Managements' Discussion and Analysis (Expressed in Canadian Dollars)

# **MIRACULINS INC.**

Three and Six months ended May 31, 2011 and 2010

Prepared by Management without review by the Company's Auditors.

### **Management's Discussion and Analysis**



The following management's discussion and analysis ("MD&A") is current to July 29, 2011 and should be read in conjunction with the interim financial statements for the six month period ended May 31, 2011 and the audited financial statements for the year ended November 30, 2010, and related notes, which are prepared in accordance with Canadian generally accepted accounting principles. This discussion and analysis provides an update to the Management's Discussion and Analysis for the year ended November 30, 2010, and should be read in conjunction with this document. The Company's independent auditors, KPMG LLP Chartered Accountants, have not reviewed the unaudited interim financial statements. All amounts are expressed in Canadian Dollars unless otherwise noted. Additional information regarding the Company is available on SEDAR at www.sedar.com and on the Company's website at www.miraculins.com.

### **OVERVIEW**

Miraculins Inc. ("Miraculins" or the "Company") is a medical device company committed to extending life, reducing suffering and lowering healthcare costs. Through acquisition, development and commercialization of diagnostic tests and risk assessment tools for unmet clinical needs, the Company seeks to improve the overall diagnosis quality and treatment of patients by enhancing the information available to patients and physicians. The Company is listed on the TSX Venture Exchange under the symbol "MOM".

The Company's business model is to acquire and/or develop diagnostic and risk assessment opportunities in areas where there are unmet clinical needs. Once Miraculins has advanced a technology through the necessary development stages, it partners with large diagnostic companies, reference laboratories and distribution partners to commercialize and market its technology. These types of relationships typically involve collaborative research agreements, upfront payments, milestone payments and ongoing royalties on sales. Successful execution of this model requires the convergence of product development, marketing, regulatory and corporate finance strategies.

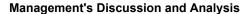
The Company's future operations are dependent upon its ability to generate product sales, negotiate collaboration or license agreements with upfront payments, obtain research grant funding, and secure additional funds. While the Company is striving to achieve these plans, there is no assurance that these and other strategies will be achieved or such sources of funds will be available or obtained on favourable terms or obtained at all.

In 2008, the Company established its preeclampsia program based on the in-license of a suite of promising markers from Mount Sinai Hospital. On January 8, 2010, the Company's preeclampsia program was partnered with Alere, Inc. (NYSE: ALR) (formerly Inverness Medical Innovations), one of the world's largest diagnostic companies. Miraculins continues to advance certain aspects of the program independently through its internal research laboratory.

On September 3, 2010, Miraculins completed the acquisition of all assets relating to the PreVu Non-Invasive Cholesterol Test ("PreVu") from PreMD Inc. PreVu has been previously cleared for sale as part of coronary artery disease (CAD) risk assessment in Canada and had previously received a CE marking which allowed the product to be sold in certain European countries. The test has also been previously cleared for sale by the Food and Drug Administration (FDA) in the United States as part of risk assessment for CAD in persons suspected of having significant CAD and/or persons with a history of myocardial infarction. Miraculins is currently focused on completing the necessary steps to make the PreVu technology available for commercial sale in Canada as early as the fourth quarter of 2011.

In addition to the preeclampsia and PreVu development programs, the Company continues to seek opportunities to advance the scientific evidence supporting its internally developed prostate cancer program and the utility of its assay for Prostate Secretory Protein (PSP94, also known as microseminoprotein-beta or MSMB). In 2010, Miraculins launched a research use only (RUO) PSP94 Immunoassay for Urine Specimens (the assay is for research use only and not for diagnostic procedures) to enable further independent study of the marker in pre-clinical and non-clinical research settings. The immunoassay is being distributed by GenWay Biotech Inc. through a one-year non-exclusive sales and marketing agreement effective August 11, 2010 and is also available through Miraculins' website.

Miraculins is continuously evaluating new licensing and acquisition opportunities that fit strategically with the Company's business model. Potential new programs of greatest interest to the Company are those that have completed discovery stage research and biomarker identification, but require additional expertise and resources to be developed into clinically validated and commercially viable assays.





The Company has continued to access capital during difficult market conditions, having successfully completed private placement financings and obtained non-dilutive grant funding to advance its programs. Miraculins is working to selectively advance the critical aspects of its development programs while securing the appropriate financing, collaboration and/or license agreements necessary to apply greater resources to the programs. The Company is continuing its capital conservation efforts by focusing on rationalizing overhead and is exploring various alternatives for further strengthening its financial position.

The Company's future operations are dependent upon its ability to generate product sales, negotiate collaboration or license agreements with upfront payments, obtain research grant funding, and secure additional funds. While the Company is striving to achieve these plans, there is no assurance that these and other strategies will be achieved or such sources of funds will be available or obtained on favourable terms or obtained at all. If the Company cannot generate product sales, negotiate collaboration or license agreements with upfront payments, obtain research grant funding, or if it cannot secure additional financing on terms that would be acceptable to it, the Company will have to consider additional strategic alternatives which may include, among other strategies, exploring the monetization of certain intangible assets as well as seeking to outlicense and/or divest assets. Based on management's current estimates and expected operating activities, sufficient financial resources exist to fund operations into the fourth quarter of the 2011 fiscal year.

### **Development Program Highlights**

- The Company's PreVu Non-Invasive Cholesterol Test is designed to address the worldwide market of cardiovascular risk assessment. This novel test measures cholesterol in the skin tissues to assess risk of coronary artery disease (CAD). Miraculins plans to make the PreVu test available for commercial sale in Canada by the fourth quarter of 2011.
- The Company's preeclampsia technology is comprised of a suite of placental development protein biomarkers for the detection and diagnosis of preeclampsia, a disease of growing incidence and a leading cause of maternal and prenatal deaths worldwide. The program is based on world leading research from Mount Sinai Hospital and is being developed through a collaborative research and development partnership with Alere, Inc. (NYSE:ALR) (formerly Inverness Medical Innovations), one of the world's largest diagnostic companies.
- The Company's prostate cancer program is centred on the biomarker PSP94 (also known as microseminoprotein-beta or MSMB). The Company's PSP94 Immunoassay for Urine Specimens (research use only and not for diagnostic procedures) has demonstrated positive analytical performance and has been launched to enable further independent study of the marker in pre-clinical and non-clinical research settings. The product is distributed by GenWay Biotech Inc. and through Miraculins' website.

The following table summarizes the Company's research and development programs:

Product	Program/Indication	Status
PreVu Non-Invasive Cholesterol Test	Coronary Artery Disease Risk Assessment	Preparing for product Launch (1)
Placental Development Biomarkers	Preeclampsia Biomarkers	Partnered with Alere, Inc. (2) Research Stage
Endoglin Assay	Preeclampsia Biomarker	Partnered with Alere, Inc. (2) Assay Development & Optimization
Prostate Secretory Protein (PSP94) Assay also known as microseminoprotein-beta (MSMB)	Prostate Cancer Biomarker	RUO Kit On Market <sup>(3)</sup> Distribution Partnership with GenWay Biotech Inc.
MIR-CR1, MIR-GP1, Suite of Markers	Cancer Biomarkers	On hold Research Stage

<sup>(1)</sup> See discussion of the Company's PreVu Program on page 3.

<sup>(2)</sup> See discussion of the Company's Preeclampsia Program on page 5.

<sup>(3)</sup> Miraculins' PSP94 Immunoassay for Urine Specimens is for Research Use Only (RUO) and not for Diagnostic Procedures

### **Management's Discussion and Analysis**



### **Corporate History**

Miraculins began operations in 2002 as a research and development company focused on the screening and identification of target proteins and peptides related to diseases. The Company's original vision was to contribute to the saving of lives through the early detection and diagnosis of cancer by developing products to increase the information available to physicians and consequently enhance the quality of treatment for cancer patients. Through basic discovery research, subsequent development and the acquisition of complimentary technologies, Miraculins established programs in the areas of prostate, colorectal, gastric, pancreatic and breast cancer.

In the spring of 2008, Miraculins announced a shift in its business model, moving the Company's focus away from basic discovery research and further down the diagnostic assay development and commercialization pathway. The Company's business plan is now focused on in-licensing/acquiring and developing diagnostic and risk assessment opportunities that address unmet clinical needs and have completed the early stage research phase.

In the fall of 2008, Miraculins announced its first technology acquisition under its new business model. The Company acquired a panel of biomarkers from Mount Sinai Hospital that have demonstrated the potential to detect or diagnose preeclampsia, a devastating condition of growing incidence affecting pregnant women that is the leading cause of maternal and prenatal deaths worldwide. The Company partnered the program with Alere, Inc. (formerly Inverness Medical Innovations) in January 2010 for development and commercialization.

In late summer 2010, Miraculins completed the acquisition of all assets relating to the PreVu Non-Invasive Cholesterol test. PreVu has past regulatory clearances in Canada and certain European countries and was test marketed on a limited basis in North America. Since closing the acquisition of the PreVu technology, Miraculins management has been focused on preparing all aspects of the product for market launch.

#### **RESEARCH PROGRAMS**

The Company is focused on developing non-invasive diagnostic tests and risk assessment tools that address unmet clinical needs in various disease areas. Resulting from market conditions and the availability of funding, over the past number of months Miraculins has focused its attention primarily on its preeclampsia program and the acquisition and subsequent advancing of its PreVu program.

The Company has also successfully developed an immunoassay for PSP94 in urine and is exploring commercialization opportunities for its intellectual property on PSP94's use in combination with other markers for detecting prostate cancer. Miraculins' PSP94 Immunoassay for Urine Specimens (research use only and not for diagnostic procedures) was successfully launched and is being distributed by GenWay Biotech Inc. to enable further independent study of the marker in pre-clinical and non-clinical research settings.

## Cardiovascular Disease Program (PreVu Non-Invasive Cholesterol Test)

Coronary artery disease (CAD), or heart disease, is a leading cause of death worldwide. Heart disease occurs when fat and cholesterol gradually accumulate in the coronary arteries, forming a plaque that narrows the artery and reduces blood flow to the heart. Undetected or untreated, this build-up can block the artery and cause a heart attack. A heart attack, also known as a myocardial infarction (MI), causes a part of the heart muscle to die, which weakens the heart's ability to pump blood. Worldwide, about 7.2 million people die from heart attacks every year.

A major risk factor for CAD is high blood cholesterol. It is estimated that more than 200 million cholesterol tests are performed per year in the United States. However, blood cholesterol test results may be highly variable over a series of days, relatively expensive to perform and often require a fasting blood sample from the patient. In fact, studies suggest that more than 70% of all heart attack patients actually have blood cholesterol levels within what is considered a normal, healthy range. So while blood cholesterol remains an important risk factor for heart disease, it is widely accepted that several risk factors for CAD must be considered to provide an accurate picture of absolute risk of disease.

### **Management's Discussion and Analysis**



Absolute cardiovascular disease risk is determined by a combination of all cardiovascular risk factors present. Other traditional and emerging risk factors include: gender; increasing age and heredity; tobacco smoking; high blood pressure; physical inactivity, diet and obesity; diabetes mellitus; C-reactive protein (CRP); homocysteine; carotid intima-media thickness (CIMT); and coronary calcium, among others. Many of these factors are costly to measure or assess, are resource intensive, are inappropriate for a primary care setting or require invasive procedures.

In September 2010, Miraculins announced the acquisition of the PreVu Non-Invasive Cholesterol test, a non-invasive skin cholesterol (or skin tissue cholesterol) test for risk assessment of CAD. As a new risk factor for heart disease, skin cholesterol provides valuable information to augment traditional CAD risk assessment. Skin contains over 11% of the body's cholesterol and ages in parallel with vascular connective tissue. As blood vessel walls accumulate cholesterol, so do the skin tissues. A high skin cholesterol level is a reliable predictor of higher cholesterol accumulation in the arteries and, accordingly, risk of heart disease.

The PreVu Point of Care Skin Cholesterol Test (PreVu POC) is a non-invasive, painless and cost effective tool to measure skin cholesterol that does not require any patient preparation or dietary changes. This test is conducted by placing a drop of detector reagent on the palm of the hand, which binds selectively to the cholesterol in the skin. After a one minute incubation period, the area is blotted dry to remove any unbound detector solution and an indicator reagent is then added. When combined, a blue colour change occurs in direct proportion to the amount of skin cholesterol present. After two minutes, a hand held spectrophotometer (colour reader) is placed over the drop to measure the precise blue colour, which indicates the skin cholesterol value.

In addition to the POC format of the test, the PreVu technology is also being developed by Miraculins in a lab-processed format called the PreVu LP Skin Cholesterol Test (PreVu LP).

In Canada and Europe, PreVu POC and PreVu LP have been previously cleared for use as part of risk assessment for CAD. In the United States, PreVu POC has previously been cleared by the FDA for use as part of risk assessment for CAD in persons with a history of heart attack and/or in persons suspected of having significant multi-vessel coronary artery disease (>50% stenosis, or blockage, in more than one vessel, as diagnosed by angiography). Skin cholesterol test results, when considered in conjunction with clinical evaluation, blood cholesterol and other risk factors identified for coronary artery disease, will aid a physician or healthcare practitioner in focusing diagnostic and patient management options.

PreVu has been successfully test marketed on a limited basis in North America, and Miraculins is currently working to relaunch the product and make the product commercially available as early as the fourth quarter of 2011. Critical steps to achieve this significant milestone are underway and include:

- reestablishing key manufacturing partnerships for both of the main components of the PreVu test, the reagent testing kits and the handheld reader (spectrophotometer);
- coordinating the establishment of an ISO 13485 certified quality system, enabling Miraculins to align its management system with regulatory requirements in order to become a medical device manufacturer of record;
- preparing for regulatory notifications required for medical device product marketing in Canada, the United States and Europe;
- refreshing the PreVu brand across all marketing and promotional platforms (including print and web), to most effectively communicate the full value proposition of the technology;
- evaluating sales channels to more expansively reach the end consumer, including retail chain pharmacies, employee
  health screening services, executive health centres, fitness and weight loss facilities, the life insurance industry,
  alternative healthcare, as well as primary care physicians and medical clinics; and
- conducting partnership discussions with multiple parties in Canada, the United States and Europe with the goal of
  activating targeted sales channels; and negotiating with interested parties for the licensing rights to PreVu in foreign
  markets.

To support the launch plan, Miraculins has appointed key consultants in the areas of scientific, manufacturing, technical development and clinical and regulatory affairs. In addition to bringing their skills to Miraculins, certain consultant resources having experience with the PreVu product prior to Miraculins acquisition also provide a continuity of technical knowledge as the product advances to commercialization. Additionally, Miraculins has selected International Aerospace and Medical Device Contractor, HEI, Inc., as its manufacturing partner for the PreVu POC handheld reader.

### **Management's Discussion and Analysis**



## Preeclampsia Program

Preeclampsia is a devastating condition affecting pregnant women that manifests abruptly and results in 15% of all premature births. In the most severe cases, it can result in seizure, stroke, coma, or death. The incidence rate is 7 – 10% of all pregnant women and has an estimated \$7 billion impact on the healthcare system annually. Currently, the sole diagnosis for preeclampsia is by its symptoms; high blood pressure and significant amounts of protein in the urine, which are non-specific to the disease. Currently, preeclampsia affects three million mothers worldwide every year and is associated with premature births and infant illness including cerebral palsy, blindness, epilepsy, deafness and lung conditions. There is no effective detection method for the risk of preeclampsia and the cause is unknown. It is estimated that preeclampsia costs the global health care system US \$3 billion per year. The potential target market for a preeclampsia test is every expectant mother, estimated to be 6 million women annually in the US alone, and greater than 12 million worldwide.

Miraculins' preeclampsia technology is based on a suite of 35 novel protein biomarkers, in-licensed from Mount Sinai Hospital, involved in the development of the placenta and the biology implicated in the development of preeclampsia. The technology was discovered through pioneering research conducted by Dr. Isabella Caniggia and her collaborators at the Samuel Lunenfeld Research Institute of Mount Sinai Hospital, and the Hospital for Sick Children.

One of the promising biomarkers in the portfolio acquired by Miraculins is a cell surface glycoprotein known as Endoglin, which has been widely studied in the independent literature, including a major study published in the New England Journal of Medicine entitled "Soluble Endoglin and Other Circulating Anti angiogenic Factors in Preeclampsia". Under the direction of independent experts from institutions across the United States, the paper reports that Endoglin levels change during gestation and that it can play a role in identifying the patients at highest risk of preeclampsia. Miraculins believes an Endoglin immunoassay will provide a strong base from which the Company can build its program. Subsequent studies have continued to report on the strong utility of Endoglin and its role in detecting preeclampsia.

On January 8, 2010, Miraculins announced a partnership with Alere, Inc. (NYSE: ALR) (formerly Inverness Medical Innovations, Inc.), a global leader in the convergence of medical diagnostic testing and health management, to advance and commercialize Miraculins' preeclampsia technology. The partnership agreement included a fee paid to Miraculins by Alere to acquire the exclusive option to license the worldwide rights to biomarkers of interest from the program. The goal of the partnership is to commercialize Miraculins' biomarkers for worldwide distribution.

The development program is established in a Collaborative Research and Option Agreement, whereby Alere, through its Biosite division, will develop tests for Miraculins' biomarkers and will evaluate their performance in large cohorts of patient blood samples. The biomarkers will also be assessed for their utility in detecting intrauterine growth restriction and other diseases of pregnancy. Alere can exercise its option to license at any time during the term of the Collaborative Research and Option Agreement. Upon exercise of the option, Miraculins will receive additional fees, developmental and commercial milestone payments, and royalties on sales.

In January 2011, Miraculins announced that significant progress had been made towards the development of tests for a number of Miraculins' preeclampsia biomarkers under the Collaborative Research and Option Agreement between the parties. A further update was provided in June 2011, when the Company announced that Alere had maintained its exclusive option on Miraculins' Preeclampsia technology through payment of a non-refundable fee in accordance with the terms of the Collaborative Reserach and Option Agreement. In accordance with the terms of that agreement, Alere must maintain the exclusive option at regular intervals.

Miraculins has retained certain commercial rights to pursue complementary commercial strategies for the markers and receives a secure supply of reagents and certain rights to intellectual property related to the biomarker Endoglin from Alere. While the development program advances through the Alere partnership, Miraculins continues to pursue complimentary strategies for its markers.

### **Management's Discussion and Analysis**



## **Prostate Cancer Program**

Through the discovery and identification of proteins specific to prostate cancer, Miraculins has developed intellectual property surrounding the combination of markers including Prostate Secretory Protein (PSP94, also known as microseminoprotein-beta or MSMB) with the goal of reducing the number of men proceeding to biopsy based on current methods. These unnecessary biopsies are costly, invasive and can lead to complications. The current standard screen for prostate cancer, the Prostate Specific Antigen (PSA) test, although sensitive, is not highly specific, sending upwards of 750,000 men for unnecessary prostate biopsies annually in the United States alone.

PSP94 is a basic 94 amino acid protein found in high concentration in the epithelial cells of the prostate. The marker has been examined in independent literature for its potential to be a cancer biomarker and was found to be decreased in the 24 hour collection of urine from men with late stage tumours compared to men with enlarged prostate or benign prostatic hyperplasia. Further research is needed to confirm the utility of PSP94 as a biomarker in men with prostate cancer. Miraculins has completed a number of studies which have added to the growing body of evidence that levels of PSP94 are differentially expressed in this disease.

Discovery and validation of the Miraculins prostate cancer markers has been conducted on nearly 600 separate and distinct patient samples including the PCSC04 study, a 200 patient, 15 site study. The data from that study showed that Miraculins' urine-based test performed with a specificity that would have eliminated approximately 23% of the biopsies for patients who did not have prostate cancer and a sensitivity that correctly identified 93% of patients who were true positives for prostate cancer.

Additionally, Miraculins has discovered that the detection of PSP94 in urine can improve the performance of free over total (F/T) PSA ratio in detecting aggressive prostate cancer, which could help significantly improve upon the standard free PSA test. The Company has successfully demonstrated that its PSP94 assay, when combined with the F/T PSA ratio, was able to differentiate men with aggressive prostate cancer (Gleason Score of 7-10, n=18) from men with favourable pathologies (Gleason Score of 6 or less, n=70) with a sensitivity of 94% and specificity of 49% (AUC=0.80). When men with the confounding condition of hypertension were removed from testing, the combination yielded even better results and successfully separated the same populations with a sensitivity of 100% and a specificity of 84% (AUC=0.87, n=7 aggressive cancer and n=37 favourable pathologies).

Miraculins has had discussions in regards to its prostate cancer program with a number of diagnostic developers and laboratory service providers and has had dialogue with the US Food and Drug Administration (FDA) through the pre IDE (Investigational Device Exemption) process. Furthermore, Miraculins research has been presented to the academic research community at various scientific meetings.

The Company has developed a PSP94 ELISA kit to allow researchers to expand the scientific data involving PSP94 using a rapid test. The kit includes a precoated 96 well plate of anti-PSP94, an anti-PSP94 peroxidase conjugate, a 12 ng/mL PSP94 calibrator, wash buffer, assay buffer, colour developer and a stop solution. The Miraculins PSP94 ELISA kit has shown extremely high sensitivity thereby minimizing the effect of potential interfering substances. The coefficient of variation (CV) for the assay is less than 7% and the dilution linearity of urine is a nearly perfect correlation coefficient of 0.999.

In 2010, Miraculins launched the PSP94 Immunoassay for urine specimens (research use only and not for diagnostic procedures) which is being distributed by GenWay Biotech Inc. to enable further independent study of the marker in preclinical and non-clinical research settings. On August 11, 2010, Miraculins entered into a one-year non-exclusive distribution agreement with GenWay Biotech for the worldwide sales and marketing of the immunoassay.

## **Other Cancer Programs**

Miraculins has a number of potential biomarkers for colorectal, gastric and pancreatic cancers. In order to effectively manage its financial and other resources, the Company is currently focused on its cardiovascular and preeclampsia programs while evaluating the next steps for this program and therefore research and development for these programs is currently on hold.



## **Colorectal Cancer Program**

- Includes biomarkers which have been shown to be 100% more sensitive than the fecal occult blood test (FOBT), the current preliminary screening standard for colorectal cancer, according to numbers available in the scientific literature.
- There are over 150,000 new diagnoses of colorectal cancer in North America each year. Although regular screening is strongly advised, the diagnostic tools for colorectal cancer are invasive and costly, and thus underused
- Miraculins has conducted studies in this area in collaboration with the European Tumour Sample Institute gGmbH, and Fox Chase Cancer Center.
- Miraculins' lead biomarker for colorectal cancer (known as MIR-CR1) has been identified by amino acid sequence, and the next step for this program involves the development of a clinical grade immunoassay for the marker.

### **Gastric Cancer Program**

- In 2008, the Company conducted an internal review of its gastric cancer program focusing on data sets of 171 samples (92 gastric cancer from stage 1 to stage 4, 79 non gastric cancer) collected at European sites, and 93 samples (72 gastric cancer from stage 1 to stage 4, 21 non gastric cancer) collected from a number of North American sites.
- Data analysis was conducted using a variety of statistical techniques including the receiver operator characteristic (ROC) curve. A perfect result with a ROC curve is an area under the curve (AUC) of 1.0 (therefore a sensitivity of 100% and specificity of 100%).
- The internal review confirmed seven blood based protein biomarkers of interest for their potential to separate gastric cancer patients from non gastric cancer patients. This included a single marker that performs with a 72% sensitivity at 95% specificity (AUC=0.925) known as MIR-GP1.
- There are over 22,000 new cases of gastric cancer diagnosed each year in the United States. Current diagnostic
  methods include gastroscope, barium x-rays, endoscopic ultrasound, and endoscopic biopsy; all of which are
  invasive and therefore suffer from low compliance.
- The market for a diagnostic in this cancer area is predominantly based on providing a general screen for the disease targeted at patients who have either a predisposition to this cancer or are in a high risk group.
- The next steps for this program involve identifying these markers through protein purification and amino acid sequencing, beginning with MIR-GP1.

## **Pancreatic Cancer Program**

- There are over 33,000 new cases of pancreatic cancer diagnosed each year in the United States with over 32,000 deaths resulting.
- Current diagnostic methods are limited to MRI, CT or CAT scan, ultrasound, barium x-ray or biopsy. There is an unmet need for a simple assay that would help to diagnose this disease in its earliest and most treatable stages.
- Miraculins has intellectual property related to pancreatic cancer markers that requires further research.

## **New Program Opportunities**

Miraculins is continually evaluating in license/acquisition opportunities in areas where there are unmet clinical diagnostic and risk assessment needs. Miraculins has evaluated and catalogued over 500 opportunities and has had numerous licensing discussions in regards to a number of promising technologies. Diagnostic technologies of greatest interest to the Company have completed discovery stage research and biomarker identification but require additional expertise and resources to be developed into validated commercially viable assays.

**Management's Discussion and Analysis** 



### **OUTLOOK**

The strategic direction of the Company is centered on the acquisition, development and commercialization of diagnostic and risk assessment tests for unmet clinical needs. In order to advance these research programs, Miraculins expects to continue incurring operating losses. Based on current projections and strategic plans, management expects expenses will increase in fiscal 2011, as compared to fiscal 2010. Any increase in expenditures would result from the continued development of current technology programs and the potential addition of complementary technologies.

The Company's financial statements have been prepared using Canadian generally accepted accounting principles ("Canadian GAAP") that are applicable to a going concern, which contemplates that Miraculins will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the normal course of business. There is substantial doubt about the appropriateness of the use of the going concern assumption because the Company has experienced operating losses and cash outflows from operations since incorporation and has not reached successful commercialization of its products.

The Company's future operations are dependent upon its ability to generate product sales, negotiate collaboration or license agreements with upfront payments, obtain research grant funding, and secure additional funds. While the Company is striving to achieve these plans, there is no assurance that these and other strategies will be achieved or such sources of funds will be available or obtained on favourable terms or obtained at all. If the Company cannot generate product sales, negotiate collaboration or license agreements with upfront payments, obtain research grant funding, or if it cannot secure additional financing on terms that would be acceptable to it, the Company will have to consider additional strategic alternatives which may include, among other strategies, exploring the monetization of certain intangible assets as well as seeking to outlicense assets or potential asset divestitures.

The ability of the Company to continue as a going concern and to realize the carrying value of its assets and discharge its liabilities and commitments when due is dependent on the successful completion of the actions taken or planned, some of which are described above, which management believes will mitigate the adverse conditions and events which raise doubt about the validity of the going concern assumption used in preparing these financial statements. There is no certainty that these and other strategies will be sufficient to permit the Company to continue as a going concern.

The Company's financial statements do not reflect adjustments in the carrying values of assets and liabilities, expenses, and the balance sheet classification used, that would be necessary if the going concern assumption were not appropriate. Such adjustments could be material.

Based on current estimates and expected operating activities, management believes the Company has sufficient financial resources to fund operations into the fourth guarter of the 2011 fiscal year.

The Company may decide to accelerate, terminate or reduce its focus in certain research areas, or commence research in new areas as a result of the Company's research progress and the availability of financial resources. These decisions are made with the goals of managing the Company's cash resources and optimizing the Company's opportunities. The availability of funding may change management's strategy over the coming year.

## **RISKS AND UNCERTAINTY**

The Company operates in a highly competitive environment that involves significant risks and uncertainties, some of which are outside of the Company's control. The Company is subject to risks inherent in the biotechnology industry, including:

#### Risks Related to the Company's Financial Condition

• The Company has not derived any revenue to date from the commercial sale of its diagnostic products. In light of the length of time and expense associated with bringing new products through commercialization, obtaining regulatory approval and bringing products to market, operating losses are expected to continue.

## **Management's Discussion and Analysis**



- The Company has mainly relied on equity financing and grant funding to support operations and will continue to need significant amounts of additional capital that may not be available to the Company on favourable terms, and may be dilutive.
- The Company may fail to obtain additional financing and be unable to fund operations and commercialize its product candidates.

The Company intends to raise additional financing, as required, through research, partnering and licensing arrangements, the exercise of warrants and options, and through equity and/or debt financing. However, there can be no assurance that these financing efforts will be successful or that the Company will continue to be able to meet ongoing cash requirements. It is possible that financing will not be available or, if available, may not be on favourable terms. The availability of financing will be affected by the results of scientific and clinical research, ability to attain regulatory approvals, the market acceptance of the Company's products, the state of the capital markets generally (with particular reference to pharmaceutical, biotechnology and medical companies), the status of strategic alliance agreements, and other relevant commercial considerations.

## Risks Related to the Company's Business and Operations

- The Company is in various stages of development of diagnostic and risk assessment products and, as a result, is
  unable to predict whether it will be able to profitably commercialize its products.
- Failure to protect intellectual property, or infringement on the intellectual property rights of others, may impede the Company's ability to operate freely.
- The Company's business is subject to significant government regulation and failure to achieve regulatory approval
  of diagnostic products would negatively affect its business.
- The Company is dependent on strategic partners, including clinical investigators and contract research
  organizations, as part of its diagnostic product development strategy, and it would be negatively affected if it is
  not able to initiate or maintain these relationships.
- The Company may be dependent on others for the manufacture, development and sale of its products. If the
  Company is unable to establish or manage collaborations in the future, there could be a delay in the manufacture,
  development and sale of products.
- Even if product candidates receive all of the required regulatory approvals, there is no guarantee of market
  acceptance or commercialization of the resulting product candidates, which will be determined by the Company's
  sales, marketing and distribution capabilities and the positioning and competitiveness of its diagnostic product
  compared with any alternatives.
- The Company's industry is characterized by rapid change and a failure by the Company to react to these changes
  could have a material adverse effect on its business.
- The Company may conduct development internationally and may be subject to laws and regulations of several
  countries which may affect the Company's ability to access regulatory agencies and may affect the enforceability
  and value of the Company's licenses and intellectual property.
- If the Company fails to hire or retain needed personnel, the implementation of its business plan could slow and future growth could suffer.

Miraculins views patents and other means of intellectual property protection as essential to the Company's core business by protecting the Company's proprietary technology from infringement by competitors. To that end, patents will be reviewed and continued to be sought in relation to those components or concepts of each of its pre-clinical and clinical diagnostic products by management of the Company to ensure the highest level of protection possible is obtained. The Company requires all employees, consultants, and parties to collaborative research agreements to execute confidentiality agreements upon the commencement of employment, consulting relationships or a collaboration with the Company. These agreements require that all confidential information developed or made known during the course of the engagement

## **Management's Discussion and Analysis**



with Miraculins is to be kept confidential. The Company also maintains agreements with scientific staff and all parties contracted in a scientific capacity, providing that all inventions resulting from work performed for Miraculins, using Miraculins' property, or relating to Miraculins' business and conceived or completed during the period covered by the agreement are the exclusive property of the Company.

### Risks Relating to the Company's Common Shares

- The Company has not paid any cash dividends on its common shares and, for the foreseeable future, the Company does not intend to pay any cash dividends on its common shares and therefore its shareholders may not be able to receive a return on their shares unless they sell them.
- The market price and trading volume of the Company's common shares may be volatile. In addition, variations in
  earnings estimates by securities analysts and the market prices of the securities of our competitors may also lead
  to fluctuations in the trading price of the common shares.
- The significant costs that the Company will incur as a result of being a public company in Canada could adversely
  affect its business.

To date, no dividends have been declared or paid on the common shares, and it is not expected that dividends will be declared or paid in the immediate or foreseeable future. The policy of the Board of Directors of the Company is to reinvest all available funds in operations. The Board of Directors may reassess this policy from time to time. Any decision to pay dividends on the common shares of Miraculins will be made by the Board of Directors based on the assessment of, among other factors, earnings, capital requirements and the operating and financial condition of the Company.

### SELECTED QUARTERLY FINANCIAL INFORMATION

The selected financial information provided in the table below is derived from the unaudited quarterly financial statements for each of the last eight quarters (in \$'s):

	Q2 - 2011	Q1 - 2011	Q4 - 2010	Q3 - 2010	Q2 - 2010	Q1 - 2010	Q4 - 2009	Q3 - 2009
Loss for the period	(352,764)	(309,300)	(406,924)	(565,714)	(268,495)	(187,677)	(197,801)	(213,497)
Investment income	3,102	2,044	2,187	846	725	167	816	1,339
Loss per share	(0.01)	(0.00)	(0.01)	(0.01)	(0.01)	(0.00)	(0.01)	(0.01)

It is important to note that historical patterns of expenditures cannot be taken as an indication of future expenditures. The amount and timing of expenditures, and therefore liquidity and capital resources, may vary substantially from period to period depending on the business and research activities being undertaken at any one time and the availability of funding from investors and prospective commercial partners.

The Company's cumulative quarterly loss over the past two years relates primarily to the expansion of the Company's research programs. The increased loss for Q4 and Q3 2010, as compared to preceding quarters, is primarily due to the professional fees and other costs related to the acquisition of PreVu assets.



### **RESULTS OF OPERATIONS**

## Research and development

Research and development expenditures include costs associated with the Company's research programs, the significant portion of which are salaries paid to research staff, equipment rental, consumables, and consulting. The Company is in the development stage and devotes a significant portion of its financial resources to research activities.

The changes in research and development expenditures, including stock-based compensation, for the six month periods ended May 31, 2011 and 2010 are reflected in the following table:

Six month periods ended May 31,	2011	2010	Increas	e (decrease)
Compensation related costs Consumables Contract research and scientific consulting Laboratory rent and occupancy costs PreVu Non-Invasive Cholesterol test Other research costs less: Government assistance	\$ 54,423 9,822 26,397 18,942 122,092 9,616 (7,987)	\$ 97,381 23,994 6,123 26,893 - 10,896 (42,826)	\$	(42,958) (14,172) 20,274 (7,951) 122,092 (1,280) 34,839
Total research and development	\$ 233,305	\$ 122,461	\$	110,844

As expected, research and development expenditures for the six month period ended May 31, 2011 were higher as compared to the same period in 2010. This net increase can be attributed to the following factors:

- Compensation related costs are lower due to a decrease in research staff as compared to the same period in the prior year.
- The Company required fewer consumables as part of its laboratory based activities related to its preeclampsia programs as compared to the same period in the prior fiscal year.
- The Company incurred certain scientific consulting costs related to its preeclampsia project supported by the Canada-Israel Industrial Research and Development Foundation (CIIRDF). No similar costs were incurred in the same period of the prior year.
- Upon expiry of its laboratory lease, the Company negotiated a reduction in total square footage rented as part of its new lease agreement.
- In 2010, the Company acquired assets related to the PreVu Non-Invasive Cholesterol test. Costs incurred in the current period were directly related to development activities of this technology.
- The decrease in other research costs is primarily related to lower overhead allocations related to the Company's preeclampsia project supported by CIIRDF as compared to the same period of the prior year.
- Government assistance relates to the cooperation and project funding agreement with CIIRDF. The Company receives funding to offset \$1 for every \$2 spent on research on the project.

The Company expects increased levels of research and development expenditures for the remainder of the fiscal year.

### **Management's Discussion and Analysis**



### **General and Administration**

General and administration expenses include those costs not directly related to research and development activities. This includes expenses associated with management services, and professional fees such as legal, audit and investor and public relations activities.

The changes in general and administration expenditures, including stock-based compensation, for the six month periods ended May 31, 2011 and 2010 are reflected in the following table:

Six month periods ended May 31,	2011			2010		
Compensation related costs Wages, consulting fees, and benefits Stock compensation related costs Business development costs Other administration costs	\$ 172,920 40,632 150,376 82,135	\$	74,740 1,610 193,830 78,707	\$	98,180 39,022 (43,454) 3,428	
Total general and administration	\$ 446,063	\$	348,885	\$	97,178	

The increase in costs for the six month period ended May 31, 2011 as compared to 2010 can be attributed to the following factors:

- The increase in wages, consulting fees, and benefits is primarily related to the appointment of new executive team members.
- The increase in stock compensation related costs is related to the granting of stock options to certain of the Company's management, directors and employees. There ware no comparable grants in the same period of the prior year.
- The decrease in business development costs is related to a decrease in investor communication fees, as compared
  to the same period of the prior year.
- The increase in other administration costs is primarily due to an increase in professional fees, as compared to the same period of the prior year.

The Company expects similar levels of general and administration expenditures for the remainder of the fiscal year when compared to the first six months of the fiscal year.

## Other Income

The changes in other income for the six month periods ended May 31, 2011 and 2010 are reflected in the following table:

Six month periods ended May 31,		2011 2010				
Collaborative research and option fees Investment and other income	\$ \$	46,427 5,146	\$ \$	38,689 894	\$ \$	7,738 4,253
Total Other Income	\$	51,573	\$	39,583	\$	11,990

The increase in other income for the current six months is the result of a higher average cash balance as compared to the same period in the prior year. In addition, the Company recognized fees received as part of the collaborative research and





option agreement with Alere Inc. The Company anticipates higher levels of investment income for the remainder of the fiscal year resulting from higher average cash on hand.

### Loss and comprehensive loss for the year

The loss and comprehensive loss for the six month periods ended May 31, 2011 and 2010 is reflected in the following table:

Six month periods ended May 31,		2011		2010		Increase	
Loss and comprehensive loss for the period Loss per share	\$ \$	662,065 0.01	\$ \$	456,172 0.01	\$ \$	205,893	

As discussed above, the increase in loss during the period resulted mainly from higher compensation costs, professional fees and PreVu development activities.

### LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed its operations from public and private sales of equity, the exercise of warrants and stock options, interest income on funds available for investment, government grants and tax credits. As at May 31, 2011, the Company had unrestricted cash totaling \$556,720 as compared with \$126,825 at November 30, 2010.

## Cash used in operating activities

Cash used in operating activities totaled \$810,928 for the six months ended May 31, 2011 from ongoing research and development programs as well as general and administration activities, compared to cash used by operating activities of \$260,961 for the same period in fiscal 2010.

### Cash used in investing activities

Cash used in investing activities totaled \$48,656 for the six months ended May 31, 2011. Of this amount, \$46,807 was for patent costs and \$1,849 was for the acquisition of property and equipment. In the previous fiscal year, cash used in investing activities totaled \$19,302. Of this amount, \$15,155 was for patent costs and \$4,147 was for the acquisition of property and equipment.

## Cash from financing activities

For the six months ended May 31, 2011, cash provided from financing activities totaled \$1,289,478. Of this amount, \$4,565 was for repayment of obligation under capital lease and \$1,294,043 was from the issuance of shares and the exercise of warrants. In the previous fiscal year, cash provided from financing activities totaled \$461,507. Of this amount, \$4,343 was for repayment of obligation under capital lease and \$465,850 was from the issuance of shares and the exercise of warrants.

### Shares, options and warrants

On December 15, 2010, the Company closed a non-brokered private placement offering (the "Q1 2011 Offering") with aggregate gross proceeds to the Company of \$730,000 from the sale of 6,083,331 units ("Units") at a price of \$0.12 per Unit. Each Unit is comprised of one common share of the Company (a "Share") and one half of one Share purchase warrant (a "Warrant"). Each Warrant entitles the holder to purchase one Share at a price of \$0.18 per Share for a period of 12 months from the date the Warrant is issued. The Warrants are callable, at the option of the Company, at any time after six months following their issuance, in the event that the Shares trade at or above \$0.25 per Share for any five out of 10 consecutive trading days. The net proceeds of the Offering are being used for research and development and working capital purposes.



On March 11, 2011, the Company announced the receipt of gross proceeds equal to \$554,000 from the exercise of 5,540,000 warrants through the Company's previously announced warrant exercise incentive program (the "Exercise Program"). Under the terms of the Exercise Program, each exercised warrant entitled the holder thereof (the "Warrantholder") to receive one common share of the Company (a "Common Share") and one-half of one common share purchase warrant, with each whole additional common share purchase warrant (each an "Incentive Warrant") entitling the holder to purchase a Common Share. Each Incentive Warrant will be exercisable at a price of \$0.18 from the date of issue until December 15, 2011. The Company issued 5,540,000 common shares and 2,770,000 Incentive Warrants to Warrantholders in exchange for the warrants that were exercised under the Exercise Program.

	July 29, 2011	May 31, 2011	November 30, 2010
Common shares issued and outstanding	67,994,157	67,694,157	54,634,826
Options outstanding	4,900,000	4,650,000	4,270,000
Warrants outstanding	8,208,332	8,508,332	12,486,000

The Company believes it has sufficient resources available to satisfy operating requirements into the fourth quarter of fiscal 2011. The Company's management may consider all financing alternatives and may seek to raise additional funds for operations from current stockholders and other potential investors. This disclosure is not an offer to sell, nor a solicitation of an offer to buy the Company's securities. Where the Company opts to pursue such financing, there is no assurance that funding will be available or obtained on favourable terms.

## **CONTRACTUAL OBLIGATIONS**

The Company periodically enters into long-term contractual agreements for the lease of laboratory facilities and equipment, management services, and certain purchased services. The following table presents commitments arising from agreements currently in force over the next five years.

	Payments due by Period							
		Within 1 year		2 - 3 years		4 - 5 years		Total
Management services agreement Contractual commitments Capital lease Accounts payable and accrued liabilities Due to related party	\$	160,000 78,333 5,160 122,714 179,318	\$	- 80,000 17,461 - -	\$	- 40,000 - - -	\$	160,000 198,333 22,621 122,714 179,318
	\$	545,525	\$	97,461	\$	40,000	\$	682,986

A summary of the Company's contractual obligations may be found in Note 12 of the unaudited interim financial statements for the six months ended May 31, 2011.

## RELATED PARTY TRANSACTIONS

Related parties consist of companies with significant influence, and companies in which certain directors, officers, or shareholders have interests. These transactions are in the normal course of operations and are measured at the exchange amount, which is the amount of consideration established and agreed upon by the related parties.

Related party transactions incurred during the six month period ended May 31, 2011 and 2010 are as follows:





	Ма	y 31, 2011	Ма	ıy 31, 2010
eneral and administration Business and administrative services				
Business and administrative services	\$	80,000	\$	100,000
Interest on due to related party		13,835		25,673
Research and development				
Rent		15,000		23,125
Clinical research services		62.698		4.989
Scientific equipment lease		5,160		-

The Chief Financial Officer's services are provided through the business and administrative services agreement with Genesys Venture Inc. (the "GVI Agreement"). In addition, intellectual property, accounting, payroll, human resources and information technology services are provided to the Company through the GVI agreement.

Clinical and research services are provided through a consulting agreement with CanAm Bioresearch Inc. (CanAm). Regulatory affairs, quality assurance and clinical support are provided to the Company through a consulting agreement with GVI Clinical Development Solutions Inc. (CDS).

As of May 31, 2011, \$179,318 (November 30, 2010 - \$255,125) is owed to Genesys Venture Inc. which bears interest of 12% per annum, calculated and compounded on a monthly basis and has no specific terms of repayment.

Included in accounts payable and accrued liabilities as of May 31, 2011 is \$13,516 (November 30, 2010 - \$12,494) owed to CDS and nil (November 30, 2010 - \$12,915) owed to CanAm, neither of which were interest bearing or had any specific terms of repayment.

### **OFF-BALANCE SHEET ARRANGEMENTS**

Other than as described above, the Company does not have any off-balance sheet arrangements.

## **CONTROLS**

## Effectiveness of disclosure controls and procedures

Management has established and maintained disclosure controls and procedures for the Company in order to provide reasonable assurance that material information relating to the Company is made known to management in a timely manner and that information required to be disclosed by the Company is reported within the time periods prescribed by applicable securities legislation.

A control system can only provide reasonable, not absolute, assurance that the objectives of the control system are met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs.

As a result of the Company's limited administrative staffing levels, internal controls which rely on segregation of duties in many cases are not appropriate or possible. Due to resources constraints and the present stage of the Company's development, the Company does not have sufficient size and scale to warrant the hiring of additional staff to correct this potential weakness at this time. To help mitigate the impact of this potential weakness and to ensure quality financial reporting, the Company is highly reliant on the performance of compensating procedures and senior management's review and approval to ensure that the controls are as effective as possible.

During the six months ended May 31, 2011, the Company made no material changes to its systems of internal controls over financial reporting.

**Management's Discussion and Analysis** 



#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in conformity with Canadian generally accepted accounting principles (Canadian GAAP) requires the Company to select from possible alternative accounting principles and to make estimates and assumptions that determine the reported amounts of assets and liabilities at the balance sheet date, and reported costs and expenditures during the reporting period. Management believes that the estimates and assumptions upon which the Company relies are reasonable based upon information available at the time these estimates and assumptions are made. Estimates and assumptions may be revised as new information is acquired, and are subject to change.

In addition to the going concern assumptions described above, management believes that its most critical policies and estimates relate to the following areas, with reference to notes contained in the audited financial statements for the year-ended November 30, 2010:

## Research and development costs

The Company's accounting policy over research and development costs may be found in Note 2(h) to the audited financial statements for the year-ended ended November 30, 2010. Research expenditures are expensed as incurred. Development expenditures are deferred when they meet the criteria for capitalization in accordance with Canadian GAAP, and the future benefits could be regarded as being reasonably certain. Related tax credits are accounted for as a reduction to research and development expenditures on the condition that the Company is reasonably certain that these credits will materialize.

## Intangible assets

The Company's accounting policy over intangible assets may be found in Notes 2(d) and 2(e) to the audited financial statements for the year-ended ended November 30, 2010. Intangible assets are reviewed for impairment on an ongoing basis whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment is recognized when the carrying amount of an asset to be held and used exceeds the projected undiscounted future net cash flows expected from its use and disposal, and is measured as the amount by which the carrying amount of the asset exceeds its fair value. Triggering events for reviews for impairment typically include abandonment of patent applications which result in the related asset being written down to a nil value.

## Stock-based compensation

The Company's accounting policy over stock-based compensation may be found in Notes 2(i), 11(c) and 11(d) to the audited financial statements for the year ended November 30, 2010. Where the Company issues warrants and stock options (to its employees, directors and officers), a fair value is derived using the Black-Scholes pricing model. The application of this pricing model requires Management to make assumptions regarding several variables, including the expected life of the options and warrants, the price volatility of the Company's stock over a relevant timeframe, the determination of a relevant risk-free interest rate and an assumption regarding the Company's dividend policy in the future.

A summary of all of the Company's significant accounting policies and estimates may be found in Note 2 to the audited financial statements for the year-ended November 30, 2010.

#### **CHANGES IN ACCOUNTING POLICIES**

### 1. New Accounting Standards adopted during the period:

There were no changes in Accounting Policies during the period.

**Management's Discussion and Analysis** 



## 2. International Financial Reporting Standards (IFRS) Changeover Plan:

In 2006, the Canadian Accounting Standards Board (AcSB) published a new strategic plan that will significantly affect financial reporting requirements for Canadian companies. The Company's first IFRS financial statements will be for the fiscal year ending November 30, 2012 and will include the comparative period for fiscal 2011.

The Company is in the process executing its implementation plan which identifies key activities to occur leading up to the changeover. The Company is nearing completion of detailed gap assessment of the current differences between Canadian GAAP and IFRS applicable to the Company. A summary analysis indicates that in most cases, the Company would opt for a prospective application when the choice is available. The Company needs to finalize its accounting policy choices within IFRS and assess its elective options under first-time adoption of IFRS.

The Company is nearing completion of necessary scoping and diagnostic activities and continues to analyze certain aspects related to the current Canadian GAAP to IFRS conversion, and is in the process of developing mock financial statements in accordance with IFRS standards.

### FORWARD-LOOKING STATEMENTS

This Management's Discussion and Analysis ("MD&A") contains forward-looking information as defined in applicable securities laws (referred to herein as "forward-looking statements") that reflect the Company's current expectations and projections about its future results. All statements other than statements of historical fact are forward-looking statements. Forward-looking statements are based on the current assumptions, estimates, analysis and opinions of management of the Company made in light of its experience and its perception of trends, current conditions and expected developments, as well as other factors which the Company believes to be relevant and reasonable in the circumstances.

The Company uses words such as "believes," "may," "plan," "will," "estimate," "continue," "anticipates," "intends," "expects," and similar expressions to identify forward-looking statements, which, by their very nature, are not guarantees of the Company's future operational or financial performance, and are subject to risks and uncertainties, both known and unknown, as well as other factors that could cause the Company's actual results, performance, prospects or opportunities to differ materially from those expressed in, or implied by, these forward-looking statements.

Specifically, this MD&A contains forward-looking statements regarding, but not limited to, the Company's:

- intention to acquire, develop and commercialize diagnostic tests for unmet clinical needs;
- intention to partner with large diagnostic companies and reference laboratories to commercialize and market technology;
- expectation regarding collaborative research agreements, upfront payments, milestone payments, ongoing royalties on sales and other sources of revenue:
- expectation regarding new diagnostic program opportunities;
- intentions regarding the protection of intellectual property;
- · business strategy; and
- intention with respect to dividends.

Inherent in forward-looking statements are known and unknown risks, uncertainties and other factors beyond the Company's ability to predict or control that may cause the actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such risk factors include, among others, the Company's stage of development, lack of product revenues, additional capital requirements, the ability to protect its intellectual property, dependence upon collaborative partners, changes in government regulation or regulatory approval processes, and rapid technological change in the industry. These factors should be considered carefully and readers are cautioned not to place undue reliance on such forward-looking statements.

Actual results and developments are likely to differ, and may differ materially, from those expressed or implied by the forward-looking statements contained in this MD&A. Such statements are based on a number of assumptions which may prove to be incorrect, including, but not limited to, assumptions about:

### Management's Discussion and Analysis



- the availability of financing for the Company's research and development projects, or the availability of financing on reasonable terms;
- · general business and economic conditions;
- the timing of the receipt of regulatory and governmental approvals for the Company's research and development projects;
- interest rates and foreign exchange rates;
- the Company's costs of research projects;
- positive results of current and future clinical trials;
- the uncertainties associated with the acceptance and demand for new products;
- research projects will not be unreasonably delayed and expenses will not increase substantially;
- government regulation will not impose requirements that significantly increase expenses or that delay or impede the Company's ability to bring new products to market;
- the Company's ability to attract and retain skilled staff;
- the impact of changes in Canadian-US dollar and other foreign exchange rates on the Company's costs and results;
- · market competition;
- tax benefits and tax rates; and
- the Company's ongoing relations with its employees and with its business partners.

Although management of the Company believes that these forward-looking statements are based on reasonable assumptions, a number of factors could cause the actual results, performance or achievements of the Company to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements contained in this MD&A and any documents incorporated by reference herein are expressly qualified by this cautionary statement. The Company cautions you that the foregoing list of important factors and assumptions is not exhaustive. Events or circumstances could cause actual results to differ materially from those estimated or projected and expressed in, or implied by, these forward-looking statements. You should also carefully consider the matters discussed under "Risk Factors" in this MD&A which provides for additional risks and uncertainties relating to the Company and its business. The Company undertakes no obligation to update publicly or otherwise revise any forward-looking statements or the foregoing list of factors, whether as a result of new information or future events or otherwise, other than as may be required by applicable legislation.