# Medifocus Inc.

FORM 51-102FI

MANAGEMENT DISCUSSION AND ANALYSIS

FOR THE THREE AND SIX MONTHS ENDED SEPTEMBER 30, 2012 AND SEMPTEMBER 30, 2011

November 28, 2012

### 1. Date

The following discussion of the results of operations of Medifocus Inc. ("the Company") for the three and six months ended September 30, 2012, dated November 28, 2012 should be read in conjunction with the Company's unaudited condensed interim consolidated financial statements for the three and six months ended September 30, 2012.

All dollar amounts are presented in Canadian dollars. Additional information relating to the Company is available on SEDAR at <u>www.sedar.com</u>.

### 2. Overview

Medifocus Inc. ["Medifocus" or the "Company"] was incorporated under the *Business Corporation Act* (Ontario) on April 25, 2005, and has been conducting Phase III clinical trials of its proprietary breast cancer treatment (APA 1000) system. The Company has begun to market and sell catheters and consoles of its newly acquired Prolieve technology. Medifocus is listed in Canada on the TSX Venture Exchange Inc. [the "Exchange"] under the symbol "MFS and in the United States on the OTC QX market under the symbol "MDFZF".

### **Forward-Looking Statements**

This management's discussion and analysis may contain statements that are "Forward-looking Statements". These include statements about the Company's expectations, beliefs, plans, objectives and assumptions about future events or performance. These statements are often, but not always, made through the use of words or phrases such as "will likely result", "are expected to", "will continue". "anticipate", "believes", "estimate", "intend", "plan", "would", and "outlook" or statements to the effect that actions, events or results "will", "may", "should" or "would" be taken, occur or be achieved. Forward-looking statements are not historical facts, and are subject to a number of risks and uncertainties beyond the Company's control. Accordingly, the Company's actual results could differ materially from those suggested by these forward-looking statements for various reasons discussed throughout this analysis. Forwardlooking statements are made on the basis of the beliefs, opinions and estimates of the Company's management on the date the statements are made and, other than in compliance with applicable securities laws, the Company does not undertake any obligation to update forward-looking statements if the circumstances or management's beliefs, opinions or estimates should change. Readers should not place undue reliance on forward-looking statements.

Following the acquisition of the Prolieve technology from Boston Scientific Corporation, on July 25, 2012, the Company recognized revenues of \$313,281 for the three and six months ended September 30, 2012. Sales of catheters and consoles are expected to increase as the Company builds up its sales team during the next quarter. The Company incurred a loss of \$1,275,334 for the six months ended September 30, 2012, compared to a net loss of \$495,574 for the same period of 2011. Salaries and wages relating to the development of Prolieve product sales added \$410,392 in expenses. Director fees and marketing expenses increased to \$87,500 and 230,898 respectively, compared to nil and \$30,714 in the same period of 2011, respectively. The Company did not realize any stock-based compensation expense for 2012, reducing expenses by \$35,594 from 2011. Consulting and professional fees increased to \$303,510 in the first six months of 2012 from \$\$64,947 in 2011, as activity following the Prolieve acquisition. Foreign exchange losses of \$89,685 were incurred in the first six months of 2012 compared to a loss of \$57,125 in the same period of 2011.

In June 2012, the Company issued 40,567,263 units pursuant to a private placement, raising gross proceeds of \$6,085,088.

In September 2012, the Company issued 22,196,795 units pursuant to a private placement, raising gross proceeds of \$3,329,520.

To date, the Company has raised funds principally through the issuance of shares. In the foreseeable future the Company will likely remain dependent on the issuance of shares to raise funds to complete its clinical trials, and on the availability of financing for the development of the Company's technology. On July 25, 2012, the Company purchased the Prolieve technology from Boston Scientific. These are productive and revenue generating assets that are expected to generate positive cash flows within 12 to 18 months. Management anticipates that additional financing will be available and may be sourced to allow the Company to continue its research and development activities. However, there can be no assurance that it will be successful.

# Clinical Milestones Accomplished

In July 2011, Medifocus initiated its first two clinical study sites to begin its pivotal Phase III study for the treatment of large breast cancers in the USA. The two clinical sites are at the University of Oklahoma Breast Institute in Oklahoma City and the Comprehensive Breast Center of Coral Springs Florida, a division of 21st Century Oncology.

Medifocus is currently working with Dr. John R. Keyserlingk, the Principal Investigator at the Ville Marie Multidisciplinary Breast Center in Montreal, Quebec to secure approval of the Institutional Review Board ["IRB"] and initiate the pivotal Phase III study.

# 3. Clinical Study Development

The Company has completed a complete series of clinical studies. The excellent clinical safety and efficacy results of the studies was the basis of what was used in obtaining the approval of both Health Canada and the USA FDA for the Company to begin its pivotal Phase III Study. Below is the list of completed clinical studies.

### Phase I FDA Safety Study

Safely heats breast tumors of up to 8cm in diameter to treatment temperature (10 patients)

(Gardner, Annals of Surgical Oncology, vol.9, No. 4, April 2002)

### Phase II FDA Dose Escalation Study

Established optimum safe heat treatment dose (25 patients) (*Vargas, Annals of Surgical Oncology, Vol.11, No.2, February 2004*)

# Phase II FDA Multi-center Randomized Study (Early State Breast Cancer – Heat Alone)

0 of 34 had positive margins with Pre-operative Focused Heat and 4 of 41 or almost 10% had positive margins in the control arm. (75 patients) (*Cancer Therapy, Vol.65, published online Aug* 25, 2008)

### Phase II FDA Multi-Center Randomized Study (Large Breast Tumors)

Patients indicated for mastectomy and neo-adjuvant chemotherapy (34 patients) experienced a 50% improvement in overall tumor shrinkage (and 3X for

eradication) when the APA System was used in conjunction with neo- adjuvant Chemotherapy

(Dooley, Annals of Surgical Oncology, Vol.17, No.4, April 2010

# Clinical Sites for the Pivotal study in Canada and the USA.

The Company has selected six clinical study sites in Canada and the USA as the core centers to begin the Pivotal trial. The principal investigator for the Canadian approved study is Dr. J. Keyserlingk (Ville Marie Medical Center, Montreal, Quebec). The principal investigator for the USA approved study is Dr. W. Dooley (Health Science Center, University of Oklahoma, Oklahoma City, Oklahoma). In July, 2011 the USA study has been initiated with both Dr. W. Dooley and Dr. M. Tomeselli (Comprehensive Breast Center, Coral Springs, Florida).

## 4. Results of Operations

Following the acquisition of Prolieve from Boston Scientific Corporation, on July 25, 2012, the Company recognized revenues of \$313,281 for the three and six months ended September 30, 2012. Sales of catheters and consoles are expected to increase as the Company builds up its sales team during the next quarter. The Company incurred a loss of \$1,275,334 for the six months ended September 30, 2012, compared to a net loss of \$495,574 for the same period of 2011. Salaries and wages relating to the development of Prolieve product sales added \$410,392 in expenses. Director fees and marketing expenses increased to \$87,500 and 230,898 respectively, compared to nil and \$30,714 in the same period of 2011, respectively. The Company did not realize any stock-based compensation expense for 2012, reducing expenses by \$35,594 from 2011. Consulting and professional fees increased to \$303,510 in the first six months of 2012 from \$\$64,947 in 2011, as activity following the Prolieve acquisition. Foreign exchange losses of \$89,685 were incurred in the first six months of 2012 compared to a loss of \$57,125 in the same period of 2011.

### **Nature of Business**

On January 16, 2006, the Company's wholly-owned subsidiary Celsion Canada Inc. purchased from Celsion Corporation (*USA*) all of the assets relating to the breast cancer Microfocus APA 1000 System ("System"), consisting of the microwave machine, the adaptive phased array ("APA") technology licensed from Massachusetts Institute of Technology ("MIT"), and all related intellectual and regulatory property (collectively, the "Business"). The Company has a

commitment to pay a 5% royalty on the net sales of products sold by and patent royalties received by the Company and its successors and assignees, the royalty not to exceed US\$18,500,000. Royalties will not be payable until the System can be placed in the market following successful completion of the pivotal clinical trial and receipt of approval to market the System in the US and Canada from the FDA and Health Canada. The Company will expense the royalties as paid.

Medifocus, Inc. is in the business of development and commercialization of minimally invasive, focused-heat treatment devices and systems to improve the outcomes and standards of care.

On July 25, 2012, the Company completed the acquisition of Prolieve, a FDA approved device for the treatment of Benign Prostatic Hyperplasia (BPH). The total purchase price for the transaction was \$5,035,610. Medifocus paid Boston Scientific Corporation \$2,535,610 (including the deposit of \$249,250) upon closing of the transaction. The balance of \$2,500,000 will be paid in quarterly installments at a rate of 10% on the sales of Prolieve products.

The Prolieve System is a medical device based on endo-thermotherapy that both heats the prostate and dilates the prostatic urethra. Prolieve was originally developed and commercialized by the current Medifocus management, product development, clinical and regulatory teams. The Prolieve System is the only minimally invasive treatment option for the symptoms of enlarged prostate (BPH) in men indicated by the FDA as an in office treatment alternative to drug therapy. Medifocus is well positioned to address the \$3 billion market for BHP treatments in the United States thru traditional sales channels and its unique mobile treatment service.

As part of the Prolieve acquisition from Boston Scientific, Medifocus acquired all of the assets of Rocky Mountain Mobile Services (RMMS). RMMS is a mobile distribution service for the Prolieve system designed to provide a positive patient experience and an opportunity for physicians to expand their practice all with compelling economic benefits.

The Prolieve System is the only treatment option indicated by the FDA as an in office treatment alternative to drug therapy. Designed with patients' needs and comfort in mind, in general, the treatment does not require sedation or post-operative catheterization and provides rapid symptomatic relief from BPH. BPH patients can be treated using Prolieve in urologic offices throughout the United States.

Medifocus, with its Microfocus APA 1000 technology plans to raise the standards of breast cancer care and treatment by using focused microwave heating to enhance neo-adjuvant chemotherapy to provide better tumor shrinkage and control, leading to improved surgical outcomes and ultimately breast preservation.

Medifocus' patented APA microwave focusing technology platform licensed from MIT provides the design of the Company's unique focused heat treatment systems with the capability to direct precision-focused microwave energy at targeted tumors, to induce thermotherapy to shrink or eradicate tumors without undue harm to surrounding tissue.

The Company's goal is to improve outcomes and standards of care in cancer treatment. Its first indication, locally advanced breast cancer ("LABC"), involves large tumors that are generally treated first with neo-adjuvant chemotherapy to induce tumor shrinkage and then followed by either radical surgery or breast conservation surgery. Depending on the final size of the tumor Medifocus' focused-heat treatment can significantly improve the efficacy of neo-adjuvant chemotherapy in shrinking LABC, reducing tumor burden and increasing the chance of breast conservation by decreasing the need for radical breast surgery. Focused microwaves can be used to shrink breast tumors up to 8 cm in diameter, vastly improving the chance of breast conservation for these patients who under normal circumstances will have no option but to undergo radical breast surgery.

The APA System can target heat treatment to cancer tumors any place in the body reliably and repeatedly. The ability to target tumors with controlled dosages of heat can be used to destroy tumors at higher temperatures, to treat tumors in combination with chemotherapy and radiation at moderate temperatures, and for increased effectiveness over those treatments individually. In addition, the APA System is able to trigger the targeted release of therapeutic drugs and genes at tumor sites at lower temperatures.

The technical breakthrough of the APA System is its ability to precisely focus microwave heating anywhere in the body. It has been demonstrated that heat alone can kill cancer tumors and increase the effectiveness of chemotherapy and radiation when used in conjunction with those treatments (Seegenschmiedt et al (editors), *Thermoradiotherapy and Thermochemotherapy*, *Vol. 1, Biology, Physiology, and Physics, Vol. 2, Clinical Applications*, Springer, Berlin, 1995). The problem historically with heat treatment for cancer tumors has not been the effectiveness

of the treatment, but the technical problem of delivering the heat dosage accurately in a repeatable manner in patients.

The proprietary APA System solves this problem by incorporating "APA" technology. The term "APA" refers to Adaptive Phased Array technology developed by MIT for military applications in the "Star Wars Program" to focus microwave energy on missiles, in order to detect and destroy them. The aspects of the APA technology relevant to Medifocus' purposes have been licensed exclusively to Medifocus, Inc.. These aspects are primarily related to the focusing of microwave energy, with the generation of energy as a secondary consideration. Medifocus' APA System incorporates further refinements in the precise focusing of microwaves and in detection feedback and mechanisms.

Although Medifocus believes the APA System can be adapted to treat additional forms of cancer, it has chosen to initially pursue commercialization of the APA System for the treatment of large breast cancer tumors and potentially other forms of breast cancer as well. The Company plans to raise the standards of breast cancer care and treatment by using focused microwave heating to enhance neo-adjuvant chemotherapy to provide better tumor shrinkage and control, leading to improved surgical outcomes and ultimately breast preservation.

The purchase of the Prolieve business assets is a significant business enhancement event for the Company. Prolieve, combined with the APA system FDA trials commences Medifocus's transformation from a development stage cancer treatment medical device company to a mature medical treatment system and device company with a revenue-generating commercial product.

# Company's Business Strategy

The Prolieve system provides a 45-minute in-office treatment that combines our microwave thermotherapy capability with a proprietary balloon compression technology to both heat the prostate and dilate the prostatic urethra. The purpose of the Prolieve system is to provide a relatively painless and effective alternative to drug therapy and certain types of surgical procedures to treat the symptoms of BPH.

Medifocus's strategy to capitalize on the proprietary Prolieve Thermodilatation platform to generate revenues through our mobile service and the sale of disposal catheter kits. Management believes, over time, Prolieve

Thermodilatation will be the leading in-office therapy for treatment of BPH symptoms.

As part of Medifocus's strategy to become a mature medical treatment and device company the Company will continue to research and develop treatment systems based on its core thermotherapy technologies. The APA focused heat technology platform can be used to develop systems to treat many cancers, the Company decided to focus initially on commercializing a system to treat breast cancer using the following strategy:

- 1. Develop the system as a tool for breast surgeons to use in combination with standard of care (SOC) neo-adjuvant chemotherapy to increase shrinkage of large and medium sized breast tumors to facilitate conversion from mastectomy to breast conservation surgery, a treatment outcome desired by both the patients and the surgeons.
- 2. Focus the initial marketing efforts to target surgeon-owned private comprehensive breast care centers in the USA and Canada.
- 3. The marketing approach is to place the system to recover cost and derive a recurring revenue stream from sales of treatment disposable sensors.
- 4. Secure adequate insurance reimbursement for focused heat treatment of breast cancer by obtaining from the American Medical Association (AMA) a temporary Category-III CPT code. This would allow clinical investigators to bill for insurance reimbursements during clinical trials, and to build an insurance reimbursement reference data base for use in the Company's filing for an official reimbursement CPT code after receipt of the PMA. Based on insurance reimbursements already received from prior clinical investigators, the Company believes that the insurance reimbursement for focused heat treatment of breast cancer should exceed \$5,000 for each treatment.
- 5. Select and secure strategic partners who will assist in obtain regulatory approval and provide distribution sales for the breast cancer treatment systems worldwide.
- 6. Collaborate with strategic R&D partners to expand the clinical indications for the breast cancer treatment system to cover treatments for other types of breast cancer such as small tumors, DCIS, benign lesions and recurrent chest wall cancer.

7. Using the demonstrated commercial success of the breast cancer system to attract other strategic partners for additional investments and collaborative R&D efforts to build a pipeline of focused heat cancer treatment products for cancers.

### **Future Growth Strategy**

Nine million men in the United States experience BPH symptoms and more than 30 million men are affected by BPH worldwide. As the population continues to age, the prevalence of BPH will continue to increase. It is generally estimated that approximately 50% of all men over the age of 55 and 90% of all men over 75 will have BPH symptoms at various times. Industry studies estimate the overall costs of BPH therapy for those patients currently seeking treatment to be approximately \$3.0 billion annually in the United States and \$8.0 to \$10.0 billion worldwide.

Revenue growth will result from increased penetration in the US Urological market of Prolieve. With the asset purchase Medifocus acquired an install base of 250 systems already place in addition to the units of the Rocky Mountain Mobile Services (RMMS). Shortly after the purchase of the Prolieve the Company began to realize revenue from the sale of our disposal catheter kits. Medifocus is also examining sales and licensing opportunities for Prolieve outside of the United States.

Product development based on the Prolieve platform technology has the opportunity to yield additional development of disposable microwave heating catheters for various deep seated anatomical sites. Using the Prolieve technology platform and the APA focused-heat platform, the Company is well positioned to develop a rich pipeline of minimally invasive and side effect-free focused-heat treatment systems and devices for cancer and other diseases.

For cancer treatments Medifocus will apply the APA System the treatment of large breast cancer tumors in combination with chemotherapy. Medifocus has calculated that large breast cancer tumor patients represent approximately 25% of the total population of breast cancer patients. Medifocus believes it can grow its business significantly by expanding the clinical indication of the APA System to include other forms and stages of breast cancer (including Ductal Carcinoma In Situ or "DCIS", early stage breast tumors, recurrent chest wall and benign lesions). Medifocus plans to conduct pilot studies on these additional indications, followed by clinical trials in order to gain regulatory approval for the expanded

indications of use. Successful receipt of regulatory approval for additional indications would greatly expand the potential markets for the APA System.

Breast cancer is a worldwide disease. Assuming Pre-market Approval from the FDA and Health Canada for the APA System is obtained; Medifocus plans to seek necessary regulatory approvals and distributors for the APA System outside of North America, in particular in Europe and Asia, to expand the market distribution. Medifocus believes that the APA System can be adopted to treat additional forms of cancer and it is Medifocus' intention, if funds are available and conditions are right, to seek strategic partners internationally to develop various APA-based focused heating systems for other major cancers.

Successful implementation of Medifocus' growth strategy would result in Medifocus becoming a global medical device cancer treatment company.

### **Significant Milestones**

Medifocus has completed a series of Clinical studies, from Phase I, Phase II, and Phase IIA and B studies under an Investigational Device Exemption (IDE) approval from the FDA.

Using the clinical safety and efficacy data from the above studies, Medifocus submitted applications to Health Canada and the FDA in the US, and received approval to conduct a pivotal Phase III study. Upon successful completion of the pivotal Phase III Study, Medifocus will then submit for commercial approval.

In June of 2009, Medifocus was granted the Investigational Testing Authorization (ITA) from Health Canada's Medical Device Bureau (MDB) for initiating Medifocus' pivotal trial with the Microfocus APA 1000 Breast Thermotherapy System for the treatment of breast cancer. The ITA application has already been reviewed by the MDB and has fulfilled Part 3 of the Medical Devices Regulations and is now authorized to conduct the pivotal trial in Canada.

In March of 2010, Medifocus was granted an IDE approval from the Food and Drug Administration (FDA) to initiate a pivotal Phase III clinical trial upon obtaining IRB approval from the clinical sites, using the Company's APA 1000 System for the treatment of breast cancer.

In May of 2010, Health Canada approved an amended pivotal Phase III study so that it will be the same as that approved by the FDA. The Company's strategy is

to obtain the PMA from both Canada and the USA to best position the APA 1000 for commercial marketing and sales worldwide.

In order to begin the actually clinical studies in Canada and the USA, after allowance by the respective regulatory agencies, each clinical site must gain IRB approval.

In October of 2010, Medifocus announced it has recently received notice of allowances for two additional international patents to expand its extensive Intellectual Properties (IP) portfolio in addition to the patents Medifocus has exclusively licensed from the MIT.

In October of 2010, University of Oklahoma Health Sciences Center's IRB has granted final approval to conduct Medifocus' pivotal Phase III Breast Cancer Treatment Study at the University of Oklahoma Breast Institute, in Oklahoma City, under the supervision of William C. Dooley, M.D. the Principal Investigator for the FDA-approved study.

In March of 2011, Medifocus announced that its company information was accepted to be made available via Standard & Poor's Market Access Program, an information distribution service that enables subscribing publicly traded companies to have their company information disseminated to users of Standard & Poor's Advisor Insight.

In July of 2011, the Western Institutional Review Board (WIRB) granted IRB approval to the Comprehensive Breast Center of Coral Springs Florida, a division of 21<sup>st</sup> Century Oncology, to conduct Medifocus' pivotal Phase III Breast Cancer Treatment Study, under the supervision of Dr. Mary Beth Tomaselli, M.D.

In July of 2011, Medifocus initiated its first two clinical study sites to begin its pivotal Phase III study for the treatment of large breast cancers. The two clinical sites are at the University of Oklahoma Breast Institute in Oklahoma City and at the Comprehensive Breast Center of Coral Springs Florida, a division of 21st Century Oncology.

### **Risk Factors**

The Company is, and will continue to be, subject to numerous risk factors, including the risks associated with: funding, planning and conducting clinical trials; the possibility of changes in applicable regulatory requirements, competition; technological change; implementation of business strategies; reliance on key personnel; protection of intellectual property; future acquisitions; and capital requirements.

For detailed review of the risk factors, please refer to the filing statement dated August 26, 2008 and filed with SEDAR.

# 5. Summary of Quarterly Results

The following table sets forth, for the quarters indicated, information relating to the Company's revenue, net loss and loss per common shares.

	Revenues	Net Loss	Basic and Diluted Net Loss / Share
September 30, 2010	_	(175,640)	(0.0069)
December 31, 2010	_	(105,121)	(0.0041)
March 31, 2011	_	(1,039,444)	(0.0400)
June 30, 2011	_	(227,829)	(0.0074)
September 30, 2011		(267,746)	(0.0083)
December 31, 2011	_	(246,929)	(0.0097)
March 31, 2012		(183,479)	(0.0054)
June 30, 2012	_	(284,500)	(0.004)
September 30, 2012	313,281	(990,834)	(0.010)

For further quarterly financial information, please refer to the Company's consolidated interim consolidated financial statements that have been filed on SEDAR. Any variations from quarter to quarter reflect normal variations in expenditures, except for the quarter ended March 31, 2011. In this quarter the Company issued stock options and share grants that increased expenditures significantly.

# 6. Liquidity

The Company's objective is to maintain sufficient liquid resources to meet operational requirements. As at September 30, 2012, the Company had cash of \$4,157,029 [March June 31, 2012 - \$60,713]. The Company's working capital position at September 30, 2012 was positive \$3,894,180 [March 31, 2012 - negative \$2,574,618]. The Company's continuing operations are dependent upon its ability to secure additional equity capital, divest assets or generate cash flow from operations in the future, none of which are assured. There can be no assurances that the Company's activities will be successful or that sufficient funds can be raised in a timely manner.

On July 25, 2012, the Company purchased the Prolieve technology from Boston Scientific. These are productive and revenue generating assets that are expected to generate positive cash flows within 12 to 18 months. Management anticipates that additional financing will be available and may be sourced to allow the Company to continue its research and development activities. However, there can be no assurance that it will be successful.

# 7. Capital Resources

As at September 30, 2012, the Company had sufficient capital resources to meet its desired development programs for fiscal 2012. In June, 2012 the Company issued 40,567,263 units pursuant to a private placement, raising gross proceeds of \$6,085,088, and in September 2012, the Company issued 22,196,795 units pursuant to a private placement, raising gross proceeds of \$3,329,520.

The completion of these financings will allow the Company to realize its commercialization and development programs in 2012 and into 2013.

## 8. Off-Balance Sheet Arrangements

As of the date of this filing, the Company does not have any off-balance sheet arrangements that have, or reasonably likely to have, a current or future effect upon the financial performance or financial condition of the Company, including, and without limitation, such considerations as liquidity and capital resources.

### 9. Transactions with Related Parties

The compensation paid or potentially payable to key management for services is shown below:

	2012	2011
Salaries and fees	\$ 250,000	\$ 250,000
Director fees	\$ 85,000	\$ —
Share-based compensation expense	\$ -	\$ —
	\$ 335,000	\$ 250,000

### 10. Critical Accounting Estimates

The Company's significant accounting policies are presented in Note 2 of the condensed interim consolidated financial statements for the six months ended September 30, 2012. To prepare financial statements in conformity with IFRS, the Company must necessarily make estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the actual results. The estimates and assumptions most critical to determining the carrying values of assets and liabilities include those related to the estimated useful lives of property, plant and equipment, amortization of intangible assets, valuation of intangible assets, and valuation of share based payments. Estimates and judgments are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in both the period of revision and future periods if the revision affects both current and future periods.

## 11. Proposed transactions

The Company has not entered into any significant transaction, nor is it currently reviewing any such transaction, which requires board approval, shareholder approval or regulatory approval that has not been discussed within this MD&A.

### 12. Future changes in Accounting Policies

The IASB and IFRS Interpretations Committee ("IFRIC") have issued certain new standards, interpretations, amendments and improvements to existing standards, mandatory for future accounting periods. The most significant of these are as follows, and except as noted below are all effective for annual periods beginning on or after January 1, 2013, with earlier adoption permitted:

The IASB issued IFRS 9, Financial Instruments in November 2009 as the first step in its project to replace IAS 39 Financial Instruments: Recognition and Measurement; in particular, it introduces new requirements for classifying and measuring financial assets. The IASB intends to expand IFRS 9 before its effective date of January 1, 2015 to add new requirements for classifying and measuring financial liabilities, derecognizing financial instruments, impairment and hedge accounting.

IFRS 10, 11, 12 and 13 were all issued in May 2011. IFRS 10 Consolidated Financial Statements replaces the consolidation guidance in IAS 27 Consolidated and Separate Financial Statements and SIC-12 Consolidation — Special Purpose Entities by introducing a single consolidation model for all entities based on control, irrespective of the nature of the investee. IFRS 11 Joint Arrangements introduces new accounting requirements for joint arrangements, replacing IAS 31 Interests in Joint Ventures. It eliminates the option of accounting for jointly controlled entities by using proportionate consolidation. IFRS 12 Disclosure of Interests in Other Entities requires enhanced disclosures about both consolidated entities and unconsolidated entities in which an entity has involvement.

IFRS 13 Fair Value Measurement replaces the guidance on fair value measurement in existing IFRS accounting literature with a single standard. It defines and provides guidance on determining fair value and requires disclosures about fair value measurements, but does not change the requirements regarding which items are measured or disclosed at fair value.

In June 2011, the IASB amended IAS 1 *Presentation of financial statements* ("IAS 1") to require presenting items in other comprehensive income in two categories: items that might be reclassified into profit or loss and those that will not be reclassified. The flexibility to present a statement of comprehensive income as one statement or as two separate statements of profit and loss and other comprehensive income remains unchanged. The amendments to IAS 1 are effective for annual periods beginning on or after July 1, 2012.

The Company has not yet determined the impact of these standards and amendments on its financial statements.

### 13. Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, accounts payable, amounts due to employees and consultants and convertible promissory debt and debentures. Unless otherwise noted, the Company is not exposed to significant interest, currency or credit risks arising from these financial instruments.

### Fair value

The fair value of accounts payable and amounts due to employees and consultants and convertible promissory debt and debentures approximates their carrying values due to their short-term maturity.

The methods and assumptions used to measure financial instruments at fair value in the consolidated statement of financial position are classified into three levels according to a defined fair value hierarchy:

- Level one includes quoted prices [unadjusted] in active markets for identical assets or liabilities.
- Level two includes inputs that are observable, other than quoted prices included in level one.
  - Level three includes inputs that are not based on observable market data.

The assets carried at fair value are cash and cash equivalents, classified within Level one of the hierarchy.

### Credit risk

Credit risk arises when a failure by counterparties to discharge their obligations could reduce the amount of future cash inflows from financial assets on hand at the end of the reporting period.

### [i] Cash, and restricted cash

The Company minimizes its exposure to credit risk by keeping the majority of its cash as cash on deposit with a major Canadian and US banks. Management expects the credit risk to be minimal.

### Foreign currency risk

The prices paid by the Company for services and supplies are paid in U.S. and Canadian dollars and the Company is raising funds in Canadian dollars. As of September 30, 2012 the Company believes the currency risk is limited and not a risk to be hedged at the present time.

### Interest rate risk

Interest rate risk arises because of changes in market interest rates. The Company has no borrowings other than its convertible debt and certain of the amounts due to employees and consultants, all of which is at fixed interest rates, and considers itself to have very minimal exposure to interest rate risk.

# Capital risk

The Company's objective when managing capital, defined as its equity, is to safeguard the entity's ability to continue as a going concern, so that it can provide returns for shareholders and benefits for other stakeholders. The Company is managing its capital structure to convert to equity as much of its current debt as possible and will issue equity to obtain funding to initiate its pivotal clinical trial. The Company is not subject to any externally imposed capital requirements. The Company's objective is to insure adequate working capital to commercialize its APA System for the treatment of cancer and it will use the sale of equity to fund its business to the point of revenue generation and asset based borrowing being sufficient to fund the business fully.

### 14. Other MD&A Disclosure

Outstanding Share Data as at November 28, 2012

	Number or Principal	Maximum Number of Common Shares Issuable, if Convertible, Exercisable or	
	Amount Outstanding	Exchangeable	
Common Shares	101,358,337	N/A	
Stock Options	3,000,000	3,000,000	
Shares to be issued	1,355,545	1,355,545	
Warrants outstanding	73,049,819	73,049,819	
Maximum common shares			
outstanding	178,763,701		

### 15. Disclosure Controls and Procedures

Disclosure controls and processes have been designed to ensure that information required to be disclosed by the Company is compiled and reported to Company management as appropriate to allow timely decisions regarding required disclosure. The Company's Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of September 30, 2012, that the Company's disclosure controls and procedures are effective to provide reasonable assurance that material information related to the Company is made known to them by employees and third party consultants working for the Company. There have been no significant changes in the Company's disclosure control and processes during the three months ended September 30, 2012.

The Company's Chief Executive Officer and Chief Financial Officer believe that our disclosure controls and processes will provide a reasonable level of assurance and that they are effective; nevertheless, they do not expect that the disclosure controls and processes will prevent all errors and frauds. 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.

# 16. Internal controls over Financial Reporting

Management is responsible for certifying the design of the Company's internal control over financial reporting ("ICFR") as required by National Instrument 52-109 – "Certification of Disclosure in Issuers' Annual and Interim Filings". ICFR is intended to provide reasonable assurance regarding the preparation and presentation of financial statements for external purposes in accordance with applicable generally accepted accounting principles ("GAAP") or IFRS. Internal control systems, no matter how well designed, have inherent limitations.

Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness in future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management, including the Chief Executive Officer and Chief Financial Officer, has evaluated the design of the Company's ICFR as of June 30, 2012, pursuant to the requirements of National Instrument 52-109. The Company has designed appropriate ICFR for the nature and size of the Company's business, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS GAAP.

Management has determined that the Company's internal controls over financial reporting have been effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS GAAP.

There were no changes in the Company's internal controls over financial reporting that occurred during the three months ended June 30, 2012 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

### 17. Approvals

The Directors of the Company have approved the disclosure contained in this MD&A and a copy will be provided to anyone who requests it.