

**Medifocus Inc.**

FORM 51-102FI

MANAGEMENT DISCUSSION AND ANALYSIS

FOR THE THREE AND SIX MONTHS ENDED  
SEPTEMBER 30, 2011

November 29, 2011

## **MANAGEMENT'S DISCUSSION AND ANALYSIS ("MD&A") FOR THE THREE AND SIX MONTHS ENDED SEPTEMBER 30, 2011**

The following discussion of the results of operations of Medifocus Inc. ["Medifocus" or the "Company"] dated November 28, 2011, for the three and six months ended September 30, 2011, and in comparison to the prior year, should be read in conjunction with the Company's audited financial statements and accompanying notes for the year ended March 31, 2011 and unaudited condensed consolidated interim financial statements for the three and six months ended September 30, 2011.

As of April 1, 2011, the Company adopted International Financial Reporting Standards ("IFRS"). The unaudited interim financial statements for the three and six months ended September 30, 2011 and September 30, 2010 have been prepared in accordance with International Accounting Standard 34, Interim Financial Reporting ("IAS 34"), using accounting policies consistent with IFRS. Readers of this MD&A should refer to note 2 of the interim financial statements for a discussion of IFRS and its effect on the Company's financial presentation. All dollar amounts are presented in Canadian dollars. Additional information relating to the Company is available on SEDAR at [www.sedar.com](http://www.sedar.com).

### **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. Forward-looking 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.

## **1. Overview**

Medifocus Inc. was incorporated under the *Business Corporation Act* (Ontario) on April 25, 2005. Prior to completion of the Reverse Takeover with Celsion (Canada) Limited ["Celsion"], the Company was classified as a Capital Pool Company pursuant to the policies of the TSX Ventures Exchange Inc. [the "Exchange"]. On November 25, 2008, the Company completed its Qualifying Transaction, as defined under the policies of the Exchange, by way of a Share Exchange Agreement with Celsion.

Concurrently with the closing of the Qualifying Transaction, Medifocus completed a private placement of 4,140,755 units, at a price of \$0.50 per unit, for aggregate gross proceeds of \$2,070,377.50. Each unit consisted of one common share of Medifocus and one common share purchase warrant. Each warrant entitled the holder to purchase one common share of Medifocus for a period of 24 months at a price per share of \$0.60. On November 25, 2010, the Company extended the expiry date of 4,090,755 outstanding common share purchase warrants by two years.

### **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 21<sup>st</sup> Century Oncology. Two patients have been treated during the three months ended September 30, 2011.

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 IRB and initiate the pivotal Phase III study.

The Company incurred a loss of \$495,574 for the six months ended September 30, 2011, compared to a net loss of \$498,152 for the same period of the previous year. Stock-based compensation expense and management fees increased the loss for the period. Marketing and investor relations expenses were reduced to \$30,714 in the six months ended September 30, 2011 from \$171,774 in 2010 as the

Company reduced activities to conserve cash. Professional fees and office expenses were also lower, mitigating the loss in the period.

On June 29, 2011, the Company closed a private placement of 1,000,000 shares for gross proceeds of \$300,000. In August 2010 and March 2011, the Company closed two private placement financings raising net cash proceeds of \$1,308,608. In addition, the Company raised a further USD \$280,000 with an issue of various non-brokered unsecured convertible debentures ["Debentures"] on January 24, 2011. The Debentures mature on January 24, 2012. The interest rate on the Debentures is 15% per annum. Upon the request of the Holders, the Debentures plus any accrued interest may be converted in whole, but not in part, into shares of Common Stock of the Company at a price of \$0.11 per Common Share. The Debenture may be prepaid in whole or in part at any time by the Company.

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. Management anticipates that additional financing will be available and may be sourced to allow the Company to continue its research activities. However, there can be no assurance that it will be successful.

## **2. Clinical Study Development**

The Company has completed a complete series of clinical studies. The excellent clinical safety and efficacy results of the studies were used to secure the approval of both Health Canada and the USA Food and Drug Administration (FDA) for the Company to begin its Phase III Pivotal 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 Stage 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) 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. In Canada, the principle investigator for the Canadian approved study is Dr. J. Keyserlingk (Ville Marie Medical Center, Montreal, Quebec). In the USA, the principle 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 (Health Science Center, University of Oklahoma, Oklahoma City, Oklahoma and Dr. M. Tomeselli (Comprehensive Breast Center, Coral Springs, Florida).

## **3. Results of Operations**

The Company incurred a loss of \$267,746 for the three months ended September 30, 2011, compared to a net loss of \$175,640 for the same period of the previous year. Stock-based compensation expense and higher management fees increased the loss for the period. Marketing and investor relations expenses were reduced to \$15,555 in the three months ended September 30, 2011 from \$47,964 in 2010 as the Company reduced activities to conserve cash. Office expenses were lower, mitigating the loss in the period. Foreign exchange losses increased to \$56,718 in the period compared to a gain of \$14,465 for the same period of 2010.

The net loss for the six months ended September 30, 2011 was 495,574, compared to a net loss of \$498,152 in the same period of 2010. Development and investor relations expenses were reduced from \$171,774 in 2010 to \$30,714 in 2011 due to reduced activities in order to conserve cash. General and administrative expenses and professional fees were also reduced. Higher management fees and stock-based compensation offset the reductions in expenses. Foreign exchange losses

were \$57,125 for the six months ended September 30, 2011, compared to a loss of \$14,748 in 2010.

During the year ended March 31, 2011, the Company re-negotiated the terms of the promissory note issued in conjunction with the bridge financing of USD \$150,000 in 2007. The bridge financing lender received a promissory note from the Company for USD \$150,000 with interest payable at 1.5% per month on the face value. The face value and accrued interest were payable December 21, 2009, and were extended to September 30, 2010. The interest rate for the extended period has increased to 1.667% per month from 1.5%. The Company paid USD \$15,000, that was applied against outstanding interest, during the year, and the lender agreed to convert USD \$54,000 of accrued interest into 275,510 common shares of the Company. Accordingly, this has been removed from promissory note payable and recorded as shares to be issued.

The Company has liabilities of \$446,341 owing to employees and consultants for past compensation. Of this amount, USD \$149,638 bears interest at 5% per annum and is payable by April 1, 2011. Accrued interest of \$28,056 to September 30, 2011 is included in the total liability. The Company has not paid the amounts owing to employees and consultants as at November 25, 2011. Due to the demand note nature of the amounts due to employees and consultants, the Company has recognized these as short term liabilities.

### **Nature of Business**

On January 16, 2006 Celsion purchased from Celsion Corporation (*USA*) all of the assets relating to 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 tumor targeted cancer treatment devices and

systems. It 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, reduce tumor burden and increase 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.

Medifocus owns a proprietary medical device that 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. 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, Medifocus 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.

### **Company’s Business Strategy**

Even though 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 to allow clinical investigators to bill for



insurance reimbursements during clinical trials and thereby, 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. Use 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**

The first clinical indication Medifocus will apply the APA System to is 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 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 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 Investigational Device Exemption (IDE) approval from the FDA to initiate a pivotal Phase III clinical trial upon obtaining institutional review board (IRB) approval from the clinical sites, using the Company's Microfocus 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 was 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 actually begin the clinical studies in Canada and the USA, after allowance by the respective regulatory agencies, each clinical site must gain Institutional Review Board (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 Institutional Review Board 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 June of 2011, Medifocus announced its shares commenced trading on the OTCQX tier of the OTC marketplace, the United States' 3<sup>rd</sup> largest U.S. equity trading venue after the NASDAQ and NYSE.

In July of 2011, Medifocus announced that the Western Institutional Review Board (WIRB) has 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 announced it has successfully 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 21<sup>st</sup> Century Oncology.

During the three months ended September 30, 2011, two patients have been enrolled and treated through clinical trials.

## **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.

#### **4. Liquidity**

In June 2011, the Company issued 1,000,000 common shares for gross proceeds of \$300,000. Approximately \$298,495 has been expended on product development assets. In August 2010, and March 2011 the Company closed two private placement financings raising net cash proceeds of \$1,605,982. In addition, the Company raised a further USD \$280,000 with an issue of various non-brokered unsecured convertible debentures on January 24, 2011. The Company's total liabilities exceed its current assets by \$1,916,085. The Company is actively seeking financing to fund its clinical trials and working capital for the year.

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. Management anticipates that additional financing will be available and may be sourced to allow the Company to continue its research activities. However, there can be no assurance that it will be successful.

#### **5. Capital Resources**

The Company does not have sufficient capital resources to meet its desired development programs for fiscal 2012. Financing plans have been delayed with the collapse in financial markets. The Company raised \$1,457,695 in net cash proceeds through three private placements during the year ended March 31, 2011, however, further funding is required. An additional \$280,000 was raised in December 2010 and January 2011 through the issuance of a Convertible Debenture. The Convertible Debentures mature 12 months after the date of issue and bear interest at 15% per annum, payable upon the earliest to occur of the maturity date or conversion in full into common shares of the Company. The Company is currently considering various alternatives to raise the required funds.

## 6. 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 results of operations or financial condition of the Company, including, and without limitation, such considerations as liquidity and capital resources.

## 7. Transactions with Related Parties

Included in amounts expensed and payable is approximately \$173,415 owed to the Chief Executive Officer for salary and un-reimbursed expenses.

On March 17, 2011 in accordance with the Company's approved compensation strategy, and pursuant to the terms and conditions of the Corporation's Stock Option Plan, the Company issued stock options and shares to Directors and Officers as detailed below.

<b>Participant</b>	<b>Shares Grant</b>	<b>Options Vesting on March 17, 2011</b>	<b>Options Vesting on March 19, 2012</b>	<b>Total Options Grant</b>
Grant Walsh	450,000	250,000	250,000	500,000
Joseph Chan	250,000	150,000	150,000	300,000
Gus Chow	150,000	150,000	150,000	300,000
Ernie Eves	500,000	500,000	N/A	500,000
Joe Tai	350,000	150,000	150,000	300,000
Dr. Augustine Cheung	600,000	900,000	N/A	900,000
John Mon	500,000	600,000	N/A	600,000
Mirsad Jakubovic	200,000	300,000	N/A	300,000

The options have an exercise price of \$0.20 per Share and a term of five (5) years. The share grants were all recognized at a price of \$0.18 per share. The following amounts were paid as salary and consulting fees in the six months ended September 30,

	<u>2011</u>	<u>2010</u>
Chief Executive Officer	120,000	120,000
Chief Financial Officer	25,000	20,000
Chief Operating Officer	100,000	100,000

There were no share based payments to Directors or Officers during the six months ended September 30, 2011 and September 30, 2010. Stock-based compensation expense was recognized in the period for previously issued stock options.

## **8. Critical Accounting Estimates**

The Company's significant accounting policies are presented in Note 2 of the consolidated financial statements for the six months ended September 30, 2011.

## **9. Future Accounting Changes**

The IASB and International Financial Reporting 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 to add new requirements for classifying and measuring financial liabilities, derecognizing financial instruments, impairment and hedge accounting. The IASB has proposed to adjust the effective date of IFRS 9 to January 1, 2015.

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.

## **10. Financial Instruments and Other 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 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 balance sheets 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

The Company minimizes its exposure to credit risk by keeping the majority of its cash as cash on deposit with a major Canadian chartered bank. 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, 2011 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.

### **Liquidity risk**

Liquidity risk includes the risk that the Company will not be able to meet operational liquidity requirements to conduct its business of commercializing the APA System for the treatment of cancer.

The Company's operating cash requirements include amounts necessary to conduct its pivotal clinical trial to obtain regulatory approval to commercialize the APA System in North America. The Company's objective is to maintain sufficient liquid resources to meet operational requirements. As at September 30, 2011, the Company had cash of \$142,328 [2011 - \$522,208]. In addition, at



September 30, 2011, the Company's working capital position was negative \$1,916,085 [2011 - negative \$1,457,695]. 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.

### 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.

The Company is not involved in any hedging program, nor is it party to any financial instruments that may have an impact on its financial position.

## 11. Other MD&A Disclosure

### *Outstanding Share Data as at November 28, 2011*

	Number or Principal Amount Outstanding	Maximum Number of Common Shares Issuable, if Convertible, Exercisable or Exchangeable
Common Shares	31,531,442	N/A
Stock Options	3,700,000	3,700,000
Shares to be issued	6,867,615	6,867,615
Warrants outstanding	10,285,752	10,285,752
Maximum common shares outstanding		52,384,809

### *Summary of quarterly results*

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

	<b>Revenues</b>	<b>Net Loss</b>	<b>Basic and Diluted Net Loss / Share</b>
December 31, 2009	<b>351</b>	(115,979)	(0.005)
March 31, 2010	<b>1,045</b>	(344,244)	(0.0141)
June 30, 2010	—	(322,512)	(0.0131)
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)

## **12. 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 March 31, 2011, 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 and six months ended September 30, 2011.

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.

### **13. 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 September 30, 2011, 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 and six months ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

### **14. Recent developments**

On August 4, 2011, Medifocus announced that as a result of the Company not filing its annual financial statements for the year ended March 31, 2011 and

related annual filings by the filing deadline of July 29, 2011, the Ontario Securities Commission, as principal regulator, issued a temporary cease trade order on August 4, 2011 prohibiting all trading in the securities of the Company, whether direct or indirect, for a period of 15 days. As a result, trading in the Company's common shares has been suspended by the TSX Venture Exchange.

On August 19, 2011, Medifocus filed its Financial Statements for the year ended March 31, 2011, related Management's Discussion and Analysis and other related annual filings. These documents are available for consultation under the Company's profile on SEDAR at [www.sedar.com](http://www.sedar.com).

Medifocus has applied for the revocation of the cease trade orders respectively issued by the Ontario Securities Commission ("OSC") on August 16, 2011 and the British Columbia Securities Commission on August 9, 2011, and is continuing to work with the OSC to revoke the cease trade order. The Company will also apply to the TSX Venture Exchange for trading of its common shares to be reinstated.

## **15. Approvals**

Additional information about the Company is available at [www.medifocusinc.com](http://www.medifocusinc.com) and on the SEDAR website at [www.sedar.com](http://www.sedar.com).