Managements' Discussion and Analysis (Expressed in Canadian Dollars)

# **MIRACULINS INC.**

Three and six months ended May 31, 2013

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 26, 2013 and should be read in conjunction with the unaudited condensed interim financial statements for the three and six month periods ended May 31, 2013, which have been prepared under International Financial Reporting Standards ("IFRS"). Except as otherwise noted, the financial information contained in this MD&A and in the condensed interim financial statements has been prepared in accordance with IFRS. 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 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 technologies 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 two primary technology programs are in the areas of cardiovascular disease and maternal health. Miraculins cardiovascular disease program is focused on the PreVu® Non-Invasive Skin Cholesterol Test ("PreVu"), a non-invasive tool for risk assessment of coronary artery disease ("CAD"). Miraculins has been working independently and with distribution partners to develop markets for PreVu. Upon the commencement of the commercial rollout of PreVu, which occurred during the first quarter of fiscal 2013, Miraculins earned the first commercial revenue for PreVu. The Company's maternal health program is centred on a suite of markers for preeclampsia. In 2010, Miraculins partnered its preeclampsia program with Alere, Inc., one of the world's largest diagnostic companies. Alere diligently advanced the markers subject to a Collaborative Research and Option Agreement and in January 2013 exercised its exclusive option and licensed the novel biomarker Endoglin, concluding the collaborative program. On March 11, 2013, Miraculins announced that it plans to add to its suite of maternal health biomarkers by signing a non-binding term sheet to license methods and reagents for detecting hydroxylated Hypoxia Inducible Factor 1 alpha ("HIF-1aOH"), a promising biomarker with potential in differentiating high and low risk pregnancies, including risk of preeclampsia.

Miraculins continues to evaluate new licensing and acquisition opportunities that fit strategically with the Company's business model, while remaining focused on the commercial roll-out of the Company's PreVu technology, which has transitioned Miraculins into a sales and marketing organization. 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 commercial products or achieve their commercial potential. The Company is currently working towards the conclusion of its acquisition of its newest technology program, a ground breaking, non-invasive diabetes screening technology called the Scout DS® (the "SCOUT DS").

Historically, the Company has continually accessed capital during difficult market conditions, having completed private placement and debt financings, and obtained non-dilutive grant funding to advance its programs to fund general operating, ongoing product development, inventory and sales and marketing related costs, including a \$1.1 million financing that closed on April 8, 2013. Miraculins continues to work to selectively advance the critical aspects of its development programs while obtaining the appropriate financing, collaboration and/or license agreements necessary to apply greater resources to its programs. Based on management's current estimates and expected operating activities, sufficient financial resources exist to fund operations into the fourth quarter of fiscal 2013.

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Management has forecast that its expected expenditure levels and contracted commitments will exceed the Company's net cash flows and working capital early in the fourth quarter of fiscal 2013 unless further financing is obtained. The Company's future operations including the completion of the launch of its products are dependent upon its ability to secure additional funds, generate product sales, negotiate collaboration or license agreements with upfront payments, and/or obtain research grant funding. 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. Historically, the Company has obtained funding via the issuance of shares and warrants and long-term debt and expects to require additional capital early in the fourth quarter of fiscal 2013. If the Company cannot secure additional financing on terms that would be acceptable to it, generate product sales, negotiate collaboration or license agreements with upfront payments, and/or obtain research grant funding, the Company will have to consider additional strategic alternatives which may include, among other strategies, cost curtailments, delays of product launch expenditures, exploring the monetization of certain intangible assets, as well as seeking to outlicense and/or divest assets.

On December 20, 2012, the Company announced that London Drugs, one of Canada's leading pharmacy chains will be expanding its offering of the PreVu Point of Care (POC) Test to pharmacy locations in major markets throughout western Canada, which has now been completed. Management plans to review the results of the rollout which tested single day clinics, as opposed to making the test available as a regular offering on an on-going basis. Other metrics such as pricing, the impact of in-store promotional material, customer experience and physician follow-up are also planned for review. The rollout includes a period of market exclusivity for London Drugs in delivering the technology through its retail pharmacy platform into the western Canadian marketplace and follows a successful pilot program in eleven London Drugs location that occurred in October and November of 2012. During the pilot launch, the PreVu POC Test was made available for a special introductory price of \$19.99 and was performed in-store by London Drugs pharmacists.

On January 7, 2013, the Company announced that PharmaChoice, one of Canada's largest pharmacy networks comprised of over 350 independently-owned stores, will be the first pharmacy network to introduce the PreVu POC Test in Ontario and Atlantic Canada, through a Phase One launch in up to 50 of its stores in the first half of 2013. This introductory campaign will see the PreVu POC test conducted in-store by PharmaChoice pharmacists as part of a series of special PreVu Cardiovascular Risk Assessment Clinics. Phase Two of the expansion is expected to see additional PharmaChoice locations being added, with the goal of all participating stores transitioning to offering PreVu testing as an ongoing risk assessment service available either through walk-up request or by appointment.

On January 10, 2013, the Company announced that Alere has exercised its exclusive option and licensed the novel biomarker Endoglin from the Company, concluding a three-year Collaborative Research and Option Agreement program. As the license agreement covers only Endoglin, the Company has agreed to certain amendments to the original terms of the license agreement, including a reduced option exercise price and a modification of milestones and payments. Upon commercialization of Endoglin products by Alere, the Company will receive ongoing royalties on sales pursuant to terms set out in the license agreement. Additionally, the Company maintained its rights to pursue complementary commercial strategies for the Endoglin biomarker, utilizing certain Alere controlled intellectual property and reagents.

On January 28, 2013, the Company provided the market with an overview of its plans for its PreVu technology for the 2013 year. The Company announced that the coming year is expected to be one of potential growth, and one of market development. The Company also walked through its plans for the four principal market segments for PreVu, namely: Retail Pharmacy, Primary Care Physicians, Life Insurance, and Health and Wellness Service Providers. Revenue from PreVu was earned in the first guarter of fiscal 2013 upon the commencement of the commercial rollout of PreVu.

On February 4, 2013, the Company announced that it was to receive the Life Science Company of the Year Award from the Life Science Association of Manitoba at an awards ceremony that was held on February 13, 2013. The award is presented annually to a private sector company based in Manitoba that has made a positive impact on the life sciences sector in the past year as is active in paving the road toward future wealth and job creation in the province.

On February 12, 2013, the Company announced the start of a pilot study to measure skin cholesterol levels in patients beginning statin therapy. The pilot study, sponsored by the Company is being conducted at the Winnipeg Clinic and will measure skin cholesterol levels using the PreVu Lab Processed Test. The study is designed to assess the degree of correlation between changes in skin cholesterol and serum cholesterol during statin treatment, and how statin treatment impacts skin cholesterol levels based on measurements taken at multiple time points over a six-month period.

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On February 19, 2013, the Company announced the appointment of two key members to its international market development team, to help guide the Company's efforts in developing international markets for its PreVu technology. The Company has engaged Mr. Charles G. Nell and Mr. Paul Mordente, both proven pharmaceutical sales executives and business development leaders, who will focus their efforts on the United States and the United Kingdom/European Union, respectively, with the primary goal of introducing PreVu into the retail pharmacy segments in those territories. Additional goals of the international market development team are to support the Company's efforts in general market development activities in these markets including identifying and evaluating potential distribution partners, evaluating distribution alternatives and facilitating meetings with key industry members with the objective of establishing and ultimately growing sales in international markets across multiple segments.

On March 11, 2013, the Company announced its plans to add to its suite of maternal health biomarkers under license from Mount Sinai Hospital's Samuel Lunenfeld Research Institute by signing a term sheet to license certain intellectual property, methods and reagents for detecting hydroxylated Hypoxia Inducible Factor 1 alpha ("HIF-1aOH"), a promising biomarker with potential in differentiating high and low risk pregnancies, including risk of preeclampsia. The technology is part of the pioneering research on preeclampsia and placental development being conducted by Dr. Isabella Caniggia, Senior Investigator at the Samuel Lunenfeld Research Institute, in collaboration with Dr. Martin Post, a senior scientist at the Hospital for Sick Children. In addition to its promise in maternal health and preeclampsia, HIF-1aOH also presents an opportunity as a cancer biomarker and of further note, the license will include unique monoclonal antibodies highly sensitive to HIF-1aOH and the exclusive rights to manufacture reagents that measure the biomarker using materials developed by Dr. Caniggia. The Company is currently advancing a development plan for a kit to detect and measure HIF-1aOH in bodily fluid, which if successful could lead to near term commercial research use product and allow for more widespread research into utility of this novel biomarker. The ultimate goal for the biomarker development program would be worldwide sales of the biomarker technology, either alone or in combination with other markers, in a diagnostic kit for the early detection of preeclampsia or as a pregnancy risk assessment tool.

On March 15, 2013, in conjunction with Pear Healthcare Solutions, the Company announced the accreditation of a national program for pharmacists with the course name Cardiovascular Risk Assessment: Focus on Non-Invasive Skin Cholesterol Screening. All Canadian pharmacists are under obligation by their respective provincial authorities to engage in lifelong learning and competency enhancements that supports optimal, patient centered, outcome focused care through medication management and effective pharmacy practice. With the national accreditation of the program Canadian pharmacists can now earn credits to meet this requirement by learning about the benefits of providing cardiovascular risk assessment onsite and skin cholesterol's role within that environment as an emerging biomarker in coronary artery disease risk assessment and screening.

On April 8, 2013, the Company announced the closing of a private placement offering (the "Offering") with aggregate gross proceeds to the Company of \$1,050,950 from the sale of 11,677,223 units ("Units") at a price of \$0.09 per Unit. Each Unit was comprised of one common share (a "Share") of the Company and one half of one Share purchase warrant (a "Warrant"). Each Warrant entitles the holder to purchase one Share at a price of \$0.11 per Share for a period of twelve months from the date the Warrant is issued. The net proceeds of the Offering is being used for general corporate purposes including sales and marketing costs related to the Company's PreVu test. Certain persons assisted the Company by introducing potential subscribers for the Offering and were paid a finders' fee of 8% of the total subscription proceeds received from subscribers introduced to the Company by each particular person. Additionally, these person were issued compensation warrants ("Compensation Warrants") equal to 8% of the total number of Units subscribed for by subscribers introduced to the Company by each particular person. Each Compensation Warrant entitles the holder thereof to purchase one Share at a price of \$0.09 per Share for a period of twelve months from the date of issue. The Shares, Warrants and Compensation Warrants will be restricted from transfer for a period of four months and a day from the date of closing in accordance with applicable securities laws.

On June 4, 2013, the Company announced that it has granted an aggregate of 2,475,000 stock options at an exercise price of \$0.10 per Common Share, to certain directors, officers, employees, consultants and management company employees of the Company. The options are set to expire five years from the date of grant.

On July 2, 2013, the Company announced that it had executed a final purchase agreement with VeraLight, Inc. ("VeraLight") on June 28, 2013, to acquire all of the relevant assets, including intellectual property, licenses and regulatory approvals, inventories, data and marketing materials, relating to VeraLight's Scout DS® (the "SCOUT DS") technology, a groundbreaking diabetes screening technology that non invasively measures changes in a person's skin indicative of prediabetes and type 2 diabetes, enabling cost effective, easily accessible screening of those at risk.

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### The SCOUT DS® Acquisition

The SCOUT DS, which in 80 seconds rapidly tests individuals without blood draw or the need to fast and produces immediate results, will be sold individually, as well as on a bundled basis with the PreVu POC Test, as determined by market applications. The SCOUT DS is indicated for use for the non-invasive screening of individuals 18 years or older that are at risk for prediabetes and/or type 2 diabetes.

The SCOUT DS has already received clearance from Health Canada for commercial distribution, has been granted a CE Mark in the European Union, and is also cleared for sale in Mexico. Commercial piloting of the technology has already taken place in Canada, and multiple preliminary distribution channels have also been established or advanced - which Miraculins is reviewing related to renewal and confirmation – including in countries that may recognize Health Canada and CE regulatory clearances such as Saudi Arabia, Qatar, the United Arab Emirates, India, Jordan, Brazil, Turkey and Kuwait.

Miraculins will be reviewing its FDA strategy regarding the SCOUT DS towards seeking US marketing clearance as quickly as possible. In the interim, distribution in the United States of the SCOUT DS system remains limited to investigational use only.

# **Technology and Market Highlights**

- Diabetes is the fastest growing disease in history, although up to 90% of type 2 diabetes is preventable with early detection and intervention.
- By utilizing visible light to non-invasively measure changes in a person's skin indicative of pre-diabetes and type 2 diabetes (by having a patient place their forearm on a portable, table-top instrument that measures Advanced Glycation End Products in the skin), the SCOUT DS finds more pre-diabetics faster, easier and more cost-effectively than all alternative world-standard tests including Fasting Plasma Glucose, Oral Glucose Tolerance, Hemoglobin A1C, and Finger Stick Blood Glucose.
- By 2020 it is estimated that 52% of the U.S. population will have pre-diabetes or type 2 diabetes.
- Over 628 million people worldwide have pre-diabetes or type 2 diabetes, which is projected to grow to 912 million by 2030 (a 45% increase); currently 500 million people in the world have undiagnosed pre-diabetes and undiagnosed type 2 diabetes.
- Complications from diabetes can lead to blindness, kidney disease, cardiovascular disease and amputation.
- Loss of activity further exacerbates the cost of diabetes which impacts healthcare systems worldwide by over \$500 billion (US) annually; Atlanta Centers for Disease Control estimate U.S. diabetes costs exceed \$218 billion (US) annually.

### **Acquisition Highlights**

Miraculins intends to acquire all of the relevant assets, including intellectual property, licenses and regulatory approvals, inventories, data and marketing materials, relating to VeraLight's SCOUT DS technology, in exchange for a combination of cash and Miraculins' common shares.

The purchase price payable by Miraculins to VeraLight pursuant to the purchase agreement will consist of the following:

- a) the payment of \$50,000 on closing and \$100,000 within 90 days of closing;
- b) the issuance to VeraLight of an aggregate of 13,060,315 common shares in the capital of Miraculins (the "Payment Shares") on the earlier of the third anniversary of the closing date and upon the achievement of the \$7 Million Dollar Milestone (as defined below), provided that VeraLight may require the Payment Shares to be issued to it at any time after the first anniversary of closing;
- c) the issuance to VeraLight of the following additional common shares in the capital of Miraculins (together with the Payment Shares, the "Securities"), upon the achievement of the following milestones:

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- i. 1,000,000 common shares upon achievement of cumulative gross revenues in connection with the acquired business of \$1.000.000:
- ii. 3,000,000 common shares upon achievement of cumulative gross revenues in connection with the acquired business of \$3,000,000;
- iii. 3,000,000 common shares upon achievement of cumulative gross revenues in connection with the acquired business of \$5,000,000;
- iv. 3,000,000 common shares upon achievement of cumulative gross revenues in connection with the acquired business of \$7,000,000 (the "\$7 Million Dollar Milestone");
- v. 3,000,000 common shares upon achievement of cumulative gross revenues in connection with the acquired business of \$10,000,000 (the "\$10 Million Dollar Milestone");
- vi. within 30 days of achievement of the \$10 Million Dollar Milestone, such number of common shares equal to 19.9% (after giving effect to the issuance) of the aggregate number of common shares of Miraculins that are issued subsequent to the closing pursuant to the exercise of stock options, warrants and other convertible securities that are issued and outstanding on closing; and
- vii. on each annual anniversary of the achievement of the \$10 Million Dollar Milestone and ending on the anniversary following the exercise or expiry of the last stock options, warrants and other convertible securities that are issued and outstanding on closing, such number of common shares equal to 19.9% (after giving effect to the issuance) of the aggregate number of common shares of Miraculins that are issued during the prior year pursuant to the exercise of stock options, warrants and other convertible securities that are issued and outstanding on closing; and
- d). the assumption of approximately \$20,000 in trade payables owing by VeraLight.

The purchase agreement contains representations, warranties and covenants typical of a transaction of this nature. In addition:

- a) VeraLight agreed that it and its affiliates, collectively, are prohibited from holding in excess of 19.9% of the issued and outstanding shares of Miraculins for a period of 10 years following the closing of the transaction;
- b) Miraculins agreed that for a period of 3 years following closing, and 2 years thereafter provided that VeraLight holds 10% or more of the issued and outstanding shares of Miraculins, it shall include one nominee of VeraLight as part of management's proposed slate of directors to be elected by shareholders of Miraculins at its annual meetings;
- c) Miraculins agreed to grant VeraLight certain rights allowing VeraLight to maintain its proportion of equity ownership in Miraculins by participating in future equity financings for a period of 3 years from closing; and
- d) Miraculins agreed to grant a first ranking security over the assets being purchased to VeraLight to secure the full and timely performance of all of its obligations to VeraLight under the purchase agreement, including the obligation to maintain active manufacturing operations and to invest a minimum amount each fiscal year in the acquired business, until the Payment Shares are issued or the \$7 Million Dollar Milestone is achieved.

The closing of the transaction is subject to regulatory approval relating to the issuance of common shares of Miraculins to VeraLight, and other customary closing conditions. Miraculins expects the transaction to close on or prior to July 27, 2013.

Miraculins will additionally be retaining two key VeraLight personnel who were instrumental in the development of the technology and the manufacturing of the instrumentation, and who will be working for Miraculins towards the continued advancement of the SCOUT DS worldwide.

On July 24, 2013, the Company announced the execution of an agreement with H-E-B, the number one food retailer in South and Central Texas and the State's largest private company, that will see the Phase One launch of the PreVu POC Test into the United States exclusively in 20 H-E-B Texas store locations to be determined during the fourth quarter of calendar 2013. Upon completion of the Phase One launch, H-E-B will have the option to expand PreVu POC testing to additional H-E-B locations commencing in 2014.

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### **Development Program Highlights**

- The Company's PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test is designed to address the worldwide market of coronary artery disease risk assessment. This innovative test measures cholesterol in the skin tissues as a new clinical tool to assist with CAD risk assessment. During fiscal 2012, Miraculins has worked independently and with distribution partners on market development for the Canadian medical professional and Canadian retail pharmacy segments, respectively, and has commenced commercial roll-out in these segments resulting in revenues earned during the first quarter of 2013.
- 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 has been developed through a collaborative research and development partnership with Alere, Inc., one of the world's largest diagnostic companies. Alere has exercised its exclusive option and licensed the novel biomarker Endoglin, concluding a three-year Collaborative Research and Option Agreement program. On March 11, 2013, the Miraculins announced that it plans to add to its suite of maternal health biomarkers by signing a non-binding term sheet to license methods and reagents for detecting hydroxylated Hypoxia Inducible Factor 1 alpha ("HIF-1aOH"), a promising biomarker with potential in differentiating high and low risk pregnancies, including risk of preeclampsia.

#### **Corporate History**

Miraculins began active 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.

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 technologies 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. in January 2010 for development and potential commercialization and Alere has exercised its exclusive option and licensed the novel biomarker Endoglin, in January 2013 concluding the three-year Collaborative Research and Option Agreement program. Miraculins has retained certain commercial rights to pursue complimentary 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. In addition, the Company has the right to seek other developmental and commercial partners for the placental development biomarkers not licensed with Alere. The Company is evaluating opportunities for these other biomarkers. On March 11, 2013, the Miraculins announced that it plans to add to its suite of maternal health biomarkers by signing a non-binding term sheet to license methods and reagents for detecting hydroxylated Hypoxia Inducible Factor 1 alpha ("HIF-1aOH"), a promising biomarker with potential in differentiating high and low risk pregnancies, including risk of preeclampsia.

In late summer 2010, Miraculins completed the acquisition of all assets relating to the PreVu Non-Invasive Skin Cholesterol Test. PreVu is a revolutionary new CAD risk assessment technology that measures cholesterol levels in a patient's skin non-invasively, painlessly and without the need for fasting. Since closing the acquisition of the PreVu technology, Miraculins has been focused on preparing all aspects of the product for market launch and has begun its commercial roll-out of the product through Canadian retail pharmacies in 2013.

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#### **RESEARCH PROGRAMS**

The Company is focused on developing non-invasive diagnostic tests and risk assessment technologies that address unmet clinical needs in various disease areas. As a result of market conditions and the limited availability of investment funding Miraculins has focused its attention primarily on advancing its preeclampsia program and capitalizing on the acquisition of its PreVu program. The Company had previously developed an immunoassay for PSP94 in urine and had intellectual property on PSP94's use in combination with other markers for detecting prostate cancer. The immunoassay for PSP94 is no longer being supported by Miraculins. The Company has been continually reviewing cancer biomarker programs that have been on hold since 2008 with an eye towards out-license, advancing or canceling these programs.

# Coronary Artery Disease Risk Assessment Program (PreVu Non-Invasive Skin Cholesterol Test)

Coronary Artery Disease ("CAD") is a leading cause of death worldwide. CAD 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 of plaque 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 or prevents 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 250 million cholesterol tests are performed per year in the United States. While blood cholesterol remains one of several important risk factors for heart disease, it is widely accepted that multiple risk factors for CAD must be considered to provide a more accurate picture of the absolute risk of disease, which is an individual's risk of experiencing an event over a specific time horizon, generally ten years.

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, are not easily accessible by the broader population or require invasive procedures. In addition, many individuals are still getting through this assessment net, as evidenced by growing incidences of heart attacks worldwide. Therefore, a clear unmet medical need exists for new CAD risk factors to identify hidden risk individuals early and help avoid that critical first coronary event.

In September 2010, Miraculins announced the acquisition of the PreVu Non-Invasive Skin Cholesterol Test technology, a new and non-invasive clinical tool to assist with risk assessment of CAD. As a new risk marker for heart disease, skin cholesterol measurement provides first-stage screening and valuable information to complement traditional CAD risk assessment. Skin contains roughly 11% of the body's cholesterol by weight and ages in parallel with vascular connective tissue. As blood vessel walls accumulate cholesterol, peer reviewed clinical data has shown that so too may skin tissues. An elevated skin cholesterol level is a reliable predictor of the risk of higher cholesterol accumulation in the arteries and, accordingly, the increased risk of heart disease. Elevated levels of skin cholesterol have been shown to be strongly associated with an increased risk of CAD as measured by treadmill stress testing and coronary angiography, as well as by testing for coronary calcium, carotid artery thickening and carotid artery plaque.

The PreVu POC Test is conducted by placing a drop of detector reagent on the palm of the hand, held in place in a small well in a foam pad that adheres to the palm with medical grade adhesive, 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 precisely measure its hue, generating a measure of a patient's skin cholesterol value, which places the patient on a scale showing their risk of CAD based on clinical data for the biomarker. The results are immediately available.

In addition to the POC format of the test, the PreVu technology is also being developed by Miraculins and partner Gamma-Dynacare Medical Laboratories in a lab-processed format called the PreVu Non-Invasive Skin Cholesterol Lab Processed ("LP") Test or the PreVu LP Test. This format of the test has been designed as a simple collection device that allows a patient or administrator to painlessly capture skin cells and cholesterol from the palm of the hand with a medical grade adhesive in about ten seconds. The sample is then sent into a central processing lab for measurement and results reporting.

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The PreVu POC Test has received Health Canada clearance and has been CE-Marked for sale within the European Union. In Canada and the European Union, the PreVu LP Test has been previously cleared for use as part of risk assessment for CAD. In the United States, the PreVu POC Test 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). In the United States, 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.

Miraculins has focused on making the PreVu technology available for commercial sale with the following highlights:

# **Prepared for Commercialization and Met Regulatory Requirements**

- Received formal ISO Certificate of Registration by The BSI Group Inc. designating Miraculins as a medical device
  manufacturer with a certified quality management system
- PreVu® Non-Invasive Skin Cholesterol Point of Care (POC) Test CE Marked and officially registered within the European Union
- PreVu® Non-Invasive Skin Cholesterol POC Test cleared for sale by Health Canada
- Outlined and reiterated details of the FDA's clearance for its PreVu® Non-Invasive Skin Cholesterol POC Test, which was issued prior to Miraculins' acquisition of the PreVu technology and remains in effect in the U.S. marketplace
- Developed and launched an English language Canadian web site for its PreVu® Non-Invasive Skin Cholesterol POC Test at www.prevu.com
- Developed and launched a French language Canadian web site for its PreVu® Non-Invasive Skin Cholesterol Test at www.prevu.com
- Received Notice of Allowance from the United States Patent and Trademark Office for a patent that covers the use of
  spectrophotometric measurements for the non-invasive analysis of skin cholesterol (POC technology) and issued a
  patent by the State Intellectual Property Office of the People's Republic of China that covers use of a tape stripping
  device for skin sampling (LP technology)
- Announced \$130,000 in grant funding from the Manitoba Commercialization Support for Business (CSB) Program to support commercialization of its PreVu® Non-Invasive Skin Cholesterol Test
- Announced the start of a pilot study to measure skin cholesterol levels in patients beginning statin therapy
- Announced the accreditation of a national program for pharmacists with the course name Cardiovascular Risk Assessment: Focus on Non-Invasive Skin Cholesterol Screening

### **Established Distribution Partnerships and Developed Sales Channels**

- Entered into an agreement with Pear Healthcare Solutions Inc., a leading provider of in-pharmacy health screening and education services, that will see the PreVu® Non-Invasive Skin Cholesterol POC Test distributed to the Canadian retail pharmacy market segment
- Successfully completed the retail pharmacy launch of the PreVu® Non-Invasive Skin Cholesterol POC Test in 11 London Drugs locations in Western Canada, which generated a dynamic response from the public and media. The launch included the provision of store level promotion and advertising and the validation of a number of logistical processes, resulting in a number of patients tested with PreVu at an introductory price of \$19.99
- Conducted an expansive education and awareness campaign to over 3,600 medical doctors in Vancouver/Lower Mainland as well as Winnipeg (pilot regions) in advance of the London Drugs launch
- Conducted a follow-up expansion of PreVu clinics in 74 London Drugs stores beginning in March 2013
- Announced that PharmaChoice, one of Canada's largest pharmacy networks comprised of over 350 independentlyowned stores, would be the first pharmacy network to introduce the PreVu POC Test in Ontario and Atlantic Canada,
  through a Phase One launch in 2013. Some PreVu clinics began in March and April and additional clinics commenced
  in July and will be running through the summer and fall
- Announced the appointment of two key members, Mr. Charles G. Nell and Mr. Paul Mordente, to its international
  market development team, to help guide the Company's efforts in developing international markets for PreVu
- Announced the execution of an agreement with H-E-B, the number one food retailer in South and Central Texas and the State's largest private company, that will see the Phase One launch of the PreVu POC Test into the United States exclusively in 20 H-E-B Texas store locations to be determined during the fourth quarter of calendar 2013.

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### **Retained Experienced Leaders/Advisors**

- Renowned cardiologist Dr. G.B. John Mancini, MD, FRCPC, FACC appointed to the PreVu Medical Advisory Board and named Chair
- Preeminent Canadian Cardiologist, Scientist and University Professor, Dr. Milan Gupta, MD, FRCPC, FACC appointed to the PreVu Medical Advisory Board
- Distinguished U.S. Cardiologist Dr. Henry A. Solomon, MD, FACP, FACC appointed to the PreVu Medical Advisory Board as first U.S. based member

To support the launch plan overall, 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 technology prior to Miraculins' acquisition also provides a continuity of technical knowledge as the product advances to commercialization.

The PreVu business model is to sell products in key market segments through established distribution companies that will purchase PreVu products from the Company and then resell them through their networks of retailers, or market them directly to the end consumer.

The Company's PreVu revenues are generated from the sale of test kit consumables and the custom designed hand-held readers that are utilized to read the PreVu POC Test result and guide the test operator through the test process. PreVu POC Test reagent kits contain all of the components required to deliver 40 complete tests. The testing format requires basic operator training and therefore the test is not currently sold as an over-the-counter product.

Additional revenues may be derived from territorial licensing or marketing partnerships with corporate or brand partners who have an interest in promoting skin cholesterol as a new biomarker for risk of coronary artery disease ("CAD"), as a way of differentiating their health and wellness, pharmaceutical, or consumer/grocery products.

The Company has identified four principal market segments for PreVu, and has been actively working to explore and/or develop these markets, namely:

- 1. Retail Pharmacy
- 2. Primary Care Physicians
- 3. Life Insurance
- Health and Wellness Service Providers

# 1. Retail Pharmacy Sector:

The retail pharmacy market is believed to represent a significant opportunity for PreVu based on access to millions of patients/consumers globally. Additionally, there is a growing role for neighbourhood pharmacists in delivering health and wellness products and health awareness programs to the public, providing a clear opportunity for the PreVu POC Test.

The Company plans to continue to focus on the introduction of the PreVu POC Test through Canadian retail pharmacy locations in conjunction with its distribution partner Pear Healthcare Solutions Inc. While there are similar retail pharmacy models worldwide, the Canadian marketplace is a very important market for the Company, given the Company is headquartered in Canada and considering the presence of over 6,000 retail chain pharmacy locations, along with a significant number of well-organized and professionally operated independent pharmacies. Canada also presents a cost-effective opportunity to refine the PreVu pharmacy model before exporting the concept to other international markets.

Successful market development in the retail pharmacy segment requires the participation of pharmacy partners, coordinated management of distribution logistics, sophisticated point of sale material and store level advertising, test operator training, physician education and public relations management. These major areas are being advanced as the PreVu roll-out continues in this market segment.

Efforts continue towards evolving a plan for a United States market introduction that would allow the test to be offered through pharmacies in accordance with the cleared indication for use. Miraculins is engaging in exploratory meetings with select pharmacies in the U.S. to discuss the potential opportunity further.

Efforts have also begun to identify a pharmacy partner in the European Union, with a focus on English or French speaking markets due to the Company's current marketing materials and labeling being available in those languages.

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



The Company appointed two key members, Mr. Charles G. Nell and Mr. Paul Mordente, to its international market development team, to help guide the Company's efforts in developing international markets for PreVu who will focus their efforts on the United States and the United Kingdom/European Union, respectively, with the primary goal of introducing PreVu into the retail pharmacy segments in those territories.

Summary of Goals/Plans for 2013 - Retail Pharmacy:

- Manage a successful PreVu expansion in Western Canada, as recently announced, through London Drugs pharmacy locations
- Manage a successful PreVu rollout in Eastern Canada, as recently announced, through select PharmaChoice locations
- Launch PreVu into the Quebec marketplace through retail chain/independent pharmacies
- Continue to work with distribution partner Pear Healthcare to develop, sustain and expand PreVu's distribution network throughout the retail pharmacy market in Canada
- Hold exploratory discussions with U.S. based pharmacies towards a PreVu U.S. launch strategy
- Seek to establish a PreVu pilot program with a European Union based pharmacy chain

### 2. Primary Care Physicians

Miraculins is continuing to analyze the potential of the PreVu POC Test in the Primary Care Physician ("PCP") market segment. It is generally viewed by medical device distributors in the Canadian market that the wide spread sale of a point-of-care test into the physician market will need to be preceded by reimbursement by the Canadian healthcare system. In the U.S. market, there is a greater precedence for a user pay model for a point-of-care test within the PCP market segment. However, significant adoption of the PreVu POC Test may require recognition and/or reimbursement from private health insurers or other organizations.

A strategic review of the reimbursement landscape was commissioned by the Company for Canada and the U.S. and was provided by industry experts including OptumInsight, a leading health services business specializing in improving the performance of the health system by providing analytics, technology and consulting services that enable better decisions and results. The initial phase of this review process has been completed and the Company is considering opportunities to implement the results into its ongoing strategy.

Summary of Goals/Plans for 2013 – Primary Care Physicians:

- Continued exploration of the Canadian PCP market segment and determination of potential market size for PreVu POC Test and estimated market development costs
- Engage in discussions with U.S. based medical device distributors with access to broad PCP networks across the U.S.

# 3. Life Insurance

The second format of the PreVu test technology, the PreVu Lab Processed (LP) Test, has been in further development through the Company's partnership with Gamma-Dynacare Medical Laboratories, one of Canada's largest and most respected providers of laboratory services and solutions (discussed further under "Other Activities" below).

The PreVu LP Test was originally designed to service the life insurance market in the U.S. for certain insurance policies where the provider does not typically require the applicant to submit to a physical or to provide a blood sample for traditional CAD risk factors such as serum cholesterol, due to the time and expense associated with such tests. The strategy was that with the provision of at least one risk marker for CAD, namely skin cholesterol using the convenient PreVu LP Test, the insurance company could better understand the risk profile for each applicant on a much more timely and cost effective basis and proceed accordingly.

Miraculins has been steadily working on reactivating the life insurance market for PreVu and has engaged in discussions with leading U.S. based life insurance companies and potential distribution partners who are active in the life insurance market. The Company has found that there is continuing interest in the PreVu technology from key companies, and expects to continue discussions with a goal of developing a clear strategy for this market.

At present, the PreVu LP Test has not been cleared in the United States for use in the life insurance industry (or for any other use). An earlier version of the PreVu LP Test has previously been cleared for use in Canada and CE Marked in the European Union.

#### Management's Discussion and Analysis



Summary of Goals/Plans for 2013 - Life Insurance:

- Continue to engage in discussions with key industry companies and establish an action plan for this market segment
- Provide further market updates regarding the PreVu LP Test and life insurance market segment

#### 4. Health and Wellness Services Providers:

The health and wellness service provider market segment is comprised of highly trained, generally registered or accredited, providers of health and wellness services including naturopaths, dieticians and chiropractors. Additionally, this market segment could also include mobile or public setting health risk screening service providers. It is thought that the non-invasive aspect of the PreVu POC Test could allow this segment to become more involved in CAD screening, or supplement current CAD screening activities.

The primary focus of the Company in this market segment to date has been on introducing the PreVu POC Test to registered Naturopathic Doctors ("NDs") in Canada through industry trade shows, industry specific advertising, direct communication and, through distribution partners. The ND market holds potential as a robust market for PreVu based on the focus of the ND community on preventative health and optimum wellness. According to the Canadian Association for Naturopathic Doctors, there are over 1800 registered NDs in Canada and efforts continue to promote PreVu to registered NDs.

Miraculins also plans to begin to explore the potential of the PreVu POC Test with other health and wellness service providers working with patient and customer groups who would benefit from access to new, non-invasive tools for CAD risk assessment.

Summary of Goals/Plans for 2013 – Health and Wellness Service Providers:

- Continue to develop the naturopathic doctor market in Canada
- Evaluate potential opportunities with additional accredited medical professionals including dieticians and chiropractors
- Explore alternatives for additional Canadian retail clinic opportunities including executive health clinics, public settings, and large employer health screening services
- Look for potential distribution partners and key stakeholders for this market segment nationally and internationally

#### **Other Activities**

# **Laboratory Processed Test (LP) Format**

Considerable product development activity is being directed towards the PreVu LP Test, Miraculins second testing format for skin cholesterol. Gamma-Dynacare Medical Laboratories, the Company's exclusive Canadian partner for the PreVu LP Test, has been making steady and continued progress towards the development and implementation of an in-house system for processing the PreVu LP Test.

The PreVu LP Test non-invasively measures the amount of cholesterol that has been deposited in skin tissues by painlessly and rapidly collecting skin cells from the palm of the hand using a proprietary medical adhesive collection device, which is then sent to a central reference laboratory for processing. Results are then reported to test providers and/or patients a short while later. This format could ultimately be distributed, to varying degrees, in all of the identified market segments.

# **Scientific Awareness and Development**

The Company is continually evaluating opportunities to highlight existing, or develop additional scientific support that will build upon the awareness of skin cholesterol as an emerging biomarker for the assessment of CAD risk.

#### **Expansion of PreVu Medical Advisory Board**

The addition of members to the PreVu Medical Advisory Board is continually being considered, in part to support the Company's plan to expand PreVu into new markets.

#### Management's Discussion and Analysis



### PR Activities/Healthcare Community Education

The Company continues to engage in an expansive and integrated public relations and educational campaign to enhance the awareness of the science of skin cholesterol as an emerging new biomarker for risk of CAD, and the PreVu technology designed to measure it. This campaign is two-pronged, with one focus being the general public, and the other being medical/healthcare community members, including specialists working in areas of cardiovascular and heart health. Public relations and promotional activities are ongoing, however, they tend to be intensified around specific market development landmarks.

### 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 US 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. 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 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. 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., a global leader in the convergence of medical diagnostic testing and health management, to advance and potentially 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 was to commercialize Miraculins' biomarkers for worldwide distribution. The development program was established in a Collaborative Research and Option Agreement, whereby Alere developed tests for Miraculins' biomarkers and evaluated their performance in large cohorts of patient blood samples.

On January 10, 2013, the Company announced that Alere exercised its exclusive option and licensed the novel biomarker Endoglin from the Company, concluding the three-year Collaborative Research and Option Agreement program. As the license agreement covers only Endoglin, the Company has agreed to certain amendments to the original terms of the license agreement, including a reduced option exercise and a modification of milestones and payments. Upon commercialization of Endoglin products by Alere, the Company will receive ongoing royalties on sales pursuant to terms set out in the license agreement.

Miraculins has retained certain commercial rights to pursue complementary commercial strategies for the markers and receive a secure supply of reagents and certain rights to intellectual property related to the biomarker Endoglin from Alere. In addition, the Company has the right to seek other developmental and commercial partners for the placental development biomarkers not licensed with Alere. The Company is evaluating opportunities for these other biomarkers.

#### Management's Discussion and Analysis



On March 11, 2013, the Company announced its plans to add to its suite of maternal health biomarkers under license from Mount Sinai Hospital's Samuel Lunenfeld Research Institute by signing a non-binding term sheet to license methods and reagents for detecting hydroxylated Hypoxia Inducible Factor 1 alpha ("HIF-1aOH"), a promising biomarker with potential in differentiating high and low risk pregnancies, including risk of preeclampsia. The technology is part of the pioneering research on preeclampsia and placental development being conducted by Dr. Isabella Caniggia, Senior Investigator at the Samuel Lunenfeld Research Institute, in collaboration with Dr. Martin Post, a senior scientist at the Hospital for Sick Children. In addition to its promise in maternal health and preeclampsia, HIF-1aOH also presents an opportunity as a cancer biomarker and of further note, the license will include unique monoclonal antibodies highly sensitive to HIF-1aOH and the exclusive rights to manufacture reagents that measure the biomarker using materials developed by Dr. Caniggia. The Company is currently advancing a development plan for a kit to detect and measure HIF-1aOH in bodily fluid, which if successful could lead to near term commercial research use product and allow for more widespread research into utility of this novel biomarker. The ultimate goal for the biomarker development program would be worldwide sales of biomarker technology, either alone or in combination with other markers, in a diagnostic kit for the early detection of preeclampsia or as a pregnancy risk assessment tool.

### **Cancer Programs**

Prior to changing its business model in 2008, Miraculins' primary focus was research and development with the goal of discovering novel biomarkers for cancer. During this period a series of early stage biomarker discovery programs were established. In order to effectively manage its financial and other resources, the Company is currently focused on its cardiovascular and preeclampsia programs and research and development for these cancer programs has been on hold since 2008. The Company cancelled its research programs surrounding pancreatic and gastric cancer during 2012. The Company had previously developed an immunoassay for PSP94 in urine and had intellectual property on PSP94's use in combination with other markers for detecting prostate cancer. The immunoassay for PSP94 is no longer being supported by Miraculins. The Company has been continually reviewing anticipated costs required to advance the remaining early stage programs. In considering alternatives, the Company evaluates the potential for these programs, the intellectual property, the stage of the research, the likelihood of success and the potential for an acceptable return on investment. Alternatives for the remaining cancer programs, which include colorectal and prostate cancer biomarkers, include seeking an out-licensing partner, advancing the research independently, or canceling the program.

### **New Program Opportunities**

Miraculins is continually evaluating in license/acquisition opportunities in areas where there are unmet clinical diagnostic and risk assessment needs. 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 or achieve their commercial potential. The Company is currently working towards the conclusion of its acquisition of its newest technology program, a ground breaking, non-invasive diabetes screening technology called the Scout DS® (the "SCOUT DS").

### **OUTLOOK**

The strategic direction of the Company is centred on the acquisition, development and commercialization of diagnostic and risk assessment tests for unmet clinical needs. In order to advance these research and development programs, Miraculins expects to continue incurring operating losses. Based on current projections and strategic plans, management expects expenses will increase in fiscal 2013, as compared to fiscal 2012. Any increase in expenditures would result from the continued development and commercialization of current technology programs and the potential addition of complementary technologies. The Company has begun its commercial roll-out of the PreVu product through Canadian pharmacies in 2013 and has begun earning revenue commencing in the first quarter of 2013.

The Company's financial statements have been prepared on a going concern basis in accordance with IFRS. The going concern basis of presentation assumes that the Company 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 Company's ability to continue as a going concern as the Company has experienced operating losses and cash outflows from operations since incorporation and has accumulated a deficit of \$15,233,445 as at May 31, 2013.





Management has forecast that its expected expenditure levels and contracted commitments will exceed the Company's net cash flows and working capital early in the fourth quarter of fiscal 2013 unless further financing is obtained. The Company's future operations including the completion of the launch of its products are dependent upon its ability to secure additional funds, generate product sales, negotiate collaboration or license agreements with upfront payments, and/or obtain research grant funding. 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. Historically, the Company has obtained funding via the issuance of shares and warrants and long-term debt and expects to require additional capital early in the fourth quarter of fiscal 2013. If the Company cannot secure additional financing on terms that would be acceptable to it, generate product sales, negotiate collaboration or license agreements with upfront payments, and/or obtain research grant funding, the Company will have to consider additional strategic alternatives which may include, among other strategies, cost curtailments, delays of product launch expenditures, exploring the monetization of certain intangible assets, as well as seeking to outlicense and/or divest assets.

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 many factors, including, but not limited to the successful completion of the actions taken or planned, some of which are described above, which are intended to 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 the Company's working capital will be sufficient through fiscal 2013 or that the above described 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 that would be necessary if the going concern assumption were not appropriate. If the going concern basis was not appropriate for these financial statements, then adjustments would be necessary to the carrying value of assets and liabilities, the reported revenues and expenses, and the statement of financial position classifications used.

Based on current estimates and expected operating activities management believes the Company has sufficient financial resources to fund operations into the fourth quarter of fiscal 2013.

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. The Company may also look to purchase new technologies in order to expand its suite of products. 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, which could have a material adverse effect upon the Company, its business and future prospects. Investors should carefully consider the risks and uncertainties described below, as well as other information contained in this MD&A. The risks and uncertainties described below are not exhaustive. There may be risks and uncertainties not presently known to the Company or that the Company believes to be immaterial which could adversely affect the Company and its business in the future.

**Management's Discussion and Analysis** 



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

- The Company has mainly relied on equity and debt financing and grant funding to support operations and will continue to need significant amounts of additional capital. 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 Company may fail to obtain additional financing and be unable to fund operations and commercialize its product candidates. The availability of financing will be affected by the results of scientific and clinical research, the Company's 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. Any future equity financing could result in significant dilution to existing shareholders.
- The Company has begun to earn revenue in 2013 through its commercial roll-out of the PreVu product but, 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 unless and until the Company is able to generate sufficient revenues from the commercial sale of its diagnostic products.
- The Company must meet its debt repayment obligations and failure to do so could cause the lender to demand on
  its security on the Company's long-term debt. There can be no assurance that the Company will continue to meet
  its debt repayment obligations.

#### 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. There can be no assurance that
  the Company will be able to 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. There can be no assurance that the Company's intellectual property rights will not be challenged by third parties, that the Company will receive patents it seeks, or that the Company will receive any necessary licenses. The Company could incur substantial costs in enforcing its intellectual property rights or defending its intellectual property rights against claims brought by others. 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 given the Company's financial position 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 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. Despite these practices, there can be no assurance that the Company will be able to successfully protect its intellectual property rights.
- The Company's business is subject to significant government regulation and failure to achieve and maintain regulatory approval of diagnostic products would negatively affect its business. The process for obtaining such approval, including clinical trials, varies by country and type of product, and the process can be time consuming and costly.

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



- 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. Furthermore, a failure of any of these strategic partners to perform their obligations or to continue in the partnership could delay or halt the development strategy. There can be no assurance that these strategic partners will not pursue other technologies or develop alternative products competing with those of the Company.
- 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, or if the Company encounters difficulties
  with these collaborations, 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 products
  compared with any alternatives.
- The Company's ability to successfully market certain diagnostic products may depend in part on the extent to which reimbursement for the cost of such products will be available from government health administration authorities, private health insurers and other organizations. Significant uncertainty exists as to whether newly approved healthcare products will qualify for reimbursement, or the timing by which such reimbursement can be secured. Furthermore, challenges to the price of medical products and services are becoming more frequent. There can be no assurance that adequate third-party coverage will be available to establish price levels, which would allow the Company to realize an acceptable return on its investment in product development. Although non-reimbursed, user-pay models may be available to the Company, uncertainty exists to the degree to which lack of available reimbursement by government health administration authorities, private health insurers and other organizations could limit market adoption of the Company's products. Reimbursement issues and decisions vary country by country as to procedure and time for review and/or reimbursement approval.
- The Company's industry is characterized by intense competition and rapid change and a failure by the Company to react to such competition and change could have a material adverse effect on its business. Competitors may develop products that are more effective and less costly than those developed by the Company. There can be no assurance that developments by others will not cause the Company's products to become non-competitive.
- 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.
- The testing and commercial use of diagnostic products involves exposure to product liability claims. Although the Company maintains liability insurance for certain claims, there is no assurance that such coverage will provide protection against all risks, or that such insurance will continue to be available on terms which would be acceptable to the Company. If a product liability claim was brought against the Company, it could have a material adverse affect on the Company and its financial condition.
- The Company is dependent on certain members of its management and scientific staff. If the Company fails to
  retain this staff, or to hire qualified key personnel, the implementation of the Company's business plan could slow
  and the Company may be unable to successfully develop and commercialize products.



# 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 policy of the Board of Directors of the Company is to retain 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.
- The market price and trading volume of the Company's common shares have been volatile, and may continue to be volatile in the future. Variations in earnings estimates by securities analysts and the market prices of the securities of competitors may also lead to fluctuations in the trading price of the common shares. In addition, the financial markets may experience significant price and volume fluctuations that affect the market price of the Company's common shares that are not related to the Company's operating performance. Broad market fluctuation and economic conditions generally, and in the medical device sector specifically, may adversely affect the market price of the Company's 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.

#### SELECTED QUARTERLY FINANCIAL INFORMATION

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

	Q2 - 2013	Q1 - 2013	Q4 - 2012	Q3 - 2012	Q2 - 2012	Q1 - 2012	Q4 - 2011	Q3 - 2011
Product sales	-	31,520	-	-	-	-	-	_
License fee Income	-	24,990	-	-	-	-	-	-
Collaborative researc	h and option							
fee income	- '	11,655	25,253	31,372	38,640	31,575	23,822	21,350
Cost of goods sold	-	13,806	-	-	-	-	-	-
Selling, general and a	administration							
expenses	648,003	555,162	487,320	409,276	555,910	374,158	299,445	252,230
Research and develo	pment							
expenses	21,046	75,015	242,326	191,929	128,138	133,013	152,293	94,899
Loss for the period	(747,380)	(660,532)	(797,329)	(639,141)	(713,000)	(548,258)	(558,725)	(349,896)
Loss per share	(0.01)	(0.01)	(0.01)	(0.01)	(0.01)	(0.01)	(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 to the expansion of the Company's research and development programs culminating in the commercialization of the PreVu Non-Invasive Skin Cholesterol Test ("PreVu"). The increased losses in Q4 2011 and in the fiscal 2012 and 2013 quarters as compared to previous quarter relate to costs associated with the move towards commercialization of PreVu. The Q4 2011 loss has also increased due to an increase in the revaluation of the royalty obligation and interest on the long-term debt obtained in Q4 2011. The 2012 quarterly losses have also increased as a result of interest on the long-term debt and increased stock-based compensation expense, as a result of significant stock options issued in fiscal 2012.



### **RESULTS OF OPERATIONS**

#### Revenues

The change in revenues for the six month periods ended May 31, 2013 and 2012 is reflected in the following table:

Six month periods ended	N	lay 31, 2013	May 31, 2012	Increase (Decrease)		
Product sales	\$	31,520	\$ -	\$	31,520	
License fees	\$	24,990	\$ -	\$	24,990	
Collaborative research and option fee income	\$	11,655	\$ 70,215	\$	(58,560)	

The increase in product sales for the six months ended May 31, 2013 is the result of PreVu being sold commercially through the Company's launch with London Drugs in western Canada and PharmaChoice in Ontario and the Atlantic provinces in the first quarter of 2013.

The Company is currently involved in piloting the PreVu POC Test in various market segments though third party distribution partners. Miraculins' business model is to establish distribution partners that will be responsible for selling and servicing these market segments. Buying cycles for end users can often be long and protracted. As a result, during this market introduction period, the Company anticipates that there may be periods of limited revenue which have been accounted for with the Company's planned financing activities.

The increase in license fees for the six months ended May 31, 2013 is the result of Alere having exercised its exclusive option and licensed the novel biomarker Endoglin from the Company, concluding a three-year Collaborative Research and Option Agreement program. As the license agreement will now cover only Endoglin, the Company has agreed to certain amendments to the original terms of the license agreement, including a reduced option exercise price and a modification of milestones and payments. Upon commercialization of Endoglin products by Alere, the Company will receive ongoing royalties on sales pursuant to terms set out in the license agreement.

The decrease in collaborative research and option fee income for the six months ended May 31, 2013 as compared to the similar period in 2012 is the result of Alere licensing Endoglin from the Company. As a result, there are no longer any collaborative research and option fees being collected by the Company

The Company expects limited amounts of product sales for the remainder of the fiscal year.

#### **Cost of Goods Sold**

Cost of goods sold represents direct product costs associated with PreVu.

The change in cost of goods sold for the six month periods ended May 31, 2013 and 2012 are reflected in the following table:

Six month periods ended	May 31, 2013			May 31, 2012 Increase (Decrease					
Cost of goods sold	\$	13,806	\$	-	\$	13,806			

The increase in cost of goods sold is a result of the cost of the PreVu product that was sold in the first quarter of 2013.

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



The Company expects higher levels of cost of goods sold for the remainder of the fiscal year corresponding to the expected increase in product sales.

#### Selling, General and Administration

Selling, 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. Beginning in the first quarter of 2013 and commencing with the commercial launch and rollout of the PreVu technology, costs associated with PreVu are included within selling, general and administration expenses.

The changes in selling, general and administration expenditures, including stock-based compensation, for the six month periods ended May 31, 2013 and 2012 are reflected in the following table:

Six month periods ended		May 31, 2013			Increase (Decrease)		
PreVu Non-Invasive Cholesterol test costs	\$	310,751	\$	-	\$	310,751	
Amortization of PreVu intangible assets less: Government assistance		81,869 (51,734)		-		81,869 (51,734)	
		340,886		-		340,886	
Compensation related costs		460.907		064 711		105.000	
Wages, consulting fees, and benefits Stock compensation related costs		469,807 33.695		364,711 216.277		105,096 (182,582)	
Other administration costs		358,777		349,080		9,697	
Total selling, general and administration	\$	1,203,165	\$	930,068	\$	273,097	

The increase in costs for the six month period ended May 31, 2013 as compared to the similar period in 2012 can be attributed to the following factors:

- The increase in PreVu test costs is a result of these costs being included in research and development in the prior
  period as the technology was not commercialized. With the commercialization and rollout of PreVu occurring during
  fiscal 2013, these costs, together with the requirement to begin to amortize the acquired intellectual property related to
  the PreVu technology, are included in selling, general and administration.
- Government assistance relating to the PreVu program is a result of the Company receiving a grant from the Province of Manitoba through the Manitoba Commercialization Support for Business (CSB) Program to a maximum of \$130,000 to support the PreVu Non-Invasive Cholesterol Test. During the six months ended May 31, 2013, \$62,433 was recognized under the CSB program. \$51,734 was recorded as a reduction of the related expenditures within selling, general and administration expenses and the remaining \$10,699 was recorded as a reduction to intangible assets. No amounts were recorded during the six months ended May 31, 2012 under this program as the grant funding was approved subsequent to Q2 2012.
- The increase in wages, consulting fees, and benefits is primarily related to salary increases and the Company hiring additional employees.

#### Partially offset by:

The decrease in stock compensation related costs is due to fewer stock options granted to certain of the Company's
management, directors, employees and consultants during the six months ended May 31, 2013 as compared to the six
months ended May 31, 2012. This resulted in the compensation related to stock option grants being significantly
higher in the prior period.

The Company expects higher levels of selling, general and administration expenditures for the remainder of the fiscal year.

#### Management's Discussion and Analysis



#### Research and development

Research and development expenditures include costs associated with the Company's research and development programs. During the six months ended May 31, 2012, the significant portion of these costs are development activities related to the commercialization of the PreVu technology. During the six months ended May 31, 2013, PreVu was commercialized and costs associated with PreVu are included in selling, general and administration expenses for this period.

The change in costs for the six month period ended May 31, 2013 as compared to the six months ended May 31, 2012 can be attributed to the following factors:

Six month periods ended	May 31, 2013			May 31, 2012	Increase (decrease)		
PreVu Non-Invasive Cholesterol test less: Government assistance	\$	-	\$	228,135 (19,942)	\$	(228,135) (19,942)	
Other Research and Development Activities		-		208,193		(208,193)	
Compensation related costs Laboratory rent and occupancy costs Contract research and scientific consulting Consumables		25,000 - -		25,000 20,753 500		(20,753) (500)	
Other research costs Amortization less: Government assistance		63,561 7,500 -		455 6,250 -		63,106 1,250 -	
		96,061		52,958		43,103	
Total research and development	\$	96,061	\$	261,151	\$	(165,090)	

The overall decrease in costs for the six month period ended May 31, 2013 as compared to the similar period on 2012 can be attributed to the following factors:

- The decrease in PreVu costs is a result of these costs being included in research and development in the prior period as the technology was not commercialized. With the commercialization and rollout of PreVu occurring during fiscal 2013, these costs were included in selling, general and administration.
- Government assistance relating to the PreVu program during the six months ended May 31, 2012 is a result of the Company receiving a grant from the Province of Manitoba through the Manitoba Technology Commercialization Program (TCP) to a maximum of \$100,000 to support the PreVu Non-Invasive Cholesterol Test. During the six months ended May 31, 2012, \$19,942 was recognized under the TCP program. The program provided funding to cover up to 50% of eligible costs including legal fees, patenting, marketing studies, literature development, product certification, prototyping, process validation and technical consulting costs to a maximum of \$100,000.
- Expenses associated with the Company's other research and development activities, including the maternal health and cancer programs and other research and development costs have increased during the six months ended May 31, 2013, when compared to the six months ended May 31, 2012 as costs were incurred as a result of Alere licensing the Endoglin biomarker, including \$32,500 of non-cash expenses relating to the issuance of shares to Mount Sinai Hospital as a result of the licensing. The Company terminated its laboratory lease in January of 2012 and incurred a one-time payment of \$17,500 as a result of this lease termination during the six months ended May 31, 2012. There were no occupancy costs relating to research and development during the six months ended May 31 2013.

The Company expects lower levels of research and development expenditures for the remainder of the fiscal year as the PreVu technology is now commercially available.

#### Management's Discussion and Analysis



#### **Finance Income**

The change in finance income for the six month periods ended May 31, 2013 and 2012 is reflected in the following table:

Six month periods ended	May 31, 2013		May 31, 2012	Increase (Decrease	
Finance income	\$	4,303	\$ 5,980	\$	(1,677)

Finance income was consistent between the six months ended May 31, 2013 and the six months ended May 31, 2012 due to similar levels of cash on hand as a result of financings in the respective periods. The Company anticipates similar levels of investment income for the remainder of the fiscal year.

# **Finance Expense**

The change in finance expense for the six month periods ended May 31, 2013 and 2012 is reflected in the following table:

Six month periods ended	riods ended		May 31, 2012	Increase (Decrease)	
Finance expense	\$	167,435	\$ 144,330	\$	23,105

Finance expense for the six months ended May 31, 2013 is primarily the result of the accretion on the royalty obligation associated with the acquisition of PreVu of \$75,000 and interest on long-term debt of \$84,818, as well as a royalty paid to Mount Sinai Hospital in connection with Alere licensing the Endoglin biomarker from the Company of \$6,236. During the six months ended May 31, 2012, the finance expense primarily related to the accretion on the royalty obligation associated with the acquisition of PreVu of \$62,000 and interest on long-term debt of \$80,372. The Company anticipates similar levels of finance expense as a result of the outstanding debt for the remainder of the fiscal year.

### Loss and comprehensive loss for the period

The loss and comprehensive loss for the six month periods ended May 31, 2013 and 2012 is reflected in the following table:

Six month periods ended		May 31, 2013			May 31, 2012 Increase (Decreas			
Loss and comprehensive loss for the period	\$	1,407,912	\$	1,261,258	\$	146,654		
Loss per share	\$	0.01	\$	0.02	\$	(0.01)		

As discussed above, the increase in loss for the six months ended May 31, 2013 as compared to the six months ended May 31, 2012 primarily resulted from increases in selling, general and administration expenses, primarily wages, consulting fees and benefits and professional fees, partially offset by lower stock-based compensation expenses.

Management's Discussion and Analysis



#### LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed its operations from public and private sales of equity, issuance of debt, the exercise of warrants and stock options, interest income on funds available for investment and, government grants. As at May 31, 2013, the Company had unrestricted cash totaling \$634,442 as compared with \$911,808 at November 30, 2012.

#### Cash used in operating activities

Cash used in operating activities totaled \$1,132,788 for the six months ended May 31, 2013 as a result of selling, general and administration activities as well as ongoing research and development activities, compared to cash used by operating activities of \$1,039,420 for the six months ended May 31, 2012. The increase in cash used in operating activities of \$93,368 is mainly due to a higher net loss during the six months ended May 31, 2013 after adjusting for non cash items and a decrease in accounts payable.

# Cash from financing activities

For the six months ended May 31, 2013, cash from financing activities totaled \$901,142. Of this amount, \$971,911 resulted from the issuance of common shares and warrants as a result of the financing that was closed during the period, partially offset by interest paid on long-term debt and a royalty paid to Mount Sinai Hospital in connection with Alere licensing the Endoglin biomarker. For the six months ended May 31, 2012 cash from financing activities was \$2,384,791. Of this amount, \$2,433,455 resulted from the issuance of common shares and warrants as a result of the financing that was closed during the period. An additional \$30,000 was obtained upon the exercise of stock options and a payment of \$16,711 related to the repayment in its entirety of the obligation under finance lease.

#### Cash used in investing activities

Cash used in investing activities totaled \$45,720 for the six months ended May 31, 2013. Of this amount, \$34,640 was for patent and trademark costs and \$11,080 was for the acquisition of property and equipment. During the six months ended May 31, 2012, cash from investing activities totaled \$2,246. Of this amount, \$18,981 was paid for patent and trademark costs and \$9,840 was paid for the acquisition of property and equipment. Additionally, the Company received proceeds of \$26,575 on the sale of scientific equipment, which was being held for resale.

### Shares, options and warrants

On January 8, 2010, the Company announced that it had entered into a Collaborative Research and Option Agreement (the "Alere Agreement") with Alere, Inc. ("Alere") (formerly "Inverness Medical Innovations") to advance and commercialize Miraculins' preeclampsia technology. In connection with the Alere Agreement, the Company amended certain terms of its Mount Sinai Hospital ("MSH") Agreement. In consideration for the amendments, Miraculins was to issue 250,000 common shares from treasury to MSH if Alere exercised its option to license under the Alere Agreement. Alere exercised its option on January 10, 2013 to license under the Alere Agreement, and the Company issued 250,000 common shares to MSH with fair value of \$32,500.

On April 5, 2013, the Company closed a private placement offering (the "Q2 2013 Offering") of 11,677,323 units ("Units") at a price of \$0.09 per Unit with aggregate gross proceeds to the Company of \$1,050,950. Each Unit is comprised of one common share (a "Share") and one half of one Share purchase warrant (a "Warrant"). Each whole Warrant entitles the holder to purchase one Share at a price of \$0.11 at any time within twelve months from the date of issuance of the Warrant. There were 5,838,612 warrants issued within the Q2 2013 Offering. The fair value equal to \$75,429, net of warrant issue costs, was assigned to the warrants upon issuance. Included in warrant issue costs of \$6,656 is \$482 of non-cash compensation recognized for warrants issued related to the Q2 2013 offering.

Certain persons assisted the Company by introducing potential subscribers for the Offering and were paid a finder's fee of 8% of the total subscription proceeds received from subscribers introduced to the Company by each particular person. Additionally, these persons were issued compensation warrants ("Compensation Warrants") equal to 8% of the total number of Units subscribed for by subscribers introduced to the Company by each particular person. Each Compensation Warrant entitles the holder thereof to purchase one Share at a price of \$0.09 per Share for a period of twelve months from the date of issue.





Subsequent to May 31, 2013, the Company issued 2,575,000 stock options at an exercise price of \$0.10 per common share, to certain directors, officers, employees, consultants and management company employees of the Company.

	July 26, 2013	May 31, 2013	November 30, 2012
Common shares issued and outstanding	104,896,043	104,896,043	92,968,820
Options outstanding	10,060,000	7,485,000	8,085,000
Warrants outstanding	17,654,681	17,654,681	11,649,827

The Company believes it has sufficient financial resources to fund operations into the fourth quarter of fiscal 2013. The Company's management is reviewing all financing alternatives including raising 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 leases of office 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								
Management services agreement Contractual commitments Accounts payable and accrued liabilities Long-term debt including interest					2 - 3 years		4 - 5 years		Total
	\$	58,333 86,000 279,448 1,090,000	\$	- 133,500 - -	\$	- 40,000 - -	\$	58,333 259,500 279,448 1,090,000	
	\$	1,513,781	\$	133,500	\$	40,000	\$	1,687,281	

Effective January 1, 2013 the Company amended the terms of the business and administration services agreement with Genesys Venture Inc. ("GVI"), including the provision of Chief Financial Officer services. The Company is committed to pay \$8,333 per month or \$100,000 per annum for a period of one year.

The Company is obligated to pay an annual licence maintenance fee beginning on October 15, 2011, which is the third anniversary date of a license agreement with the Mount Sinai Hospital in Toronto, Canada. For further information refer to Note 6 contained in the audited financial statements for the year ended November 30, 2012.

The Company is obligated to pay royalties to PreMD based on any future commercial sales of PreVu Skin Cholesterol test equal to 10 percent of gross revenue associated with PreVu. The Company retains the right to buy-out the royalty at anytime for a one-time payment of \$1,000,000. Royalties for the six months ended May 31, 2013 total \$3,152 in regards to the royalty obligation (2012 - nil), with payments of \$3,152 made during the six months ended May 31, 2013 (2012 - nil).

The Company is obligated to pay royalties to Canada-Israel Industrial Research and Development Foundation ("CIIRDF") based on any future product revenues, if any, from the exploitation of the preeclampsia technology contemplated in the project funding agreement equal to 2.5 percent up to a maximum of the amounts funded under the agreement. To May 31, 2013, no royalties are due and/or payable.

#### Management's Discussion and Analysis



The Company is obligated to pay a royalty to MSH, subject to minimum annual royalties, of a stipulated percentage of the net sales of licensed products related to the worldwide rights to commercialize a portfolio of biomarkers for use in developing diagnostic assays for the early detection of preeclampsia, if any, along with other milestone payments. If the Company sublicenses any rights under the MSH Agreement to a third party, the Company shall pay MSH a stipulated percentage of sublicense fee and sub-license royalty fee. In conjunction with Alere's decision to license under the Alere Agreement on January 10, 2013, a royalty of \$6,234 became payable to MSH and was paid during the six months ended May 31, 2013 and is recorded within finance expense (2012 - nil).

Subsequent to May 31, 2013, the Company and the Lender in regards to the long-term debt agreed to defer payment of the July 2013 interest payment of \$30,000 for a thirty day period.

A summary of the Company's contractual obligations may be found in Note 10 of the condensed interim financial statements for the three and six months ended May 31, 2013.

#### **RELATED PARTY TRANSACTIONS**

As of November 30, 2011 \$68,712 was owed to GVI, a party which was related to the Company until November 1, 2011, when a director who controlled GVI resigned from the Board of Directors, which bore interest at 12% per annum, calculated and compounded on a monthly basis until September 30, 2011. On January 20, 2012, the payable to GVI was settled in exchange for \$4,416 of cash and 952,533 Common Shares with a fair value of \$64,296 being issued to GVI for payment for services rendered in accordance with the terms of an agreement between the two parties.

The Company has an on-going consulting agreement with a shareholder to provide services as needed from time to time. For the three and six months ended May 31, 2013, \$12,068 and \$21,068 respectively (2012 - \$62,500 and \$65,500) has been recorded in selling, general and administration expenses relating to this consulting agreement. As at May 31, 2013, \$15,000 (November 30, 2012 - nil) is recorded in prepaid expenses in relation to this contract.

### **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.

#### Management's Discussion and Analysis



During the six months ended May 31, 2013, the Company made no material changes to its systems of internal controls over financial reporting.

#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in conformity with International Financial Reporting Standards (IFRS) 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 revenue 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 assumption previously described, management believes that its most critical accounting policies and estimates relate to the following areas, with reference to notes contained in the audited financial statements for the year ended November 30, 2012:

### Research and development costs

The Company's accounting policy over research and development costs may be found in Note 3(f)(i) to the Company's audited financial statements for the year ended November 30, 2012. Expenditures on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, are recognized in profit and loss as incurred. Development activities involve a plan or design for the production of new or substantially improved products and processes. Development expenditures are capitalized only if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Company intends to and has sufficient resources to complete the development and to use of sell the asset. No development costs have been capitalized to date.

### **Acquired intellectual property**

The Company's accounting policy over acquired intellectual property may be found in Note 3(f)(ii) to the Company's audited financial statements for the year ended November 30, 2012. Costs incurred for acquired intellectual property will be amortized over the estimated period that it is available for use in the manner intended by management, which is estimated to be three to five years.

### Patents and trademarks

The Company's accounting policy over patents and trademarks may be found in Note 3(f)(iii) to the Company's audited financial statements for the year ended November 30, 2012. Costs incurred for patents and trademarks are capitalized and amortized from the date of issuance on a straight-line basis over their respective legal lives or economic life, if shorter. Trademarks have an indefinite life. Costs incurred in successfully obtaining a patent or trademark are measured at cost less accumulated amortization and accumulated impairment losses. The cost of servicing the Company's patents and trademarks is expensed as incurred.

### Revenue recognition

The Company's accounting policy over revenue recognition may be found in Note 3(c) to the Company's audited financial statements for the year ended November 30, 2012. Revenue from the sale of goods will be measured by reference to the fair value of consideration received or receivable for goods supplied. Revenue from sales will be recognized when all the following conditions have been satisfied:

- The Company has transferred to the buyer the significant risks and rewards of ownership of the goods.
- The Company retains neither continuing managerial involvement to the degree usually associated with ownership nor
  effective control over the goods sold.
- The amount of revenue can be measure reliably.
- It is probable that the economic benefits associated with the transaction will flow to the Company, and
- The costs incurred or to be incurred in respect of the transaction can be measured reliably.

#### Management's Discussion and Analysis



The Company may enter into sales agreements with customers that have multiple element arrangements. When these multiple elements have stand-alone value to the customer, the components are accounted for separately, based on the relative selling prices, using the appropriate revenue recognition criteria as described above.

Royalty and license revenues will be recognized in revenue once an option to license a technology is exercised and as the contracted services are performed in accordance with the terms of the specific agreement.

Up-front payments and option fees received for the use of technology where further services are to be provided or fees received on the signing of collaborative research agreements are recognized over the period of performance of the related activities within collaborative research and option fees on the statement of net loss and comprehensive loss. Amounts received in advance of recognition are included in deferred collaborative research and option fees.

### Inventory

The Company's accounting policy over inventory may be found in Note 3(d) to the Company's audited financial statements for the year ended November 30, 2012. Inventory consists of parts to be used in the manufacture of finished medical devices that are held for resale, as well as finished and fully assembled and tested medical devices and purchased testing kit inventories that are held for resale. Inventory is recorded based on the first in first out principle and is valued at the lower of cost and net realizable value.

# Stock-based compensation

The Company's accounting policy over stock-based compensation may be found in Notes 3(i)(ii) and 12(c) to the Company's audited financial statements for the year ended November 30, 2012. The grant date fair value of share-based payment awards granted to employees is recognized as a personnel expense, with a corresponding increase in equity, over the period that the employees unconditionally become entitled to the awards. The amount recognized as an expense is adjusted to reflect the number of awards for which the related service and non-market vesting conditions are expected to be met, such that the amount ultimately recognized as an expense is based on the number of awards that do meet the related service and non-market performance conditions at the vesting date. For share-based payment awards with non-vesting conditions, the grant date fair value of the share-based payment is measured to reflect such conditions and there is no true-up for differences between expected and actual outcomes.

Share-based payment arrangements in which the Company receives goods or services as consideration for its own equity instruments are accounted for as equity-settled share-based payment transactions. In situations where equity instruments are issued and some or all of the goods or services received by the entity as consideration cannot be specifically identified, they are measured at fair value of the share-based payment.

# Impairment of non-financial assets

The Company's accounting policy over impairment of non-financial assets may be found in Note 3(h)(ii) to the Company's audited financial statements for the year ended November 30, 2012. The carrying amounts of the long-lived non-financial assets, including intangible assets and property and equipment, are reviewed at each reporting date to determine whether there is any indication of impairment. If any such indication exists, then the asset's recoverable amount is estimated. Intangible assets that have indefinite lives and intangible assets not yet put into use are evaluated for impairment at least annually.

An impairment exists when the carrying value of an asset exceeds its recoverable amount, which is the higher of its fair value less costs to sell or its value in use. The fair value less costs to sell calculation is based on available data from observable market prices, less incremental costs. The value in use calculation is based on a discounted cash flow model. These calculations require the use of estimates and forecasts of future cash flows. Qualitative factors, including market size and market growth trends, strength of customer demand and degree of variability in cash flows, as well as other factors, are considered when making assumptions with regard to future cash flows and the appropriate discount rate. A change in any of the significant assumptions or estimates used to evaluate the underlying assets could result in a material change to the results of operations.

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



Impairment losses recognized in prior periods are assessed at each reporting date for any indications that the loss has decreased or no longer exists. An impairment loss is reversed, to the extent that the asset's carrying amount does not exceed the carrying amount that would have been determined, net of amortization, if no impairment had been recognized. Write-downs as a result of impairment are recognized in research expense in the statement of comprehensive loss.

A summary of all of the Company's significant accounting policies and estimates may be found in Note 3 to the audited financial statements for the year ended November 30, 2012.

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

There were no changes in Accounting Policies during the period.

#### **NEW STANDARDS AND INTERPRETATIONS NOT YET ADOPTED**

### IFRS 9 Financial Instruments: Classification and Measurement

IFRS 9 (2009) replaces the guidance in IAS 39 *Financial Instruments: Recognition and Measurement*, on the classification and measurement of financial assets. The Standard eliminates the existing IAS 39 categories of held to maturity, available-for-sale and loans and receivables.

Financial assets will be classified into one of two categories on initial recognition:

- financial assets measured at amortized cost; or
- financial assets measured at fair value.

Under IFRS 9 (2010), for financial liabilities measured at fair value under the fair value option, changes in fair value attributable to changes in credit risk will be recognized in other comprehensive income ("OCI"), with the remainder of the change recognized in profit and loss.

IFRS 9 (2010) supersedes IFRS 9 (2009) and is effective for annual periods beginning on or after January 1, 2015, with early adoption permitted. For annual periods beginning before January 1, 2015, either IFRS 9 (2009) or IFRS 9 (2010) may be applied.

The Company intends to adopt IFRS 9 (2010) in its financial statements for the annual period beginning on December 1, 2015. The extent of the impact of adoption of IFRS 9 (2010) has not yet been determined.

#### IFRS 13 - Fair Value Measurement

In May 2011, the IASB published IFRS 13 Fair Value Measurement, which is effective prospectively for annual periods beginning on or after January 1, 2013, with earlier application permitted. The disclosure requirements of IFRS 13 need not be applied in comparative information for periods before initial application. IFRS 13 replaces the fair value measurement guidance contained in individual IFRSs with a single source of fair value measurement guidance. It defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, i.e. an exit price. The standard also establishes a framework for measuring fair value and sets out disclosure requirements for fair value measurements to provide information that enables financial statement users to assess the methods and inputs used to develop fair value measurements and, for recurring fair value measurements that use significant unobservable inputs (Level 3), the effect of the measurements on profit or loss or other comprehensive income. IFRS 13 explains how to measure fair value when it is required or permitted by other IFRSs. IFRS 13 does not introduce new requirements to measure assets or liabilities at fair value, nor does it eliminate the practicability exceptions to fair value measurements that currently exist in certain standards.

The Company intends to adopt IFRS 13 prospectively in its financial statements for the annual period beginning on December 1, 2013. The extent of the impact of adoption of IFRS 13 has not yet been determined.

Management's Discussion and Analysis



# Annual Improvement to IFRSs 2009-2011 Cycle - Various Standards

In May 2012, the IASB published Annual Improvements to IFRSs - 2009-2011 Cycle as part of its annual improvements process to make non-urgent but necessary amendments to IFRS effective for annual periods beginning on or after January 1, 2013 with retrospective application.

The impending changes that potential have an effect on the Company include:

• IAS 1 *Presentation of Financial Statements* - the changes involve amendments to the presentation and disclosure of comparative information beyond the minimum and the presentation of the opening statement of financial position.

The Company intends to adopt the amendments to the standards in its financial statements for the annual period beginning on December 1, 2013. The extent of the impact of the adoption of the amendments has not yet been determined.

### 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 not being unreasonably delayed and expenses not increasing substantially;
- government regulation not imposing 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.