

# **Medifocus Inc.**

FORM 51-102FI

MANAGEMENT DISCUSSION AND ANALYSIS

FOR THE THREE AND NINE MONTHS ENDED  
December 31, 2009

February 23, 2010

## **1. Date**

This Management Discussion and Analysis (“MD&A”) for the three and nine months ended December 31, 2009 is dated February 23, 2010 and should be read in conjunction with the Company’s interim consolidated financial statements for the three and nine months ended December 31, 2009, and the annual consolidated financial statements for the year ended March 31, 2009. All financial information is prepared in accordance with Canadian generally accepted accounting principles (“GAAP”) and is expressed in Canadian dollars.

## **2. Overview**

Medifocus Inc. [“Medifocus” or the “Company”] 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”]. The company was a non-operating public enterprise and did not meet the definition of a business under the provision of EIC -124; therefore the acquisition did not constitute a business combination under the provisions of EIC- 10. Accordingly, the acquisition has been accounted for as a capital transaction rather than a business combination.

### **Qualifying Transaction**

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.

Pursuant to the terms and subject to the conditions of the Share Exchange Agreement, the Company issued an aggregate of 11,200,000 Medifocus Shares at a deemed issue price of \$0.50 per share to the shareholders of

Celsion and agreed to pay to such shareholders an amount of \$165,000 following the completion of the Qualifying Transaction. The Share Exchange Agreement was negotiated at arm's length among Medifocus, Celsion and the shareholders of Celsion. An additional 100,000 common shares were issued to Infund Management Limited for past services rendered to Celsion.

In addition 903,112 units, valued at \$0.50 per unit were issued to Celsion Corporation (*USA*) in respect of a portion of the indebtedness previously incurred by Celsion following its acquisition from Celsion Corporation (*USA*) of the business now being carried by Celsion. Another 763,168 units were issued to the holders of the 2006 Bridge Notes of Celsion with respect to the conversion of \$310,556 in principal amount of such notes, plus accrued interest. In both cases the units bear the same terms and conditions as the units being offered in connection with the private placement described below.

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 consists of one common share of Medifocus and one common share purchase warrant. Each warrant entitles the holder to purchase one common share of Medifocus for a period of 24 months at a price per share of \$0.60.

Management has negotiated with employees and consultants, payment of the monies owed to each for past services. The Company has issued, subsequent to the end of the period, 3,092,105 common shares to employees and consultants in settlement of \$2,370,863 of these liabilities. The Company has recorded the value of \$463,816 for the shares and recognized a gain on the settlement of debt of \$1,907,047.

The Company has liabilities of \$469,207 owing to employees and consultants for past compensation that has been classified as long-term debt. Of this amount, \$172,982 bears interest at 10% per annum and is payable by April 1, 2011. Accrued interest of \$27,365 to December 31, 2009 is included in the total liability. The Company also has negotiated with some employees and consultants to pay \$260,819 owing to these employees in 4 equal payments each concurrent with the Company

raising one million dollars in financing. The Company has made one payment during the year and has included the balance of \$195,615 as a long-term liabilities.

### **3. Clinical Development Milestones Accomplished**

#### **Health Canada Clearance to initiate pivotal trial**

The Company has received notification from Health Canada in 2008 that all conditions to begin the pivotal trial in Canada for focused heat treatment of breast cancer under the above treatment protocol has been satisfied and is ready to begin the study pending approval from the research ethics board (REB) of each participating hospital in Canada. Currently, two sites in Canada have been selected. They are Ville Marie Medical Center in Montreal and North York General Hospital in Toronto. On June 9, 2009, Health Canada granted full Investigational Testing Authority (ITA) approval to allow initiation of the pivotal Phase III study in Canada.

#### **Submission to FDA to begin the pivotal trial in the USA**

The Company submitted an application package to the FDA in the United States of America (USA) to obtain an Investigational Device Exemption (IDE) to start the same pivotal Phase III trial in the USA. The IDE package was submitted to the FDA in mid June of 2009. After a comprehensive review by the FDA to the Company's application, Medifocus has fully satisfied 19 of the 21 initial concerns or request for additional information. On January 22, 2010, the Company filed its response to the remaining two comments from the FDA. Receipt of the PMA from both the FDA and Health Canada will position the Company to commercialize and launch the breast cancer system initially in North America and then worldwide via distributors.

### **Clinical Sites for the Pivotal study in Canada and the USA are placed**

The Company has selected six clinical study sites in Canada and the USA as the core centers to begin the Pivotal trial. The two sites in Canada are led by two very active and experienced breast surgeons; Dr. J. Keyserlingk (Ville Marie Medical Center, Montreal, Quebec) and Dr. N. Downs (North York General Hospital, Toronto, Ontario). In the USA, the sites and investigators are Dr. H. Vargas ( Harbor Medical Center, UCLA, Los Angeles, California), Dr. J. Harness (St. Joseph Hospital, Orange, California), Dr. W. Dooley (Health Science Center, University of Oklahoma, Oklahoma City, Oklahoma), and Dr. M. Tomeselli (Comprehensive Breast Center, Coral Springs, Florida). The four USA sites selected were the most active participants of the Company's FDA phase1, Phase 2 and randomized Phase2 studies which established the safety and efficacy of focused heat for treatment of breast cancer. Dr. J Harness is the current president of the American College of Breast Surgeons. Both Dr. Dooley and Dr. Harness are considered by many to be thought leaders in treatment of breast cancer.

### **Memorandum of Understanding signed with University of Hong Kong to begin clinical studies.**

Medifocus has also signed a memorandum of understanding with the Queen Mary Hospital in Hong Kong as an additional participant of the trial once the IDE approval from the FDA to begin the pivotal trial in the USA has been received. The addition of The Queen Mary Hospital in Hong Kong is for two strategic reasons. First the Company will rely on Queen Mary to provide the majority of the data for smaller sized tumors to support expanding the clinical indications to include medium sized tumors and second, clinical data from Queen Mary may be used to support an application for commercial market approval from the Chinese SFDA to begin commercial sales of the breast cancer systems in China. The Company plans to use eight clinical sites for the pivotal study.

## 4. Results of Operations

The net loss for the three month period ended December 31, 2009 is \$115,979 compared to a loss of \$622,927 in three month period ended December 31, 2008. Foreign exchange gains and lower professional fees contributed to the improved bottom line for the three months. Lower accretion expenses and a decrease in interest expense of \$66,390 also contributed to the improved bottom line for the three months ended December 31, 2009.

The net loss for the nine month period ended December 31, 2009 is \$536,388 compared to a loss of \$1,242,217 in the nine month period ended December 31, 2008. Foreign exchange gains, lower accretion expenses and a decrease in interest expense of \$131,224 contributed to the improved bottom line for the nine months ended December 31, 2009.

### **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.

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 for increased effectiveness over those

treatments alone and 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. 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 Company's purposes have been licensed exclusively to the Company. These aspects relate primarily to the focusing of microwave energy, with the generation of energy as a secondary consideration. The company's APA System incorporates further refinements in the precise focusing of microwaves and in detection feedback and mechanisms.

### **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 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.



## **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; 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.

## **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.

## 5. 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 as prepared under generally accepted accounting principles in Canada.

	Revenues	Net Income (Loss)	Basic and Diluted Net Income(Loss)/ Share
March 31, 2008	—	(432,593)	(4,184.09)
June 30, 2008	—	(234,733)	(2,270.36)
September 30, 2008	—	(422,498)	(4,086.45)
December 31, 2008	<b>18,288</b>	(622,927)	(0.072)
March 31, 2009	<b>14,889</b>	951,535	0.111
June 30, 2009	<b>9,970</b>	(142,042)	(0.005)
September 30, 2009	<b>3,534</b>	(278,367)	(0.011)
December 31, 2009	<b>351</b>	(115,979)	(.005)

## 6. Liquidity

As at December 31, 2009, the Company had cash and cash equivalents of \$132,680. The Company has a working capital deficiency of \$507,440 at December 31, 2009. The Company is actively searching for additional financing.

## 7. Capital Resources

Additional funds are required for the Company to finance its desired development programs in the future. The Company is currently considering various alternatives to raise the required funds.

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

## **9. Transactions with Related Parties**

Included in long-term liabilities is approximately \$130,018 owed to the Chief Executive Officer for un-reimbursed expenses.

The Company has paid marketing fees of \$195,000 and administrative fees of \$36,000 to two Companies in which a Director of Medifocus is also a Director.

## **10. Critical Accounting Estimates**

The Company's significant accounting policies are presented in Note 2 of the interim consolidated financial statements for the nine month period ended December 31, 2009.

## **11. Changes in Accounting Policies**

Effective January 1, 2007, the Company adopted four new accounting standards issued by the Canadian Institute of Chartered Accountants ("CICA") in 2005: Handbook Section 1530 *Comprehensive Income*; Handbook Section 3855 *Financial Instruments - Recognition and Measurement*; Handbook Section 3861 *Financial Instruments - Presentation and Disclosure*; and Handbook Section 3865 *Hedges*. These accounting policy changes were adopted on a prospective basis; accordingly, comparative amounts for prior periods have not been restated.

(a) Comprehensive Income (Section 1530)

Section 1530 sets out reporting and disclosure standards with respect to comprehensive income and its components. Comprehensive income is composed of net income and other comprehensive income. The Company does not have any components of comprehensive income except for net income and therefore this policy has had no impact on the Company's financial statements.

(b) Financial Instruments – Recognition and Measurement (Section 3855); Presentation and Disclosure (Section 3861)

Section 3855 sets out standards for recognizing and measuring financial assets, financial liabilities and non-financial derivatives. It requires that financial assets and financial liabilities, including derivatives, be measured at fair value on initial recognition and recorded on the balance sheet. Measurement in subsequent periods depends on whether the financial instrument has been classified as held-for-trading, available-for-sale, held-to-maturity, loans and receivables, or other financial liabilities. Section 3861 sets out standards for the presentation and disclosure of financial instruments.

Financial assets and financial liabilities held-for-trading are measured at fair value with changes in those fair values recognized in net income. Financial assets and financial liabilities considered held-to-maturity, loans and receivables, and other financial liabilities are measured at amortized cost using the effective interest method of amortization. Available-for-sale financial assets are measured at fair value with unrealized gains and losses recognized in other comprehensive income. Investments in equity instruments classified as available-for-sale that do not have a quoted market price in an active market are measured at cost.

The Company has made the following classifications:

- Cash, short-term investments and interest bearing deposits are classified as “held-for-trading” and measured at fair value. Gains and losses resulting from change in fair values are recorded in net income.

- Accounts receivable and Royalty tax recoverable are classified as “loans and receivables” and are recorded at amortized cost, which upon their initial measurement is equal to their fair value. Subsequent measurements are recorded at amortized cost using the effective interest rate method.
- Accounts payable is classified as “other financial liabilities” and are initially measured at their fair value. Subsequent measurements are recorded at amortized cost using the effective interest rate method.

(c) Hedges (Section 3865)

Section 3865 sets out standards on the use of hedge accounting. The Company currently does not have any hedges in place and therefore this policy has had no impact on the Company’s financial statements.

(d) Impact upon adoption of CICA Handbook Sections 1530, 3855, 3861 and 3865

The adoption of these new accounting standards has had no impact on the Company’s consolidated financial statements.

(e) Accounting changes

Effective January 1, 2007, the Company adopted the revised CICA Handbook section 1506 Accounting Changes, relating to changes in accounting policies, changes in accounting estimates and errors. Adoption of these recommendations had no effect on the consolidated financial statements for the nine-month period ended September 30, 2008 except for the disclosure of accounting changes that have been issued by the CICA but have not yet been adopted by the Company because they are not effective until a future date (refer to Future Accounting Standards below).

The Company is currently assessing the impact of these new accounting standards on its financial statements.

In March 2007, the CICA approved Handbook Section 3031, Inventories, which replaces the existing Handbook Section 3030, Inventories. This standard is effective for interim and annual financial statements relating to fiscal years beginning on or after January 1, 2008, with earlier application encouraged. The standard provides more guidance on the

measurement and disclosure requirements for inventories. The Company currently does not have any inventory and therefore this standard has had no impact on the Company's financial statements.

## 12. Financial Instruments and Other Instruments

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.

## 13. Other MD&A Disclosure

Outstanding Share Data as at February 23, 2010

	<b>Number or Principal Amount Outstanding</b>	<b>Maximum Number of Common Shares Issuable, if Convertible, Exercisable or Exchangeable</b>
Common Shares	<b>24,336,445</b>	<b>N/A</b>
Stock Options	<b>665,000</b>	<b>665,000</b>
Shares to be issued	<b>3,092,105</b>	<b>3,092,105</b>
Warrants outstanding	<b>5,807,035</b>	<b>5,807,035</b>
Maximum common shares outstanding		<b>33,905,085</b>

## 14. Disclosure Controls and Procedures

Management, including the Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures as of December 31, 2009.

Based on this evaluation, the Chief Executive Officer and Chief Financial Officer has concluded that the Company's disclosure controls and procedures, as defined in Multilateral Instrument 52-109 – Certification of Disclosure in Issuers' Annual and Interim Filings, are effective to ensure that information required to be disclosed in reports filed or submitted by the Company under Canadian securities legislation is recorded, processed, summarized and reported within the time periods specified in those rules.

## **15. 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.