

# **Medifocus Inc.**

FORM 51-102FI

MANAGEMENT DISCUSSION AND ANALYSIS

FOR THE THREE MONTHS ENDED  
JUNE 30, 2014 AND JUNE 30, 2013

August 29, 2014

## 1. Introduction

The following sets out the Management's Discussion and Analysis ("MD&A") of the financial position and results of operations for the three months ended June 30, 2014 of Medifocus Inc. (the "Company", "Medifocus" or we). The MD&A should be read in conjunction with the Company's condensed interim consolidated financial statements for the three months ended June 30, 2014 and 2013. The MD&A is dated August 29, 2014. All dollar amounts are presented in United States dollars. The functional currency of the Company and its subsidiary is the United States dollar, and the presentation currency is the United States dollar. Additional information relating to the Company is available on SEDAR at [www.sedar.com](http://www.sedar.com).

Certain information provided by the Company in this MD&A and in other documents publicly filed throughout the year that are not recitation of historical facts may constitute forward-looking statements. The words "may", "would", "could", "will", "likely", "estimate", "believe", "expect", "forecast" and similar expressions are intended to identify forward-looking statements.

Readers are cautioned that such statements are only predictions and the actual events or results may differ materially. In evaluating such forward-looking statements, readers should specifically consider the various factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements.

### 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.

## **2. Reporting currency**

Effective April 1, 2014, the Company changed its reporting and functional currency from the Canadian dollar to the U.S. dollar in anticipation of filing its financial statements with the U.S. Securities and Exchange Commission; The Company has translated its financial statements for comparative into the new reporting currency using the current rate method. Items reported in the statements of loss and comprehensive loss and of cash flows for the comparative period have been translated into the new reporting currency using the average exchange rates prevailing during each reporting period. Assets and liabilities have been translated using the exchange rate prevailing at the end of the reporting period. Exchange differences arising from the translation are included as a separate component of other comprehensive income.

## **3. Overview of Financial Performance**

The Company recognized revenues of \$1,649,469 for the three months ended June 30, 2014. This is an increase of \$400,649 over the same three month period of 2013 an increase of 32%, reflecting the continued acceptance of the Prolieve technology in the market. Operating expenses for the three months ended June 30, 2014 were \$1,814,653 compared to \$1,683,398 for the three months ended June 30, 2013.

During the year ended March 31, 2014, Medifocus created Medifocus Holding Limited, together with Ideal Concept Group Limited to develop our Prolieve business and APA technology in Asia Pacific. Medifocus owns 40% of Medifocus Holdings Limited and Idea Concept Group holds 60%. Medifocus Holdings Limited will evaluate opportunities in Asia Pacific; engage in clinical testing and obtaining approval from China Food and Drug Administration of the People's Republic of China ("CFDA") for all products relating to Prolieve and the APA technology.

Medifocus Holdings Limited is required to pay Medifocus a royalty of 5% of the first \$10,000,000 in sales of the catheter kits and control units utilized in the Prolieve business. After \$10,000,000 in sales has been reached, the royalty decreases to 3%. For all other products developed by Medifocus, MH Ltd. is required to pay Medifocus royalty of 7.5% on net sales of such products.

In the last quarter of fiscal 2014, the Company raised gross proceeds of \$5,540,000 through an issue of convertible redeemable debentures paying interest of 8% per annum.

#### **4. Company History and Business**

Medifocus was incorporated under the *Business Corporations Act* (Ontario) on April 25, 2005. The Company 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".

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 Microfocus APA 1000 Breast Cancer Treatment System ("APA 1000"), 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 APA 1000 can be commercialized following successful completion of the pivotal clinical trial and receipt of marketing approval in the US from the United States Food and Drug Administration (the "FDA") and in Canada from Health Canada. The Company will expense the royalties as paid.

On July 24, 2012, the Company acquired the Prolieve® Thermodilatation System ("Prolieve") technology and related business assets from Boston Scientific Corporation ("BSC") through an asset purchase agreement. The Prolieve is a FDA approved device for the treatment of enlarged prostate, medically known as Benign Prostatic Hyperplasia ("BPH"). The total purchase price for the transaction was \$5,035,610 of which \$2,535,610 was paid on the closing of the transaction. The balance of \$2,500,000 will be paid in quarterly installments at a rate of 10% of Medifocus' Prolieve sales.

The Company currently owns two technology platforms with comprehensive US and international patent protection:

1: The Endo-thermotherapy Platform-a catheter-basis focused heat technology platform that utilizes natural body openings to deliver precise microwave thermotherapy to the diseased sites. The Prolieve Thermodilatation System for the treatment of BPH was developed based on the Endo-thermotherapy Platform. The same platform can potentially be used to treat cancers in prostate, rectum, cervix and esophagus.

2: The Adaptive Phased Array (APA) Microwave Focusing Platform-invented by MIT and licensed to Medifocus, directs precisely focused microwave energy at tumor center to induce shrinkage or eradication of tumors without undue harm to surrounding tissue. The APA technology was originally developed by MIT for military applications in the U.S. Department of Defense' "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 for medical applications 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. The Company's APA 1000 Breast Cancer Treatment System, developed from the APA technology platform, has received approval from the FDA and Health Canada to conduct the pivotal Phase III clinical trials. The APA Microwave Focusing Platform can provide the design basis for future focused heat cancer treatment systems for surface, subsurface and deep seated localized and regional cancers, such as lung and liver cancers.

### Prolieve® Thermodilatation System

Medifocus manufactures and markets a non-surgical, office-based therapy for the treatment of symptoms and obstruction resulting from the enlargement of prostate also known as benign prostatic hyperplasia ("BPH").

### What Is BPH?

Millions of aging men experience symptoms resulting from BPH, a non-cancerous urological disease in which the prostate enlarges and constricts the urethra. The prostate is a walnut-sized gland surrounding the male urethra that produces seminal fluid and plays a key role in sperm preservation and transportation. The prostate frequently enlarges with age. As the prostate expands, it compresses or constricts the urethra, thereby restricting the normal

passage of urine. This restriction may require a patient to exert excessive bladder pressure to urinate. Because urination is one of the body's primary means of cleansing impurities, the inability to urinate adequately increases the possibility of infection and bladder and kidney damage, and impacts quality of life.

### BPH Symptoms

The symptoms of BPH usually involve problems with emptying the bladder or storing urine in the bladder. However, the severity of the symptoms can vary widely, from mild and barely noticeable to serious and disruptive. Common BPH symptoms include:

- Pushing or straining to begin urination
- A weak urinary stream
- Dribbling after urination
- A frequent need to urinate, sometimes every 2 hours or less
- A recurrent, sudden, or uncontrollable urge to urinate
- Feeling the bladder has not completely emptied after urination
- Pain during urination
- Waking at night to urinate

In extreme cases, a man may be completely unable to urinate. In such situations, emergency medical attention is required.

An enlarged prostate does not cause prostate cancer or directly affect sexual function. However, many men experience sexual dysfunction and BPH symptoms at the same time. This is due to aging and the common medical conditions older men often encounter, including vascular disease and diabetes. Since all these conditions increase with aging, sexual dysfunction tends to be more pronounced in men with BPH.

### BPH Complications

BPH is not a form of prostate cancer and does not lead to prostate cancer. Thus, BPH is not life-threatening. However, as many men know, BPH may be a lifestyle-restriction and can cause great discomfort, inconvenience, and awkwardness and complications such as:

- Acute urinary retention, which is a condition that results in a complete inability to urinate. A tube called a catheter may be needed to drain urine from the bladder.
- Chronic urinary retention, which is a partial blockage of urine flow that causes urine to remain in the bladder. In rare cases, this may lead to kidney damage if it goes undiagnosed for too long.
- Urinary tract infection, which can cause pain or burning during urination, foul-smelling urine, or fever and chills.
- Other complications from BPH may include bladder stones or bladder infections.
- Having BPH does not directly affect one's sexual function. However, it is common for the symptoms of BPH and sexual dysfunction to occur at the same time.

### Prevalence of BPH and Treatment Market Potentials

BPH is an age-related disorder, the incidence of which increases with maturation of the population. Industry estimates suggest that 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 BPH treatment market worldwide to be at least several billion dollars.

### Treatment Alternatives for BPH

Several types of treatments are available for enlarged prostate. They include medications, surgery and minimally invasive surgery. The best treatment choice for patients depends on several factors, including how much the symptoms bother them, the size of their prostate, other health conditions the patients may have, their age and preference. If their symptoms aren't too bad, they may decide not to have treatment and wait to see whether their symptoms become more bothersome over time.

### Watchful Waiting

When a patient first develop symptoms caused by BPH, physicians generally prescribe drugs as the first treatment option, but usually leave the decision to their patients. Due to the low success rate, high costs, side effects, and

complications associated with BPH drug therapies, some patients diagnosed with BPH prefer to be regularly monitored by their doctors, but choose not to begin a drug therapy. The patients who opt out of therapy fall into a group referred to as “watchful waiting.” Often, BPH symptom persistence and worsening or an acute urinary event may force the patient to move on to some other form of therapy.

## Drug Therapy

Medications are the most common treatment for moderate symptoms of prostate enlargement but if patients stop using medicine, the symptoms will usually return. Medications used to relieve symptoms of enlarged prostate include several different types of drugs, such as Alpha-Blockers (such as Flomax®) and Alpha Reductase Inhibitors (such as Proscar®). Drug therapy is expensive and must be maintained for life and does not offer consistent relief to a large number of BPH patients. Many patients who begin drug therapy for BPH drop out within the first year, primarily due to the ineffectiveness of currently available drug therapies. Currently available BPH drugs also have appreciable side effects, such as: headache, fatigue, impotence, dizziness, and low blood pressure.

## Surgical Intervention

Two of the primary surgical procedures to treat BPH are transurethral resection of the prostate (TURP) and Laser. TURP has traditionally been a common procedure for enlarged prostate for many years. It's a procedure in which the prostatic urethra and surrounding diseased tissue in the prostate are trimmed with a telescopic knife, thereby widening the urethral channel for urine flow. While the TURP procedure generally has been considered the most effective treatment available for the relief of BPH symptoms, the procedure has shortcomings. In the first instance, TURP generally requires from one to three days of post-operative hospitalization. In addition, a substantial percentage of patients who undergo TURP encounter significant complications, which can include painful urination, infection, retrograde ejaculation which means semen released during ejaculation enters the bladder rather than exiting the penis, impotence, incontinence, and excessive bleeding.

Laser surgeries (also called laser therapies) use high-energy lasers to destroy or remove overgrown prostate tissue. Options for laser therapy depend on prostate size, the location of the overgrown areas. During prostate laser surgery, a combined visual scope and laser is inserted through the tip of the patient's penis



into the urethra which is surrounded by the prostate. Using the laser, doctors remove prostate tissue that's squeezing the urethra and blocking urine flow, thus making a new larger tube for urine to pass through. Lasers use concentrated light to generate precise and intense heat. Risks of laser surgery include: temporary difficulty urinating and post treatment catheterization, urinary tract infection, narrowing of the urethra as scars form, retrograde ejaculation, and erection problems. Accordingly, neither drug therapies nor the surgical alternatives appear to provide fully satisfactory, cost-effective treatment solutions for BPH sufferers.

### Our Approach: Prolieve Thermodilatation System

Our Endo-thermotherapy Platform-based Prolieve Thermodilatation System was originally developed and commercialized by the current Medifocus management, product development, clinical and regulatory teams while at Celsion Corporation, which subsequently sold the Prolieve business to Boston Scientific Corporation for US\$60 million. In July 2012, Medifocus reached an agreement with Boston Scientific Corporation for the purchase of all of the assets of its Prolieve business, including all Prolieve inventory, the mobile services assets, as well as the intellectual property associated with the Prolieve technology.

The Prolieve system provides a 45-minute in-office treatment that combines our microwave thermotherapy capability with a proprietary balloon compression technology to simultaneously heat the prostate and dilate the prostatic urethra that has been obstructed by the BPH disease. 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. This technology is designed to be used by medical professionals in an office based setting without placing their patients under general anesthesia.

The Prolieve system consists of a microwave generator, conductors, a computer and software programs that control the focusing and application of heat, plus a specially designed flexible balloon catheter. Prolieve is the only patented microwave device that both dilates and heats the prostate at the same time, which enhances patient comfort and preserves healthy urethral tissue during the treatment.

The combined effect of this “heat plus compression” therapy is twofold: first, the heat denatures the proteins in the wall of the urethra, causing a stiffening of the

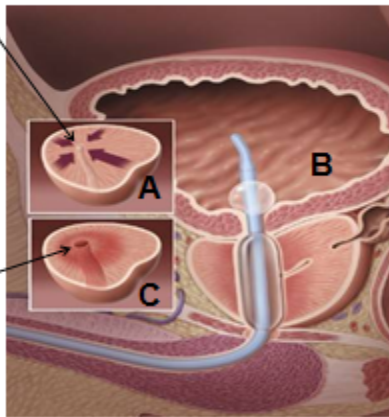
opening created by the inflated balloon, forming a biological stent that gives the patient immediate clinically documented relief from their BPH disease. Second, the heat serves effectively to kill off prostate cells outside the wall of the urethra, thereby creating sufficient space for the enlarged natural opening. In addition, the Prolieve system's temperature (46° C to 54° C) is sufficient to kill prostatic cells surrounding the urethra wall, thereby creating space for the enlargement of the urethra opening. However, the relatively low temperature is not sufficient to cause swelling in the urethra. Most patients are able to void immediately after the procedure, not requiring post-treatment catheterization.

### Prolieve Treatment Illustration Heat + Dilation

Figure A: Constricted Urethra BEFORE Prolieve Treatment

Figure B: Placement of Prolieve Proprietary Heat/Dilation Catheter, 45-minute treatment

Figure C: Bio-logical stent formed in the Urethra AFTER Prolieve Treatment



We believe the Prolieve therapy is an efficacious, safe and cost-effective alternative to medication and other more invasive surgical based treatments without the complications and the side effects associated with those procedures. Prolieve is the only microwave therapy to be randomized against drug therapy in FDA clinical trials and to show superior results than medication in those trials.

Medifocus's goal is to establish Prolieve as the preferred therapeutic alternative considered for medical professionals for their BPH patients in the earlier stages of BPH disease. Prolieve provides a clear alternative for patients that do not want to continue on chronic BPH medication because they are unhappy with the side effects, costs and/or results. Currently, BPH patients can be treated using Prolieve in urologists' offices throughout the United States. In addition, the Prolieve treatment is also made available to physicians utilizing our nationwide mobile service provider.

Medifocus' strategy to capitalize on the proprietary Prolieve Thermodilatation System is to generate recurring revenues through our mobile service and the sale of our disposal catheter kits.

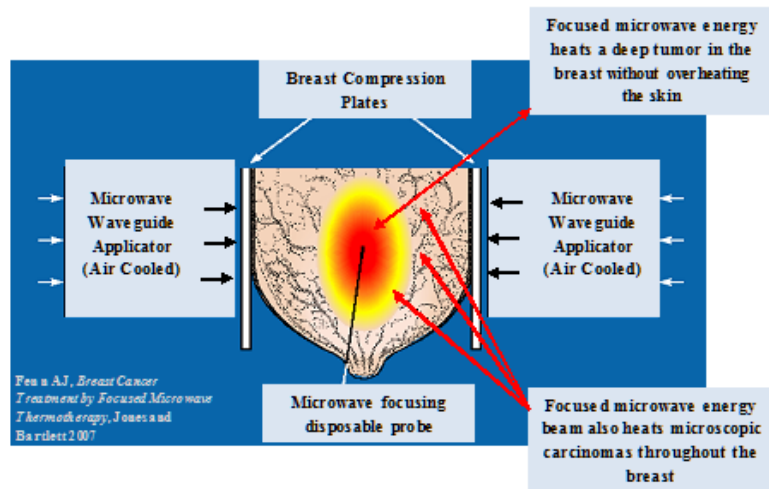
### The APA 1000 Breast Cancer Treatment System

Medifocus' patented APA microwave focusing technology 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 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.

Working with researchers at MIT, the current Medifocus management and engineering teams have developed the APA 1000 Breast Cancer Treatment System, incorporating further refinements in the precise focusing of microwaves and in detection feedback and mechanisms. We have received approval from the FDA and Health Canada to conduct the pivotal Phase III clinical trials for the APA 1000.

Microwave is a form of electromagnetic radiation. Microwaves focused on tumors in the breast result in localized heating of the cancer cells. Higher water content of the breast tumor relative to the surrounding fatty tissue means preferential heating of the tumor and minimal damage to healthy tissue. Microwave treatment can result in tumor necrosis, induced apoptosis (programmed cell death), or cell death -- and the heat enhances the effects of the chemotherapy drug, resulting in tumor shrinkages within a matter of weeks.

When using Medifocus' patented focused-microwave technology, a minimally invasive disposable catheter sensor is inserted into the breast under ultrasound guidance to provide feedback signals for microwave focusing and temperature measurement. The breast is then immobilized by compression, which also serves to reduce blood-flow and increase the efficiency of heat delivery for effective treatment, and microwave energy is applied to the breast via two parallel-opposed microwave applicators. A proprietary feedback, tracking, and control mechanism ensures that the microwave energy is focused on the center of the tumor, while a computer algorithm controls the amount of energy applied to the tumor, and monitors the temperature to ensure optimum effectiveness.



An Artist's Impression of APA Microwave Breast Thermotherapy Concept

The first indication the APA 1000 is to treat locally advanced breast cancer (“LABC”). LABC with large size tumors (3-8 cm in diameter) represents a large percentage of all newly detected breast tumors in North America. The current Standard of Care (SOC) for LABC is to use neo-adjuvant chemotherapy to induce tumor shrinkage followed by breast conservation surgery (BCS) if the tumor shrinks sufficiently, or complete breast removal surgery (mastectomy) if the tumor does not respond. Currently, the rate of successful conversion to BCS is as low as about 30%. In Phase II clinical studies, our APA 1000 System had been shown clinically to be able to enhance the efficacy of neo-adjuvant chemotherapy in shrinking large breast cancer tumors, improving the chance of breast conservation, and decreasing the need for radical breast surgery.

## 5. Going Concern

The consolidated financial statements have been prepared on the "going concern" basis, which presumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of business for the foreseeable future. There are material uncertainties related to adverse conditions and events that cast significant doubt about the Company's ability to continue as a going concern for a reasonable period of time in future.

The Company's operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, dependence on significant customers, lack of operating history and uncertainty of future profitability and possible fluctuations in financial results. Since inception, the Company has incurred substantial operating losses, principally from expenses associated with the Company's research and development programs. The Company believes these expenditures are essential for the commercialization of its technologies. The Company expects its operating losses to continue for the foreseeable future as it continues its product development efforts, and when it undertakes sales and marketing activities. The Company's ability to achieve profitability is dependent upon its ability to obtain governmental approvals, produce, and market and sell its new product candidates. There can be no assurance that the Company will be able to commercialize its technology successfully or that profitability will ever be achieved. The operating results of the Company have fluctuated significantly in the past. The Company expects that its operating results will fluctuate significantly in the future and will depend on a number of factors, many of which are outside the Company's control. The Company will need substantial additional funding in order to complete the development, testing and commercialization of its product candidates. The commitment to these projects will require additional external funding, at least until the Company is able to generate sufficient cash flow from sale of one or more of its products to support its continued operations. If adequate funding is not available, the Company may be required to delay, scale back or eliminate certain aspects of its operations or attempt to obtain funds through unfavourable arrangements with partners or others that may force it to relinquish rights to certain of its technologies, products or potential markets or that could impose onerous financial or other terms. Furthermore, if the Company cannot fund its ongoing development and other operating requirements, particularly those associated with its obligations to conduct clinical trials under its licensing agreements, it will be in breach of these licensing agreements and could therefore lose its license rights, which could have material adverse effects on its business. Management is continuing its efforts to obtain additional funds so that the Company can meet its obligations and sustain operations.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future

profitable operations, the ability to generate sufficient cash from operations, and potential other funding sources, including cash on hand, to meet the Company's obligations as they become due.

Management believes the going-concern basis is appropriate for the accompanying consolidated financial statements based on its current operating plan through March 31, 2015.

## **6. Results of Operations**

The Company recognized revenues of \$1,649,469 for the three months ended June 30, 2014. This is an increase of \$400,649 over the same three month period of 2013 an increase of 32%, reflecting the continued acceptance of the Prolieve technology in the market. The cost of goods sold increased from \$800,609 in the three months ended June 30 2013 to \$1,023,956 for the same three months of 2014. The gross margin percentage increased to 38% in the three months ended June 30, 2014 from 36% in the same period of 2013. Operating expenses for the three months ended June 30, 2014 were \$1,814,653 compared to \$1,683,398 for the three months ended June 30, 2013. Amortization of Prolieve intellectual property was \$35,261 for the Three months ended June 30, 2014.

The Company incurred salaries and wages expense of \$776,458 and sales and marketing expenses of \$155,088. Medifocus has established its sales management structure and is adding regional sales people across the nation. The Company has organized its Mobile Service Operations to strategically and effectively provide a nation-wide service for Prolieve treatment.

Sales and marketing expenses include travel, brochures and marketing materials incurred in growing Prolieve sales. The Company incurred research and development expenses of \$52,771, including PMA and FDA fees. The Company has implemented its own Quality Management System ("QMS") system which has passed FDA approval.

The Company incurred development and investor relations expenses of \$79,060 during the three months ended June 30, 2014 as compared to \$94,392 in the same period of 2013. No stock based compensation expense was recognized in the three months ended June 30, 2014, a reduction of \$53,073 from the same period of 2013.

Director fees have decreased to \$41,667 in 2014 from \$32,110 in 2013. Professional fees have increased by \$138,192 during the three months ended June 30, 2014 from \$147,006 recognized for the three months ended June 30, 2013. General and administrative expenses jumped from \$107,395 in 2013 to \$170,274 in the three months ended June 30, 2014, reflecting the growth in the company over the year. Interest expense of \$216,292 was recognized for the three months ended June 30, 2014, an increase from \$68,829 from the same period of 2013, reflecting the higher debt being held by the company during 2014.

## 7. Business Acquisition

On July 24, 2012 the Company purchased from Boston Scientific Corporation all of the assets, and assumed certain liabilities, relating to the Prolieve Thermodilatation System (“Prolieve”), a FDA approved device for the treatment of Benign Prostatic Hyperplasia (“BPH”). The total purchase consideration consisted of the following:

Cash	\$ 2,535,610
Fair value of contingent consideration	<u>1,170,439</u>
Total consideration	<u>\$ 3,706,049</u>

The maximum amount payable pursuant to the terms of the contingent consideration is \$2.5 million; its fair value was determined by calculating its present value based on its payment terms using an interest rate of 24% (the Company's estimated unsecured borrowing rate). The contingent consideration is paid quarterly at a rate of 10% of sales of Prolieve products. The fair value of the contingent consideration is adjusted for changes in the estimated future payments with the amount of adjustment reflected in profit or loss.

The Company accounted for its acquisition of Prolieve by recording all tangible assets and intangible assets acquired, and liabilities assumed, at their respective fair values on the acquisition date. The fair value assigned to identifiable intangible assets acquired was determined using a cost approach and was based on the Company's best estimates; this intangible asset is being amortized on a straight-line basis over its estimated useful life of ten years.

The following summarizes the fair value of the assets acquired and liabilities assumed in the transaction:

Inventory	\$1,200,000
Intangible assets	<u>2,506,049</u>
Total consideration	<u>\$ 3,706,049</u>

## 8. Prior Period Correction of an Error

### *Fair value of contingent consideration*

Management of Medifocus, while preparing financial statements for the year ended March 31, 2014, reviewed their presentation of the fair value of the contingent consideration payable to Boston Scientific Corporation pursuant to the purchase of the Prolieve Thermodilatation System. The full value of the contingent consideration of \$2,395,529 had been presented as interest and debt payable to Boston Scientific Corporation. The Company determined that the fair value of the contingent consideration was \$1,065,698. The discount of the contingent consideration to fair value of \$1,329,561 adjusted the purchase price of the intangible assets.

Accordingly, the Company has adjusted all comparative amounts presented in the current financial statements affected by the accounting error as follows:

	As Previously Recorded	Adjustment	As Restated
<b>Consolidated Statements of Financial Position</b>			
Intangible assets- Prolieve intellectual properties	<u>3,835,610</u>	(1,329,561)	<u>2,506,049</u>
Payable to Boston Scientific Corporation - Current	(254,032)		
Interest payable to BSC - Current	(149,301)		
Payable to Boston Scientific Corporation	(811,666)		
Interest payable to BSC	<u>(1,180,260)</u>		
Contingent consideration payable to Boston Scientific Corporation	<u>(2,395,529)</u>	1,329,561	<u>(1,065,698)</u>
Deficit - end of year	<u>14,964,244</u>	(97,046)	<u>14,867,198</u>



	As Previously Recorded	Adjustment	As Restated
<b>Consolidated Statements of Loss and Comprehensive Loss</b>			
Amortization of intangible assets	<u>285,000</u>	(97,046)	<u>187,954</u>
Net loss and comprehensive loss	<u>(5,848,643)</u>	97,046	<u>(5,751,597)</u>
Loss per share, basic and diluted	0.049		0.049

## 9. Investment in associate

On November 8, 2013 Medifocus entered into an agreement with Ideal Concept Group Limited (“Ideal Concept”) to develop our Prolieve business and APA technology in a geographic area referred to as Asia Pacific (the “Agreement”). The countries comprising Asia Pacific are not specified in the Agreement. Pursuant to the Agreement, Medifocus and Ideal Concept agreed to capitalize a company, Medifocus Holding Limited (“MH Ltd.”), to develop this business. MH Ltd. was incorporated in the British Virgin Islands on June 28, 2012. The Agreement states that, at the outset, Ideal Concept will own 60% of MH Ltd and we will own 40%.

Through June 30, 2014, Medifocus Inc. and Ideal Concept have made total contributions to MH Ltd. of approximately \$159,000 and \$530,000, respectively. In addition to the capital contributions, the shareholders are obligated to provide loans to the MH Ltd. of up to HKD4,000,000 (or approximately \$520,000). Ideal Concept has agreed, through November 8, 2014, to loan Medifocus the funds necessary to satisfy our portion of the required shareholder contributions to Medifocus Holding. Such loan would bear interest at 6% per year and be secured by our ownership interest in MH Ltd. No such loans have been made to us by Ideal Concept. Pursuant to the terms of the Agreement and a License and Distribution Agreement dated as of November 8, 2013 MH Ltd. will engage in clinical testing, and obtaining approval from China Food and Drug Administration of the People's Republic of China (“CFDA”) for all products relating to Prolieve and the APA technology.

The Agreement outlines the respective obligations of Ideal Concepts and Medifocus. Medifocus will be responsible for:

(i) providing MH Ltd. with an exclusive license to our rights in the Prolieve business and APA technology; (ii) applying for and maintaining the patents and other intellectual property rights throughout the world; (iii) directing and managing all research and development activities in Asia Pacific; and (iv) providing on-site and off-site technical support and training to MH Ltd.'s personnel. Ideal Concept's responsibilities will include: (i) formulating a business plan to evaluate opportunities in Asia Pacific; (ii) assisting in the performance of clinical trials relating to CFDA approval; (iii) providing assistance in establishing manufacturing arrangements for products; and (iv) managing the financial affairs of MH Ltd, including the cash flow, arranging funding, and assisting in developing markets in Asia Pacific.

MH Ltd. is required to pay Medifocus a royalty of 5% of the first \$10,000,000 in sales of the catheter kits and control units utilized in the Prolieve business. After \$10,000,000 in sales has been reached, the royalty decreases to 3%. For all other products developed by Medifocus, MH Ltd. is required to pay Medifocus royalty of 7.5% on net sales of such products.

The Company has concluded that it has significant influence but not control over MH Ltd. and therefore measures its investment in MH Ltd. using the equity method. For the year ended March 31, 2014, the Company's share of MH Ltd. losses of are \$198,000. Medifocus recognized \$159,000 of the loss in profit and loss, which is the value of Medifocus' investment in MH Ltd. at March 31, 2014. The balance of the loss of \$39,000 has not been recognized by Medifocus as at June 30, 2014.

## **10. Liquidity and capital resources**

The Company's primary cash requirements are to fund operations, including research and development programs and collaborations, to support general and administrative activities, and to fund acquisitions of products or businesses. The Company's future capital requirements will depend on many factors, including, but not limited to:

- sales of the Company's Prolieve products and services;
- pricing and payment terms with customers;
- costs of raw materials and payment terms with suppliers;

- capital expenditures and equipment purchases to support product launches; and
- business and product acquisitions.

During the fiscal year ended March 31, 2014, the Company raised gross proceeds of \$5.54 million from the sale of convertible redeemable debentures and warrants (the "Units"). Each Unit consists of (i) a \$10,000 face value convertible redeemable debenture, bearing 8% annual interest and due in three years (the "Note"), which is convertible into shares of common stock beginning six months after the Closing Date of the offering at a conversion price of \$0.25 per share, and (ii) three-year warrants to purchase 20,000 shares of common stock at a price of \$0.30 per Share. The net proceeds from the offering is used for Prolieve operations and for general corporate purposes including research and development activities, capital expenditures, repayment of debt and working capital.

The CAD \$550,000 promissory note made to a lender in July 2012, and the accrued but unpaid interest of CAD \$139,000 as at June 30, 2014, was originally due October 23, 2013. The lender has extended the due date of this promissory note to June 30, 2014. The Company has paid approximately CAD \$195,000, and the remaining balance is outstanding as at August 29, 2014.

The Company will need substantial additional funding in order to complete the development, testing and commercialization of its product candidates. The commitment to these projects will require additional external funding, at least until the Company is able to generate sufficient cash flow from sale of one or more of its products to support its continued operations. If adequate funding is not available, the Company may be required to delay, scale back or eliminate certain aspects of its operations or attempt to obtain funds through unfavorable arrangements with partners or others that may force it to relinquish rights to certain of its technologies, products or potential markets or that could impose onerous financial or other terms. Furthermore, if the Company cannot fund its ongoing development and other operating requirements, particularly those associated with its obligations to conduct clinical trials under its licensing agreements, it will be in breach of these licensing agreements and could therefore lose its license rights, which could have material adverse effects on its business. Management is continuing its efforts to obtain additional funds so that the Company can meet its obligations and sustain operations.

We do not have any committed sources of financing and cannot give assurance that alternate funding will be available in a timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of

shares of common stock, convertible debt or other equity-linked securities, which financings could dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. We recently have entered into an arrangement with an investment banker to help us raise up to \$10.0 million in capital (consisting of debt, equity or equity-linked securities or a combination thereof) on a best effort basis in near future. We also have a firm commitment underwriting agreement with the same banker to help us raise up to \$20.0 million in the sale of our common stock. There are no assurances that these efforts will be successful and all are subject to market conditions, among other things. Our cash and cash equivalents of \$ 272,027 on hand at June 30, 2014 is not sufficient to fund operations through fiscal 2015. We will need to raise substantial additional capital in the near future to fund our planned future operations beyond 2014, and we anticipate that such financing transactions will likely be dilutive to our current shareholders. If we are not able to raise additional capital, we will need to take certain measures to reduce our operating costs, including reducing staff, curtailing our research and development efforts and our clinical trials, and reducing costs we plan to spend to grow our Prolieve business. As such, we would not be able to maintain the growth of the Prolieve business, complete the development and commercialization of our APA technology.

## **11. 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.

The following is a summary of the risk factors that we believe are most relevant to our business. These are factors that, individually or in the aggregate, could cause our actual results to differ significantly from anticipated or historical results.

*We have a history of significant losses and expect to continue to incur losses until sufficient revenue can be generated from Prolieve sales*

Since incorporation in 2005, our expenses have exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$22,179,469 at June 30, 2014,

including losses of \$1,198,051 for the three months ended June 30, 2014. Because we presently have limited revenues from sales of our Prolieve system and related disposables and we are committed to continuing our product research, development and commercialization programs, we will continue to experience significant operating losses unless and until we generate significant revenue from Prolieve, as well as the development of other new products and these products have been clinically tested, approved by the FDA or other regulatory authorities and successfully marketed.

*We cannot accurately predict our revenue in the future.*

Since 2005 we have devoted our resources to developing the APA 1000, but we will not be able to commercialize the APA 1000 until we have completed Phase III clinical testing and obtained all necessary governmental approvals. On July 24, 2012, we acquired from Boston Scientific Corporation the Prolieve Thermodilatation system business for the treatment of BPH—and, since that time, we have assembled a sale and service team to market the Prolieve system. All of our current revenue is derived from sales of our Prolieve control units and more importantly, our single-use treatment catheters and treatments delivered through our mobile service. We can give no assurance as to how much revenue will be generated by Prolieve sales. Our lack of product diversification means that we may be negatively affected by changes in market conditions and in regulation (including regulation affecting reimbursement for our products). In addition, at the present time our APA 1000 system is still in clinical testing stage and cannot be marketed until we have completed clinical testing and obtained necessary governmental approval. Accordingly, our revenue sources are, and will remain extremely limited until and unless our Prolieve system is marketed successfully and/or until our other new products are clinically tested, approved by the FDA or other regulatory authorities and successfully marketed. We cannot guarantee that our products will be successfully tested, approved by the FDA or other regulatory authorities, or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

*If we are not able to obtain necessary funding, we will not be able to complete the development, testing, and commercialization of our treatment systems.*

We will need substantial additional funding in order to expand sales of the Prolieve, to complete the development, testing, and commercialization of APA 1000 system, as well as other potential new products. We have made a significant

commitment to our APA 1000 system's research and development project and it is our intention at least to maintain, or increase the pace and scope of these activities. Such commitment will require additional external funding, at least until we are able to generate sufficient cash flow from sale of Prolieve to support our continued operations. We do not have any committed sources of financing and cannot offer any assurances that additional funding will be available in a timely manner, on acceptable terms or at all. 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. If adequate funding is not available, we may be required to delay, scale back or eliminate certain aspects of our operations or attempt to obtain funds through unfavorable arrangements with partners or others that may force us to relinquish rights to certain of our technologies, products or potential markets or that could impose onerous financial or other terms. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligations to conduct clinical trials under our licensing agreements, we will be in breach of these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

*Our internal sales and marketing capability is limited and we must enter into alliances with others possessing such capabilities to commercialize our products internationally.*

Currently our only source of revenues is from the sale of Prolieve control units and disposables within the United States. Consequently, we are dependent upon our limited sales and marketing capability for the successful marketing of our Prolieve system. There can be no assurance that we will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our Prolieve system.

We intend to market our other products, if and when such products are approved for commercialization by the FDA or other regulatory authorities, either directly or through other strategic alliances and distribution arrangements with third parties. There can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on advantageous terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional expense. There can be no assurance that, to the extent that we sell products directly or we enter into any commercialization arrangements with third parties,

such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our products and services.

*We depend on third-party suppliers to manufacture our products and may not be able to obtain these products on favorable terms or at all.*

We currently contract for the manufacture of both our Prolieve control units and disposables from single or limited source suppliers. The FDA must approve the vendors that supply us with Prolieve control units and disposables, and both our suppliers and the suppliers of our suppliers must comply with FDA regulations including good manufacturing practices. Accordingly, we are dependent upon our contract manufacturers to comply with FDA requirements.

In the event a supplier should lose its regulatory status as an approved source, or otherwise would cease to supply us, we would attempt to locate an alternate source. However, we may not be able to obtain the required products or components in a timely manner, at commercially reasonable prices or at all. To the extent that alternative sources of supply are not available on a timely basis and at reasonable cost, the loss of any of our suppliers could have a material adverse effect on our business. The loss of any of these suppliers would require that we obtain a replacement supplier, which would result in delays and additional expense. In addition, our suppliers are in turn dependent upon single or limited-source suppliers for critical components of our products. Although we believe that alternative sources of supply ultimately would be available both to us and to our suppliers if the need arose, the need to identify and qualify such alternative suppliers pursuant to FDA requirements would entail significant time and expense.

*We rely on third parties to conduct all of our clinical trials.*

We rely on third parties to conduct all of our clinical trials. We currently have only 25 full-time employees. We rely, and expect to continue to rely, on third-party CROs to conduct all of our clinical trials. Because we do not conduct our own clinical trials, we must rely on the efforts of others and cannot always control or predict accurately the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not anticipate significantly increasing our personnel in the foreseeable future and therefore, expect to continue to rely on third parties to conduct all of our future clinical trials. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they do not carry out the

trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become prohibitively expensive, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

*Our APA 1000 system and future products utilizing the adaptive phased array technology depend on license agreements with MIT to permit us to use patented technologies.*

Our success will depend, in substantial part, on our ability to maintain our rights under license agreements granting us rights to use patented technologies. We have entered into an exclusive license agreement with MIT under which we have exclusive rights to commercialize medical treatment products and procedures based on MIT's Adaptive Phased Array technology. The MIT license agreement contains license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that we must meet by certain deadlines. If we were to breach these or other provisions of the license agreement, we could lose our ability to use the subject technology, as well as compensation for our efforts in developing or exploiting the technology. Any such loss of rights and access to technology could have a material adverse effect on our business.

Further, we cannot guarantee that any patent or other technology rights licensed to us by others will not be challenged or circumvented successfully by third parties, or that the rights granted will provide adequate protection. We are aware of published patent applications and issued patents belonging to others, and it is not clear whether any of these patents or applications, or other patent applications of which we may not have any knowledge, will require us to alter any of our potential products or processes, pay licensing fees to others or cease certain activities. Litigation, which could result in substantial costs, may also be necessary to enforce any patents issued to or licensed by us or to determine the scope and validity of others' claimed proprietary rights. We also rely on trade secrets and confidential information that we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees, and consultants. We cannot guarantee that these agreements will not be breached, that, even if not breached, that they are adequate to protect our trade secrets, that we will have adequate remedies for any breach or that our



trade secrets will not otherwise become known to, or will not be discovered independently by, competitors.

### *Protection of Intellectual Property*

As much of Medifocus' potential success and value lies in its ownership and use of intellectual property, its inability or failure to protect its intellectual property may negatively affect its business and value. Medifocus' ability to compete effectively is dependent in large part upon the maintenance and protection of the intellectual property it owns and licenses from MIT. Medifocus will rely on patents, trademarks, trade secret and copyright law, as well as confidentiality procedures to establish and protect its intellectual property rights. It may be possible for a third party to copy or otherwise obtain and use the proprietary technology presently owned by or licensed to us without authorization. Policing unauthorized use of our intellectual property is difficult. The steps Medifocus takes may not prevent misappropriation of its intellectual property, and the agreements Medifocus enters into may not be enforceable. In addition, effective intellectual property protection may be unavailable or limited in some jurisdictions outside the United States. Litigation may be necessary in the future to enforce or protect Medifocus' intellectual property rights or to determine the validity and scope of the proprietary rights of others. That litigation could cause Medifocus to incur substantial costs and divert resources away from the business, which in turn could have a material adverse effect on Medifocus' business, results of operations, financial condition and profitability.

### *Medifocus may be subject to damaging and disruptive intellectual property litigation*

Although Medifocus is not aware that its products or services infringe any published patents or registered trademarks, Medifocus may be subject to infringement claims in the future. Because patent applications are kept confidential for a period of time after filing, applications may have been filed that, if issued as patents, could relate to the business of Medifocus.

Parties making claims of infringement may be able to obtain injunctive or other equitable relief that could effectively block Medifocus from providing its products and services the United States and other jurisdictions and could Medifocus to pay substantial damages. In the event of a successful claim of infringement, Medifocus may need to obtain one or more licenses from third parties, which may not be available at a reasonable cost, if at all. The defence of any lawsuit could result in time-consuming and expensive litigation, regardless of the merits of such claims, as well as resulting damages, license fees, royalty

payments and restrictions on Medifocus' ability to provide its products or services, any of which could harm its business.

*Our business is subject to numerous and evolving state, federal and foreign regulations and we may not be able to secure the government approvals needed to develop and market our products.*

Our research and development activities, pre-clinical tests and clinical trials, and ultimately the manufacturing, marketing and labeling of our products, all are subject to extensive regulation by the FDA and foreign regulatory agencies. Pre-clinical testing and clinical trial requirements and the regulatory approval process typically take years and require the expenditure of substantial resources. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates. Delays or rejections in obtaining regulatory approvals would adversely affect our ability to commercialize any product candidates and our ability to generate product revenues or royalties.

The FDA and foreign regulatory agencies require that the safety and efficacy of product candidates be supported through adequate and well-controlled clinical trials. If the results of pivotal clinical trials do not establish the safety and efficacy of our product candidates to the satisfaction of the FDA and other foreign regulatory agencies, we will not receive the approvals necessary to market such product candidates.

Even if regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed. In addition, we are subject to inspections and regulations by the FDA. Medical devices must also continue to comply with the FDA's Quality System Regulation ("QSR"). Compliance with such regulations requires significant expenditures of time and effort to ensure full technical compliance. The FDA stringently applies regulatory standards for manufacturing.

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate FDA regulations. FDA guidelines specify that a warning letter is issued only for

violations of “regulatory significance” for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA’s review of product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted product approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on the Company.

We are also subject to record keeping and reporting regulations, including FDA’s mandatory Medical Device Reporting, or MDR, regulation. Labeling and promotional activities are regulated by the FDA and, in certain instances, by the Federal Trade Commission.

Many states in which we do or in the future may do business or in which our products may be sold impose licensing, labeling or certification requirements that are in addition to those imposed by the FDA. There can be no assurance that one or more states will not impose regulations or requirements that have a material adverse effect on our ability to sell our products.

In many of the foreign countries in which we may do business or in which our products may be sold, we will be subject to regulation by national governments and supranational agencies as well as by local agencies affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. There can be no assurance that one or more countries or agencies will not impose regulations or requirements that could have a material adverse effect on our ability to sell our products.

Failure to comply with applicable regulatory requirements, can result in, among other things, warning letters, fines, injunctions and other equitable remedies, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant approvals, pre-market clearance or pre-market approval, withdrawal of approvals and criminal prosecution of the

Company and its employees, all of which would have a material adverse effect on our business.

*Legislative and regulatory changes affecting the health care industry could adversely affect our business.*

There have been a number of federal and state legislations during the last few years to subject the pricing of health care goods and services to government control and to make other changes to the United States health care system. We cannot predict the effect health care reforms may have on our business and we can offer no assurances that any of these reforms will not have a material adverse effect on our business.

*The success of our products may be harmed if the government, private health insurers and other third-party payors do not provide sufficient coverage or reimbursement.*

Our current and future revenues are subject to uncertainties regarding health care reimbursement and reform. Our ability to commercialize our new cancer treatment system successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. The reimbursement status of newly approved medical products is subject to significant uncertainty. We cannot guarantee that adequate third-party insurance coverage will be available for us to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA. Accordingly, even if coverage and reimbursement are provided by government, private health insurers, and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for health care providers. We may be unable to sell our products on a profitable basis if third-party payers deny coverage, provide low reimbursement rates.

*Our products may not achieve sufficient acceptance by the medical community to sustain our business.*

Although we have received a Pre-Market Approval ("PMA") from the FDA for our Prolieve system for the treatment of BPH, we can offer no assurance that the Prolieve system will be accepted by the medical community widely. Our breast cancer treatment development project using the APA technology is currently in Phase III clinical trials. It may prove not to be effective in practice. If testing and clinical practice do not confirm the safety and efficacy of our systems or, even if further testing and practice produce positive results but the medical community does not view these new forms of treatment as effective and desirable, our efforts to market our new products may fail, with material adverse consequences to our business.

*Technologies for the treatment of BPH and cancer are subject to rapid change and the development of treatment strategies that are more effective than our technologies could render our technologies obsolete.*

Various methods for treating BPH and cancers currently are, and in the future may be expected to be, the subject of extensive research and development. Many possible treatments that are being researched, if successfully developed, may not require, or may supplant, the use of our technologies. The successful development and acceptance of any one or more of these alternative forms of treatment could render our technology obsolete as a cancer treatment method. We face intense competition from other providers of therapies and treatments for BPH and breast cancer. Many of our competitors are significantly larger than we are and have greater financial, technical, research, marketing, sales, distribution and other resources.

*We may not be able to hire or retain key officers or employees that we need to implement our business strategy and develop our products and business.*

Our success depends significantly on the continued contributions of our executive officers, scientific and technical personnel and consultants, and on our ability to attract additional personnel as we seek to implement our business strategy and develop our products and businesses. During our operating history, we have assigned many essential responsibilities to a relatively small number of individuals. However, as our business and the demands on our key employees expand, we have been, and will continue to be, required to recruit additional qualified employees. The competition for such qualified personnel is intense, and

the loss of services of certain key personnel or our inability to attract additional personnel to fill critical positions could adversely affect our business. Further, we do not carry “key man” insurance on any of our personnel. Therefore, loss of the services of key personnel would not be ameliorated by the receipt of the proceeds from such insurance.

*Our success will depend in part on our ability to grow and diversify, which in turn will require that we manage and control our growth effectively.*

Our business strategy contemplates growth and diversification. Our ability to manage growth effectively will require that we continue to expend funds to improve our operational, financial and management controls, reporting systems and procedures. In addition, we must effectively expand, train and manage our employees. We will be unable to manage our businesses effectively if we are unable to alleviate the strain on resources caused by growth in a timely and successful manner. There can be no assurance that we will be able to manage our growth and a failure to do so could have a material adverse effect on our business.

*We face intense competition and the failure to compete effectively could adversely affect our ability to develop and market our products.*

There are many companies and other institutions engaged in research and development of various technologies, both for prostate disease and cancer treatment products that seek treatment outcomes similar to those that we are pursuing. We believe that the level of interest by others in investigating the potential of possible competitive treatments and alternative technologies will continue and may increase. Potential competitors engaged in all areas of BPH and cancer treatment research in the United States and other countries include, among others, major pharmaceutical, specialized technology companies, and universities and other research institutions. Most of our competitors and potential competitors have substantially greater financial, technical, human and other resources, and may also have far greater experience, than do we, both in pre-clinical testing and human clinical trials of new products and in obtaining FDA and other regulatory approvals. One or more of these companies or institutions could succeed in developing products or other technologies that are more effective than the products and technologies that we have been or are developing, or which would render our technology and products obsolete and non-competitive. Furthermore, if we are permitted to commence commercial sales of any of our products, we will also be competing, with respect to

manufacturing efficiency and marketing, with companies having substantially greater resources and experience in these areas.

*We may be subject to significant product liability claims and litigation.*

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$5,000,000 per incident. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim with our own limited resources, which could have a material adverse effect on our business. In addition, liability or alleged liability could harm the business by diverting the attention and resources of our management and by damaging our reputation.

*We have not paid dividends in the past and do not intend to do so for the foreseeable future.*

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. Therefore, our stockholders cannot achieve any degree of liquidity with respect to their shares of Common Stock except by selling such shares.

*Future sales of shares of our common stock or other class of securities may negatively affect our stock price.*

Future sales of our common stock and/or other securities could have a significant negative effect on the market price of our common stock and the number of shares outstanding of our common stock could increase substantially. This increase, in turn, could dilute future earnings per share. Dilution and the availability of a large amount of shares for sale, and the possibility of additional issuances and sales of our common stock or other class of securities may negatively affect both the trading price and liquidity of our common stock.

*Our stock price has been, and could be, volatile.*

Market prices for our Common Stock and the securities of other medical, high technology companies have been volatile. Our Common Stock has had a high price of \$0.25 and a low price of \$0.10 in the 52-week period ending July 29, 2014. Factors such as announcements of technological innovations or new products by

us or by our competitors, government regulatory action, litigation, patent or proprietary rights developments and market conditions for medical and high technology stocks in general can have a significant impact on the market for our Common Stock

*Our stock historically has been thinly traded. Therefore, stockholders may not be able to sell their shares freely.*

While our Common Stock is listed on the TSXV, the volume of trading historically has been relatively light. Therefore, there can be no assurance that our stockholders will be able to sell their shares of our Common Stock at the time or at the price that they desire, or at all. The illiquidity of our stock may impair our ability to raise any capital we may require in the future through an equity financing. There can be no assurance that any market will continue to exist for our common stock.

## **12. Critical Accounting Estimates**

The preparation of the consolidated financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Information about assumptions and estimation uncertainties that have a significant risk of resulting in a material adjustment are as follows:

- i) The Company maintains an allowance for doubtful accounts for estimated losses that may occur if parties are unable to pay balances owing to the Company. This allowance is determined based on a review of specific parties' historical experience and economic circumstances.
- ii) The Company makes estimates for possible write-downs for excess, obsolete, or slow-moving inventory. Any significant or unanticipated change in these estimates could have a significant impact on our reported operating results.



iii) The Company makes estimates related to the extent of warranty claims for products sold. Any unexpected increases in actual warranty claims could affect our reported operating results.

iv) The Company makes estimates related to the values assigned to assets in the purchase price allocation in a business combination. Changes in these assumptions could result in a change in the value of our inventory and Intangible assets - Prolieve intellectual property.

v) The Company makes estimates related to the useful lives of property and equipment, intangible assets- Prolieve intellectual property, and the related amortization.

vi) The Company periodically assesses the recoverability of long-lived assets, and intangible assets. The recoverability analysis requires the Company to make assumptions about future operations. Changes to one or more assumptions would result in a change in the recoverable amount calculated and/or amortization expensed.

vii) The Company makes estimates and utilizes assumptions in determining the fair value for stock based compensation expense, warrants and the bifurcation of convertible debt, using Black-Scholes computations.

viii) Deferred income tax assets are recognized for all deductible temporary differences, carry-forward of unused tax assets and unused tax losses, to the extent that it is probable that future taxable profit will be available against which the deductible temporary differences and carry-forward of unused tax assets and unused tax losses can be utilized. At June 30, 2014, the Company has assessed that it is not probable that sufficient taxable profit will be available to use deferred income tax assets based on operating losses in prior years, therefore, there are no balances carried in the consolidated statements of financial position for such assets.

ix) The Company applies judgment in assessing whether material uncertainties exist that would cause significant doubt as to the whether the Company could continue as a going concern.

### 13. Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, refundable deposits, accounts payable and accrued liabilities, promissory notes and the liability portion of its convertible 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 the Company's financial instruments carried at amortized cost 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 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. The company is exposed to credit risk primarily through its cash, accounts receivable, and refundable deposits. The company has cash deposits with a reputable financial institution, from which management believes the risk of loss to be remote. The risk inherent to accounts receivable is effectively mitigated by the company's close, frequent monitoring of accounts.

#### *Exchange rate risk and sensitivity*

The Company's reporting currency and its functional currency is the U.S. dollar and, accordingly, the Company reports its financial results in U.S. dollars. All assets and liabilities are translated into U.S. dollars based on exchange rates at the end of every reporting period; income and expense items are translated at the average exchange rates prevailing during the reporting period. Foreign currency

translation adjustments are accumulated in other comprehensive income (loss), a component of stockholder's equity.

#### *Interest rate risk*

Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market interest rates would have a significant impact on their realized value. The interest rates on our various outstanding debt instruments, including promissory and convertible notes, are fixed. Because of the fixed rates, a change in market interest rates would not have a material impact on interest expense associated with the debt.

#### *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 Prolieve and completing development, testing and commercialization of 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, including marketing and sales of Prolieve. 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 the sales and marketing of its Prolieve technology, 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. There were no changes to the Company's management of capital from the prior year.

#### 14. 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, 2012	313,281	(990,834)	(0.010)
December 31, 2012	630,150	(2,060,844)	(0.018)
March 31, 2013	862,538	(2,415,419)	(0.025)
June 30, 2013	1,248,810	(1,173,544)	(0.010)
September 30, 2013	1,175,188	(1,399,706)	(0.011)
December 31, 2013	1,282,837	(1,464,500)	(0.012)
March 31, 2014	1,677,138	(2,096,551)	(0.018)
June 30, 2014	1,649,469	(1,198,051)	(0.001)

For further quarterly financial information, please refer to the Company's condensed interim consolidated financial statements that have been filed on SEDAR.

## 15. Transactions with Related Parties

The management team and directors, along with their remuneration for the three months ended June 30, 2014 is presented below:

Individual	Position	Cash	Option	Shares	Total
Grant B. Walsh (1)	Chairman of the Board	\$16,250			\$16,250
Dr. Augustine Y. Cheung	CEO	\$60,000			\$60,000
Joseph S. C. Chan	Director	\$8,750			\$8,750
Dr. Augustine P. Y. Chow	Director	\$5,000			\$5,000
Tak Cheung Yam	Director	\$5,000			\$5,000
John Mon	COO	\$53,000			\$53,000
Mirsad Jakubovic	Director/CFO	\$18,750			\$18,750

(1) Mr. Walsh was paid an additional \$9,000 for reimbursable travel and administrative expenses.

## 16. Commitments

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 technology, the APA technology licensed from MIT, and all related intellectual and regulatory property (collectively, the "Business"). The Company has a commitment to pay a 5% royalty to Celsion on the net sales of products sold by and patent royalties received by the Company and its successors and assignees. Total royalties paid are 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 has an additional commitment to pay a 5% royalty to MIT on the net sales of products, upon commercialization.

Future minimum payments under operating leases and contractual commitments are as follows:

2015	\$ 144,614
2016	\$ 149,475
2017	\$ 155,528
2018	\$ 145,751

## 17. Contingencies

The Company has agreed to indemnify its directors and officers and certain of its employees in accordance with the Company's by-laws. The Company maintains insurance policies that may provide coverage against certain claims.

The Company has agreed to pay Boston Scientific Corporation \$2,500,000 of the purchase price for the acquisition of Prolieve (note 4), in quarterly instalments at a rate of 10% of Prolieve sales

## 18. Other MD&A Disclosure

Outstanding Share Data as at August 29, 2014

	Number or Principal Amount Outstanding	Maximum Number of Common Shares Issuable, if Convertible, Exercisable or Exchangeable
Common Shares	117,260,411	N/A
Stock Options	8,365,000	8,365,000
Warrants outstanding	94,978,852	86,106,807
Maximum common shares outstanding		220,604,263

## **19. 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.

## **20. 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.

Please refer to "Subsequent Events" for a discussion on the acquisition of the Prolieve assets from Boston Scientific Corporation.

## **21. New Accounting Standards**

### *(a) Standards adopted in the current reporting period*

During the year, the Company adopted the following standards, with no impact on its reported financial position or financial performance:

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.

*(b) Standards to be adopted in future reporting periods*

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 for the Company are as follows:

IFRS 9 *Financial Instruments* is effective for annual periods beginning on or after January 1, 2018, and sets out revised requirements for recognizing and measuring financial instruments. Among other things, the standard replaces the current requirements for classifying financial assets with a new model for measuring such assets at either amortized cost or at fair value, based on an entity’s business model for managing the assets and on their contractual cash flow characteristics. It also introduces a single, forward-looking “expected loss” impairment model and a substantially reformed approach to hedge accounting. The Company intends to adopt the new Standard on its effective date and has yet to consider the impact on its financial reporting.

IFRS 15 *Revenue from Contracts with Customers* is effective for annual periods beginning on or after January 1, 2017, and provides new requirements for recognizing revenue. The new Standard's core principle is for a company to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which the company expects to be entitled in exchange for those goods or services. The new Standard sets out enhanced disclosures about revenue, provides guidance for transactions that were not previously addressed comprehensively (for example, service revenue and contract modifications) and improves guidance for multiple-element arrangements. The Company intends to adopt the new Standard on its effective date and has yet to consider the impact on its financial reporting.

**22. 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 June 30, 2014, 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 year ended March 31, 2014 and the three months ended June 30, 2014.

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.

### **23. 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 March 31, 2014, 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, 2014 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

#### **24. 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.

#### **25. Subsequent events**

Subsequent to the end of the period, the Company received short term advances from shareholders and other lenders of \$1,595,000.