# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JUNE 30, 2016

This management's discussion and analysis has been prepared as of August 19, 2016 and should be read in conjunction with the financial statements of iCo Therapeutics Inc. ("iCo" or the "Company") for the three months ended June 30, 2016 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.

## **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 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 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 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 inlicensing 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.

# Corporate Re-organization

On January 18, 2016, we announced that the Company was undertaking a strategic re-organization in an effort 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 that could include other industries outside of life sciences.

## **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  $\mu$ g monotherapy), minus 21 letters (700  $\mu$ g monotherapy), minus 14 letters (350  $\mu$ g + laser arm) and minus 14 letters (350  $\mu$ g + 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  $\mu$ g monotherapy arm gained five letters or greater of vision versus 13% in the 700  $\mu$ g monotherapy arm, 12% in the 350  $\mu$ g + laser arm and 11% in the 350  $\mu$ g + Lucentis arm. At four months, patients gaining five letters or more for the 350  $\mu$ g, 700  $\mu$ g, 350  $\mu$ g + laser and 350  $\mu$ g + 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  $\mu$ g monotherapy and 700  $\mu$ g monotherapy arms, meaning there was greater loss of VA in the 700  $\mu$ g monotherapy cohort. There was no statistically significant difference in mean VA between the 350  $\mu$ g monotherapy and either 350  $\mu$ g + laser or 350  $\mu$ g + Lucentis arms. When using MI analysis there was no statistically significant difference observed between 350  $\mu$ g monotherapy and each of the 700  $\mu$ g monotherapy, 350  $\mu$ g + laser and 350  $\mu$ g + Lucentis arms.

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

Management determined that the Phase 2 iCo-007 diabetic macular edema (DME) data that has been presented, along with our internal analysis, did not demonstrate any subgroup response rates that warrant further financial investment by iCo in the DME program. 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"), 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. 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, payable in IMMUNE shares. 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 (with associated anti-dilution provisions) 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. As a result of the merger, our investment in Immune Pharmaceuticals was adjusted to 654,486 shares and 123,649 warrants.

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. 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. 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. On March 31 2015, Immune Pharmaceuticals announced that it is expanding 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 Nonalcoholic Steatohepatitis (NASH). development program will include pre-clinical studies and initiation of a pilot Phase II clinical trial. It was also announced that subsequent to initiating in 2014 an enhanced Good 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. On October 7, 2015, Immune Pharmaceuticals announced that it had submitted an Investigational New Drug Application (IND) in the U.S. to expand recruiting 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 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.

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. The UC trial is expanding to Eastern Europe with site initiations to be completed in the fourth quarter of 2016. An additional phase 2a trial in Atopic Dermatitis (AD) is in final planning stages in Canada. In the second quarter of 2016, new pre-clinical data was generated in AD and a new provisional patent was filed in partnership with Hadasit, the technology transfer of Hadassah hospital, for oral use of anti-eotaxin antibodies in (NASH). Immune also advanced process development for its new cell line for the production of bertilimumab. Immune expects to bridge to the new cell line starting in mid-2017. Immune is assessing options for development of a sub-cutaneous formulation 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" (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 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 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 to support an Investigational New Drug application ("IND") to the US Food and Drug Administration ("FDA") prior to commencing a Phase 1 clinical trial in humans. 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. 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. 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. 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 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. Phase 1A study data is expected to be available in 2017. iCo has also been building its intellectual property position around the Oral Amphotericin B asset. iCo now has eleven issued patents with Europe and seven additional patents pending 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. Recently, the Company secured an additional Cdn\$200,000 grant for our AmpB Delivery System for the 2016 fiscal year.

# 2016 Q2 Corporate and Partner Activities

In the second quarter of 2016, the following milestones were accomplished:

#### iCo-007

None

# <u>iCo-008</u>

None

# **Oral AmpB Delivery System**

• The Company secured an additional Cdn \$200,000 grant for our AmpB Delivery System for the 2016 fiscal year.

## **Corporate**

- On April 13, 2016, the Company filed on SEDAR that it was withdrawing its Notice Declaring Intention To Be Qualified Under National Instrument 44-101 *Short Form Prospectus Distribution* (NI 44-101).
- On June 27, 2016, the Company announced that all nominees listed in the management information circular dated May 30, 2016 were elected as directors at its 2016 Annual Meeting of Shareholders, held on June 24 2016. On a vote by ballot, the following 4 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:

Director	For	%	Withheld	%
Andrew Rae	7,319,096	88.78	924,560	11.22
William Jarosz	8,005,096	97.11	238,560	2.89
John Meekison	8,005,096	97.11	238,560	2.89
Susan Koppy	8,002,096	99.07	241,560	2.93

#### **Subsequent Events**

• 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. The UC trial is expanding to Eastern Europe with site initiations to be completed in the fourth quarter of 2016. An additional phase 2a trial in Atopic Dermatitis (AD) is in final planning stages in Canada. In the second quarter of 2016, new pre-clinical data was generated in AD and a new provisional patent was filed in partnership with Hadasit, the technology transfer of Hadassah hospital, for oral use of anti-eotaxin antibodies in (NASH). Immune also advanced process development for its new cell line for the production of bertilimumab. Immune expects to bridge to the new cell line starting in mid-2017. Immune is assessing options for development of a sub-cutaneous formulation of bertilimumab.

## **Selected Quarterly 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 three and six month period ending June 30, 2016 and 2015.

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

	Three Months ended June 30		Six Months ended June 30	
	2016	2015	2016	2015
Total comprehensive income (loss)	\$(193,270)	\$(738,607)	\$(1,053,680)	\$(991,003)
Weighted average number of shares outstanding, basic and diluted	84,457,713	84,457,713	84,457,713	84,457,713
Net gain (loss) per share, basic and diluted	\$(0.00)	\$(0.01)	(\$0.01)	(\$0.01)

The loss from operations for the three months ended June 30, 2016 decreased by \$545,337 as compared to the three months ended June 30, 2015 mainly as a result of reduced operating costs resulting from the Company's reorganization announced on January 18, 2016 and reduced research and development expenses.

#### Selected Balance Sheet Data

	Six Months	Year ended
	ended June 30,	December 31,
	2016	2015
Cash, cash equivalents and short term investments	\$2,726,166	\$3,753,982
Net working capital surplus (deficit)	\$2,684,948	\$3,688,048
Total assets	\$2,843,166	\$3,895,827
Total shareholders' equity	\$2,738,586	\$3,780,615

Cash, cash equivalents and short term investments decreased by \$1,027,816 to \$2,726,166 as at June 30, 2016 as compared to \$3,753,982 for the year ended December 31, 2015. As a result of this decrease in cash and cash equivalents and short term investments, along with a decrease in accruals and accounts payables, working capital decreased by \$1,003,100 to \$2,684,947 as at June 30, 2016 from \$3,688,048 in December 31, 2015.

The Company experienced a decrease in total assets to \$2,843,166 as at June 30, 2016 from \$3,895,827 as at December 31, 2015.

# Comparison of the Six Months Ended June 30, 2016 and June 30, 2015

# Results of Operations

	Q2 2016	Q2 2015	Change	Change
	\$	\$	\$	%
Loss (gain) on other investments	32,244	176,906	(144,662)	-82%
Interest income	8,757	28,366	(19,609)	-69%
Other income	144,216	10,188	134,028	1316%
Research and development	407,815	325,603	82,212	25%
General and administrative	683,065	760,070	(77,005)	-10%
Foreign exchange loss/(gain)	83,529	(303,629)	387,158	-128%
Other comprehensive loss (income)	_	(70,607)	(70,607)	100%
Total comprehensive loss	1,053,680	991,003	62,677	6%

We incurred a total comprehensive loss of \$1,053,680 for the six months ended June 30, 2016 compared to a total comprehensive loss of \$991,003 for the six months ended June 30, 2015, representing an increased loss of \$62,677. The increase in loss for the six months ended June 30, 2016 is primarily the result of changes in foreign exchange from a gain of \$303,629 in the quarter ending June 30, 2015 to a loss of \$83,529 in the quarter ending June 30, 2016.

# Research and Development

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

Research and development expenses were \$407,815 for the six months ended June 30, 2016 compared to \$325,603 for the six months ended June 30, 2015, representing an increase of \$82,212. For the three months ending June 30, 2016 expenses were \$88,966 compared to \$176,049 for the three month period ending June 30, 2015, representing a decrease of \$87,083. For the six month period ending June 30, 2016 compared to the six month period ending June 30, 2015, the increase expenses were primarily the result of initiating the manufacturing scale up of our Oral AmpB Delivery System. During the three month period ending June 30, 2016, reduced activity in the manufacturing scale up of our Oral AmpB resulted in a decrease of \$87,083 compared to the three month period ending June 30, 2015.

#### General and Administrative

For the six months ended June 30, 2016 general and administrative expenses were \$683,065 compared to \$760,070 for the six months ending June 30, 2015, representing a decrease of \$77,005. For the three months ending June 30, 2016 expenses were \$215,405 compared to \$480,852 for the three month period ending June 30, 2015 representing a decrease of \$265,447. For both the six month period and the three month period ending June 30, 2016, the decreased in expenses was attributable to the reduction on operating costs as a result of the January 18, 2016 reorganization.

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. Accordingly, we believe that general and administrative expenses should remain at current levels or even decline somewhat 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 six months ended June 30, 2016 was \$83,529 compared to foreign exchange gain of \$303,629 for the same period in 2015, representing a decrease of \$387,158. For the three months ending June 30, 2016 foreign exchange loss was \$13,655 compared to \$67,494 for the three month period ending June 30, 2015 representing a decrease of \$53,839. For both the six month period and the three month period ending June 30, the changes reflect fluctuations in the exchange rate for U.S.

The U.S. dollar cash and accounts payable balance for June 30, 2016 were \$727,683 (Q2 2015 – \$2,438,382) and \$7,295 (Q2 2015 – \$26,123) respectively.

# **Selected Quarterly Information**

The table below sets forth unaudited quarterly results prepared by management for the eight previous quarters to June 30, 2016:

(unaudited)	2016 Q2	2016 Q1	2015 Q4	2015 Q3
Expenses	318,026	856,382	549,625	219,191
Gain (loss) on other investments	(3,650)	(28,594)	80,599	20,929
Other income	124,955	19,261	14,283	15,487
Interest income	3,451	5,306	6,666	5,907
Other comprehensive loss (gain)	-	-	(70,607)	-
Total comprehensive loss (gain)	193,270	860,409	544,580	165,386
Basic and diluted gain (loss) per				
share	(0.00)	(0.01)	(0.01)	(0.00)
(unaudited)	2015 Q2	2015 Q1	2014 Q4	2014 Q3
Expenses	724,395	57,649	296,333	468,059
Gain (loss) on other investments	(34,824)	23,345	395,796	(90,017)
Impairment on other				
investments	-	(165,424)	36,727	-
Other income	(18,934)	(23,922)	(282,874)	(79,251)
Interest income	16,204	12,162	9,586	10,265
Other comprehensive loss (gain)	-	70,607	1,012,565	(682,203)
Total comprehensive loss (gain)	738,607	275,741	856,295	(393,677)
Basic and diluted gain (loss) per				
share	(0.01)	(0.00)	(0.00)	(0.00)

Liquidity, Capital Resources and Outlook

	Q2 2016	YE 2015	Change	Change
	\$	\$	\$	%
Current assets	2,789,528	3,803,260	(1,013,732)	-27%
Current liabilities	104,580	115,212	(10,632)	-9%
Working capital	2,684,948	3,688,048	(1,003,100)	-27%
Accumulated deficit	31,668,166	30,614,487	1,053,679	3%

As at June 30, 2016, we had cash and cash equivalents and short-term investments of \$2,726,166 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 June 30, 2016, the Company had working capital of \$2,684,948 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  $2^{nd}$  fiscal quarter 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.

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 outflow of \$1,522,025 for the six months ended June 30, 2016 reflecting overall operating costs for the Company for the period of \$\$1,023,779, plus \$498,245 of investing related activities related to the purchase of short-term investments. This compares to a net cash outflow of \$742,993 for the six months ended June 30, 2015 reflecting overall operating costs for the Company for

the period of \$2,286,356, plus \$1,442,550 of investing related activities related to the purchase of short-term investments.

# **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 June 30, 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")

In connection with the licensing agreement between IONIS 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 indications pursued and developed. In addition, the Company may be required to pay royalties on future revenues.

#### 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 such time as 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 six

months ending June 30, 2016, iCo recognized \$144,216 (Q2 2015 – \$10,188) of the IRAP grant as other income.

# **Transactions with Related parties**

During the three months ended June 30, 2016:

- a) the Company incurred consulting fees from directors totalling CDN \$126,370 (Q2 2015 US\$6,250). The amounts outstanding as at June 30, 2016 totalled CDN\$nil (Q2 2015 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 \$nil (Q2 2015 \$9,000). The amounts outstanding as at June 30, 2016 totalled \$nil (Q2 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 impairment of intangible assets, clinical trial accruals, and 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 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.

## 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 common shares of Immune Pharmaceuticals 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 Pharmaceuticals are now traded in the market, however; there is an applied discount rate applied due to a restriction period.

#### 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 June 30, 2016 and December 31, 2015 are as follows:

	June, 30 2016 US balance \$	Dec. 31 2015 US balance \$
Cash and cash equivalents Accounts payable and accrued liabilities	727,683 (7,295)	2,712,190 (1,254,082)
	720,388	1,458,108

Based on the US\$ balance sheet exposure at June 30, 2016, with other variables unchanged, the effect of 10% change in exchange rates on the net current monetary (liabilities)/assets would be \$72,038 (Dec. 31, 2015 - \$145,810).

### 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 June 30, 2016, cash and cash equivalents held in savings accounts or short-term investments are \$1,520,433. 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:

		Maturity
	T 4	Greater
	Less than	than one
	one year	year
	\$	\$
Accounts payable and accrued liabilities	104,580	-

#### 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:

	Cash and cash equivalents and short- term investments \$	Insured amount \$	Non- insured amount \$
CIBC Raymond James Manulife	492,703 2,212,460 21,003	100,000 2,212,460 21,003	392,703 -
	2,726,166	2,333,463	392,703

#### **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 <a href="www.sedar.com">www.sedar.com</a>.

# **Outstanding Share Capital**

As at August 19, 2016, we had an unlimited number of authorized common shares with 84,457,713 common shares issued and outstanding.

As at August 19, 2016, we had 22,407,448 warrants outstanding.

As at August 19, 2016, we had 2,735,000 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 September 26, 2016 to February 16, 2021.

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 three months ended June 30, 2016.