Managements' Discussion and Analysis (Expressed in Canadian Dollars)

# MIRACULINS INC.

Three and Nine months ended August 31, 2014

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 October 30, 2014 and should be read in conjunction with the unaudited condensed interim financial statements for the three and nine month period ended August 31, 2014 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. This discussion and analysis provides an update to the Management's Discussion and Analysis for the year ended November 30, 2013, and should be read in conjunction with this document. The Company's independent auditors, KPMG LLP Chartered Accountants, have not reviewed the unaudited condensed interim financial statements. All amounts are expressed in Canadian Dollars unless otherwise noted. Additional information regarding the Company is available on SEDAR at www.sedar.com and on the Company's website at www.miraculins.com.

#### **OVERVIEW**

Miraculins 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 early commercialization phase in the areas of diabetes and cardiovascular disease. The Company's diabetes program is focused on the Scout DS® Non Invasive Diabetes Screening Test, the first non invasive diabetes screening system designed to provide a highly sensitive and convenient method for diabetes screening based on diabetes related biomarkers present in the skin. The technology had previous commercial activity and Miraculins is working to continue to build momentum for the technology in the marketplace. Miraculins cardiovascular disease program is focused on the PreVu® Non Invasive Skin Cholesterol Point-of-Care (POC) Test, a non invasive tool to assist with the risk assessment of coronary artery disease ("CAD").

Miraculins also continues to evaluate new licensing and acquisition opportunities that fit strategically with the Company's business model. Potential new programs of greatest interest to the Company are those that have completed discovery stage research and biomarker identification, but require additional expertise and resources to be developed into commercial products or achieve their commercial potential.

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. 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, management estimates that sufficient financial resources exist to fund operations into the fourth quarter of fiscal 2014.

Management has been implementing, certain operating costs control measures in an effort to conserve cash and manage the Company's burn rate. Depending upon available financing, the Company could decide to accelerate, terminate, or cut back on certain business areas, or commence and explore new business areas. These are complex decisions with the goal of optimizing investment returns and managing the cash burn rate.

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



Management has forecast that its expected expenditure levels and contracted commitments will exceed the Company's net cash flows and working capital during the fourth guarter of fiscal 2014 unless further financing is obtained. On July 30, 2014, the Company closed a private placement offering with gross proceeds of \$500,000, but additional sources of funding will be required in the fourth guarter of fiscal 2014 to carry on operations. The Company's debt has been extended and is now due on December 31, 2015 as further described in note 8 to the condensed interim financial statements. 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. 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 out license and/or divest assets or a merger, sale or liquidation of the Company. Any divestiture of assets would be subject to the satisfaction of obligations under the security interests described in note 4 and note 8 to the condensed interim financial statements.

### **Lead Technology Summary**

- The Company's Scout DS® Non-Invasive Diabetes Screening Test rapidly tests individuals without blood draw or the need to fast and produces results in 90 seconds. The Scout DS® has 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 commenced in Canada. Multiple preliminary distribution channels have also been established or advanced prior to Miraculins involvement with the technology which Miraculins is reviewing 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 has executed a definitive agreement for the sale and distribution of Scout DS® diabetes screening devices into China, as well as filed pre-submission documentation with the FDA towards securing a pathway for marketing clearance in the U.S. for the Scout DS®.
- 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 biomarker to assist with CAD risk assessment. Since acquiring the technology, Miraculins has worked independently and with distribution partners on market development for the Canadian medical professional and the Canadian and United States retail pharmacy segments, respectively, and conducted limited pilot level introduction in some of these segments resulting in nominal revenues earned during fiscal 2013.

### **Recent Developments**

Developments indicated are at the time of the dates specified.

#### Scout DS® Non-Invasive Diabetes Test

**On December 23, 2013**, the Company announced that it had filed pre submission documentation with the United States Food and Drug Administration (FDA) for its Scout DS® System towards securing its ultimate marketing clearance in the United States. The pre submission documentation filing is the first formal step by Miraculins in establishing a clinical and regulatory plan for the regulatory clearance of the Scout DS® in the United States. Based on feedback from this cooperative process with the FDA, Miraculins will develop appropriate study protocols in support of FDA marketing clearance.

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



On January 31, 2014, the Company announced that it has executed a term sheet ("Term Sheet") with Cachet Pharmaceutical Co., Ltd. ("Cachet") to appoint Cachet as the exclusive Chinese distributor for the Scout DS® Non Invasive Diabetes Screening Test. The Term Sheet has now established the principal terms and conditions of the proposed distribution agreement (the "Agreement") between Miraculins and Cachet for China, including Scout DS® device unit pricing, upfront and milestone payments, product ordering and diligence requirements, and ongoing responsibilities of the parties. Specifically, the Term Sheet provides that Miraculins would receive up to \$500,000 USD in upfront and milestone payments, staged between signing the Agreement and the successful conclusion of the China Food and Drug Administration ("CFDA") regulatory clearance process. In addition, Cachet would place a first order for Scout DS® devices valued at \$15 million USD on signing of the Agreement, which would be supported by the issuance of a proper banking guarantee and activated upon CFDA regulatory clearance.

The term of the Agreement would extend for five years from the date of CFDA clearance, subject to minimum annual order quantities by Cachet. If minimum orders were met, this would represent an additional order value of \$75 million USD in Scout DS® device orders over the length of the term. Miraculins would be responsible for leading the CFDA clearance process and its related costs. Cachet would provide guidance and support for the process as necessary.

Upon marketing clearance of the Scout DS® in China, Cachet would be responsible for all sales and marketing costs. Miraculins would provide sales and marketing guidance and support as required, and would provide a limited number of not for sale devices to Cachet for use in market development activities. Miraculins would retain the right to establish programs for ongoing device servicing and maintenance once the Scout DS® devices are sold into the field.

The Term Sheet provides Cachet with an exclusive period of 90 days within which to finalize definitive documentation for the Agreement. The completion of the definitive documentation and the execution of the Agreement remain subject to all necessary contractual, regulatory and corporate approvals of both Miraculins and Cachet and the completion of satisfactory due diligence. The Term Sheet provisions are not legally binding except for provisions regarding exclusivity, confidentiality and governing law. It is anticipated that definitive documentation will be completed within 90 days. There is, however, no assurance that the parties will enter into definitive documentation or execute the Agreement contemplated by the Term Sheet.

On June 25, 2014, the Company announced that it had finalized the major terms of a definitive agreement (the "Agreement"), that would see the Scout DS® Diabetes Screening Test distributed exclusively in China by Cachet Pharmaceutical Co., Ltd. ("Cachet"). These terms are substantially similar to those outlined in the Company's term sheet announcement made January 31, 2014, and include the placement of an initial order for Scout DS® devices valued at \$15 Million USD on the signing of the Agreement, to be activated upon Chinese Food and Drug Administration regulatory clearance.

The key deal terms will be announced once the Agreement has been executed. The execution of the Agreement remains subject to all final corporate approvals of the parties. There is no assurance that the parties will enter into the final Agreement.

On July 24, 2014, the Company announced the publication of results from the ENGINE (Evaluation of a Noninvasive Diabetes Screening Device in Subjects at Risk for Diabetes) study, which highlights the effectiveness of the Company's Scout DS® NonInvasive Diabetes Screening Device. The study, which is available online ahead of press publication by the Journal of Clinical and Translational Endocrinology, concluded that the elimination of overnight fasting, the absence of blood, and the rapid, real-time communication of screening results are aspects of noninvasive skin fluorescence spectroscopy (Scout DS® measurement) that facilitate opportunistic screening of individuals at risk for type 2 diabetes, while delivering performance that is comparable to fasting plasma glucose and HbA1c testing for detection of abnormal glucose tolerance. The published article is entitled "Noninvasive Skin Fluorescence Spectroscopy for Detection of Abnormal Glucose Tolerance".

On August 14, 2014, the Company announced that it had executed a definitive agreement (the "Agreement") for the sale and distribution of Scout DS® diabetes screening devices into China with Catalyn Medical Technologies Limited ("Catalyn"), a privately-owned and Hong Kong based medical device import company. Cachet Pharmaceutical Co., Ltd. has been co-appointed as the exclusive distributor of the Scout DS® devices in Mainland China by Miraculins and Catalyn.

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



Key terms of the agreement include:

- The term of the Agreement is to extend for five years from the date of procurement of CFDA (Chinese Food and Drug Administration) regulatory clearance of the Scout DS<sup>®</sup> device, subject to minimum Scout DS<sup>®</sup> device sales orders being met;
- Miraculins to receive certain upfront and milestone payments;
- Initial minimum guaranteed order for \$15 Million USD in Scout DS® devices for the first year of the term, confirmed on execution of the Agreement, and to be activated on procurement of CFDA regulatory clearance of the Scout DS® device:
- Subsequent minimum orders for \$15 Million USD in Scout DS® devices for each of years two, three and four
  of the term, totaling \$45 Million USD;
- Subsequent minimum order for \$30 Million USD in Scout DS® devices in year five of the term;
- Miraculins to be responsible for leading the CFDA regulatory clearance process and its related costs, with Cachet providing guidance and support as necessary;
- Miraculins to retain the right to establish programs for ongoing device servicing and maintenance once the Scout DS® devices are sold into the field.

**On August 28, 2014,** the Company announced its plans to file pre-submission documentation with the United States Food and Drug Administration (USFDA) regarding the *de novo* classification of its Scout DS<sup>®</sup> device, as a next step in securing marketing clearance in the United States.

The *de novo* classification process provides a potential pathway to Class I or Class II classification for medical devices for which general controls, or general and special controls, provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

The Company had previously filed documentation with the USFDA for the Scout DS® device in December 2013. The purpose of that documentation was to solicit general feedback from regulatory officials for assistance in establishing a specific clinical and regulatory plan for the marketing clearance of the Scout DS® device in the United States. The process highlighted the need for the Company to compile a more detailed information package including a study protocol intended to support regulatory clearance.

The pre-submission for a de novo process is intended to allow the USFDA to review and provide feedback on the suitability of the *de novo* classification process for the Scout DS® device, as well as for the planned data to be gathered and submitted by the Company to obtain marketing clearance. The *de novo* process is generally considered to be appropriate for "novel" medical devices whose risk profiles do not warrant Class III designation which is a more expensive and time consuming approval process.

**On September 25, 2014**, the Company announced that it has received the first payment of US\$150,000 under the definitive agreement (the "Agreement") that it signed with Catalyn Medical Technologies Limited ("Catalyn"), a privately-owned and Hong Kong based medical device import company, for the sale and distribution of Scout DS® diabetes screening devices into China. Pursuant to the Agreement Miraculins and Catalyn appointed Cachet Pharmaceutical Co., Ltd. as the exclusive distributor of the Scout DS® devices in Mainland China. Under the terms of the Agreement, which was executed by the parties on August 14, 2014, Miraculins was to receive the first payment from Catalyn within thirty (30) business days following the execution of the Agreement.

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#### PreVu® POC Test

**On June 18, 2014**, the Company announced that it had executed a Letter of Intent ("LOI") with Citizen Doctor Pvt. Ltd. ("CDPL"), an Indian healthcare services company, to appoint CDPL as the exclusive distributor for the PreVu® Noninvasive Skin Cholesterol Point-of-Care (POC) Test in India. The LOI also provides for the assignment of nonexclusive distribution rights for PreVu® POC to CDPL in certain other Asian countries.

The non-binding LOI has established the principal terms and conditions of the proposed distribution agreement (the "Agreement") between Miraculins and CDPL, exclusively for India and non-exclusively for certain other Asian countries, including PreVu® POC Spectrophotometer and Reagent Kit pricing, upfront and milestone payments, product ordering and diligence requirements, and ongoing responsibilities of the parties. In addition, CDPL would place a guaranteed first order for 20,000 PreVu® POC tests on signing of the Agreement, which would be activated upon Indian regulatory clearance. The LOI provides the parties with a period of 90 days within which to finalize definitive documentation for the Agreement.

The term of the Agreement would extend for five years from the date of Indian regulatory clearance, subject to minimum annual order quantities by CDPL. If minimum orders were met, this would represent a total order value of approximately \$4 Million USD in projected PreVu® Spectrophotometer and Reagent Kit sales over the length of the term. Miraculins would be responsible for leading the Indian regulatory clearance process, with its related costs being the responsibility of CDPL. Guidance and support for the regulatory process would be provided by CDPL as necessary.

With India being a country that relies heavily on predicate country regulatory clearances as regards healthcare products, it is anticipated that the regulatory clearances PreVu® POC has already received in Canada, the European Union, and the U.S., will be advantageous to the process.

Upon clearance of the PreVu® POC in India, CDPL would be responsible for all sales and marketing costs. Miraculins would provide sales and marketing guidance and training support as required. Miraculins would retain the right to establish programs for ongoing device servicing and maintenance once the PreVu® POC devices begin to be sold into the field.

# **Corporate Developments**

On December 23, 2013, the Company entered into an amending agreement to extend the \$1,000,000 non-convertible secured loan with a lender (the "2011 Lender") that was originally announced on October 13, 2011. The loan has been extended for an additional six months and will now mature on October 14, 2014. The loan will continue to bear interest at a rate of 12% per annum, payable quarterly, and any overdue payment will bear additional interest at a rate of 6% per annum, for a combined interest rate of 18% per annum on any overdue payment. As consideration for the extension of this loan, the Company issued 100,000 common shares (pre-consolidation - 1,000,000 common shares) of the Company to the 2011 Lender. Additionally, the Company entered into a shares for debt agreement with the 2011 Lender and issued 126,806 shares (pre-consolidation - 1,268,055 shares) to satisfy \$63,403 of interest owing on the loan.

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On December 23, 2013, the Company announced it had arranged a non-convertible secured loan of up to \$1,000,000 from a third party lender (the "2013 Lender"). Any amounts advanced under this loan will be evidenced by promissory notes purchased by the 2013 Lender at a 10% discount to the principal amount of the promissory note. Assuming full draw down under this loan, the aggregate purchase price of the promissory notes will be \$900,000. All amounts owing under this loan will be due and payable on December 31, 2014 and will bear interest at 12% per annum, payable quarterly. In addition, any overdue payment will bear additional interest at a rate of 6% per annum for a combined interest rate of 18% per annum on any overdue payment. In certain circumstances, the Company has the option to satisfy its obligations with respect to any interest payable on the loan by issuing common shares at a discounted price. As consideration for providing the loan, in connection with each purchase of a promissory note by the 2013 Lender, the Company will issue common shares equal to 10% of the principal amount of the promissory note based on the closing price of the Company's common shares on the trading day immediately preceding the purchase of the promissory note. The Company has the option to request the 2013 Lender to advance additional tranches under this loan, which the 2013 Lender may approve or reject at its sole discretion. The loan is secured by a general security interest in favour of the 2013 Lender over all tangible and intangible assets of the Company, excluding the assets relating to the Scout DS®, which were acquired on July 31, 2013.

**On January 10, 2014**, the Company closed the initial tranche under the loan with the 2013 Lender and received an initial advance of \$250,000 when the 2013 Lender purchased a promissory note for \$278,000. As consideration for providing the initial tranche of the loan, the Company issued 55,600 common shares (pre-consolidation - 556,000 common shares) to the 2013 Lender.

**On January 24, 2014**, the Company announced that effective at the opening of the market on January 27, 2014, the Company's issued and outstanding common shares were consolidated on the basis of one post-consolidation common share for every ten pre-consolidation common shares. The Company's name and trading symbol did not change as a result of the consolidation. The Company's common shares were reduced from 123,652,043 to 12,365,204 issued and outstanding as a result of the consolidation.

**On February 3, 2014**, the Company announced the resignation of Lisa Suennen from the Miraculins Board of Directors resulting from her departure from Psilos Group, and the appointment in her place of David A. Eichler. David A. Eichler is a Managing Member of Psilos Group and joined Psilos in 1999 and focuses primarily on investments in the medical technology and healthcare services sectors.

On February 10, 2014, the Company closed the second tranche under the loan with the 2013 Lender and received an additional advance of \$150,000 when the 2013 Lender purchased a promissory note for \$166,667. As consideration for providing the second tranche of the loan, the Company issued 33,333 common shares to the 2013 Lender and subsequently issued an additional 17,172 common shares to the 2013 Lender in connection with the second tranche of the loan.

**On March 20, 2014**, the Company closed the third tranche under the loan with the 2013 Lender and received an additional advance of \$150,000 when the 2013 Lender purchased a promissory note for \$166,667. As consideration for providing the third tranche of the loan, the Company issued 75,758 common shares to the 2013 Lender.

**On April 4, 2014**, the Company announced a non-brokered private placement offering (the "Offering") of up to 2,000,000 units ("Units") at a price of \$0.25 per Unit for gross proceeds of up to \$500,000 and on April 11, 2014 the Company announced the first closing of the Offering with aggregate gross proceeds to the Company of \$116,000 from the sale of 464,000 Units. Each Unit will be comprised of one common share of the Company (a "Share") and one Share purchase warrant. Each warrant (a "Warrant") will entitle the holder to purchase one Share at a price of \$0.35 per Share for a period of 12 months from the date the Warrant is issued. The Warrants will be callable, at the option of the Company, at any time after four months following their issuance, in the event that the closing price of the Shares is at or above \$0.50 per Share for any five out of 10 consecutive trading days. The net proceeds of the Offering will be used for general operating, ongoing product development, inventory and sales and marketing related costs.

On April 21, 2014, the Company announced that David Eichler has stepped down from the Company's Board of Directors.

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On April 24, 2014, the Company announced that it will be a featured, new technology exhibitor at the Master Investor Conference held on April 26, 2014 in London, England.

**On May 16, 2014**, the Company announced that it has entered into amending agreements to extend its CDN\$1,000,000 nonconvertible secured loan with Gretchen Ross (the "2011 Lender") that was originally announced on October 13, 2011 and previously extended on December 23, 2013, and to extend its CDN\$611,334 nonconvertible secured loan from a third party lender (the "2013 Lender") that was originally announced on December 23, 2013. The loans have been extended and will now mature on December 31, 2015. The loans will continue to bear interest at 12% per annum and the interest will accrue until December 31, 2015. To date, no bonus shares have been issued in regards to these loan extensions.

**On May 26, 2014**, the Company closed a private placement offering (the "May 2014 Offering") of 2,600,000 units at a price of \$0.10 per unit with aggregate gross proceeds to the Company of \$260,000. Each Unit is comprised of one common share (a "Share") and one Share purchase warrant (a "Warrant"). Each Warrant entitles the holder to purchase one Share at a price of \$0.15 at any time within 24 months from the date of issuance of the Warrant. There were 2,600,000 warrants issued within the May 2014 Offering. The fair value equal to \$51,290, net of warrant issue costs, was assigned to the warrants upon issuance. Share issue costs total \$8,538 related to the May 2014 Offering.

One finder assisted the Company by introducing a subscriber to the Offering and was paid a finder's fee of 10% of the total subscription proceeds received from the subscriber introduced to the Company by the finder.

**On May 29, 2014**, the Company announced that at its annual and special meeting of shareholders (the "Meeting"), Harry Bloomfield, Christopher Moreau, William Roberts and Michael Stasiuk were reelected as directors of the Company to hold office until the next annual meeting of shareholders, or until their successors are duly elected or appointed. James Mellon had advised the Company prior to the Meeting that he would not be standing for reelection.

On July 23, 2014, the Company announced a private placement offering (the "Q3 2014 Offering") for gross proceeds up to \$250,000 from the sale of up to 2,272,727 units ("Units") at a price of \$0.11 per Unit. Each Unit will comprised of one common share of the Company (a "Share") and one Share purchase warrant (a "Warrant"). Each warrant entitles the holder to purchase one Share at a price of \$0.15 per Share for a period of twelve months from the date the Warrant is issued. Certain person may assist the Company by introducing potential subscribers for the Q3 2014 offering and will be entitled to receive a finder's fee payable in cash and share purchase warrants. The net proceeds of the Q3 2014 Offering will be used for general corporate purposes.

**On July 30, 2014,** the Company announced it closed its previously announced private placement offering (the "Offering"). The Offering was over-subscribed with aggregate gross proceeds to the Company of \$500,000 from the sale of 4,545,455 units ("Units") at a price of \$0.11 per Unit. Each Unit is comprised of one common share of the Company (a "Share") and one Share purchase warrant (a"Warrant").

Each whole Warrant entitles the holder to purchase one Share at a price of \$0.15 per Share for a period of twelve months from the date the Warrant is issued. The Shares and Warrants will be restricted from transfer for a period of four months and a day from the date hereof in accordance with applicable securities laws. The net proceeds of the Offering shall be used for general corporate purposes.

# Preeclampsia/Endoglin

**On January 30, 2014**, the Company announced that Alere Inc. ("Alere") had elected not to proceed further in the direct commercial development of a professional diagnostic product for the biomarker Endoglin, but instead will support Miraculins in seeking commercialization opportunities for Endoglin by supplying key antibodies that were developed by Alere. As part of this decision, Alere has declined to proceed further with its Endoglin license from Miraculins and the parties have agreed to work to enhance Miraculins' rights to receive a secure supply of high quality, proprietary Endoglin reagents manufactured by Alere.

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#### **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 shifted 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 had exercised its exclusive option and licensed the novel biomarker Endoglin in January 2013 concluding a three-year Collaborative Research and Option Agreement program.

On January 30, 2014, the Company announced that Alere had elected not to proceed further in the direct commercial development of a professional diagnostic product for the biomarker Endoglin, but instead will support Miraculins in seeking commercialization opportunities for Endoglin.

In late summer 2010, Miraculins completed the acquisition of all assets relating to the PreVu® Non-Invasive Skin Cholesterol Test. PreVu® is a new CAD risk assessment technology that measures cholesterol levels in a patient's skin non-invasively, painlessly and without the need for fasting. Following the closing of the acquisition of the PreVu® technology, Miraculins was focused on the pilot introduction of the product through select retail pharmacies.

In August 2013, the Company completed the acquisition of all the relevant assets, including intellectual property, licenses and regulatory approvals, inventories, data and marketing materials, relating to VeraLight's Scout DS® technology, a 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. Since closing the acquisition of the Scout DS® technology, Miraculins has been focused on maintaining and growing commercial activities in the Canadian pharmacy space while evaluating opportunities to grow activities internationally, in China and elsewhere.

# SCOUT DS® PRODUCT ACQUISITION HIGHLIGHTS

Miraculins acquired 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 consists 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 1,308,032 common shares (pre-consolidation 13,080,315 common shares) 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:
  - i. 100,000 common shares (pre-consolidation 1,000,000 common shares) upon achievement of cumulative gross revenues in connection with the acquired business of \$1,000,000;
  - ii. 300,000 common shares (pre-consolidation 3,000,000 common shares) upon achievement of cumulative gross revenues in connection with the acquired business of \$3,000,000;

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- iii. 300,000 common shares (pre-consolidation 3,000,000 common shares) upon achievement of cumulative gross revenues in connection with the acquired business of \$5,000,000;
- iv. 300,000 common shares (pre-consolidation 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. 300,000 common shares (pre-consolidation 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 specified amount each fiscal year in the acquired business, until the Payment Shares are issued or the \$7 Million Dollar Milestone is achieved.

### **LEAD TECHNOLOGIES**

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 maintaining its preeclampsia program and capitalizing on the acquisition of its Scout DS® and PreVu® programs. 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.

The introduction of new medical device technology into the marketplace is a complex and multi-faceted process that often involves long buying cycles and requires multiple pilot testing programs. These 'pilot programs', which allow for market feedback to be secured under controlled distribution scenarios, provide important information for consideration and preparation for commercial launches in the future. Different market segments require different strategies and different levels of investment to successfully penetrate. During the pilot program phase, the Company does not expect to generate significant or regular revenue.

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# Scout DS® Non-Invasive Diabetes Test

On August 1, 2013, the Company announced that it has closed the acquisition from VeraLight, Inc. ("VeraLight") of all the relevant assets, including intellectual property, licenses and regulatory approvals, inventories, data and marketing materials, relating to 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.

The Scout DS®, which in 90 seconds rapidly tests individuals without blood draw or the need to fast, provides immediate results and is indicated for use for the non-invasive screening of individuals 18 years or older that are at risk for pre-diabetes and/or type 2 diabetes.

The Scout DS® has 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 prior to Miraculins involvement with the technology - which Miraculins is reviewing – 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.

On December 23, 2013, the Company announced that it has filed pre-submission documentation with the USFDA (United States Food and Drug Administration) for its Scout DS® System towards securing its ultimate marketing clearance in the United States. The pre-submission documentation filing, a formal written request from an applicant for feedback from the USFDA, was the first formal step by Miraculins in establishing a clinical and regulatory plan for the regulatory clearance of the Scout DS® in the United States. Based on feedback from this cooperative process with the FDA, on August 28, 2014 the Company announced its plans to file pre-submission documentation with the FDA regarding the *de novo* classification of its Scout DS® device, as the second formal step in securing marketing clearance in the United States. The *de novo* classification process provides a potential specific pathway to Class I or Class II classification for medical devices for which general controls, or general and special controls, provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

The pre-submission for a de novo classification is intended to allow the USFDA to review and provide further feedback on the suitability of the de novo classification process specifically for the Scout DS® device, as well as for the planned data to be gathered and submitted by the Company to obtain marketing clearance. The de novo process is generally considered to be appropriate for "novel" medical devices whose risk profiles do not warrant Class III designation which is a more expensive and time consuming approval process. For more information on the Pre-Submission Program, visit the FDA website at http://www.fda.gov.

### Scout DS® Technology and Key Market Highlights

- Diabetes is one of the fastest growing diseases in history, although up to 90% of type 2 diabetes is preventable
  with early detection and intervention.
- 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.

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



• 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® could find 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.

Miraculins has re-appointed Pear Healthcare Solutions Inc. ("Pear"), a leading provider of in-pharmacy health screening and education services, as the distributor for the Scout DS® to the Canadian retail pharmacy/grocery market. Pear is also the Company's Canadian distributor for the PreVu® Non-Invasive Skin Cholesterol Point-of-Care (POC) Test to the same market segment. Prior to Miraculins' acquisition of the Scout DS®, Pear was appointed as Canadian distributor for the technology and had successfully established pilots for this ground-breaking, non-invasive diabetes test. These included localized trials with national and regional brand pharmacy/grocery retailers including Zellers, Costco, Rexall, and PharmaSave. In addition, Pear has designed a comprehensive CE Module (Continuing Education) on non-invasive diabetes testing, which has been recognized by the Canadian Pharmacists Association as accredited programming, and has also developed a special preparatory program to ready pharmacists prior to their taking the Certified Diabetes Educator exam. These programs are offered through Pear's Health eLearning initiative and online learning portal, which allows pharmacists to conveniently participate in accredited CEs on such topics as cardiovascular disease, diabetes and osteoporosis. As a result, Pear's commitment to national diabetes education and preventive testing has been significant and unparalleled among service providers to the industry.

A major Canadian supermarket chain, in collaboration with Pear conducted a special pilot of the Scout DS® technology as part of a series of pharmacy diabetes clinics to be held at 35 store locations in fall 2013. The fall clinics were conducted to help retail customers learn more about their risk of diabetes, and its effects and complications, along with the best ways to control it through dietary modification, physical activity, ongoing monitoring and other healthcare applications and approaches. This was a successful pilot and the chain has expressed a desire to expand the pilot and make Scout DS® screening available through multiple other locations in eastern Canada in January 2015.

A patient who's Scout DS® screening result suggests a likelihood of pre-diabetes or type 2 diabetes should be recommended to see their doctor to have a diagnostic blood test done to make a diagnosis. Pilots like this allow pharmacies to introduce this new technology to their customers and to learn how to maximize the in-store potential of this exciting new screening test. After the pilot phase is successfully completed, this lays the groundwork for the potential expansion of the Scout DS® across all stores within the chain. Beyond this specific application, Miraculins and Pear are working to establish additional pilots in other retail chains with the objective of having the Scout DS® available to Canadians in various pharmacies.

Five new Scout DS® publications have appeared in peer-reviewed journals since April 2013. These studies include research demonstrating the superiority of the Scout DS® system when compared to random capillary glucose in an at-risk population, published in Diabetes Research and Clinical Practice in April 2013. Recent Scout DS® publications are as follows:

- 1. Tentolouis N. et al. Screening for HbA1c-defined prediabetes and diabetes in an at-risk Greek population: Performance comparison of random capillary glucose, the ADA diabetes risk test and skin fluorescence spectroscopy. Diabetes Research and Clinical Practice 2013: 100(1): 39-45.
- 2. Cleary PA. et al. Clinical and Technical Factors Associated with Skin Intrinsic Fluorescence in Subjects with Type 1 Diabetes from the DCCT/EDIC Study. Diabetes Technology and Therapeutics 2013:15(6): 466-474.
- 3. Orchard TJ. et al. The Association of Skin-Intrinsic Fluorescence With Type 1 Diabetes Complications in the DCCT/EDIC Study. [Published online ahead of print June 28, 2013 Diabetes Care. Doi: 10.2337/dc12-2661.
- 4. Olson BP. et al. Noninvasive Skin Fluorescence Spectroscopy Is Comparable to Hemoglobin A1c and Fasting Plasma Glucose for Detection of Abnormal Glucose Tolerance. Journal of Diabetes Science and Technology 2013: 7(4): 990–1000.
- 5. Shah S. et al. Advanced glycation endproducts in children with diabetes. [Published online ahead of print August 5, 2013] Journal of Pediatrics. Doi: 10.1016/jpeds.2013.06.044.

In addition to these current publications, the clinical and scientific evidence underlying the Scout DS<sup>®</sup> has been developed in a number of clinical studies, across more than 30 clinical sites and over 4,300 patients, involving over 15,000 measurements.

#### Management's Discussion and Analysis



Key clinical evidence for Scout includes:

- 1. ENGINE trial, a prospective, multi-centre study which was conducted in 2010 on more than 500 patients at 12 clinical sites in the United States. The purpose of the ENGINE trial was a real-world comparison of Scout DS® to fasting plasma glucose (FPG) and HbA1c (glycated hemoglobin) for diabetes screening, and using a 2-hour oral glucose tolerance test (OGTT) as the reference standard. FPG and HbA1c are common laboratory based diabetes tests. The study concluded that Scout DS® detection of abnormal glucose tolerance was equivalent to FPG and HbA1c at false positive rates that are appropriate for screening, and furthermore the sensitivity of Scout DS® was higher than that of FPG and HbA1c at their common diabetes screening thresholds.
- 2. POSSE trial, a 2012 comparison of Scout DS® against random capillary glucose (RCG) in a workplace screening model of more than 650 individuals in a four day period. The trial was conducted in collaboration with Blue Cross/Blue Shield of Louisiana using HbA1c as the reference standard. The study concluded that Scout DS® was more accurate than RCG in this setting.
- 3. NSEEDS trial, a 2010/2011, multi-centre comparison of Scout DS® against FPG and Hba1c with 2-hour OGTT as the reference standard. In addition to demonstrating equivalence or superiority to existing methods, the study demonstrated reproducibility of the Scout DS® and showed that the coefficient of variation (CV) of the Scout DS® was equivalent to FPG.
- 4. GREECE trial, a 2011/2012, comparison of Scout DS® against random capillary glucose (RCG) and the American Diabetes Association diabetes risk test (ADADRT) with a 2-hour OGTT as the reference standard. The study demonstrated that the Scout DS® was superior to RCG and ADADRT for detection of diabetes and pre-diabetes.
- 5. TCOYD trial, a 2010/2011, assessment of Scout DS® as an accurate tool for identifying individuals with previously diagnosed type 2 diabetes. The study demonstrated the Scout DS® ability to correctly identify 93.7% of previously identified diabetic individuals.

On November 19, 2013, the Company announced its plans for the Scout DS® non-invasive diabetes screening technology for the upcoming fiscal year, which is anticipated to include U.S. regulatory activity and expected sales expansion within Canadian pharmacy and employee health screening markets.

Additionally on January 31, 2014, the Company announced a term sheet with Cachet Pharmaceutical Co. Ltd. ("Cachet"), a 4 Billion RMB market cap (\$654 Million USD) wholesale/retail drug distribution and medical device distributor, with over 2.5 Billion RMB (\$408 Million USD) in annual sales. Cachet is majority state-owned and listed on the Shenzhen Stock Exchange (stock name: Cachet; stock code: 002462).

The Term Sheet establishes the principal terms and conditions of the proposed appointment of Cachet as the exclusive Chinese distributor for the Scout DS®, including device unit pricing, upfront and milestone payments, product ordering and diligence requirements, and ongoing responsibilities of the parties. Specifically, the Term Sheet provides that Miraculins would receive up to \$500,000 USD in upfront and milestone payments, staged between signing the distribution agreement (the "Agreement") and the successful conclusion of the China Food and Drug Administration ("CFDA") regulatory clearance process. In addition, Cachet would place a first order for Scout DS® devices valued at \$15 million USD on signing of the Agreement, which would be supported by the issuance of a proper banking guarantee and activated upon CFDA regulatory clearance.

The term of the Agreement would extend for five years from the date of CFDA clearance, subject to minimum annual order quantities by Cachet. If minimum orders were met, this would represent an additional order value of \$75 million USD in Scout DS® device orders over the length of the term. Miraculins would be responsible for leading the CFDA clearance process and its related costs. Cachet would provide guidance and support for the process as necessary (see Corporate History: Scout DS® Acquisition Highlights for further information).

Upon clearance of the Scout DS® in China, Cachet would be responsible for all sales and marketing costs. Miraculins would provide sales and marketing guidance and support as required, and would provide a limited number of not-for-sale devices to Cachet for use in market development activities. Miraculins would retain the right to establish programs for ongoing device servicing and maintenance once the Scout DS® devices are sold into the field.

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



The Term Sheet provides Cachet with an exclusive period of ninety days within which to finalize definitive documentation for the Agreement. The completion of the definitive documentation and the execution of the Agreement remain subject to all necessary contractual, regulatory and corporate approvals of both Miraculins and Cachet and the completion of satisfactory due diligence. The Term Sheet provisions are not legally binding except for provisions regarding exclusivity, confidentiality and governing law. It is anticipated that definitive documentation will be completed within 90 days. There is, however, no assurance that the parties will enter into definitive documentation or execute the Agreement contemplated by the Term Sheet.

On June 25, 2014, the Company announced that it had finalized the major terms of a definitive agreement (the "Agreement"), that would see the Scout DS® Diabetes Screening Test distributed exclusively in China by Cachet Pharmaceutical Co., Ltd. ("Cachet"). These terms are substantially similar to those outlined in the Company's term sheet announcement made January 31, 2014, and include the placement of an initial order for Scout DS® devices valued at \$15 Million USD on the signing of the Agreement, to be activated upon Chinese Food and Drug Administration regulatory clearance.

The key deal terms will be announced once the Agreement has been executed. The execution of the Agreement remains subject to all final corporate approvals of the parties. There is no assurance that the parties will enter into the final Agreement.

On July 24, 2014, the Company announced the publication of results from the ENGINE (Evaluation of a Noninvasive Diabetes Screening Device in Subjects at Risk for Diabetes) study, which highlights the effectiveness of the Company's Scout DS® NonInvasive Diabetes Screening Device. The study, which is available online ahead of press publication by the Journal of Clinical and Translational Endocrinology, concluded that the elimination of overnight fasting, the absence of blood, and the rapid, real-time communication of screening results are aspects of noninvasive skin fluorescence spectroscopy (Scout DS® measurement) that facilitate opportunistic screening of individuals at risk for type 2 diabetes, while delivering performance that is comparable to fasting plasma glucose and HbA1c testing for detection of abnormal glucose tolerance. The published article is entitled "Noninvasive Skin Fluorescence Spectroscopy for Detection of Abnormal Glucose Tolerance".

The ENGINE trial was a prospective, multi-centre study conducted on more than 500 patients at 12 clinical sites in the United States. The purpose of the ENGINE trial was a real-world comparison of Scout DS® to fasting plasma glucose (FPG) and HbA1c (glycated hemoglobin) for type 2 diabetes screening, using a 2-hour oral glucose tolerance test (OGTT) as the reference standard. FPG and HbA1c are common laboratory-based diabetes tests. All members of the study cohort were at risk for type 2 diabetes according to the ADA (American Diabetes Association) guidelines and therefore members of the intended-use population for Scout DS®. The cohort also had a representative mixture of patient age, sex, ethnicity, and BMI (Body Mass Index).

On August 14, 2014, the Company announced that it had executed a definitive agreement (the "Agreement") for the sale and distribution of Scout DS® diabetes screening devices into China with Catalyn Medical Technologies Limited ("Catalyn"), a privately-owned and Hong Kong based medical device import company. Cachet Pharmaceutical Co., Ltd. has been coappointed as the exclusive distributor of the Scout DS® devices in Mainland China by Miraculins and Catalyn.

Key terms of the agreement include:

- The term of the Agreement is to extend for five years from the date of procurement of CFDA (Chinese Food and Drug Administration) regulatory clearance of the Scout DS® device, subject to minimum Scout DS® device sales orders being met;
- Miraculins to receive certain upfront and milestone payments;
- Initial minimum guaranteed order for \$15 Million USD in Scout DS® devices for the first year of the term, confirmed on execution of the Agreement, and to be activated on procurement of CFDA regulatory clearance of the Scout DS® device;
- Subsequent minimum orders for \$15 Million USD in Scout DS® devices for each of years two, three and four
  of the term, totaling \$45 Million USD:
- Subsequent minimum order for \$30 Million USD in Scout DS® devices in year five of the term;
- Miraculins to be responsible for leading the CFDA regulatory clearance process and its related costs, with Cachet providing guidance and support as necessary;

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 Miraculins to retain the right to establish programs for ongoing device servicing and maintenance once the Scout DS® devices are sold into the field.

On September 25, 2014, the Company announced that it has received the first payment of \$150,000 USD under the definitive agreement (the "Agreement") that it signed with Catalyn Medical Technologies Limited ("Catalyn"), a privately-owned and Hong Kong based medical device import company, for the sale and distribution of Scout DS® diabetes screening devices into China. Pursuant to the Agreement Miraculins and Catalyn appointed Cachet Pharmaceutical Co., Ltd. as the exclusive distributor of the Scout DS® devices in Mainland China. Under the terms of the Agreement, which was executed by the parties on August 14, 2014, Miraculins was to receive the first payment from Catalyn within thirty (30) business days following the execution of the Agreement. Should the Company not receive Chinese Food and Drug Administration approval, 50% of the up front payment is refundable under the agreement.

In the period since the acquisition of the Scout DS® technology closed, the Company has significantly advanced various initiatives to maintain and build Scout DS® market momentum, including:

- Maintaining ISO:13485 and ISO:9001 certification of the Scout DS<sup>®</sup> manufacturing facility in New Mexico, by successfully passing an ISO audit;
- Enabling new scientific research studies, with third party collaboration, exploring the potential for new market segments and test utility expansion;
- Re-appointing Pear Healthcare Solutions as the distributor of the Scout DS® to the Canadian Pharmacy segment;
- Facilitating placement of the Scout DS<sup>®</sup> into a major Canadian retail/food pharmacy chain pilot program;
- Entering into a Term Sheet for the licensing rights for the Scout DS<sup>®</sup> in Mainland China;
- Finalizing a formal agreement for the sale and distribution of Scout DS® devices in Mainland China;
- Evaluating previous international Scout DS<sup>®</sup> distributors to identify opportunities for reappointment;
- Filing pre-submission documentation with the USFDA as the first formal step towards determining a pathway for the clearance of Scout DS<sup>®</sup> to be sold in the U.S., and
- Announcing plans to file pre-submission documentation with the FDA regarding the de novo classification of its Scout DS® device, as the second formal step in securing marketing clearance in the United States.

The Company's primary business model is to sell Scout DS® devices to established distributors in key market segments, which will then subsequently be rented or leased to their network of customers on a weekly, monthly or annual basis. These customers will utilize the devices to offer diabetes testing to the general public (the end user). The Company's revenues will be generated from the initial sale of the devices to the distributors, and from charging them a percentage of the rental or leasing revenue garnered from their customers, and possibly device servicing as well. Use of the Scout DS® device requires the additional purchase of proprietary consumable cleaning materials that will generate moderate additional revenue per test. Further revenues may be generated through territorial licensing, or through marketing partnerships with corporate brand partners who have an interest in further linking their brands and products with health and wellness and the convenient screening of prediabetics or type 2 diabetics, and may involve the payment of upfront, milestone and maintenance fees.

#### Primary Sales & Distribution Channels

The Company has identified two leading market segments for the Scout DS®, and is actively working to develop these markets in Canada, namely:

- Retail Pharmacy Settings offering ongoing diabetes clinics to the public.
- Health and Wellness/Employee Screening partnering with established service providers conducting employee screening and workplace wellness initiatives.

### Retail Pharmacy Settings

Individuals are increasingly interacting with healthcare professionals in settings outside of the physician's office. This includes accessing personal health, disease risk and screening information in settings such as retail pharmacies or large grocery stores with in-store pharmacy operations. As diabetes is not only a leading contributor to morbidity and mortality, but also largely preventable through early detection and intervention, the Company expects to see growing demand for the non-invasive, rapid testing offered by the Scout DS® device within retail pharmacy screening settings.

### Management's Discussion and Analysis



The process of selling and marketing new health screening technology to this segment generally begins with pilot screenings, where the pharmacy can offer the technology through a limited number of its stores to gauge both customer and staff feedback and to refine operational issues, promotional techniques and community awareness programming. Once a pilot is complete, the potential of chain-wide or national expansion presents. However, buying cycles for the pilots and for the subsequent decision to expand the program throughout a given chain can be subject to extended review and consideration.

Initial pilot feedback – although limited at this stage - has shown positive consumer response to the Scout DS® and support for the technology by pharmacy teams. Despite this the Company anticipates that challenges for Scout DS® in retail pharmacy settings will be comparable to those experienced with the PreVu® offering.

Retail pharmacy culture has traditionally offered risk assessment and prevention programs such as PreVu® and Scout DS® testing on an occasional and rotating basis, including those programs dealing with weight loss, smoking cessation and osteoporosis, among others, which often follow the calendar (i.e. February in Canada is traditionally seen as "Heart Health Month" and November is traditionally seen as "Diabetes Awareness Month"). Such a retail culture may limit Scout DS® testing as well to a rotating and cyclical schedule in retail stores and as a result, the Company has been additionally focused on developing an offering for pharmacies that would also see turn-key Scout DS® diabetes testing kiosks set up within the pharmacy and operated by dieticians or other such health professionals, under the control and direction of the Company. Such offerings may make it easier for pharmacies to offer Scout DS® diabetes testing to customers on a more regular and sustained basis, and also increase the profile of the test within the store with the presence of a highly visible and branded kiosk station.

### Health and Wellness/Employee Screening

Generally defined as employer sponsored or endorsed activities aimed at improving health related behaviours, employee screening can include policies, education, coaching, on-site fitness facilities, and importantly as it pertains to Scout DS®, medical screenings. Although, a focus on workplace wellness can lead to increased productivity through more satisfied and motivated employees, these programs are also increasingly being recognized for their economic impact through the reduction of absenteeism, disability and healthcare claims associated with diseases such as diabetes. Wellness initiatives are estimated to save an employer an average of \$394 per employee per year, while costing an average of \$159 per employee per year, resulting in a significant return.

Of note, people with diabetes incur medical costs that are two to three times higher than those without diabetes and a person with diabetes can face direct costs for medication and supplies ranging from \$1,000 to \$15,000 a year. There is an expectation on the part of the Company that the painless, rapid and non-invasive features of the Scout DS® device will be seen as significantly advantageous within an employee screening setting. Both employers and corporate insurance companies have an interest in reducing the economic impact of declining health status on health insurance premiums and payouts, and are therefore key target customers within this segment.

There are a significant number of well-established distributors that provide a variety of employee screening services to large employers (generally considered to have more than 500 employees). The Company will look to identify and establish relationships with these distributors.

Prior to its acquisition by the Company, the Scout  $DS^{@}$  was demonstrated to a number of large Canadian employers. In addition to identifying possible distribution partners, the Company plans on following up with these employers and establishing them as early adopters within this segment.

### Additional Key Initiatives and Activities

In addition to pursuing opportunities within retail pharmacy and employee health screening segments in Canada, the Company will be simultaneously advancing an additional series of initiatives, including:

#### Management's Discussion and Analysis



#### FDA Clearance

Miraculins filed a pre submission with the FDA on December 23, 2013 as a first formal step to determine a regulatory pathway so the Scout DS® can be marketed within the United States, and on August 28, 2014 announced its plans to file pre-submission documentation with the FDA regarding the de novo classification of its Scout DS® device, as the second formal step in securing marketing clearance in the United States.. It is believed that there are more than 25 million diabetics in the U.S., with roughly 7 million diabetics undiagnosed. In addition, there are an estimated 79 million pre diabetics in the U.S., many of which are unaware of their status. Based on the dramatic impact of diabetes on the American public and the country's healthcare system, the U.S. would be expected to be a robust geographical market for Scout DS®, with well- established sales and distribution channels existing in the market segments the Company has already identified for the device in Canada.

### Territorial Licensing

As diabetes is a global epidemic, the Scout DS® technology holds tremendous promise in territories around the world. In certain markets, based on a number of factors, technology licensing is favoured as compared to establishing a distribution partnership structure. Miraculins is evaluating the potential of these markets, and recently announced on August 14, 2014 that it had executed a formal agreement for the sale and distribution of Scout DS® devices in Mainland China.

### Evaluating Previous Distributors

The Scout DS<sup>®</sup> is currently cleared for use in Canada, Mexico and the European Union and has registrations in India, Saudi Arabia, Kuwait, Bahrain, Qatar, and Turkey. Prior to Miraculins acquisition of the technology, a number of distributors had been engaged to various degrees in these markets. The Company is actively evaluating a number of these markets and distributor relationships to determine if there is a collective strategic fit for renewed representation.

### Establishment of a Scout DS® Medical Advisory Board

The Company is planning to establish a formal Medical Advisory Board for Scout, incorporating scientific and medical leaders in diabetes and related areas. The purpose of a Medical Advisory Board is to advise the Company on approaches to promoting an understanding of Scout DS® and non-invasive diabetes screening, provide recommendations for the scientific and research goals of the technology and help with the overall awareness of the new technology within the medical community itself.

### Scientific Awareness and New Research Opportunities

The Company is continually evaluating opportunities to build additional scientific awareness and support of Scout DS® as a non-invasive diabetes screening technology, by highlighting existing study data and by commissioning new research opportunities.

#### Outsourcing Manufacturing

The Company is in the process of transitioning manufacturing of the Scout DS® device from a Company manufacturing facility in New Mexico, to a contract manufacturing partner in the continental United States. Production with the selected manufacturing partner is expected to begin in the fourth quarter of 2014.

### PR Activities and Healthcare Community Education

Miraculins is reviewing prior public relations efforts, as well as healthcare education and awareness materials and initiatives related to the Scout DS® while considering new opportunities to enhance awareness of Scout DS® and non-invasive diabetes screening within the general public and healthcare community. Such new opportunities will be ongoing, but will tend to be intensified around specific market development initiatives and milestones.

Management's Discussion and Analysis



# PreVu® Non-Invasive Skin Cholesterol Point-of-Care (POC) 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 partnered with 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.

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 the introduction of the PreVu® technology with the following key historical 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<sup>®</sup> 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
- Announced that previously unpublished data from a major study of more than 9,000 North American life insurance applicants, that could open the door for skin cholesterol testing to be utilized as a new risk assessment tool in U.S. life insurance underwriting.
- Announced the publication of a review article entitled "The Relationship Between Skin Cholesterol Testing and Parameters of Cardiovascular Risk: A Systematic Review" authored by A. Yashar Tashakkor, MD, and G. B. John Mancini, MD, FRCPC

### 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 chain-wide expansion of PreVu® clinics in London Drugs stores beginning in March 2013 providing important information for shaping future pilot programs.
- Announced that PharmaChoice would be the first pharmacy network to introduce the PreVu® POC Test in Ontario and Atlantic Canada, through a Phase One launch in 2013.
- 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 saw the Phase One launch of the PreVu® POC Test into the United States exclusively in 20 H-E-B Texas store locations during the fourth guarter of calendar 2013.

### Management's Discussion and Analysis



 Executed a Letter of Intent with Citizen Doctor Pvt. Ltd. ("CDPL"), an Indian healthcare services company, to appoint CDPL as the exclusive distributor for the PreVu® Non-invasive Skin Cholesterol Point-of-Care (POC) Test in India.
 The Letter of Intent also provides for the assignment of non-exclusive distribution rights for PreVu® POC to CDPL in certain other Asian countries to be fully defined in a definitive agreement. There is no assurance that the parties will enter into a definitive Agreement.

To support the introduction of PreVu® 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 expected to be 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 previously identified four principal market segments for PreVu®, and has been actively working to explore and/or develop these markets, namely:

- Retail Pharmacy
- Primary Care Physicians
- Life Insurance
- Health and Wellness Service Providers

#### 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 thousands of retail chain pharmacy locations, a significant number of well-organized and professionally operated independent pharmacies, as well as additional pharmacies operating within large national and regional brand grocery chains. 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 introduction of PreVu® continues in this market segment.

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



Initial pilot feedback has shown positive consumer response to the PreVu® test and support for the technology by pharmacy teams. Challenges though include retail pharmacy culture which has traditionally offered risk assessment and prevention programs such as PreVu® on an occasional and rotating basis, including those programs dealing with weight loss, smoking cessation, osteoporosis, diabetes screening, among others, which often follow the calendar (i.e. February in Canada is traditionally seen as "Heart Health Month"). Such a retail culture may limit PreVu® testing to a rotating and cyclical schedule in retail stores and as a result, the Company has been additionally focused on developing an offering for pharmacies that would see turn-key PreVu® testing kiosks set up within the pharmacy and operated by dieticians or other such health professionals, under the control and direction of the Company. Such offerings may make it easier for pharmacies to offer PreVu® testing to customers on a more regular and sustained basis, and also increase the profile of the test within the store with the presence of a highly visible and branded kiosk station.

Efforts have been made towards United States market introduction through pharmacies, including 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 saw the PreVu® POC Test piloted in upwards of 20 H-E-B Texas store locations during the fourth quarter of calendar 2013. U.S. consumer and pharmacy team response to PreVu® testing was also very positive and the Company acquired a great deal of useful operational and market-based data that it will be incorporating into additional pilot introductions and expansion of PreVu® into the U.S. in the future.

Efforts continue on identifying 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.

### 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.

### Life Insurance

The second format of the PreVu® test technology, the PreVu® Lab Processed (LP) Test, underwent 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 continues to be interested in reactivating the life insurance market for PreVu® and recently announced previously unpublished study data further supporting skin cholesterol's use in the life insurance market segment. The Company has engaged in discussions with leading U.S. based life insurance companies and potential distribution partners who are active in the life insurance market and has found that there is continuing interest in the PreVu® technology from key companies.

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



### 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 Company has been exploring the potential of engaging Registered Dieticians across the country to conduct PreVu® testing, including through dedicated PreVu® testing kiosks the Company has been evaluating.

### Other Activities

### Laboratory Processed Test (LP) Format

Product development activity was directed towards the PreVu® LP Test, Miraculins second testing format for skin cholesterol. Gamma-Dynacare Medical Laboratories, is the Company's exclusive Canadian partner for 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.

### PR Activities/Healthcare Community Education

The Company has engaged in 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 has been 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/Endoglin

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 biomarker's, 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.

#### Management's Discussion and Analysis



Miraculins has historically advanced the markers subject to a Collaborative Research and Option Agreement with Alere, Inc. ("Alere"), one of the world's largest diagnostic companies. The collaborative program concluded in January 2013 with Alere retaining development rights for the Endoglin marker. On January 30, 2014, the Company announced that Alere had elected not to proceed further in the direct commercial development of a professional diagnostic product for the biomarker Endoglin, but instead will support Miraculins in seeking commercialization opportunities for Endoglin.

There is a growing body of scientific research, including multiple research and clinical studies conducted by Alere, confirming that Endoglin contributes to the pathogenesis of preeclampsia. As the Lab Developed Test ("LDT") route now presents the greatest potential near-term commercialization pathway for Endoglin, Miraculins is evaluating plans to focus on advancing discussions with potential partners who have expertise and capabilities in this space, with full support from Alere. LDTs are *in vitro* diagnostic tests that are developed, validated and used for in-house pathology and diagnostic purposes. Tests can either be marketed as a kit through the FDA's risk-based review process, or they can be sold to the market as a testing service under LDT definition, with the lab falling under Clinical Laboratory Improvement Amendments (CLIA) regulation. The LDT pathway can be a much quicker way to introduce a test to the market.

### **Cancer Programs**

Prior to 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, diabetes 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 include seeking an outlicensing 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.

### **OUTLOOK**

The strategic direction of the Company is centred on the acquisition, development and commercialization of diagnostic and risk assessment technologies 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 as fiscal 2014 concludes, as compared to fiscal 2013. 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 began a pilot introduction of the PreVu® through Canadian pharmacies in 2013 which has generated nominal revenues commencing in the first quarter of 2013. The PreVu® technology has been piloted in H.E.B. pharmacies in the United States. The Company's Scout DS® technology was piloted in a Canadian pharmacy chain in the fourth quarter of fiscal 2013 and on August 14, 2014 the Company executed a formal agreement for the sale and distribution of Scout DS® devices in Mainland China which will require additional investment to fulfill.





Management has been implementing during recent quarters, certain operating costs control measures, including delaying significant planned expenditures in an effort to conserve cash and manage the Company's burn rate. Depending upon available financing, the Company could decide to accelerate, terminate, or cut back on certain business areas, or commence and explore new business areas. These are complex decisions with the goal of optimizing investment returns and managing the cash burn rate.

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 \$18,581,123 as at August 31, 2014 and a working capital deficiency of \$443,492.

Management has forecast that its expected expenditure levels and contracted commitments will exceed the Company's net cash flows and working capital during the fourth quarter of fiscal 2014 unless further financing is obtained. as additional sources of funding will be required during fiscal 2014 to carry on operations. The Company's debt has been extended and is now due on December 31, 2015 as described in note 8 of the Company's condensed interim financial statements. 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. 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 out license and/or divest assets or a merger, sale or liquidation of the Company. Any divestiture of assets would be subject to the satisfaction of obligations under the security interests described in note 4 and note 8.of the Company's condensed interim financial statements.

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 can be no assurance that the Company will be able to obtain sufficient financing to meet future operational needs 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 management's current estimates and expected operating activities, management estimates that sufficient financial resources exist to fund operations into the fourth quarter of fiscal 2014.

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 balance of the coming year.

Management's Discussion and Analysis



### **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.

### 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 market development of the PreVu® and Scout DS® technologies 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 or lease 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.

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



- 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.
- 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.

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



- 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 effect 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.

**Management's Discussion and Analysis** 



#### 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):

	Q3 - 2014	Q2 - 2014	Q1 - 2014	Q4 - 2013	Q3 - 2013	Q2 - 2013	Q1 - 2013	Q4 - 2012
Product sales	3,000	3,000	3,459	19,667	-	-	31,520	-
License fee Income	-	-	-	-	-	-	24,990	-
Collaborative researc	h and option							
fee income	- '	-	-	-	-	-	11,655	25,253
Cost of goods sold	266	267	356	-	-	-	13,806	-
Selling, general and a	administration							
expenses	590,889	607,742	602,565	855,481	881,377	648,003	555,162	487,320
Research and develo	pment							
expenses	44,927	23,291	23,439	22,549	21,490	21,046	75,015	242,326
Net finance costs	(46,955)	109,955	(6,346)	242,375	85,132	81,601	85,834	98,026
(Decrease) increase i	n valuation of	contingent sh	are					
consideration	92,000	(246,000)	(618,000)	-	-	-	-	-
Loss for the period	(770,837)	(482,081)	(2,390)	(1,107,311)	(985,059)	(747,380)	(660,532)	(797,329)
Loss per share	(0.04)	(0.04)	-	(0.10)	(0.09)	(0.07)	(0.07)	(0.09)

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 losses over the past two years relate to the expansion of the Company's technology programs culminating in the commercialization of the PreVu® Non-Invasive Skin Cholesterol Test ("PreVu"). The increasing losses relate to costs associated with the move towards commercialization of PreVu®. Additionally, the loss in the third quarter of fiscal 2013 relates to costs associated with the acquisition of the Scout DS® technology, which occurred during the third quarter of 2013 and the loss in the fourth quarter of fiscal 2013 relate to costs associated with the commercialization of the Scout DS®. The reduction in the net loss reported in the first and second quarters and subsequent increase in the net loss in the third quarter of fiscal 2014 as compared to prior quarters is primarily the result of a revaluation in the contingent share consideration associated with the Scout DS® acquisition resulting in a reduction of the net loss of \$618,000 in the first quarter and \$264,000 in the second quarter and an increase of the net loss of \$92,000 in the third quarter.



#### **RESULTS OF OPERATIONS**

### **Revenues**

The change in revenues for the nine month periods ended August 31, 2014 and 2013 is reflected in the following table:

Nine month periods ended		ust 31, 2014	Aug	ust 31, 2013	Increase (Decrease)		
Product sales License fees Collaborative research and option fee income	\$	9,459	\$	31,520	\$	(22,061)	
	\$	-	\$	24,990	\$	(24,990)	
	\$	-	\$	11,655	\$	(11,655)	

The decrease in product sales for the nine months ended August 31, 2014 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 resulting in higher revenues in the prior period.

The Company is currently involved in piloting the PreVu® POC Test and the Scout DS® in various market segments through 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 decrease in license fees for the nine months ended August 31, 2014 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 during the first quarter of 2013 resulting in a license fee being earned by the Company. On January 30, 2014, the Company announced that Alere Inc. ("Alere") had elected not to proceed further in the direct commercial development of a professional diagnostic product for the biomarker Endoglin, but instead will support Miraculins in seeking commercialization opportunities for Endoglin by supplying key antibodies that were developed by Alere. As part of this decision, Alere has declined to proceed further with its Endoglin license from Miraculins and the parties have agreed to work to enhance Miraculins' rights to receive a secure supply of high quality, proprietary Endoglin reagents manufactured by Alere.

The decrease in collaborative research and option fee income for the nine months ended August 31, 2014 as compared to the similar period in 2013 is the result of Alere licensing Endoglin from the Company in January of 2013. 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 2014 fiscal year. No license fees are expected to be received during the remainder of the 2014 fiscal year.

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

Cost of goods sold represents direct product costs associated with PreVu® and the Scout DS®.

The change in cost of goods sold for the nine month periods ended August 31, 2014 and 2013 are reflected in the following table:

Nine month periods ended	August 31, 2014			st 31, 2013	Increase (Decrease)	
Cost of goods sold	\$	889	\$	13,806	\$	(12,917)

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



The decrease in cost of goods sold is consistent with the decrease in revenues between the nine months ended August 31, 2014 and 2013.

The Company expects limited amounts of cost of goods sold for the remainder of the 2014 fiscal year corresponding with 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. Beginning in the third quarter of 2013 and commencing with the acquisition of the Scout DS® technology, costs associated with the Scout DS® are included within selling, general and administration expenses.

The changes in selling, general and administration expenditures, including stock-based compensation, for the nine month periods ended August 31, 2014 and 2013 are reflected in the following table:

Nine month periods ended	Aug	just 31, 2014	Aug	just 31, 2013	Increase (Decrease)		
Scout DS® technology costs Amortization of Scout DS® intangible assets	\$	165,978 88,785	\$	62,551 -	\$	103,427 88,785	
		254,763		62,551		192,212	
PreVu® Non-Invasive Cholesterol test costs Amortization of PreVu® intangible assets less: Government assistance		72,227 144,368 -		423,201 130,999 (51,734)		(350,974) 13,369 51,734	
		216,595		502,466		(285,871)	
Compensation related costs Wages, consulting fees, and benefits Stock compensation related costs Other administration costs		678,882 196,872 454,084		702,614 154,192 662,719		(23,732) 42,680 (208,635)	
Total selling, general and administration		1,801,196	\$	2,084,542	\$	(283,346)	

The decrease in costs for the nine month period ended August 31, 2014 as compared to the nine months ended August 31, 2013 can be attributed to the following factors:

- The decrease in PreVu® test costs is a result of costs being deferred in the nine months ended August 31, 2014 given limited cash resources.
- The decrease in other administration costs is a result cost constraints implemented during the nine months ended August 31, 2014.
- The decrease in wages, consulting fees, and benefits is a result of the Company having fewer employees for the nine months ended August 31, 2014.

### Partially offset by:

• The increase in Scout DS® technology costs is a result of the technology being acquired on July 31, 2013 and costs primarily include consulting, regulatory expenses and facility rental costs.

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



- The decrease in government assistance relating to the PreVu® program is a result of the Company receiving grant funding from the Province of Manitoba through the Manitoba Commercialization Support for Business (CSB) Program during the three months ended February 28, 2013 to offset costs of the PreVu® program
- The increase in stock compensation related costs as a result of the value of stock options granted in August of 2014.

The Company expects a higher level of Scout DS® technology costs and a similar level of compensation costs for the remainder of the 2014 fiscal year.

#### Research and development

Research and development expenditures include costs associated with the Company's research and development programs.

The change in costs for the nine month period ended August 31, 2014 as compared to the nine months ended August 31, 2013 can be attributed to the following factors:

Nine month periods ended	Augı	August 31, 2014			Increase (decrease)		
Compensation related costs Maternal health program costs Amortization and other costs	\$	25,000 - 66,657	\$	37,500 68,457 11,594	\$	(12,500) (68,457) 55,063	
Total research and development	\$	91,657	\$	117,551	\$	(25,894)	

The overall decrease in costs for the nine month period ended August 31, 2014 as compared to the nine months ended August 31, 2013 can be attributed to the following factors:

 Expenses associated with the Company's maternal health program have decreased during the nine months ended August 31, 2014, when compared to the nine months ended August 31, 2013 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 during the nine months ended August 31, 2013.

### Partially offset by:

 The increase in amortization and other costs as a result of an impairment write-down pertaining to patents no longer being pursued that totaled \$39,668 during the nine months ended August 31, 2014.

The Company expects low levels of research and development expenditures for the remainder of the 2014 fiscal year as the PreVu® and Scout DS® technologies are commercially available for sale and as such costs are recorded within selling, general and administration expenses.

### Finance Income

The change in finance income for the nine month periods ended August 31, 2014 and 2013 is reflected in the following table:

Nine month periods ended	August 31, 2014			ıst 31, 2013	Increase (Decrease)		
Finance income	\$	12,351	\$	7,311	\$	5,040	

Finance income has increased between the nine months ended August 31, 2014 and 2013 due to higher levels of cash on hand during the nine months ended August 31, 2014. The Company anticipates lower levels of finance income for the remainder of the 2014 fiscal year.

Management's Discussion and Analysis



### **Finance Expense**

The change in finance expense for the nine month periods ended August 31, 2014 and 2013 is reflected in the following table:

Nine month periods ended	August 31, 2014			ust 31, 2013	Increase (Decrease)	
Finance expense	\$	150,474	\$	252,567	\$	(102,093)

Finance expense for the nine months ended August 31, 2014 was lower than the nine months ended August 31, 2013 as the Company recognized a recovery of \$65,902 on the revaluation of the Company's PreVu® royalty obligation from the acquisition of PreVu®. This is partially offset by higher finance expense relating to interest on the Company's secured debt, including debt that was obtained during the nine months ended August 31, 2014. The Company anticipates higher levels of finance expense as a result of its new non-convertible secured loan obtained in December 2013 of up to \$1,000,000 from a third party lender, which bears interest at 12% per annum, for the fiscal 2014 year.

### **Decrease in Valuation of Contingent Share Consideration**

The change in the valuation of contingent share consideration for the nine month periods ended August 31, 2014 and 2013 is reflected in the following table:

Nine month periods ended		ust 31, 2014	Aug	August 31, 2013 Increase (Decre				
Decrease in valuation of contingent share consideration	\$	772,000	\$	-	\$	772,000		

The decrease in the valuation of contingent share consideration for the nine months ended August 31, 2014 was in a recovery position as the Company recognized a reduction of \$772,000 to the contingent share consideration that had been recorded when the Scout DS® was acquired on July 31, 2013. The reduction is primarily a result of lower share prices for Miraculins shares throughout the period as share price and volatility are key factors in the valuation of the contingent share consideration. The Company anticipates the valuation of contingent share consideration to fluctuate each quarter depending on a variety of inputs and factors.

### Loss and comprehensive loss for the period

The loss and comprehensive loss for the nine month periods ended August 31, 2014 and 2013 is reflected in the following table:

Nine month periods ended	nth periods ended August 31, 2014			gust 31, 2013	Increase (Decrease)		
Loss and comprehensive loss for the period	\$	(1,255,308)		(2,392,971)	\$	(1,137,663)	
Loss per share	\$	(0.09)		(0.24)	\$	(0.15)	

As discussed above, the change in the Company's loss for the nine months ended August 31, 2014 as compared to the nine months ended August 31, 2013 primarily resulted from the Company recognizing a \$772,000 recovery on the revaluation of contingent share consideration associated with the Scout® acquisition as well as a recovery of \$65,902 on the revaluation of the Company's PreVu® royalty obligation from the acquisition of PreVu®.

**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 August 31, 2014, the Company had unrestricted cash totaling \$93,460 as compared with \$159,757 at November 30, 2013.

### Cash used in operating activities

Cash used in operating activities totaled \$1,370,812 for the nine months ended August 31, 2014 and was lower than the cash used in operating activities of \$1,666.399 for the nine months ended August 31, 2013 due to a lower net loss for period after adjusting for non-cash items.

#### Cash from financing activities

For the nine months ended August 31, 2014, cash from financing activities totaled \$1,356,549. Of this amount, \$819,347 resulted from proceeds of private placement financings completed during the period, \$550,000 resulted from the Company obtaining additional secured debt during the nine months August 31, 2014, partially offset by interest paid totaling \$12,798. For the nine months ended August 31, 2013 cash from financing activities was \$899,847. Of this amount, \$971,911 resulted from proceeds of private placement financings completed during the period, \$62,504 related to interest payments and \$9,560 related to royalties paid relating to the Company's maternal health program and its PreVu® royalty obligation.

#### Cash used in investing activities

Cash used in investing activities totaled \$52,034 for the nine months ended August 31, 2014. Of this amount, \$51,708 was for patent and trademark cost and \$3,926 was for the acquisition of property and equipment, partially offset by the Company receiving \$3,600 from the sale of scientific equipment during the period. During the nine months ended August 31, 2013, cash used in investing activities totaled \$112,254. Of this amount, \$101,174 was paid for patent and trademark costs and \$11,080 was paid for the acquisition of property and equipment.

### **Shares, options and warrants**

On December 23, 2013, the Company announced that it had arranged a non-convertible secured loan of up to \$1,000,000 with a third party lender as described in note 8 to the financial statements. As consideration for providing the loan, in connection with each purchase of a promissory note by the lender under the loan agreement, the lender will receive shares of the Company equal to 10% of the principal amount of the promissory note based on the closing price of the Company's shares on the trading day before the purchase of the promissory note. On January 10, 2014, the Company issued 55,600 shares (pre-consolidation - 556,000 shares) in connection with the closing of the first tranche under the loan agreement. On February 10, 2014, the Company issued 33,333 shares in connection with the closing of the second tranche under the loan agreement and subsequently issued an additional 17,172 common shares to the 2013 Lender in connection with the second tranche of the loan. On March 20, 2014, the Company issue 75,758 shares in connection with the closing of the third tranche under the loan agreement. Further information regarding these transactions is contained in note 8 to the Company's condensed interim financial statements.

On December 23, 2013, the Company announced that it has entered into an amending agreement to extend the \$1,000,000 non-convertible secured loan with a lender that was originally announced on October 13, 2011 as described in note 8. As consideration for the extension of the loan, the Company issued 100,000 shares (pre-consolidation - 1,000,000 shares) to the lender. Additionally, the Company entered into a shares for debt agreement with the lender and issued 126,806 shares (pre-consolidation - 1,268,055 shares) to satisfy \$63,403 of interest owing on the loan. Further information regarding these transactions is contained in note 8 to the Company's condensed interim financial statements.

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



On April 11, 2014 the Company closed a private placement offering (the "April 2014 Offering") of 464,000 units at a price of \$0.25 per unit with aggregate gross proceeds to the Company of \$116,000. Each Unit is comprised of one common share (a "Share") and one Share purchase warrant (a "Warrant"). Each Warrant entitles the holder to purchase one Share at a price of \$0.35 at any time within twelve months from the date of issuance of the Warrant. The Warrants are callable, at the option of the Company, at any time after four months following their issuance, in the event that the closing price of the Shares is at or above \$0.50 per Share for any five out of 10 consecutive trading days. There were 464,000 warrants issued within the April 2014 Offering. The fair value equal to \$\$22,112, net of warrant issue costs, was assigned to the warrants upon issuance. Share issue costs total \$6,785 related to the April 2014 Offering.

On May 26, 2014, the Company closed a private placement offering (the "May 2014 Offering") of 2,600,000 units at a price of \$0.10 per unit with aggregate gross proceeds to the Company of \$260,000. Each Unit is comprised of one common share (a "Share") and one Share purchase warrant (a "Warrant"). Each Warrant entitles the holder to purchase one Share at a price of \$0.15 at any time within 24 months from the date of issuance of the Warrant. There were 2,600,000 warrants issued within the May 2014 Offering. The fair value equal to \$51,290, net of warrant issue costs, was assigned to the warrants upon issuance. Share issue costs total \$8,538 related to the May 2014 Offering.

One finder assisted the Company by introducing a subscriber to the Offering and was paid a finder's fee of 10% of the total subscription proceeds received from the subscriber introduced to the Company by the finder.

On July 30, 2014, the Company closed a private placement offering (the "July 2014 Offering") of 4,545,455 units at a price of \$0.11 per unit with aggregate gross proceeds to the Company of \$500,000. Each Unit is comprised of one common share (a "Share") and one Share purchase warrant (a "Warrant"). Each Warrant entitles the holder to purchase one Share at a price of \$0.15 at any time within 12 months from the date of issuance of the Warrant. There were 4,545,455 warrants issued within the July 2014 Offering. The fair value equal to \$57,312, net of warrant issue costs, was assigned to the warrants upon issuance. Share issue costs total \$40,350 related to the July 2014 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 \$0.15 per Share for a period of twelve months from the date of the July 2014 Offering. There were 230,007 Compensation Warrants issued.

The Company is obligated to issue shares in certain circumstances as a part of the acquisition of the Scout DS® technology as described in Note 4 to the Company's condensed interim financial statements.

	October 30, 2014	August 31, 2014	November 30, 2013
Common shares issued and outstanding	20,227,732	20,227,732	12,209,608
Options outstanding	1,954,000	1,954,000	988,500
Warrants outstanding	8,390,729	8,791,995	2,718,001

Management continues to implement and maintain certain operating costs control measures in an effort to conserve cash and manage the Company's burn rate. Depending upon available financing, the Company could decide to accelerate, terminate, or cut back on certain business areas, or commence and explore new business areas. These are complex decisions with the goal of optimizing investment returns and managing the cash burn rate.

Based on management's current estimates and expected operating activities, management estimates that sufficient financial resources exist to fund operations into the fourth quarter of fiscal 2014. 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.

**Management's Discussion and Analysis** 



#### **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								
		Within 1 year		2 - 3 years		4 - 5 years		Total	
Management services agreement Contractual commitments Accounts payable and accrued liabilities Long-term debt including interest	\$	36,668 86,000 539,742	\$	- 71,000 - 2,020,878	\$	- 40,000 - -	\$	36,668 197,000 539,742 2,020,878	
	\$	662,410	\$	2,091,878	\$	40,000	\$	2,794,288	

Effective January 1, 2014 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 \$9,167 per month or \$110,000 per annum for a period of one year. The agreement can be terminated with 90 days notice.

The Company is obligated to pay an annual license 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 8 contained in the audited financial statements for the year ended November 30, 2013.

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. There were no royalties paid or accrued for the three and nine months ended August 31, 2014. Royalties for the three and August months ended August 31, 2013 totaled \$174 and \$3,326, respectively, in regards to the royalty obligation, with \$174 and \$3,326 paid during the three and nine months ended August 31, 2013.

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 August 31, 2014, no royalties are due and/or payable.

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 nine months ended August 31, 2013 and was recorded within finance expense. No royalties were accrued or paid for the three and nine months ended August 31, 2014.

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



On December 23, 2013, the Company entered into an amending agreement to extend the \$1,000,000 non-convertible secured loan with a lender (the "2011 Lender") that was originally announced on October 13, 2011. The loan has been extended for an additional six months and will mature on October 14, 2014. The loan will continue to bear interest at a rate of 12% per annum, payable quarterly, and any overdue payment will bear additional interest at a rate of 6% per annum, for a combined interest rate of 18% per annum on any overdue payment. As consideration for the extension of this loan, the Company issued 100,000 common shares (pre-consolidation - 1,000,000 common shares) of the Company to the 2011 Lender. Additionally, the Company entered into a shares for debt agreement with the 2011 Lender and issued 126,806 shares (pre-consolidation - 1,268,055 shares) to satisfy \$63,403 of interest owing on the loan. On May 16, 2014, the Company entered into an additional amending agreement with the 2011 Lender to extend the \$1,000,000 non-convertible secured loan. The loan with the 2011 Lender now matures on December 31, 2015. Additionally, the 2011 Lender has agreed to accrue all interest until December 31, 2015.

Additionally, on December 23, 2013, the Company announced it had arranged a non-convertible secured loan of up to \$1,000,000 from a third party lender (the "2013 Lender"). Any amounts advanced under this loan will be evidenced by promissory notes purchased by the 2013 Lender at a 10% discount to the principal amount of the promissory note. Assuming full draw down under this loan, the aggregate purchase price of the promissory notes will be \$900,000. All amounts owing under this loan will be due and payable on December 31, 2014 and will bear interest at 12% per annum, payable quarterly. In addition, any overdue payment will bear additional interest at a rate of 6% per annum for a combined interest rate of 18% per annum on any overdue payment. In certain circumstances, the Company has the option to satisfy its obligations with respect to any interest payable on the loan by issuing common shares at a discounted price. As consideration for providing the loan, in connection with each purchase of a promissory note by the 2013 Lender, the Company will issue common shares equal to 10% of the principal amount of the promissory note based on the closing price of the Company's common shares on the trading day immediately preceding the purchase of the promissory note.

On January 10, 2014, the Company closed the initial tranche under this loan and received an initial advance of \$250,000 when the 2013 Lender purchased a promissory note for \$278,000. As consideration for providing the initial tranche of the loan, the Company issued 55,600 common shares (pre-consolidation - 556,000 common shares) to the 2013 Lender in connection with the first tranche of the loan..

On February 10, 2014, the Company closed the second tranche under this loan and received an additional advance of \$150,000 when the 2013 Lender purchased a promissory note for \$166,667. As consideration for providing the second tranche of the loan, the Company issued 33,333 common shares to the 2013 Lender and subsequently issued an additional 17,172 common shares to the 2013 Lender in connection with the second tranche of the loan.

On March 20, 2014, the Company closed the third tranche under this loan and received an additional advance of \$150,000 when the 2013 Lender purchased a promissory note for \$166,667. As consideration for providing the third tranche of the loan, the Company issued 75,758 common shares to the 2013 Lender in connection with the third tranche of the loan.

On May 16, 2014, the Company entered into an amending agreement with the 2013 Lender to extend the \$611,334 non-convertible secured loan. The loan with the 2013 Lender now matures on December 31, 2015. Additionally, the 2013 Lender has agreed to accrue all interest until December 31, 2015.

The Company has the option to request the 2013 Lender to advance additional tranches under this loan, which the 2013 Lender may approve or reject at its sole discretion.

A summary of the Company's contractual obligations may be found in Note 10 of the condensed interim financial statements for the three and nine months ended August 31, 2014.

#### **RELATED PARTY TRANSACTIONS**

The Company has an on-going consulting agreement with a shareholder to provide services as needed from time to time. For the three and nine months ended August 31, 2014, \$22,749 and \$26,082, respectively (2013 - \$14,000 and \$35,068), has been recorded in selling, general and administration expenses relating to this consulting agreement. As at August 31, 2014 \$6,668 is recorded within prepaid expenses relating to amounts paid under this consulting agreement (November 30, 2013 - nil).

Management's Discussion and Analysis



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

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

#### **CONTROLS**

#### Effectiveness of disclosure controls and procedures

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

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

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

During the nine months ended August 31, 2014, 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, 2013:

### **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, 2013. Costs incurred for acquired intellectual property - PreVu® is being amortized over the estimated period that it is available for use in the manner intended by management, commencing with the commercial launch of the products associated with the acquired intellectual property - PreVu®, which is estimated to be five years.

Management's Discussion and Analysis



### 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, 2013. Costs incurred for patents, patents pending 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, 2013. Revenue from the sale of goods is measured by reference to the fair value of consideration received or receivable for goods supplied. Revenue from product sales is 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.

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.

Lease revenue from leasing Scout DS® devices to customers under operating leases is recognized as earned over the term of the lease on a straight-line basis.

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, 2013. Inventory consists of parts to be used in the manufacture of finished PreVu® medical devices that are held for resale, as well as finished and fully assembled and tested PreVu® medical devices and purchased PreVu® 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.

Management's Discussion and Analysis



### Stock-based compensation

The Company's accounting policy over stock-based compensation may be found in Notes 3(i)(ii) and 11(c) to the Company's audited financial statements for the year ended November 30, 2013. 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, 2013. 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.

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, 2013.

### **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 replaces the guidance in International Accounting Standard ("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:

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



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

Under IFRS 9, 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.

The mandatory effective date has not yet been determined by the IASB.

### IFRS 15, Revenue from Contracts with Customers

IFRS 15, Revenue from Contracts with Customers, issued by the IASB in May 2014, is applicable to all revenue contracts and provides a model for the recognition and measurement of gains or losses from sales of some non-financial assets. The core principle is that revenue is recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard will also result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively [for example, service revenue and contract modifications] and improve guidance for multiple-element arrangements. IFRS 15 is effective for annual periods beginning on or after January 1, 2017 and is to be applied retrospectively, with earlier adoption permitted. Entities will transition following either a full or modified retrospective approach. The Company is currently evaluating the impact of the above standard on its financial statements.

#### Amendments to IAS 32, Financial Instruments: Presentation

Amendments to IAS 32 were issued to clarify the existing requirements for offsetting financial assets and financial liabilities. The amendments are effective for annual periods beginning on or after January 1, 2014. The Company does not expect the adoption of these amendments to have a material impact on the consolidated financial statements.

### IFRIC 21, Levies

IFRIC 21, *Levies*, addresses various accounting issues relating to levies imposed by a government. This interpretation is effective for annual periods beginning on or after January 1, 2014. The Company is currently assessing the impact the adoption of this interpretation may have on the consolidated financial statements.

### Amendments to IAS 39, Financial Instruments: Recognition and Measurement

In June 2013, Novation of Derivatives and Continuation of Hedge Accounting was issued, which amends IAS 39, *Financial Instruments Recognition and Measurement*. Under these narrow scope amendments there would be no need to discontinue hedge accounting if a hedging derivative was novated, provided certain criteria are met. These amendments are effective for annual periods beginning on or after January 1, 2014. The Company does not expect the adoption of these amendments to have a material impact on its consolidated financial statements.

### 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:

- 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.