

## **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2016**

This management's discussion and analysis has been prepared as of April 19, 2017 and should be read in conjunction with the financial statements of iCo Therapeutics Inc. ("iCo" or the "Company") for the year ended December 31, 2016 and the related notes thereto. Our financial statements are prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the ISAB 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-008, the Oral AmpB Delivery System and our recently concluded option to acquire a novel, glaucoma asset; our expectations regarding future research and development expenses; and the sufficiency of the Company's financial resources to fund operations up to the 2<sup>nd</sup> quarter of 2018 based on current anticipated expenditures. Forward-looking statements include, but are not limited to, those statements set out in this MD&A under Business Overview and Strategy, 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 working as consultants with the Company;
- d) The Company will successfully maintain all necessary commitments to product licenses 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;
- f) Immune Pharmaceuticals Phase 2 studies will not be unreasonably delayed.

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 consultants; 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 some of 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
- have 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, such as the novel glaucoma asset optioned from Laboratorios SALVAT.

### 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 before we must make a commitment to do so. This approach allows us to review additional data before deciding 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

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

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 permitting iCo to outsource these services on a cost-effective basis. Because our manufacturing needs are currently sporadic, we believe that it is more efficient to outsource manufacturing.

### Corporate Re-organization

On January 18, 2016, we announced that the Company was undertaking a strategic re-organization to preserve its asset base and maximize shareholder value. Steps taken included: cash preservation through the termination of employees and reduction of general and administrative expenses; enhanced efforts to partner existing assets; and the search for additional business opportunities.

### Products

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

#### *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”), Cambridge Antibody 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. We remain interested in pursuing further clinical development of this program in individuals with a serious sight threatening form of allergic conjunctivitis known as vernal keratoconjunctivitis. The Company would need to access additional capital through partnering or financing before deciding to advance this program.

On June 24, 2011, the Company granted IMMUNE an exclusive license for the development and commercialization rights to the systemic uses of iCo-008. The Company retained worldwide exclusive rights to all uses and applications in the ocular field. In consideration for granting the license, the Company received upfront consideration of US\$200,000 cash plus 600,000 IMMUNE shares (valued at US\$2.00 per share) and 200,000 IMMUNE warrants. In addition, as part of the license agreement, the

Company may receive up to US\$32 million in milestone payments as well as royalties on net sales of licensed products. IMMUNE also shares in funding 50% of the patent prosecution and maintenance costs of the iCo-008 patent family.

On August 26, 2013, IMMUNE completed a merger with Epicept Corporation, and the merged company began trading on NASDAQ under the name Immune Pharmaceuticals Inc and the symbol IMNP. The original IMMUNE shares and warrants were exchanged for 654,386 common shares and 123,649 warrants in the merged company. During 2015, the Company sold all of its shares in the merged company (realizing net proceeds of \$1,011,569) but is still holding the warrants at December 31, 2016.

#### ***iCo – 008 development undertaken by Immune***

In early 2015, Immune developed an enhanced Good Manufacturing Process for Bertilimumab, the new process has higher comparable performance and improved productivity than the previous process. This was an important step to support production of clinical supplies for future trials.

#### ***iCo – 008 in Ulcerative Colitis (UC)***

Following authorization from Israeli health authorities, Immune Pharmaceuticals initiated a Phase 2 double-blind placebo controlled study with Bertilimumab (iCo-008), in patients with moderate-to-severe ulcerative colitis. Patients were to be enrolled initially from up to ten hospitals in Israel and later in other countries pending approval of local health authorities. 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. Up to forty-two patients are expected to be enrolled into the study. 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. On November 17, 2015, Immune Pharmaceuticals announced that the first patient had been enrolled into the Phase 2 clinical trial evaluating the safety and efficacy of Bertilimumab in Ulcerative Colitis.

The UC trial was expanded to Eastern Europe with completion of the trial estimated by Immune to be in the first half of 2017.

#### ***iCo – 008 for Bullous Pemphigoid (BP)***

In early 2015, Immune expanded its Phase II program with Bertilimumab to the treatment of bullous pemphigoid (BP), a rare auto-immune condition that affects the skin and causes the formation of blisters.

On October 7, 2015, Immune Pharmaceuticals announced that it had submitted an Investigational New Drug Application (IND) in the U.S. to expand recruitment for Bertilimumab, for the treatment of Bullous Pemphigoid, and subsequently announced On November 9, 2015 that the U.S. Food and Drug Administration (FDA) had accepted Immune Pharmaceutical's IND application.

On August 16, 2016, Immune announced that Bertilimumab continues to accrue patients in its two phase 2a clinical trials in bullous pemphigoid (BP) and ulcerative colitis (UC). The BP trial has expanded to six US centers in addition to the two Israeli centers. The first US center was initiated in August 2016 and started to screen patients with others to follow shortly. Immune estimates that the BP trial will be completed in the first half of 2017.

On February 28, 2017, Immune announced that it broadened enrollment eligibility criteria based on the data reported from three patients that have completed treatment to date in its ten-patient open label study of Bertilimumab in the treatment of Bullous Pemphigoid ("BP"). In those patients, the Bullous Pemphigoid Disease Activity Index ("BPDAI") was reduced by an average of 84% and oral prednisone was tapered down to 10mg or less. No significant adverse events were reported. Based on these preliminary results, the Company has also submitted a request for orphan drug designation for Bertilimumab in BP. BP is a rare autoimmune blistering disease of the skin, which is painful and itchy, and occurs predominantly in patients more than 60 years of age.

The study was initially focused on patients who had been recently diagnosed with BP. Investigators involved in the study have desired to permit entry of patients who are not newly diagnosed, but are having difficulty being tapered off chronic steroids, so-called taper resistant patients. As is often the case in rare diseases, there is little prior information to guide study design, and we believe that early studies such as this one have the potential to inform future efforts. The initial data in the ongoing study support the ability to now include such taper resistant patients, and test whether the ability to taper would improve when treated with the study drug, Bertilimumab.

### ***Immune recent funding activity***

On November 17, 2016, Immune announced that it had secured up to \$11 M USD in new financing which will be dedicated to the clinical advancement of Bertilimumab.

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

iCo's experimental oral formulations ("Oral AmpB Delivery System") of Amphotericin B ("AmpB") began development at the University of British Columbia ("UBC") under Dr. Kishor Wasan. Dr. Wasan subsequently moved from the University of British Columbia to the University of Saskatchewan to become Professor and Dean, College of Pharmacy and Nutrition and remains an advisor to iCo. 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, AmpB was shown to have a limited oral bioavailability due to its low aqueous solubility and membrane permeability". 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 several 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 would be valuable for the treatment of Visceral Leishmaniasis ("VL"), known for its high mortality rates. Current AmpB therapy for VL or fungal infections requires one or more 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 completed several 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. iCo's Oral AmpB Delivery System has 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. To this end we worked 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, was awarded several grants including: CIHR POP I and POP II grants and National Research Council Funding through the Industrial Research Assistance Program (“IRAP”). 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 Oral 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. As at March 31, 2017 the Company had fully utilized the funds available from IRAP.

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 included the recruitment of eight HIV-infected subjects successfully treated with HAART with detectable latent viral reservoir. Leukapherisis 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 the Oral AmpB Delivery System 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 our Oral AmpB Delivery System. Samples from one patient were determined not to be susceptible to reactivation. In the remaining subjects, the Oral Amp B Delivery System 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 26, 2015, we announced that the company had engaged Corealis Pharma Inc. (“Corealis”) a contract manufacturing organization, for analytical development, formulation optimization and scale-up of the Oral AmpB Delivery System. This work culminated in the development of new capsule formulations to deliver Amphotericin B.

During 2016, the Company was able to demonstrate scalable and stable drug product in a higher dose form with the new capsule formulations. The Company went on to conduct pre-clinical, pharmacokinetic and distribution studies using these optimized formulations. Conclusions drawn from these pre-clinical studies were that: the optimized formulations exhibited pharmacokinetic (PK) and tissue accumulation data with clinical and commercial relevance and; that once daily regime may be possible for our drug candidate in certain indications.

On January 23, 2017, the Company announced it had initiated multiple, additional pre-clinical studies with its Oral Amphotericin B program including a multi-day fasted/fed study, a 7-day dose range finding study and, importantly, a 14 day GLP toxicology study. All three studies were completed during Q1 2017 with reported results expected in Q2 2017. Upon evaluation of these results the Company will finalize its plans for initiating a Phase 1A study which could present an opportunity for Phase 1A study data in the latter half of 2017.

These studies were funded substantially by a grant provided by IRAP and for the year ended December 31, 2016, the Company has recognized \$251,199 in IRAP grants recorded as other income in the Statement of Loss and Comprehensive Loss. Additional grant money for 2017 has been secured, totaling \$150,000, allowing the Company to undertake critical studies with no impact on corporate financial runway.

iCo has also been building its intellectual property position around the Oral Amphotericin B asset. iCo now has twelve issued patents and six pending patent applications, as it moves towards the clinic. iCo continues to work towards obtaining additional non-dilutive sources of capital for its Oral AmpB Delivery System including potential grant opportunities in Europe.

#### *iCo-007*

The Company had been developing iCo-007 in diabetic macular edema, but analysis of results from a Phase 2 study in June 2014 did not demonstrate response rates that warranted further investment in the clinical development of this technology for diabetic macular edema. Management continued to investigate other potential indications for the technology but was unable to identify other opportunities. Consequently, during the year the Company notified Ionis Pharmaceuticals it had abandoned this technology. The Company has no ongoing financial obligations or liabilities under its license agreement to Ionis Pharmaceuticals because of this abandonment.

### **2016 Key Corporate and Partner Activities**

During 2016, the following milestones were accomplished:

#### **iCo-008**

- On Feb. 24, 2016, Immune Pharmaceuticals announced the publication of new data on the role of eotaxin-1 in Ulcerative Colitis (UC) and Crohn's Disease (CD). The article, published in Digestive Disease Science, presented results of an observational clinical study intended to characterize serum and intestinal wall eotaxin-1 levels in inflammatory bowel disease (IBD) patients, and explored the effect of targeting eotaxin-1 by specific antibodies in an animal IBD model. These studies were conducted under the oversight of Professor Goldin, Chairman of the Digestive Diseases Institute at Shaare Zedek Medical Center of the Hebrew University School of Medicine in Jerusalem, and supported in part by an unrestricted grant from Immune Pharmaceuticals.
- On August 16, 2016, Immune announced that Bertilimumab continues to accrue patients in its two phase 2a clinical trials in bullous pemphigoid (BP) and ulcerative colitis (UC). The BP trial

has expanded to six US centers in addition to the two Israeli centers. The first US center was initiated in August 2016 and started to screen patients with others to follow shortly. Immune estimates that the BP trial will be completed in the first half of 2017. The UC trial is expanding to Eastern Europe with site initiations to be completed in the fourth quarter of 2016. Immune estimates UC trial will also be completed in the first half of 2017. An additional phase 2a trial in Atopic Dermatitis (AD) is in final planning stages in Canada

- On November 17, 2016, Immune announced that it had secured up to \$11 M USD in new financing which will be dedicated to the clinical advancement of Bertilimumab.

### **Oral AmpB Delivery System**

- The Company secured an additional \$200,000 grant for our AmpB Delivery System for the 2016 fiscal year. In total, the Company recognized \$251,199 as other income which included this additional grant.
- The Company conducted pre-clinical pharmacokinetic and distribution studies during the year. Conclusions drawn from these pre-clinical studies were that: the optimized formulations exhibited pharmacokinetic (PK) and tissue accumulation data with clinical and commercial relevance and; that once daily regime may be possible for our drug candidate in certain indications. These studies were funded substantially by an IRAP grant.

### **SALVAT Option Agreement**

Effective November 7, 2016, the Company acquired an exclusive option to in-license the worldwide development and commercialization rights to a novel glaucoma asset from Laboratorios SALVAT (“SALVAT”). The Company also agreed that if it exercises the option it will out-license EU commercialization rights back to SALVAT. If the Company exercises the option on, or before, May 7, 2017, a payment of US\$1.25 million would be due. If the option is exercised between May 8 and August 7, 2017 a payment of US\$1.5 million is due. The option expires nine months after grant on August 7, 2017. SALVAT will continue to maintain the 29 patents covering the asset during the option period.

### **Corporate**

- On January 18, 2016, iCo announced that the company was undertaking a strategic re-organization to preserve its asset base and maximize shareholder value. Management significantly reduced iCo’s monthly burn rate and fixed costs, which included the termination of all employees. Personnel related expenses (excluding termination payments) decreased by 48% in 2016 compared to 2015. Andrew Rae and John Meekison were retained in a reduced consulting capacity to continue their CEO and CFO positions, respectively. Dr. Peter Hnik who has acted as Chief Medical Officer historically, was also retained in a consulting capacity. Non-essential expenses were eliminated during the year.
- On February 17, 2016, iCo announced that it granted an aggregate of 850,000 options to acquire common shares of the Company at an exercise price of \$0.05 to directors, officers and consultants to the Company. The options will expire on February 16, 2021 and shall vest as follows: 1/5 on today’s date (the “Effective Date”), 1/5 three (3) months after the Effective Date, 1/5 six (6) months after the Effective Date, 1/5 nine (9) months after the Effective Date and the remaining

1/5 to vest ratably per month beginning ten (10) months after the Effective Date and ending eighteen (18) months after the Effective Date.

- On August 19, 2016, the Company announced that John Meekison was resigning as CFO of the Company and that Michael Liggett was replacing him as CFO.

### **Subsequent Events**

- On January 23, 2017, the Company announced it had initiated multiple, additional pre-clinical studies with its Oral Amphotericin B program including a multi-day fasted/fed study, a 7-day dose range finding study and, importantly, a 14 day GLP toxicology study. iCo completed all three studies during Q1 2017, with reported results expected in Q2 2017. Upon evaluation of these results the Company will finalize its plans for initiating a Phase 1A study which could present an opportunity for Phase 1A study data in the latter half of 2017. Additional grant money of \$150,000 was secured for Q1 2017 from IRAP, allowing the Company to undertake critical studies with no impact on corporate financial runway. As at March 31, 2017 the Company had fully utilized the funds available from IRAP with an expected claim of approximately \$135,000.
- On February 28, 2017, Immune announced that it broadened enrollment eligibility criteria based on the data reported from three patients that have completed treatment to date in its ten-patient open label study of Bertilimumab in the treatment of Bullous Pemphigoid ("BP"). In those patients, the Bullous Pemphigoid Disease Activity Index ("BPDAI") was reduced by an average of 84% and oral prednisone was tapered down to 10mg or less. No significant adverse events were reported. Based on these preliminary results, the Company has also submitted a request for orphan drug designation for Bertilimumab in BP. BP is a rare autoimmune blistering disease of the skin, which is painful and itchy, and occurs predominantly in patients more than 60 years of age. The study was initially focused on patients who had been recently diagnosed with BP. Investigators involved in the study have desired to permit entry of patients who are not newly diagnosed, but are having difficulty being tapered off chronic steroids, so-called taper resistant patients. As is often the case in rare diseases, there is little prior information to guide study design, and we believe that early studies such as this one have the potential to inform future efforts. The initial data in the ongoing study support the ability to now include such taper resistant patients, and test whether the ability to taper would improve when treated with the study drug, Bertilimumab.

### **Selected Annual Information**

The financial information reported here in has been derived from financial statements prepared in accordance with IFRS. The Company uses the Canadian dollar ("CDN") as its functional and presentation currency. From time to time, the Company may deal with several contract research organizations, consultants and suppliers in other countries (primarily the United States). Our financial results may be subject to fluctuations between the Canadian dollar and other international currencies, in particular the U.S. dollar.

The following table represents selected financial information for the Company's years ended December 31, 2016, 2015 and 2014.

The financial statements have been prepared on a historical cost basis except for the other investments which is recorded at fair value.

*Selected Statement of Operations Data*

	Year ended December 31		
	2016	2015	2014
Total comprehensive income (loss)	\$(1,489,923)	\$(1,724,314)	\$(2,079,657)
Weighted average number of shares outstanding, basic and diluted	84,457,713	84,457,713	84,457,713
Net gain (loss) per share, basic and diluted	\$(0.02)	\$(0.02)	\$(0.02)

The comprehensive loss for the year ended December 31, 2016 decreased by \$234,391 as compared to the year ended December 31, 2015, mainly because of lower general and administration expenses and an increase in other income recognized during 2016. The decrease in the comprehensive loss would have been greater except in the prior year there was a significant foreign exchange gain of \$431,588 which reduced the comprehensive loss for 2015. In the prior year, the foreign exchange gain recognized resulted from a weakening Canadian dollar relative to the US dollar and higher average US dollar cash balances held by the Company during the prior year.

*Selected Balance Sheet Data*

	Year ended December 31, 2016	Year ended December 31, 2015
Cash and cash equivalents	\$2,361,000	\$3,753,982
Net working capital surplus	\$2,286,091	\$3,688,048
Total assets	\$2,452,128	\$3,895,827
Total shareholders' equity	\$2,313,902	\$3,780,615

Cash and cash equivalents decreased by \$1,392,982 to \$2,361,000 as at December 31, 2016 as compared to \$3,753,982 for the year ended December 31, 2015. The decrease reflects primarily funds used in operations during the period. Because of this decrease in cash and cash equivalents, working capital decreased by \$1,401,957 to \$2,286,091 as at December 31, 2016 from \$3,688,048 in December 31, 2015.

The Company experienced a decrease in total assets to \$2,452,128 as at December 31, 2016 from \$3,895,827 as at December 31, 2015 primarily due to a lower cash and cash equivalents balances at December 31, 2016

**Comparison of the 2016 and 2015 financial years**

*Results of Operations*

	2016	2015	Change	Change
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	\$	\$	\$	%
Loss (gain) on other investments	41,374	90,049	(48,675)	(54)
Interest income	16,591	40,939	(24,348)	(59)
Other income	251,199	34,387	216,812	631
Research and development	741,773	648,439	93,334	(14)
General and administrative	917,932	1,563,347	(645,415)	(41)
Foreign exchange loss/(gain)	56,634	(431,588)	(488,222)	N/A
Other comprehensive loss (income)	-	(70,607)	(70,607)	(100)
Total comprehensive loss	1,489,923	1,724,314	(234,391)	(14)

We incurred a total comprehensive loss of \$1,489,923 for the year ended December 31, 2016 compared to a total comprehensive loss of \$1,724,314 for the year ended December 31, 2015, representing a decreased loss of \$234,391. The decrease in the loss is primarily the result of lower general and administration offset by changes in foreign exchange, from a gain of \$431,588 in the year ended December 31, 2015 to a loss of \$56,634 for the year ended December 31, 2016.

### *Research and Development*

Our research and development expenses consist primarily of consultants' compensation and contract research organizations.

Research and development expenses were \$741,773 for the year ended December 31, 2016 compared to \$648,439 for the year ended December 31, 2015, representing an increase of \$93,334. During both years, the Company's research and development efforts were focused on its Oral AmpB program. During the year ended December 31, 2016 the Company conducted a preclinical pharmacokinetic and distribution study using its optimized formulations. Conclusions drawn from these pre-clinical studies were that: the optimized formulations exhibited pharmacokinetic (PK) and tissue accumulation data with clinical and commercial relevance and; that once daily regime may be possible for our drug candidate in certain indications. In the prior year, the activities were related primarily to the manufacturing of our Oral AmpB.

### *General and Administrative*

For the year ended December 31, 2016 general and administrative expenses were \$917,932 compared to \$1,563,347 for the year ended December 31, 2015, representing a decrease of \$645,415. The decrease in expenses was attributable to the reduction in operating costs because of the January 18, 2016 reorganization. Excluding termination payments, personnel costs were lower during the current year as well as professional fees.

### *Foreign Exchange*

From time to time, the Company may deal with several contract research organizations, consultants and suppliers in other countries (primarily the United States). The Company holds cash in US dollars to pay these vendors and carries US dollar accounts payable balances. Changes in the CDN-US dollar exchange rate during the time the Company holds these monetary assets and liabilities results in a foreign exchange gain/loss being recognized in the Statement of Loss and Comprehensive Loss. Accordingly, our financial results may be subject to fluctuations between the Canadian dollar and other international currencies, the U.S. dollar

Foreign exchange loss for the year ended December 31, 2016 was \$56,634 compared to a foreign exchange gain of \$431,588 for 2015, representing a decrease of \$488,222. For both years, the changes reflect fluctuations in the exchange rate for U.S and net US dollar monetary assets held by the Company.

The U.S. dollar cash, cash equivalents and accounts payable balance for December 31, 2016 were US\$665,981 (2015 – US\$1,318,143) and US\$28,289 (2015 – US\$17,410) respectively.

### Selected Quarterly Information

The table below sets forth unaudited quarterly results prepared by management for the eight previous quarters to December 31, 2016:

(unaudited)	2016 Q4	2016 Q3	2016 Q2	2016 Q1
Expenses	237,637	304,294	318,026	856,382
Gain (loss) on other investments	(4,200)	(4,930)	(3,650)	(28,594)
Other income	10,210	96,773	124,955	19,261
Interest income	3,424	4,410	3,451	5,306
Other comprehensive loss (gain)	-	-	-	-
Total comprehensive loss (gain)	228,203	208,841	193,270	860,409
Basic and diluted gain (loss) per share	(0.00)	(0.00)	(0.00)	(0.01)
(unaudited)	2015 Q4	2015 Q3	2015 Q2	2015 Q1
Expenses	549,625	219,191	724,395	57,649
Gain (loss) on other investments	80,599	32,411	(34,824)	23,345
Impairment on other investments			-	(165,424)
Other income	14,283	15,487	(18,934)	(23,922)
Interest income	6,666	5,907	16,204	12,162
Other comprehensive loss (gain)	(70,607)	-	-	70,607
Total comprehensive loss (gain)	544,580	165,386	738,607	275,741
Basic and diluted gain (loss) per share	(0.01)	(0.00)	(0.01)	(0.00)

### Liquidity, Capital Resources and Outlook

	December 31, 2016	December 31, 2015	Change	Change
	\$	\$	\$	%
Current assets	2,424,317	3,803,260	(1,378,493)	(36)
Current liabilities	138,226	115,212	23,014	20
Working capital	2,286,091	3,688,048	(1,401,957)	(38)
Accumulated deficit	32,104,410	30,614,487	1,489,923	5

As at December 31, 2016, we had cash and cash equivalents and short-term investments of \$2,361,000 compared to \$3,753,982 as at December 31, 2015. 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, 2016, the Company had working capital of \$2,286,091 compared to \$3,688,048 as at December 31, 2015. Working capital is calculated by subtracting Current Liabilities from Current Assets.

Our remaining investment in Immune Pharmaceuticals consists of 123,649 warrants, exercisable at US\$2.63 and expiring on June 23, 2021. The warrants are financial assets recorded at fair value through profit or loss.

We anticipate that the combination of year-end cash on hand will be sufficient to fund operations into the 2<sup>nd</sup> half of 2018 based on the current expenditure profile.

### **Management of Cash Resources**

We use cash flow forecasts to estimate cash requirements for the ensuing twelve-month period. Based on these requirements, we raise equity capital as required to provide the necessary 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. Given the volatility of the Canadian and US dollar exchange rate, the company estimates its USD expenses for the year and sets appropriate levels of USD cash and cash equivalent balances. By holding US dollars, the Company remains subject to currency fluctuations which effect its loss and comprehensive loss during any given year.

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 enough to meet our business objectives in the event of unforeseen circumstances or a change in our strategic direction.

### **Comparison of Cash Flow**

We realized a net cash outflow of \$1,392,982 for the year ended December 31, 2016 reflecting cash used in operations of Company of \$1,332,713, plus \$4,035 used in investing activities. This compares to a net cash outflow of \$1,953,805 for the year ended December 31, 2015 reflecting cash used in operations of \$3,095,380 less \$1,009,705 from investing activities related to the net sale short-term investments of \$1,011,569.

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

#### ***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, 2016 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:

#### ***IONIS (formerly "ISIS")***

During the year, in connection with the licensing agreement between IONIS and the Company, the Company notified IONIS it was abandoning its iCo-007 program and as such the Company has no further contractual commitments or liabilities under this licensing agreement.

#### ***Medimmune***

In connection with the licensing agreement between Medimmune and the Company, the Company was required to make upfront 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\$7,000,000 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 iCo-009 (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 a New Drug Application (“NDA”) for iCo-009 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 obligates 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 Oral AmpB Delivery System. All the research funding obligations have been met by the Company.

#### ***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 ended December 31, 2016, iCo recognized \$251,199 (2015 – \$34,387) of the IRAP grant as other income. The Company fully utilized this grant in the subsequent quarter with an expected claim of approximately \$135,000.

#### **Transactions with Related parties**

During the year ended December 31, 2016:

- a) the Company incurred consulting fees from directors totalling CDN \$249,569 (2015 - US\$25,000). The amounts outstanding as at December 31, 2016 totalled CDN \$28,619 (Q3 2015 - US\$ nil). All transactions were recorded at their exchange amounts. the Company incurred directors' fees totalling \$nil (2015 - \$36,000). The amounts outstanding as at December 31, 2016 totalled \$nil (2015 - \$ 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 fair value of other investments.

a) 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 period 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.

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

#### *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.

### **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 warrants of Immune Pharmaceuticals have been recorded at their fair value on the date they were acquired and at subsequent period end dates. Management has classified these warrants as available for sale. The Company uses Level 3 inputs to value these instruments. There is no active market for these warrants but the shares that the warrants can be exchanged into are traded on the NASDAQ stock exchange.

## **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.

Balances in foreign currencies at December 31, 2016 and December 31, 2015 are as follows:

	<b>December 31, 2016</b>	<b>Dec. 31 2015</b>
	<b>US balance</b>	<b>US balance</b>
	<b>\$</b>	<b>\$</b>
Cash and cash equivalents	665,981	1,318,143
Accounts payable and accrued liabilities	(28,289)	(17,410)
	<u>637,693</u>	<u>1,300,733</u>

Based on the US\$ balance sheet exposure at December 31, 2016, with other variables unchanged, if the Canadian dollar were to weaken against the US dollar by 10%, relative to the rate at December 31, 2016, the net monetary assets would be approximately \$95,000 greater. If the Canadian dollar were to strengthen against the US dollar by 10%, relative to the rate at December 31, 2016, the net monetary assets would be approximately \$78,000 less

#### 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, 2016, cash and cash equivalents held in savings accounts or short-term investments are \$2,361,000. 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 one year \$</b>	<b>Greater than one year \$</b>
Accounts payable and accrued liabilities	138,226	-

### **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.

### **Risks and Uncertainties**

The primary risk factors affecting the Company are set forth in our Annual Information Form 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 19, 2017, we had an unlimited number of authorized common shares with 84,457,713 common shares issued and outstanding.

As at April 19, 2017, we had 22,407,448 warrants outstanding.

As at April 19, 2017, we had 1,995,000 options outstanding. Each option entitles the holder to purchase one additional common share at exercise prices ranging from \$0.05 to \$0.73 and expiry dates ranging from March 8, 2017 to January 23, 2022.

For a detailed summary of all outstanding securities convertible or exercisable into equity securities of the Company refer to Note 5 of the Financial Statements for the year ended December 31, 2016.