's board of directors and management. The proceeds of the offering have been allocated in priority to the bertilimumab phase II proof of concept trials in ulcerative colitis and in bullous pemphigoid, an orphan auto-immune dermatological indication and for general corporate and working capital purposes.
- On August 14, 2014, Immune Pharmaceuticals announced that patient screening initiation for its bullous pemphigoid Phase 2 study had commenced as at July 30<sup>th</sup>, 2014.
- On September 18, 2014 Immune Pharmaceuticals announced that it had initiated the screening of patients for a Phase 2 proof of concept clinical trial exploring the safety and efficacy of bertilimumab in the treatment of ulcerative colitis.
- On November 25, 2014, Immune Pharmaceuticals announced the closing of an underwritten public offering of 3,450,000 units. Gross proceeds raised through the offering were \$8.625 million. Separately, \$1.0 million recently invested in the Company privately by an existing investor converted into 400,000 units, consisting of 400,000 shares of common stock and warrants to purchase up to 100,000 shares of common stock at the same term as the underwritten public offering, bringing the total gross proceeds raised in November 2014 to \$9.625 million.

### **Oral AmpB Delivery System**

- On August 19, 2014, we reported results of a study using our Oral AmpB Delivery System to target latent HIV reservoirs. The study, conducted by ImmuneCarta®, the immune monitoring

business unit of Caprion, evaluated *in vitro* effectiveness of Oral AmpB in reactivating latent HIV viral reservoirs which remain present in individuals despite intensive treatment with antiretroviral therapy. Memory cells, or white blood cells, from eight HIV-infected subjects with a durable viral suppression using antiretroviral therapy (HAART) were obtained and exposed *in vitro* to various concentrations of Oral AmpB. Samples from one patient were determined not to be susceptible to reactivation. In the remaining subjects, Oral AmpB demonstrated a reactivation response of HIV viral production in six out of seven *in vitro* cultures with detectable HIV reservoir. Some HIV reservoirs are not possible to reactivate and this may explain why one culture did not show reactivation response.

- On October 22, 2014, we announced next steps for our Oral AmpB Delivery System, having previously announced positive findings from its *in vitro* work involving samples from HIV/AIDS patients exposed to HAART therapy. iCo now plans to complete pre-clinical studies and regulatory filings to move forward with an initial Phase 1A clinical trial, utilizing approximately \$700,000 of the total \$1.1million funding and technological advice from NRC-IRAP) under the CHTD Program.
- The preparation and regulatory filings are expected to be completed in the second half of 2015, with initiation of a Phase 1A study early in the first quarter of 2016.
- On November 4, 2014, we announced that presentations regarding the company's Oral AmpB Delivery System were being made at the American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition. The event took place at the San Diego Convention Center November 2 - 6.
- Dr. Kishor M. Wasan, Professor and Dean, College of Pharmacy and Nutrition at the University of Saskatchewan, presented the following:
  - Poster on November 4: *Novel Oral Amphotericin B Formulation Remains Highly Effective against Murine Systemic Candidiasis following Exposure to Tropical Temperature*
  - Panel Moderation on November 5: *Antimicrobials, Super BUGS and Global Health*
  - Presentation on November 5: *Development of a Tropically Stable Oral Lipid Formulation of Amphotericin B for the Treatment of Systemic Fungal Infections and Visceral Leishmaniasis*

## Corporate

- On January 21, 2014, we announced an overnight marketed offering of equity securities (the "Offering"). Pursuant to the Offering, iCo issued 16,206,483 units of the Company ("Units") at a price of \$0.4165 per Unit for aggregate gross proceeds of C\$6.75 million. Each Unit was exercisable into one common share of the Company (a "Common Share") and three-quarters of one common share purchase warrant (each whole warrant, a "Warrant"). Each Warrant was exercisable at a price of C\$0.539 and entitles the holder thereof to acquire one Common Share for a period of five years following the date of issuance of the Warrant. The closing was completed January 27, 2014.
- On February 25, 2014, we announced that our United States trading symbol ICOTF had received approval from The Depository Trust Company (the "DTC") providing the Company with DTC eligibility. DTC eligibility allows for iCo Therapeutics shares to be easily and economically transferred between brokerage accounts electronically. The DTC is the largest securities depository in the world and acts like a clearinghouse for brokers, providing various services.

- On June 30<sup>th</sup>, 2014, we announced that all nominees listed in the management information circular dated May 28, 2014 were elected as directors at its 2014 Annual Meeting of Shareholders, held on Friday, June 27, 2014. On a vote by ballot, the following five nominees proposed by management were elected as Directors of iCo Therapeutics to serve until the Company's next Annual Meeting of Shareholders or until their successors are elected or appointed, with shares represented at the meeting voting in favour of individual nominees as follows:

| <b>Director</b> | <b>For</b> | <b>%</b> | <b>Withheld</b> | <b>%</b> |
|-----------------|------------|----------|-----------------|----------|
| Andrew Rae      | 11,226,572 | 93.98%   | 718,926         | 6.02%    |
| Douglas Janzen  | 11,833,813 | 99.07%   | 111,685         | 0.93%    |
| William Jarosz  | 11,511,313 | 96.37%   | 434,185         | 3.63%    |
| Richard Barker  | 11,553,813 | 96.72%   | 391,685         | 3.28%    |
| Noel Hall       | 11,833,813 | 99.07%   | 111,685         | 0.93%    |

### **Subsequent Events**

On March 31, 2015, Immune Pharmaceuticals announced that it intends to expand its planned bullous pemphigoid (BP) clinical program. Immune expects to start enrolling patients in a Phase II clinical trial in Israel to be treated during the second quarter of 2015. Additionally, following an International Medical Advisory Board meeting held in San Francisco immediately prior to the American Academy of Dermatology annual meeting, Immune has decided to expand its clinical program to include US centers in the Phase II BP development program. The Company also intends to initiate studies to further investigate the relationship between eotaxin-1 levels and the Bullous Pemphigoid Disease Area Activity Index (BPDAI) and to assess the burden of illness from a medical and economic standpoint.

On April 15, 2015, Immune Pharmaceuticals announced initiation of Bertilimumab development in Liver diseases including NASH. The development program will include pre-clinical studies and initiation of a pilot Phase II clinical trial expected before the end of 2015. It was also announced that subsequent to initiating in 2014 an enhanced GMP Manufacturing process of Bertilimumab, the new process had demonstrated by end of first quarter 2015 a higher comparable performance and improved productivity than the previous process. Immune may bridge to the new process before initiation of Phase III trials.

### **Selected Annual Information**

The financial information reported here in has been prepared in accordance with IFRS. The Company uses the Canadian dollar ("CDN") as its presentation currency. The following table represents selected financial information for the Company's fiscal years 2014, 2013 and 2012.

The financial statements have been prepared on a historical cost basis except for the other investments which is recorded at fair value. The financial statements are presented in Canadian dollars which is the Company's functional currency.

*Selected Statement of Operations Data*

|                                                     | <b>Year ended<br/>December 31,</b> |                |               |
|-----------------------------------------------------|------------------------------------|----------------|---------------|
|                                                     | <b>2014</b>                        | <b>2013</b>    | <b>2012</b>   |
| Total comprehensive loss                            | \$ (2,079,657)                     | \$ (5,918,965) | \$(3,430,427) |
| Weighted average number of shares basic and diluted | 84,457,713                         | 61,484,576     | 49,499,654    |
| Basic and diluted loss per share                    | \$ (0.02)                          | \$ (0.09)      | \$ (0.07)     |

The loss from operations for the year decreased in 2014 mainly as a result of the reduction in clinical trial associated with iCo-007.

*Selected Balance Sheet Data*

|                                                      | <b>As at<br/>December 31,</b> |             |             |
|------------------------------------------------------|-------------------------------|-------------|-------------|
|                                                      | <b>2014</b>                   | <b>2013</b> | <b>2012</b> |
| Cash and cash equivalents and short term investments | \$5,707,787                   | \$1,903,389 | \$1,260,196 |
| Net working capital                                  | \$4,199,174                   | \$561,488   | \$375,121   |
| Total assets                                         | \$7,081,265                   | \$3,929,004 | \$3,013,435 |
| Long term liabilities                                | -                             | -           | -           |
| Total shareholders' equity                           | \$5,504,929                   | \$1,298,598 | \$2,049,704 |

Cash, cash equivalents and short term investments increased by \$3,804,398 to \$5,707,787 in 2014 compared to \$1,903,389 in 2013. As a result of this increase in cash and cash equivalents and short term investments, along with a decrease in accruals and accounts payables, working capital increased by \$3,637,686 to \$4,199,174 in 2014 from \$561,488 in 2013. This increase in net working capital was primarily a result of increased cash due to the January 2014 financing.

The Company experienced an increase in total assets from \$3,929,004 in 2013 to \$7,081,265 in 2014 primarily as a result of the increased cash position.

## Comparison of the 2014 and 2013 Financial Years

### *Results of Operations*

|                                   | 2014      | 2013      | Change      | Change |
|-----------------------------------|-----------|-----------|-------------|--------|
|                                   | \$        | \$        | \$          | %      |
| Loss (gain) on other investments  | 70,317    | (982,189) | 1,052,506   | 107%   |
| Impairment on other investments   | 36,727    | 458,879   | (422,152)   | -92%   |
| Interest income                   | (35,676)  | (17,108)  | 18,568      | 109%   |
| Other income                      | (336,919) | (151,004) | 185,915     | 123%   |
| Research and development          | 669,485   | 4,075,840 | (3,406,355) | -84%   |
| General and administrative        | 1,590,444 | 2,061,405 | (470,961)   | -23%   |
| Foreign exchange loss/(gain)      | 14,672    | 222,366   | (207,694)   | -93%   |
| Other comprehensive loss (income) | 70,607    | 250,776   | (180,169)   | -72%   |
| Total comprehensive loss          | 2,079,657 | 5,918,965 | (3,839,308) | -65%   |

We incurred a total comprehensive loss of \$2,079,657 for the year ended December 31, 2014 compared to a total comprehensive loss of \$5,918,965 for the year ended 2013, representing an increase of \$3,839,308. The decrease in our total comprehensive loss was principally caused by reduction in clinical trial costs associated with iCo-007 in 2014.

### *Sale of shares in Other Investment*

During the fourth quarter of the year ending December 31, 2014, the Company began to sell the IMMUNE shares. A total of 117,817 shares were sold for gross proceeds of USD \$290,256.

### *Research and Development*

Our research and development expenses consist primarily of employee compensation, related share based payments, fees paid to consultants and contract research organizations, related amortization and other costs associated with the pre-clinical and clinical trials of our drug candidates and the manufacture of clinical supplies of drug product for clinical testing.

Research and development expenses were \$669,485 for the year ended December 31, 2014 compared to \$4,075,840 for the year ended December 31, 2013, representing a decrease of \$3,406,355. Research and development expenses for the year ending December 31, 2014 were lower than the same period for the previous year primarily due to the reduced research and development costs associated with the winding down of the iCo-007 iDEAL trial. Research and development expenses for year ended December 31, 2014 primarily consisted of salaries, consultants' fees, contract research organization expenses related to the iDEAL trial for iCo-007 and research expenses related to pre-clinical studies for the Oral Amphotericin B Delivery System.

### *General and Administrative*

General and administrative expenses primarily comprise salaries, share based payments and benefits for Company employees not involved in research and development, professional fees such as legal and accounting expenses, and expenses related to office overheads. For the year ended December 31, 2014 general and administrative expenses were \$1,590,444 compared to \$2,061,405 for the year ended December 31, 2013, representing a decrease of \$470,961. The decrease in the year ended December 31,

2014 compared to the year ended December 31, 2013 was attributable to decreased stock based compensation associated with general and administrative staff, board members and consultants.

We believe the Company has sufficient personnel to manage both its research and development and public company activities and do not anticipate any increase in staffing in the foreseeable future. Accordingly, we believe that general and administrative expenses should remain at current levels in the foreseeable future.

#### *Foreign Exchange*

As the Company deals with a number of contract research organizations, consultants and suppliers in other countries (primarily the United States), our financial results are subject to fluctuations between the Canadian dollar and other international currencies, in particular the U.S. dollar. Foreign exchange loss for the year ended December 31, 2014 was \$14,672 compared to foreign exchange loss of \$222,366 for the same period in 2013, representing a decrease of \$207,694. The changes for the period primarily reflect fluctuations in the exchange rate between the Canadian and U.S. dollar.

The U.S. dollar cash and accounts payable balance for December 31, 2014 were \$2,712,190 (2013 – \$567,625) and \$1,254,082 (2013 – \$2,247,796) respectively.

#### **Selected Quarterly Information**

The table below sets forth unaudited quarterly results prepared by management for the eight previous quarters to December 31, 2014:

| (unaudited)                             | <b>2014 Q4</b> | <b>2014 Q3</b> | <b>2014 Q2</b> | <b>2014 Q1</b> |
|-----------------------------------------|----------------|----------------|----------------|----------------|
| Expenses                                | (296,333)      | 468,059        | 995,704        | 1,107,171      |
| Gain (loss) on other investments        | 395,796        | (90,017)       | 66,620         | (302,082)      |
| Impairment on other investments         | 36,727         | -              | -              | -              |
| Other income                            | (282,874)      | (79,251)       | 225,396        | (200,190)      |
| Interest income                         | (9,586)        | (10,265)       | (11,659)       | (4,166)        |
| Other comprehensive loss (gain)         | 1,012,565      | (682,203)      | 1,706,046      | (1,965,801)    |
| Total comprehensive loss (gain)         | 856,295        | (393,677)      | 2,982,107      | (1,365,068)    |
| Basic and diluted gain (loss) per share | (0.00)         | (0.00)         | (0.04)         | 0.02           |
| (unaudited)                             | <b>2013 Q4</b> | <b>2013 Q3</b> | <b>2013 Q2</b> | <b>2013 Q1</b> |
| Expenses                                | 1,074,048      | 1,806,480      | 1,615,924      | 1,863,159      |
| Gain (loss) on other investments        | (57,015)       | (127,173)      | (798,001)      | -              |
| Impairment on other investments         | 458,879        | -              | -              | -              |
| Other income                            | (109,376)      | 41,143         | (41,500)       | (41,271)       |
| Interest income                         | (8,767)        | (3,621)        | (4,609)        | (111)          |
| Other comprehensive loss (gain)         | (596,638)      | 616,958        | 261,848        | (31,392)       |
| Total comprehensive loss (gain)         | 761,131        | 2,333,787      | 1,033,662      | 1,790,385      |
| Basic and diluted gain (loss) per share | (0.02)         | (0.02)         | (0.01)         | (0.04)         |

#### *Fourth Quarter Results:*

The net loss in the fourth quarter of 2014 increased by 11% to \$856,295 from \$761,131 in the fourth quarter of 2013.

We do not anticipate earning any revenue in the foreseeable future, other than interest income earned on cash balances and/or potential licensing income from our sub-licence with Immune Pharmaceuticals, and any future licensing deals.

Net and comprehensive loss, quarter over quarter, is influenced by a number of factors including the scope of clinical development and research programs pursued; the stage (i.e. Phase I, II or III) of clinical trials undertaken; the number of clinical trials that are active during a particular period of time and the rate of patient enrollment. Each of these factors is ultimately a function of decisions made to continue the development and testing of a product candidate based on supporting safety and efficacy from clinical trial results. Consequently, expenses may vary from period to period. General and administrative expenses are dependent on the infrastructure required to support the corporate, clinical and business development objectives and initiatives of the Company. No material increase in general and administrative costs is expected over the short term.

#### **Liquidity, Capital Resources and Outlook**

|                     | <b>2014</b> | <b>2013</b> | <b>Change</b> | <b>Change</b> |
|---------------------|-------------|-------------|---------------|---------------|
|                     | <b>\$</b>   | <b>\$</b>   | <b>\$</b>     | <b>%</b>      |
| Current assets      | 5,775,510   | 2,068,918   | 3,706,592     | 179%          |
| Current liabilities | 1,576,336   | 2,630,406   | (1,054,070)   | -40%          |
| Working capital     | 4,199,174   | 561,488     | 3,637,686     | 648%          |
| Accumulated deficit | 28,819,566  | 26,810,516  | 2,009,050     | 7%            |

As at December 31, 2014, we had cash and cash equivalents and short-term investments of \$5,707,787 compared to \$1,903,389 as at December 31, 2013. All cash not required for immediate use in operations is invested in redeemable, short-term money market investments. (The aggregate amount of these short term investments is recorded on the Statement of Cash Flows as purchase of short-term investments.) As at December 31, 2014, the Company had working capital of \$4,199,174 compared to \$561,488 as at December 31, 2013. Working capital is calculated by subtracting Current Liabilities from Current Assets. The working capital of \$4,199,174 includes accrued liabilities of \$702,154 payable to JDRF over the next four months in connection with the Company's iDEAL phase II clinical trial.

Our investment in IMMUNE included two instruments, the common shares (short term) and warrants / derivatives (long term). The warrants are financial assets at fair value through profit or loss. The IMMUNE instruments become available for sale on February 25, 2014.

On January 27, 2014, we closed a financing for gross proceeds of \$6,750,000.

As of December 31, 2014, proceeds used from the January 2014 financing for the iDEAL trial are as follows:

|             | <u>Estimated Total</u><br><u>Amount</u> | <u>Allocated as at December,</u><br><u>31, 2014</u> |
|-------------|-----------------------------------------|-----------------------------------------------------|
| iDEAL Trial | \$2,000,000                             | \$1,234,564                                         |

No payments were made to JDRF for the iDEAL trial in the fourth quarter of 2014. All final payments and reconciliation of trial costs are expected to be completed in Q2 of 2015.

We anticipate that the combination of year-end cash on hand will be sufficient to fund operations into the fourth quarter of 2016.

### **Management of Cash Resources**

We use cash flow forecasts to estimate cash requirements for the ensuing twelve month period. Based on these requirements, we will raise equity capital to provide the financial resources for operations ideally for a minimum of twelve months. The timing of equity financings will depend on market conditions and the Company's cash requirements. The Company's cash flow forecasts are continually updated to reflect actual cash inflows and outflows so to monitor the requirements and timing for additional financial resources.

Further, we continue to monitor additional opportunities to raise equity capital and/or secure additional funding through non-dilutive sources such as government grants and additional license agreements. However, it is possible that our cash and working capital position may not be sufficient enough to meet our business objectives in the event of unforeseen circumstances or a change in our strategic direction (see our Annual Information Form for a description of various risk factors which may affect our future outlook).

### **Comparison of Cash Flow**

We realized a net cash inflow of \$2,588,449 for the year ended December 31, 2014. This compares to a net cash inflow of \$505,127 for the year ended December 31, 2013 reflecting overall operating costs for the Company for the year of \$2,831,848, less \$888,917 of investing related activities related to the purchase of short-term investments, less \$6,266,061 of cash inflows from the private placement in the first quarter of 2014. We expect that overall cash outflows for 2015 decline significantly as the iDEAL phase II clinical trial is now completed.

### **Long-Term Obligations and Other Contractual Commitments**

#### ***Lease commitments***

The Company's operating lease expires on December 31, 2015. The lease and operating payments totalled \$57,304 for the year 2013 (2013 – 58,370). Future estimated annual lease payments are as follows:

|       |          |
|-------|----------|
| 2015: | \$57,808 |
|-------|----------|

We are currently assessing options for office space subsequent to expiry of our existing lease.

#### ***Contractual commitments***



The Company may be required to make milestone, royalty, and other research and development funding payments under research and development collaboration and other agreements with third parties. These payments are contingent upon the achievement of specific development, regulatory and/or commercial milestones. The Company has not accrued for these payments as at December 31, 2014 due to the uncertainty over whether these milestones will be achieved. The Company's significant contingent milestone, royalty and other research and development commitments are as follows:

### ***ISIS***

In connection with the licensing agreement between ISIS and the Company, the Company may be required to make additional contingent payments of up to US\$22 million upon the achievement of certain development and commercialization milestones of iCo-007. Although we do not expect to enter Phase 3 trials for diabetic macular edema (DME) based on Phase 2 results, the next milestone for any indication remains a US\$4 million upon initiation of any Phase 3 pivotal clinical trial, given our exclusive worldwide rights to all use indications for this technology. In addition, the Company may be required to pay royalties on future revenues.

### ***Medimmune***

In connection with its licensing agreement between Medimmune and the Company, the Company was required to make up-front payments totalling US\$400,000, of which the last payment was made in December, 2007. The Company may be required to make additional contingent payments of up to US\$7 million upon the achievement of certain development and commercialization milestones. In addition, the Company may be required to pay royalties on future revenues. The Company may also be required to make additional contingent payments upon the achievement of certain development and commercialization milestones for products developed outside the ocular field.

### ***University of British Columbia ("UBC")***

On May 6, 2008, the Company signed an agreement with UBC for the exclusive worldwide licence to an Oral AmpB Delivery System (the "UBC Licence"). In consideration for the UBC Licence, the Company paid UBC an initial licence fee of \$20,000 and is required to pay annual fees to UBC for maintaining the licence until such time as a New Drug Application ("NDA") for an Oral AmpB Delivery System is approved. The Company is required to make additional contingent payments of up to \$1,900,000 in aggregate upon the achievement of certain development and commercialization milestones and is also required to pay royalties on future revenues. The UBC Licence additionally obligated the Company to contribute research funding (which may be in the form of direct payments from the Company or indirect payments, such as securing research grants) to UBC for the an Oral AmpB Delivery System program.

### ***JDRF***

The Company entered into an agreement with Juvenile Diabetes Research Foundation ("JDRF") for work related to the iCo-007 iDEAL clinical trial. The remaining expenses have been agreed to and are booked in accounts payable. See Note 8, Accounts Payable and accrued liabilities, in the financial statements for the year ending December 31, 2014.

### ***National Research Council/Industrial Research Assistance Program***

On May 31, 2012, the Company was awarded a \$1.1 million three-year, non-repayable financial contribution from the National Research Council of Canada's Industrial Research Assistance Program ("IRAP") to support iCo's Oral AmpB Delivery System as novel treatment for patients with Human Immunodeficiency Virus ("HIV"). The funding is supporting feasibility testing and pre-clinical toxicology studies, as well as human safety and efficacy clinical trials to examine the role of the Amp B Delivery System in potentially treating patients with latent HIV reservoirs. Under the grant, up to 75% of the costs of the project may be claimed subject to the \$1.1 million maximum. The Company submits monthly expenditure claims that are subject to IRAP approval and subsequent reimbursement. For the

year ending December 31, 2014, iCo has recognized \$336,919 of the IRAP grant. On October 22, 2014, we announced next steps for our Oral AmpB Delivery System, having previously announced positive findings from its *in vitro* work involving samples from HIV/AIDS patients exposed to HAART therapy. iCo now plans to complete pre clinical studies and regulatory filings to move forward with an initial Phase 1A clinical trial, utilizing approximately \$608,000 remaining of the aggregate \$1.1m funding and technological advice from NRC-IRAP under the CHTD Program. The preparation and regulatory filings are expected to be completed in the second half of 2015, with initiation of a Phase 1A study early in the first quarter of 2016.

### **Transactions with Related parties**

During the year ended December 31, 2014:

- a) the Company incurred consulting fees with a director totalling US\$25,000 (2013 - US\$25,000). The amounts outstanding as at December 31, 2014 totalled US \$nil (2013 - US\$ nil). All transactions were recorded at their exchange amounts. The amounts bear no interest and are unsecured with no terms of repayment.
- b) the Company incurred directors' fees totalling \$36,000 (2013 - \$36,000). The amounts outstanding as at December 31, 2014 totalled \$nil (2013 - \$ nil). All transactions were recorded at their exchange amounts. The amounts bear no interest and are unsecured with no terms of repayment.

### **Off Balance Sheet Arrangements**

The Company has no material undisclosed off balance sheet arrangements that have or are reasonably likely to have, a current or future effect on our results of operations or financial condition.

### **Critical Accounting Estimates and Judgments**

The preparation of financial statements in accordance with IFRS requires the Company's management to make estimates and assumptions that affect the amounts reported in these financial statements and notes. The Company regularly reviews its estimates; however, actual amounts could differ from the estimates used and, accordingly, materially affect the results of operations. Areas requiring management to make significant estimates and judgments include the impairment of intangible assets, clinical trial accruals, and valuation of investment in Immune Pharmaceuticals..

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Further details of the nature of these assumptions and conditions may be found in the relevant notes to the financial statements. Key sources of estimation uncertainty and critical judgments that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year include: the impairment of intangible assets, clinical trial accruals, and fair value of other investments.

- a) Impairment of intangible assets

The Company assesses at least on every reporting period whether there are indicators of impairment in accordance with the accounting policy stated in the note referenced in these financial statements. Following the clinical trial of 007, the management determined that the

intangible asset, ISIS (iCo-007) was impaired and written off. See note 7, Intangible assets in the December 31, 2014 financial statements.

b) Clinical trial accruals

Management examines the accruals in relation to clinical trials on a monthly basis based on the number of patients enrolled in the trials and the stage in the trials. Accruals are based on information obtained from various clinics and estimated costs based on the stage of treatment.

c) Fair value of other investments

The fair value of the other investments is determined by using valuation techniques. The Company uses its estimates and judgment to select a variety of methods as prescribed under the accounting standards. At year-end management used market value for the shares and Black Scholes model for the warrants to determining the fair value of the other investments. Management applied judgment with respect to the term of the warrants.

#### **New accounting policies adopted in 2014**

The Company has adopted the following new standards and amendments to standards, including any consequential amendments to other standards, with a date of application of January 1, 2014:

*IAS 32 - Offsetting Financial Assets and Liabilities ("IAS 32")*

The amendments to International Accounting Standards ("IAS") 32 clarify the guidance as to when an entity has a legally enforceable right to set off financial assets and financial liabilities, and clarify when a settlement mechanism provides for net settlement. This standard did not have a material impact on the Company's financial statements.

*IAS 36 - Impairment of Assets ("IAS 36")*

The amendments to IAS 36 clarify the disclosure of information about the recoverable amount of impaired assets if that amount is based on fair value less costs of disposal. The standard did not have a material impact on the Company's financial statements.

#### **Accounting standards issued and not yet applied**

A number of new standards, amendments to standards and interpretations are effective for annual periods beginning after January 1, 2014, and have not been applied in the preparing these financial statements. Those which may be relevant to the Company are set out below. The Company does not plan to adopt these standards early.

*Amendment to IFRS 2, Share-based Payment*

The amendment clarifies the definition of a 'vesting condition' and separately defines 'performance condition' and 'service condition'.

*Amendment to IFRS 13, Fair Value Measurement*

When IFRS 13 was published, paragraphs B5.4.12 of IFRS 9 and AG79 of International Accounting Standards ("IAS") 39 were deleted as consequential amendments. This led to a concern that entities no longer had the ability to measure short-term receivables and payables at invoice amounts where the impact of not discounting is immaterial. The IASB has amended the basis for conclusions of IFRS 13 to

clarify that it did not intend to remove the ability to measure short-term receivables and payables at invoice amounts in such cases. The standard is further amended to clarify that the portfolio exception in IFRS 13, which allows an entity to measure the fair value of a group of financial assets and financial liabilities on a net basis, applies to all contracts (including non-financial contracts) within the scope of IAS 39 or IFRS 9.

#### *Amendment to IAS 24, Related Party Disclosures*

The standard is amended to include, as a related party, an entity that provides key management personnel services to the reporting entity or to the parent of the reporting entity. The reporting entity is not required to disclose the compensation paid by the management entity to the management entity's employees or directors but it is required to disclose the amounts charged to the reporting entity by the management entity for services provided.

#### *IFRS 9, Financial Instruments*

IFRS 9 addresses the classification, measurement and recognition of financial assets and financial liabilities. IFRS 9 was issued in November 2009 and October 2010. It replaces the parts of IAS 39 that relate to the classification and measurement of financial instruments. IFRS 9 requires financial assets to be classified into two measurement categories: those measured at fair value and those measured at amortized cost. The determination is made at initial recognition. Where the fair value option is taken, the part of a fair value change due to an entity's own credit risk is recorded in other comprehensive income rather than the income statement, unless this creates an accounting mismatch. The Company does not expect IFRS 9 to have a material impact on the financial statements and will also consider the impact of the remaining phases of IFRS 9 when completed by the IASB.

#### *IFRS 15, Revenues from Contracts with Customers*

IFRS 15 deals with revenue recognition and establishes principles for reporting useful information to users of financial statements about the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. Revenue is recognized when a customer obtains control of a good or service and thus has the ability to direct the use and obtain the benefits from the good or service. The standard replaces IAS 18, Revenue, and IAS 11, Construction Contracts, and related interpretations. The standard is effective for annual periods beginning on or after January 1, 2017 and earlier application is permitted.

The Company is still in the process of assessing the impact on the financial statements of these new standards.

### **Financial Instruments**

#### **Fair value**

Financial instrument disclosures establish a fair value hierarchy that requires the Company to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company primarily applies the market approach for recurring fair value measurements. This section describes three input levels that may be used to measure fair value:

Level 1 - unadjusted quoted prices in active markets for identical assets or liabilities. An active market for the asset or liability is a market in which transactions for the asset or liability occur with

sufficient frequency and volume to provide information on an ongoing basis. The Company does not have any financial instruments in this category.

Level 2 - quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

*Financial instruments whose carrying value approximates fair value*

Cash and cash equivalents, short-term investments and other receivables are financial instruments whose fair value approximates their carrying value due to their short-term maturity. The input level used by the Company to measure fair value of its cash and cash equivalents and short-term investments is Level 2 as they are valued using observable market data.

The fair value of accounts payable may be less than its carrying value due to liquidity risk.

The common shares of IMMUNE have been recorded at their fair value on the date they were acquired. Management has classified these shares as available-for-sale. The Company uses Level 3 inputs to value these instruments. The shares of IMMUNE are now traded in the market, however; there is an applied discount rate applied due to a restriction period.

The following table presents the Company's assets and liabilities that are measured at fair value at December 31, 2014 and 2013.

|                                   | <b>At<br/>December<br/>31, 2014</b> |                |                |
|-----------------------------------|-------------------------------------|----------------|----------------|
|                                   | <b>Level 1</b>                      | <b>Level 2</b> | <b>Level 3</b> |
|                                   | <b>\$</b>                           | <b>\$</b>      | <b>\$</b>      |
| <b>Assets</b>                     |                                     |                |                |
| Available for sale - equity       | 1,176,592                           | -              | -              |
| Fair value through profit or loss | -                                   | -              | 60,643         |
|                                   |                                     |                |                |
|                                   | <b>At<br/>December<br/>31, 2013</b> |                |                |
|                                   | <b>Level 1</b>                      | <b>Level 2</b> | <b>Level 3</b> |
|                                   | <b>\$</b>                           | <b>\$</b>      | <b>\$</b>      |
| <b>Assets</b>                     |                                     |                |                |
| Available for sale - equity       | -                                   | -              | 1,521,003      |
| Fair value through profit or loss | -                                   | -              | 184,188        |

There were no transfers between levels in the current year.

### Market risk

Market risk is the risk that changes in market prices, such as foreign exchange rates, interest rates and equity prices, will affect the Company's income or valuation of its financial instruments.

The Company is exposed to financial risk related to fluctuation of foreign exchange rates. Foreign currency risk is limited to the portion of the Company's business transactions denominated in currencies other than the Canadian dollar, primarily expenses for research and development incurred in US\$. The Company believes that the results of operations, financial position and cash flows would be affected by a sudden change in foreign exchange rates, but would not impair or enhance its ability to pay its US\$. The Company manages foreign exchange risk by maintaining US\$ cash on hand to fund its short-term US\$ expenditures. As at December 31, 2014, US\$ denominated cash and short-term investments totalled US\$2,712,190. The US\$ denominated accounts payable and accrued liabilities exposure is US\$1,254,082.

The other investment of IMMUNE is denominated in US\$. A change in share price and foreign exchange would have the following impact:

|                                                         | <b>2014</b>                                    |                                                  |                                               |
|---------------------------------------------------------|------------------------------------------------|--------------------------------------------------|-----------------------------------------------|
|                                                         | <b>Other<br/>investments<br/>shares<br/>\$</b> | <b>Other<br/>investments<br/>warrants<br/>\$</b> | <b>Other<br/>investments<br/>Total<br/>\$</b> |
| 5% increase in share price and<br>foreign exchange rate | 1,297,194                                      | 95,988                                           | 1,393,187                                     |
| 5% decrease in share price and<br>foreign exchange rate | 1,061,875                                      | 78,575                                           | 1,140,450                                     |

### Foreign exchange risk

Foreign exchange risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates.

Balances in foreign currencies at December 31, 2014 and 2013 are as follows:

|                                          | <b>2014</b>        | <b>2013</b>        |
|------------------------------------------|--------------------|--------------------|
|                                          | <b>US balance</b>  | <b>US balance</b>  |
|                                          | <b>\$</b>          | <b>\$</b>          |
| Cash and cash equivalents                | 2,712,190          | 567,625            |
| Accounts payable and accrued liabilities | (1,254,082)        | (2,247,796)        |
|                                          | <u>(1,458,108)</u> | <u>(1,680,171)</u> |

Based on the US\$ balance sheet exposure at December 31, 2014, with other variables unchanged, the effect of 10% change in exchange rates on the net current monetary (liabilities)/assets would be \$145,810 (2013 - \$168,017).

#### Interest rate risk

The Company is subject to interest rate risk on its cash and cash equivalents and short-term investments and believes that the results of operations, financial position and cash flows would not be significantly affected by a sudden change in market interest rates relative to the investment interest rates due to the short-term nature of the investments. The only financial instruments that expose the Company to interest rate risk are its cash and cash equivalents and short-term investments. Cash and cash equivalents in excess of day-to-day requirements are placed in short-term deposits with high quality credit financial institutions and earn interest at rates available at that time.

As at December 31, 2014, cash and cash equivalents held in savings accounts or short-term investments are \$5,707,787. The interest rates range from 0.0% to 0.25%.

#### Liquidity risk

Liquidity risk is the risk that the Company will encounter difficulty in raising funds to meet cash flow requirements associated with financial instruments.

The Company continues to manage its liquidity risk by monitoring its cash flows and investments regularly, comparing actual results with budgets and future cash requirements.

The following table summarizes the relative maturities of the financial liabilities of the Company:

|                                          | <u>Maturity</u>  |                 |
|------------------------------------------|------------------|-----------------|
|                                          | <b>Less than</b> | <b>Greater</b>  |
|                                          | <b>one year</b>  | <b>than one</b> |
|                                          | <b>\$</b>        | <b>year</b>     |
|                                          | <b>\$</b>        | <b>\$</b>       |
| Accounts payable and accrued liabilities | <u>1,576,336</u> | <u>-</u>        |

## Credit risk

Credit risk arises from cash and cash equivalents, deposits with banks and financial institutions, as well as outstanding receivables. The Company invests its excess cash in short-term Guaranteed Investment Certificates. The Company has established guidelines relative to diversification, credit ratings and maturities that maintain safety and liquidity. These guidelines are periodically reviewed by the Company's Board of Directors and modified to reflect changes in market conditions.

The Company limits its exposure to credit risk, with respect to cash and cash equivalents, by placing them with high quality credit financial institutions. The Company's cash equivalents consist primarily of operating funds and deposit investments with commercial banks. Of the amounts with financial institutions on deposit, the following table summarizes the amounts at risk should the financial institutions with which the deposits are held cease trading:

|               | <b>Cash and<br/>cash<br/>equivalents<br/>and short-<br/>term<br/>investments</b> | <b>Insured<br/>amount</b> | <b>Non-<br/>insured<br/>amount</b> |
|---------------|----------------------------------------------------------------------------------|---------------------------|------------------------------------|
|               | <b>\$</b>                                                                        | <b>\$</b>                 | <b>\$</b>                          |
| CIBC          | 2,991,158                                                                        | 100,000                   | 2,891,158                          |
| Raymond James | 1,299,205                                                                        | 1,014,753                 | 284,452                            |
| Manulife      | 417,359                                                                          | 100,000                   | 317,359                            |
| BMO           | 999,965                                                                          | 100,000                   | 899,965                            |
|               | <u>5,707,687</u>                                                                 | <u>1,314,753</u>          | <u>4,392,934</u>                   |

## Risks and Uncertainties

The primary risk factors affecting the Company are set forth in our Annual Information Form for dated April 27, 2015. A copy of our annual information form is available on SEDAR at [www.sedar.com](http://www.sedar.com).

### Outstanding Share Capital

As at April 27, 2015, we had an unlimited number of authorized common shares with 84,457,713 common shares issued and outstanding.

As at April 27, 2015, we had 27,722,980 warrants outstanding.

As at April 27, 2015, we had 2,790,000 options outstanding. Each option entitles the holder to purchase one additional common share at exercise prices ranging from \$0.29 to \$0.73 and expiry dates ranging from July 16, 2014 to September 5, 2018.

For a detailed summary of all outstanding securities convertible or exercisable into equity securities of the Company refer to Note 9 of the Financial Statements for the year December 31, 2014.