## **iCO THERAPEUTICS INC.**

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

# THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

This management's discussion and analysis has been prepared as of November 26, 2010 and should be read in conjunction with the unaudited consolidated financial statements of iCo Therapeutics Inc. ("iCo" or the "Company") for the quarter ended September 30, 2010 and the related notes thereto. Our consolidated financial statements are prepared in accordance with Canadian generally accepted accounting principles ("GAAP") and all dollar amounts are expressed in Canadian dollars unless otherwise noted. Certain statements in this discussion, other than statements of historical fact, are forward-looking statements. Statements regarding future events, expectations and beliefs of management and other statements that do not express historical facts are forward-looking statements. In this discussion, the words "believe", "may", "will", "estimate", "continue", "anticipate", "intend", "expect", "plan", "predict", "potential" and similar expressions, as they relate to us, our business and our management, are intended to identify forward looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forwardlooking 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. Forwardlooking 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.

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. Additional information relating to our Company, including our annual information form, is available by accessing the SEDAR website at <a href="https://www.sedar.com">www.sedar.com</a>.

In this discussion, unless the context requires otherwise, references to "we" or "our" are references to iCo Therapeutics Inc.

# **Business Overview and Strategy**

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

We principally focus on in-licensing drug candidates with a clinical history and redose, reformulate and develop drug candidates for the treatment of sight-threatening conditions such as diabetic macular edema and severe allergic conjunctivitis and life threatening diseases such as severe systemic fungal infections. 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 reduces the risk, time and cost of developing ocular therapeutics by avoiding the uncertainty associated with 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 to 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:

- are approved for clinical trials or are in late-stage pre-clinical trials;
- have well-established safety profiles;
- have been successfully manufactured on a clinical grade basis in quantities sufficient for clinical trials; and
- have data suggestive of potential efficacy as a treatment for ocular indications.

Our initial focus has been 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 Strategic Advisory Board ("SAB") have considerable expertise in ophthalmology. Although we may in the future develop product candidates targeting conditions other than ocular disease, our current emphasis is on leveraging our expertise in ophthalmology to focus on the development of product candidates targeting ocular diseases such as diabetic macular edema and allergic conjunctivitis.

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

## **Products**

We have in-licensed three product candidates: iCo-007, iCo-008 and iCo-009 that we believe have the potential to treat sight threatening and life threatening conditions.

## iCo-007

iCo-007 is a second generation anti-sense compound that we believe reduces levels of a key protein, C-Raf Kinase, which is associated with diabetic retinopathy, including diabetic macular edema. Diabetic retinopathy, including diabetic macular edema, is an ocular complication characterized by new blood vessel growth and increased vascular permeability in the back of the eye. Fluid leaks into the macula, the part of the eye where the sharpest vision occurs, causing it to swell, and impairing vision. We recently completed a Phase I, open label, dose-escalating clinical trial at four trial sites in the United States using a single injection of iCo-007 in patients with diffuse diabetic macular edema. The primary endpoint for the trial was to assess the safety of iCo-007 at four different dosage levels in four groups ("cohorts") of patients – fifteen patients in total. However as the trial was conducted in patients with disease as opposed to healthy volunteers, as secondary endpoints we were able to collect limited data on what effect the drug may be having on the disease itself. All patients have been treated and have completed their subsequent clinic visits. The clinical trial sites have been decommissioned and the Phase I study has formally ended.

On May 17, 2010, we announced the results from the Phase I trial for iCo-007 as presented in the final study report for the Phase I trial. The trial met its primary endpoint and the intravitreal injections of iCo-007 were well tolerated. iCo-007 exhibited a good safety profile and we ultimately progressed to maximum planned dose of 1000 µg based on positive safety evaluation committee meetings two months post each dosing level. Analysis of blood plasma in patients demonstrated that iCo-007 was not detectable in the blood plasma with any of the doses used in the Phase I trial. There were signs of biological activity in responsive patients at 24 weeks with a reduction of retinal thickness ranging between 149 and 743 microns (and 115 to 743 microns if one additional patient followed only to week 18 is included). Mean change in retinal thickness for all patients completing the 24 week follow-up (12 of 15 patients) was minus 169 microns (or 40% reduction of excess retinal thickness), a positive trend. In a number of subjects there was a transient increase in retinal edema preceding biological effect. Approximately 69% of patients completing a 24 week follow up (13 of 15

patients) had stable or improved vision, defined as -5 letters or better compared to baseline and 23% of patients experienced  $\geq$ 5 letters of visual improvement. The highest dose seemed to show a smaller biological effect than lower doses. The first three doses appeared to display some dose-related biological effect. It should be noted that due to the small number of patients enrolled in the study (n=15) these results are not statistically significant nor can statistical significance be inferred.

Based on these results contained in the final study report and earlier data we had received, we have undertaken preparations for a Phase II clinical program for iCo-007. This includes clinical trial design, preparation of a "fill finish" manufacturing production run for iCo-007 drug product (whereby the iCo-007 active pharmaceutical ingredient is mixed in a solution and filled into single injection vials) and the preparation of documents and materials in advance of Investigational New Drug ("IND") submissions to regulatory authorities to gain approval for entering Phase II trials for iCo-007. On July 26, 2010 we announced that we received a no objection letter from the Therapeutics Products Directorate, a division of Health Canada. Subsequent to the end of the third quarter, we also began the "fill finish" manufacturing process. While we are confident that we have taken the necessary steps, there can be no assurance that the "fill/finish" production run will be completed successfully. The Phase II trial itself will not be undertaken until such time as we have obtained the appropriate financial resources to undertake the trial. We are also exploring a number of opportunities to obtain the funding for the Phase II trial including raising additional equity capital, strategic corporate partnerships, non-dilutive funding through various granting agencies and foundations or a combination of the above.

## iCo-008

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 signalling 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. Recent 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. It is the result of abnormal blood vessel growth and fluid leakage in the macula (the area of the retina responsible for central vision) which leads to retinal damage. In light of this new information, we are currently planning exploratory studies for iCo-008 in AMD.

Before we licensed iCo-008 from Medimmune Limited ("MedImmune"), MedImmune (then known as Cambridge Antibody Technology) conducted Phase I clinical trials testing the safety, tolerability and pharmacokinetics of iCo-008 and Phase II 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 II 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 consequently, we are currently exploring various strategic initiatives to partner with other firms or licence the systemic applications for iCo-008 for a fee as a means to fund further development of iCo-008.

We also continue to engage in discussions with third party pharmaceutical companies for the potential partnering of iCo-008 for a variety of systemic disease indications. 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.

#### iCo-009

iCo-009 is an experimental oral formulation of Amphotericin B ("AmpB") currently being developed at the University of British Columbia ("UBC"). 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. Intravenous AmpB has historically been a potent but toxic option for the treatment of serious systemic fungal infections. Systemic fungal infections are fungal infections that affect the entire body and are particularly prevalent among people whose immune systems have been weakened by certain treatments, such as organ transplant recipients, or certain conditions, such as cancer, diabetes or AIDS. Although a number of drugs have been developed for the treatment of systemic fungal infections, nonetheless systemic fungal infections remain a leading cause of death for organ transplant recipients and other patients with compromised immune systems. Further, in developing nations, oral therapy is in need for a disease called Visceral Leishmaniasis ("VL"), known for its high mortality rates. Current AmpB therapy requires repeated infusions in the hospital setting and is often associated with infusion-related adverse events, such as renal toxicity. Successful oral formulation could resolve the safety issues associated with parenteral application and enable a much broader patient access to this highly effective treatment option. Oral dosing of AmpB has not been successful in the past due to inactivation of the drug in the gut before it could get into the systemic circulation.

We have completed a number of pre-clinical studies with iCo-009 which has shown promising pharmacokinetic and tissue distribution results in two anti-fungal animal models. We are currently generating additional pre-clinical data to further demonstrate oral bioavailability, safety and efficacy prior to commencing a clinical program with iCo-009 to support an Investigational New Drug application ("IND") to the US Food and Drug Administration ("FDA") prior to commencing a Phase I clinical trial in humans. iCo-009 has also demonstrated promising results in animal models for VL conducted at independent laboratories in the United States. 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. These development programs will only be undertaken subject to obtaining appropriate financing. 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 two CIHR grants for aggregate funding support of up to \$1,200,000. This support is inclusive of certain matching funding requirements from iCo. We also entered into a collaboration development agreement with the Consortium for Parasitic Drug Development ("CPDD") for up to USD \$182,930 for the research and development of derivatives of our iCo-009 oral drug delivery technology for the treatment of neglected diseases such as Leishmaniasis and Trypanosomiasis. Subsequent to the end of the third quarter 2010, our collaboration with CPDD was successfully concluded and we are now exploring further potential collaborations, both from commercial and granting agencies to advance the iCo-009 program through additional pre-clinical testing and potentially, Phase I clinical trials.

# 2010 Q3 Corporate Highlights

The third quarter of 2010 was marked by the following highlights:

iCo-007

- On July 26, 2010, we announced that we had received a no objection letter from the Therapeutics Products Directorate, a division of Health Canada, to conduct a Phase II clinical study in Diabetic Macular Edema with iCo-007.

## iCo-009

- On September 29, 2010 we announced that the our oral Amphotericin B program, "iCo-009", was granted Orphan Drug status for the treatment of Visceral Leishmaniasis (VL) by the US Food and Drug Administration ("FDA"). The Orphan Drug Act (ODA) is intended to promote the development of products that demonstrate promise for the treatment of rare diseases or conditions. Orphan designation qualifies the sponsor of the product for tax and marketing incentives, which can include tax credits for clinical research, study design support, exemption from application-filing fees, grant funding for clinical trials, and seven years of marketing exclusivity after the approval of the drug.
- On September 22, 2010 we announced the appointments of Dr. Thomas Walsh, Dr. Coleman Rotstein, and Dr. Jack Sobel to the Scientific Advisory Board ("SAB") committee overseeing the development of iCo-009, iCo's oral Amphotericin B program for life-threatening fungal and parasitic diseases. Drs. Rotstein, Sobel, and Walsh joined Dr. Don Buell, the Chairman of the iCo-009 SAB, who was formerly Senior Medical Director at Astellas Pharma Inc.

# **Subsequent Events**

- On October 13, 2010 we announced that the company has been selected as one of Canada's Top 10<sup>TM</sup> Competition winners. Top 10<sup>TM</sup> winners are chosen by an independent expert panel of Canadian and U.S. venture capitalists.

#### **Selected Financial Information**

The financial information reported here in has been prepared in accordance with Canadian GAAP. The Company uses the Canadian dollar ("CDN") as its reporting currency. The following table represents selected financial information for the Company's fiscal three and nine month periods ending September 30, 2010 and September 30, 2009:

#### Selected Statement of Operations Data

	Three Months ended September 30		Nine Months ended September 30	
	2010	2009	2010	2009
Gain (loss) from operations	(517,044)	\$ (556,976)	(2,149,864)	\$ (1,699,285)
Weighted average number of shares				
outstanding, basic and diluted	31,418,629	29,311,613	39,296,829	27,746,031
Net gain (loss) per share, basic and diluted	\$(0.01)	\$(0.02)	\$(0.05)	\$(0.06)

The loss from operations increased for the three and nine months ended September 30, 2010 compared to the three and nine months ended September 30, 2009 as a result of higher research and development expenditures, professional fees and stock based compensation.

#### Selected Balance Sheet Data

	Nine Months ended September 30, 2010	Year ended December 31, 2009
Cash and cash equivalents	2,656,607	\$3,896,065
Net working capital	2,626,515	\$3,630,719
Total assets	3,354,639	\$4,628,550
Long term liabilities	ı	=
Total shareholders' equity	3,216,266	\$4,305,772

Cash and cash equivalents decreased by \$1,239,458 from \$3,896,065 in December 31, 2009 to \$2,656,607 at September 30, 2010.

# Comparison of the Quarters ending September 30, 2010 and September 30, 2009

# Results of Operations

We incurred a net and comprehensive loss of \$517,044 for the three months ended September 30, 2010 compared to a net and comprehensive loss of \$556,976 for the three months ended September 30 2009, representing a decrease of \$39,932. The decrease in our net and comprehensive loss was principally caused by a decrease in research and development costs.

We incurred a net loss of \$2,149,864 for the nine months ended September 30, 2010 compared to a net loss of \$1,699,285 for the same period in 2009, representing an increase of approximately \$450,579. The increase in our net loss was principally caused by an increase in research and development, professional fees and stock based compensation expenses for the nine months ended September 30, 2010.

As we are in the development stage and our products will not reach approval or become commercially viable for several years, if at all, we anticipate that the Company will continue to generate net losses for the foreseeable future. We did not have any product revenues for the nine months ended September 30, 2010 and 2009 and do not anticipate generating any product revenues in the foreseeable future.

# Interest Income

Interest income is earned primarily through interest on excess cash balances that are invested in short term, high quality investments that are highly liquid. Interest income for the three months ended September 30, 2010 was \$5,750, compared to \$628 for the three month period ending September 30, 2009, resulting in an increase of \$5,122. Interest income for the nine months ended September 30, 2010 was \$19,595, compared to \$2,875 for the nine months ended September 30, 2009, resulting in an increase of \$16,720.

The higher interest income earned in the three and nine month period ending September 30, 2010, as compared to the three and nine month period in 2009 was a result of higher cash and short term investments balances held in our treasury in 2010.

#### Research and Development

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

Research and development expenses were \$144,525 for the three months ended September 30, 2010 compared to \$275,907 for the three months ended September 30, 2009, representing a decrease of \$131,382. This decrease in the three months ending September 30, 2010 compared to the three months ending September 30, 2009 were attributable to a refund on certain research and development costs. Research and development expenses were \$984,580 for the nine months ended September 30, 2010 compared to \$867,558 for the same period in 2009, representing an increase of \$117,022. This increase was also attributable to the increase in personnel salaries and consultants' fees. Research and development expenses for nine months ended September 30, 2010 primarily consisted of salaries, consultants' fees, contract research organization expenses related iCo-007 and research expenses related to pre-clinical studies for iCo-009. As we are in the process of preparing for a Phase II clinical trial for iCo-007 intended to begin in the first half of 2011, we anticipate our research and development expenses will increase over the upcoming 12 months. However commencement of the Phase II trial and the related increase in expenses will be dependent upon our ability to obtain sufficient capital to fund the Phase II clinical trial.

# General and Administrative

General and administrative expenses primarily comprise salaries and benefits for company employees not involved in research and development, professional fees such as legal and accounting expenses, and expenses related to office overheads. For the three months ended September 30, 2010 general and administrative expenses were \$318,379 compared to \$226,601 for the three months ending September 30, 2009, representing an increase of \$91,778. The increases in the three months ending September 30, 2010 compared to the three months ending September 30, 2009 were attributable to higher personnel salaries and professional fees. For the nine months ended September 30, 2010 general and administrative expenses were \$836,506 compared to \$622,185 for the same period in 2009, representing an increase of \$214,321. This increase was also attributable to higher personnel salaries and professional fees incurred for the nine month period ending September 30, 2010 as compared to the same period for 2009.

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

#### Amortization

Amortization is comprised primarily of technology licenses that are recorded at cost and then amortized on a straight-line basis over the term of related licenses, which range from 10 to 15 years. We also amortize certain office and computer equipment on a straight-line basis over the estimated useful lives of the equipment, ranging from 2 to 5 years. The majority of the amortization recorded during the three months ended September 30, 2010 is in connection to the in-licensing of iCo-007 and iCo-008.

Amortization for the three months ended September 30, 2010 was \$29,385 compared to amortization of \$29,100 for the three months ended September 30, 2009, an increase of \$285. Amortization for the nine months ended September 30, 2010 was \$88,272 compared to amortization of \$87,057 for the nine months ended September 30, 2009, an increase of \$1,215. For both the three and nine months ended September 30, 2010, the increase is attributable to new computer equipment.

## Foreign Exchange

Because our licenses are dominated in U.S. dollars and because of our dealings with 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 three months ended September 30, 2010 was \$7,986 compared to foreign exchange gain of \$785 for the same period in 2009, representing an increase of \$8,771. Foreign exchange loss for the nine months ended September 30, 2010 was \$20,806 compared to foreign exchange loss of \$26,285 for the same period in 2009, representing a decrease of \$5,479. The changes for both the three and six month periods reflect fluctuations in the exchange rate for U.S. dollars.

# Stock Based Compensation

Stock based compensation relates to options granted under our employee stock option plan to directors, officers, employees and consultants. Compensation expense is recorded using the fair value method over the vesting period of the option. The fair value of each option granted is estimated as at the date of grant using the Black-Scholes option pricing model. Stock based compensation for the three months ended September 30, 2010 was \$22,519 compared to \$26,781 for the three months ended September 30, 2009, a decrease of \$4,262. Stock based compensation for the nine months ended September 30, 2010 was \$239,295 compared to \$99,075 for the nine months ended September 30, 2009, an increase of \$140,220.

## **Selected Quarterly Information**

The table below sets forth unaudited quarterly results prepared by management for the eight quarters to September 30, 2010.

(unaudited)	2010 Q3	2010 Q2	2010 Q1	2009 Q4
Interest income	5,750	6,975	6,870	3,479
Total expenses	584,394	810,907	835,758	612,484
Loss and comprehensive (loss)	(578,644)	(803,932)	(828,888)	(609,005)
Basic and diluted (loss) per share	(0.01)	(0.02)	(0.02)	(0.02)
(unaudited)	2009 Q3	2009 Q2	2009 Q1	2008 Q4
Interest income	628	621	1,626	5,158
Total expenses	557,604	557,707	587,049	686,346
Loss and comprehensive (loss)	(556,976)	(557,086)	(585,423)	(681,188)
Basic and diluted (loss) per share	(0.02)	(0.02)	(0.02)	(0.03)

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

## Liquidity, Capital Resources and Financial Outlook

As at September 30, 2010, we had cash and cash equivalents of \$2,656,607 compared to \$3,896,065 as at December 31, 2009. As at September 30, 2010, the Company had working capital of \$2,626,515 compared to \$3,630,719 as at December 31, 2009.

In general, the global economy is anticipated to face slow growth prospects for the foreseeable future and we remain guarded about the economic prospects for the life sciences sector for the next 12 months. It is our expectation that capital markets may continue to experience additional volatility for the remainder of 2010 and into 2011. The investment climate for the life sciences sector remains challenging and we continue to manage our expenditures very carefully and direct the majority of our internal financial resources primarily for the planning of a Phase II trial for iCo-007. We anticipate that our current cash on hand will be sufficient to fund operations into the fourth quarter of 2011, at which time we will need to obtain additional proceeds through equity or debt financing or by selling or licensing our technology for cash proceeds.

# **Comparison of Cash Flow**

We realized a net cash outflow of \$104,612 for the three months ended September 30, 2010 reflecting overall operating costs for the Company for the three month period ending September 30, 2010 of \$601,054. This compares to a net cash inflow of \$89,804 for the three months ended September 30, 2009 which consisted of a cash outflow from operations of \$438,703. The primary reason for the increase in net cash outflows is due to a combination additional consulting, personnel costs and professional fees.

We expect cash outflows for the next few months will steadily increase as we continue preparation for our Phase II clinical trial program of iCo-007 expected to begin in the first half of 2011. Initiation of the clinical trial itself will be dependent on our ability to raise sufficient capital to fund the trial. Any cash inflows will be highly dependent on our ability to raise additional capital.

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

In January 30, 2009, we signed an additional three year extension for our operating lease extending the expiration date to May 31, 2012. We will need to negotiate an extension to use our current facilities beyond this date or find new office space. We cannot be assured that any new arrangement will be negotiated at similar or lower office rental and related costs.

# **Transactions with Related parties**

During the nine months ended September 30, 2010 we recorded an expense of \$36,900 to three outside directors for board and consulting fees (for the nine months ended September 30, 2009 - \$6,380).

# **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**

Our financial statements are prepared in accordance with GAAP. These principles require management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and

disclosures within the notes. While management believes that these estimates and assumptions are reasonable, actual results could vary significantly.

We believe the following policies to be critical to understanding our financial position and results of operations as these policies require management to make significant estimates, assumptions and judgments about matters that are inherently uncertain.

## Stock based compensation

We account for stock based compensation under the fair value-based method. Under the fair value based method, stock based payments to employees and non-employees are measured at the fair value of the equity instruments issued. The fair value of stock based payments to non-employees is periodically re-measured until the services are provided or the options vest, and any change therein is recognized over the period. We use the Black-Scholes option pricing model to calculate stock option values, which requires certain assumptions about stock price volatility, expected life of the options and the risk free rate. Changes to any of these assumptions could produce different results, which could have a material impact on results.

# Intangible assets

Our intangible assets are our licenses to use various technologies, and include proprietary rights, intellectual property, patent rights and technology rights which have been acquired from third parties. Intangibles assets are amortized on a straight line basis over the terms of the related license, ranging from 10 to 15 years. Intangible assets are reviewed for impairment upon the occurrence of events or changes in circumstances indicating that the carry value of the asset may not be recoverable. A significant change in the estimates used for valuing the intangible assets or the amortization may impact its remaining useful life and therefore would impact results.

#### Income Taxes

The Company follows the liability method of accounting for income taxes. Under this method, current income taxes are recognized for the estimated income taxes payable for the current period. Future income tax assets and liabilities are recognized in the current period for temporary differences between the tax and accounting basis of assets and liabilities as well as for the benefit of losses available to be carried forward to future years for tax purposes. Future income tax assets and liabilities are measured using substantively enacted tax rates and laws expected to apply in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on future income tax assets and liabilities is recognized in operations in the period that includes the substantive enactment. The amount of future income tax assets recognized will be limited to the amount of the benefit that is more likely than not to be realized.

#### **Financial Instruments**

The Company's financial instruments consist of cash and cash equivalents, short term investments, accounts receivable and accounts payable. The carrying amounts reported in the consolidated balance sheets for these financial instruments approximate fair value because of the immediate or short-term maturity.

The Company, through its financial assets and liabilities, is exposed to various risks. The following analysis provides a measurement of risks as at September 30, 2010:

# a) Foreign exchange risk

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

Balances in foreign currencies at September 30, 2010 and December 31, 2009 are as follows:

	September 30, 2010 US balances \$	December 31, 2009 US balances \$
Cash and cash equivalent Accounts payable	17,100 (49,765)	37,785 (162,516)
_	(32,665)	(124,731)

Based on the US dollar balance sheet exposure at September 30, 2010, with other variables unchanged, a 10% change in the US dollar compared to the CDN dollar would not have a significant impact on the statement of operations, comprehensive loss and deficit.

## b) Interest rate risk

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.

## c) 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 recent problems in the global credit markets have resulted in a drastic reduction in the ability of companies to raise capital through the public markets.

The Company continues to manage its liquidity risk by being fairly consistent with outflows experienced for the nine month ended September 30, 2010 and is undertaking efforts to conserve cash resources wherever possible.

#### d) Credit risk

The Company's exposure to credit risk consists of the carrying value of its cash and cash equivalents.

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	Insured amount \$	Non-insured amount \$
CIBC	1,658,925	100,000	1,558,925
Raymond James	512,673	512,673	_
Manulife	485,009	485,009	
	2,656,607	997,682	1,558,925

## **Changes in Accounting Policies**

Credit Risk and the Fair Value of Financial Assets and Financial Liabilities

In January 2009, the Company adopted the recommendation of the Emerging Issues Committee No. 173, *Credit Risk and the Fair Value of Financial Assets and Financial Liabilities*, issued by the CICA. This abstract clarifies that an entity's own credit risk and the credit risk of its counterparty should be taken into consideration in determining the fair value of financial assets and liabilities. The adoption of this section did not have a material impact on the Company's financial statements.

#### Financial Instruments - Disclosures

In June 2009, the Company adopted the amendments to Section 3862, *Financial Instruments - Disclosures*, issued by the CICA. The amendments improved disclosures about fair value measurements of financial instruments, including the relative reliability of the inputs used to those measurements and liquidity risk, in light of concerns that the nature and extent of liquidity risk requirements were unclear and difficult to apply. The amendments to Section 3862 apply to annual financial statements relating to fiscal years ending after September 30, 2009. The adoption of this section did not have any measurement impact on the Company's financial statements.

# Goodwill and intangible assets

In February 2008, the CICA issued Handbook Section 3064, Goodwill and Intangible Assets, which replaces Handbook Section 3062, Goodwill and Other Intangible Assets, and Section 3450, Research and Development Costs. This revision aligns Canadian generally accepted accounting principles with IFRS and establishes standards for the recognition, measurement, presentation and disclosure of goodwill and intangible assets. This section applies to fiscal years beginning on or after October 1, 2008.

The adoption of this standard, effective for the Company on January 1, 2009, did not impact the Company's operating results or financial position.

## **New Accounting Pronouncements**

Business combinations, consolidated financial statements and non-controlling interests

In January 2008, the CICA introduced Handbook Section 1582 to replace Handbook Section 1581, Business Combinations, and Sections 1601 and 1602 to together replace Handbook Section 1600, Consolidated Financial Statements. The adoption of Section 1582 and collectively Sections 1601 and 1602 provides the Canadian equivalent to International Financial Reporting Standard ("IFRS") 3, Business Combinations, and International Accounting Standards ("IAS") 27, Consolidated and Separate Financial Statements, respectively. CICA 1582 applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after January 1, 2011. CICA 1601 and CICA 1602 apply to interim and annual consolidated financial statements relating to years beginning on or after January 1, 2011.

The impact of these standards, effective for the Company on January 1, 2011, on the Company's consolidated financial statements has not been determined.

International Financial Reporting Standards (IFRS)

In February 2008, the Canadian Accounting Standards Board ("AcSB") announced that the change over for publicly-listed companies to adopt IFRS, replacing Canadian GAAP will be effective for interim and annual financial statements relating to fiscal years beginning on or after January 1, 2011.

Our first annual IFRS financial statements will be for the year ending December 31, 2011 and will include a comparative period for 2010. Starting in the first quarter of 2011, we will provide unaudited consolidated quarterly financial information in accordance with IFRS and include comparative figures for 2010.

To prepare for the conversion, we have taken the following steps:

- a) Invested in employee training on the new IFRS standards. Our training efforts have primarily focused on updating those individuals, whose roles and responsibilities are directly impacted by the changes being implemented and to a lesser extent, providing other employees with a general awareness of IFRS and the implications thereof on our business practices. We have also been working with the Audit Committee of the Board of Directors to provide awareness of IFRS and guidance as to the potential impact of the changes on our consolidated financial statements and accounting practices;
- b) Begun assessing the accounting and reporting differences between IFRS and GAAP, selecting the appropriate IFRS accounting policies and development of IFRS financial statement formats. We have also developed a checklist of financial and reporting items which we believe will be affected by IFRS reporting standards. At this time, we anticipate only two major areas where IFRS reporting standards may result in a differential as compared to GAAP. These areas are: stock based compensation and potential impairment of intangible assets. We are currently assessing the future impact of the transition to IFRS will have on these areas as presented in our consolidated financial statements.
- c) Begun assessing the implications of IFRS on our internal systems and processes including documentation and internal controls. At this time, we anticipate only minor changes to our internal controls and processes however this analysis is still ongoing and our preliminary assessment may be subject to change.
- d) Begun assessing the impacts of IFRS on all other areas of our business, including contractual arrangements with our employees and third party contracts. At this time, we do not anticipate that adopting IFRS reporting standards will impact our contracts or other business practices outside of

financial reporting, however this assessment is still underway and our preliminary assessment may be subject to change.

#### **Risks and Uncertainties**

The primary risk factors affecting the Company are set fourth in our annual information form for 2010. A copy of our annual information form is available on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>.

## **Disclosure Controls and Procedures**

The Company's Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") are responsible for establishing and maintaining the disclosure controls and procedures of the Company, and have so certified, as required by Multilateral Instrument 52-109. These officers have evaluated the effectiveness of the Corporation's disclosure controls and procedures and have concluded that the disclosure controls and procedures at the Company provide management a reasonable level of assurance that information required to be disclosed by the Company on a continuous basis and in annual and interim filings or other reports is recorded, processed, summarized, and reported or disclosed on a timely basis as required.

It should be noted that while the CEO and CFO believe that the Company's disclosure controls and internal control procedures provide a reasonable level of assurance that they are effective, they do not expect disclosure controls and internal control procedures over financial reporting will prevent all errors and fraud. A control system no matter how well conceived or operated can provide only reasonable, not absolute assurance that the objectives of the control system are met.

## **Outstanding Share Capital**

As at November 26, 2010, we had an unlimited number of authorized common shares with 41,057,301 common shares issued and outstanding.

As at November 26, 2010, a total of 235,000 warrants were outstanding. These warrants were issued as part of a technology transfer agreement with Isis Pharmaceuticals, Inc. ("Isis") announced on May 25, 2010. The warrants are exercisable at \$0.61 for a period of two years, expiring on May 16, 2012.

As at November 26, 2010, we had 1,871,429 options outstanding from our Amended Stock Option Plan (2009). Each option entitles the holder to purchase one additional common share at exercise prices ranging from \$0.15 to \$1.00 and expiry dates ranging from January 31, 2011 to September 15, 2015.