Managements' Discussion and Analysis (Expressed in Canadian Dollars)

# **MIRACULINS INC.**

Three and nine months ended August 31, 2015

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 29, 2015 and should be read in conjunction with Miraculins Inc.'s ("Miraculins" or the "Company") unaudited condensed interim financial statements for the three and nine months ended August 31, 2015, 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, 2014, 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, INCLUDING GOING CONCERN CONSIDERATIONS**

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 lead technology program is in the early commercialization phase in the area of diabetes risk assessment. The 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 detecting and measuring 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' other major technology related to cardiovascular disease 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"). This program is currently under strategic review by the Company and is discussed in more detail later in the MD&A.

Miraculins also continues to remain open to the evaluation of 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 having 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. Subsequent to August 31, 2015, as disclosed in note 8(b), on October 26, 2015 the Company announced a private placement offering of up to \$250,000 and closed its first tranche for gross proceeds of \$135,000.

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 expected expenditure levels and contracted commitments will exceed the Company's net cash inflows and working capital during the fourth quarter of fiscal 2015 unless further financing is obtained. In short, additional sources of funding are required to carry on operations. Subsequent to August 31, 2015, as disclosed in note 8(b), on October 26, 2015 the Company announced a private placement offering of up to \$250,000 and closed its first tranche for gross proceeds of \$135,000. However, additional funding is still required as there is currently limited cash available. The Company's debt has previously been extended and is now due on December 31, 2015. The Company intends to renegotiate the terms of its secured debt and/or seek an additional extension of the maturity date.

The Company's strategy changed in fiscal 2015 with the Company's resources for the foreseeable future being focused on the commercialization of the Scout DS® technology. The Scout DS® technology is approved for commercial sale in Canada and Europe and the Company has launched the product through pharmacy pilots in the Canadian market with nominal revenues expected during fiscal 2015 and 2016. The Company is currently in the early stages in the process of obtaining regulatory approval for sale of the Scout DS® technology in China. Commercialization of the Scout DS® technology in the United States will be dependent on, among other things, available funding to obtain regulatory approval. The Company's future operations including the completion of the commercialization of the Scout DS® technology is dependent upon its ability to secure additional funds, renegotiate the terms and/or obtain an additional extension to the maturity date of the Company's secured debt, obtain regulatory approval in China, 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. No agreements with the lender or other potential lenders or investors have been reached yet and there can be no assurance that such agreements will be reached. Such transactions, if completed, could have a significant dilutive effect on existing shareholders. 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, renegotiate the terms and/or obtain an additional extension to the maturity date of the Company's secured debt, obtain regulatory approval in China, 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, further cost curtailments, delays of product launch and exploring the monetization of certain intangible assets, as well as seeking to outlicense 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 6of the Company's financial statements for the three and nine months ended August 31, 2015.

In summary, the ability of the Company to continue operations and execute its business plan is contingent on obtaining the necessary funds and renegotiating or extending the terms of the Company's secured debt.

## Lead Technology Summary - Scout DS®

• 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 CE Marked 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 continues to review — 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 in China, as well as filed pre submission documentation with the U.S. Food and Drug Administration regarding the de novo classification of its Scout DS® diabetes device, as a next step towards securing marketing clearance in the United States. The Company has also recently completed a pharmacy pilot with Lovell Drugs in southern Ontario for its Scout DS® Diabetes Screening Kiosk program.

# PreVu Non-Invasive Skin Cholesterol Point-of-Care (POC) Test

• The Company's other technology, the 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. This technology program is currently under strategic review by the Company, and is discussed in further detail later in the MD&A.

Management's Discussion and Analysis



#### **Recent Developments**

Developments indicated are at the time of the dates specified.

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

On **December 23**, **2014**, the Company announced that it has executed an amendment (the "Amendment") to the asset purchase agreement dated June 28, 2013 between Miraculins and VeraLight Inc. ("VeraLight") (the "APA"), wherein Miraculins acquired all of the relevant assets relating to VeraLight's Scout DS® non-invasive diabetes screening technology. The Amendment eliminates the majority of the Company's remaining obligations and terminates the obligation to issue equity to VeraLight under the APA.

In connection with the Amendment, the Company has made a one-time payment of CDN \$500,000 to VeraLight. In addition to the one-time payment, the Company has issued 1,000,000 new common share purchase warrants (the "Warrants") to VeraLight at an exercise price of CDN \$0.25 per share with a term expiring on the fifth anniversary after issuance. Of these, 450,000 of the Warrants will vest immediately and the remaining 550,000 Warrants will vest upon the earlier of (i) 12 months from the date of issuance, or (ii) a Liquidity Event (as defined in the Amendment). No common shares or warrants have previously been issued to VeraLight, and on the closing of the Amendment, VeraLight will have no right to receive common shares of the Company other than the Warrants described above.

On **January 27, 2015**, the Company announced that it will be commencing a pilot program with Lovell Drugs Ltd. ("Lovell") and Pear Healthcare Solutions Inc. ("Pear") that will see the placement of the first stand-alone, Scout DS® diabetes screening kiosks in Lovell's retail pharmacy locations in Ontario beginning in February 2015. Lovell is the oldest and one of the largest, independent drug store chains in Ontario and has been family-owned and community-minded for more than 100 years, with a reputation for innovative programming and forward-thinking product/service delivery.

This proof of concept pilot is being conducted to demonstrate that a stand-alone Scout DS® diabetes screening kiosk set up inside a pharmacy location, has the ability to not only deliver a rapid, non-invasive and superior diabetes screening clinic, but can be additionally purposed to generate a meaningful financial return on investment (ROI) for the pharmacy that would not have otherwise, or readily been achievable.

With a proven ROI model that could be easily reproduced in any pharmacy setting – independent as well as national chains – Miraculins could then make the business case for pharmacies to lease Scout DS® screening kiosks on a regular basis throughout the calendar year, to both meet the diabetes screening needs of their customers and to generate new retail revenue. The Company believes that the model it is developing will have application for retail pharmacy and pharmacy/grocery operations in North America and for similar retail settings in Europe and other countries as well.

On **February 18, 2015**, the Company announced that it had filed pre-submission documentation to the U.S. Food and Drug Administration regarding the de novo classification of its Scout® diabetes device, as a next step towards securing marketing clearance in the United States.

On **March 5, 2015**, the Company announced that its Scout DS® Diabetes Screening Kiosk pilot being conducted in partnership with Lovell Drugs Ltd. and Pear Healthcare Solutions Inc., has to date identified 145 individuals, or 41% of those screened in just 16 days, to be at elevated risk for pre-diabetes or type 2 diabetes. All customers who were identified as being at risk by the Scout DS® were recommended to follow-up with their physician for confirmatory blood testing. The Company also reports that pilot participants were pleased to complete a touch-screen survey while seated for their complimentary and non-invasive Scout DS® diabetes test, which resulted in the acquisition of valuable and traditionally difficult to procure consumer information. The survey was specifically tailored to help identify opportunities for the provision of enhanced healthcare and customer service, while isolating pathways for the pharmacy to potentially increase its revenues related to diabetes care and corresponding lifestyle change management. Both the screening and survey were preceded by participating individuals signing a consent form.

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



The Scout DS® Diabetes Screening Kiosk pilot concluded March 11, 2015. Over 560 individuals were provided with complimentary diabetes screening over a period of 23 days at pharmacies in Oshawa and Whitby, with 203 individuals (36%) identified by the Scout DS® as being at-risk of pre-diabetes, and 55 (10%) identified as being at risk of type 2 diabetes. All customers who were identified as being at-risk were recommended to follow-up with their physician for confirmatory blood testing. Additionally, the surveying was done while customers were being screened identified patients with high blood pressure and high cholesterol, those in need of medication reviews, customers who were filling prescriptions at different stores or had never had prescription filled at the screening pharmacy, smokers, those interest in weight loss, dietary and fitness counselling and new store customers who had come in specifically for a Scout DS® diabetes screen. Much of this data may be actionable by the pharmacy to increase in-store revenues, and in some cases products and services that can be offered by the pharmacy (medication reviews and smoking cessation) are covered by the Province of Ontario (other provinces as well).

On **March 10, 2015**, the Company announced that it has appointed leading occupational health physician and workplace wellness expert Dr. Alain Sotto, Hon. B.Sc., M.D., CCFP (E.M.), F.C.B.O.M to the Scout DS<sup>®</sup> Medical Advisory Board. Dr. Sotto is the Toronto Transit Commission's Occupational Medical Consultant, Investigative Coroner for York Region, and Director of the Medcan Wellness Clinic, Canada's largest executive healthcare clinic with more than 70 physicians and specialists. He is the former Chief Physician at Ontario Power Generation - Wellness Division, where he was the lead on the utility's corporate health and wellness strategy. He was also the Medical Director at Boeing Toronto for 17 years and the Medical Director for many other large employers in Toronto including Pratt and Whitney, Bombardier and McDonnell-Douglas Canada. Additionally, Dr. Sotto has served as Regional Medical Officer for the Great Lakes region at CN Railways and has been an occupational medical consultant to Stelco and several other companies.

Dr. Sotto is a certified specialist in Emergency and Family Medicine and is on staff in Family Medicine at William Osler Hospital in Brampton, where he has worked in the Emergency Department for 19 years. He has also had an active part-time Family Practice in Brampton for the last 26 years. Dr. Sotto serves on numerous medical advisory boards including the Ministry of Health and Long Term Care — Scientific Advisory Council (Ontario), Canadian Board of Occupational Medicine Executive, Benefits Canada, and the Morneau Shepell Mental Health Advisory Board. He also serves on the Sanofi Canada Healthcare Survey Advisory Board (2013, 2014, 2015), which publishes an annual report of the same name that since 1998 has been nationally tracking feedback from Canadians with employer-sponsored health benefit plans to help facilitate industry being more aware and responsive to healthcare issues and needs in the workplace. He is a highly regarded guest speaker, writer, and medical guest commentator and in November 2012, he was the Keynote Speaker at the Annual International Foundation of Employee Benefit Plans (IFEBP) speaking to 1,330 attendees on aging and wellness. The IFEBP is the largest association serving the employee benefits and compensation industry with 33,000 members.

On **April 28, 2015** the Company announced that it had recently received important feedback from the United States Food and Drug Administration (FDA) as part of the de novo pre-submission process. Based on this communication from the FDA, the Company plans to continue advancing on the de novo clearance pathway for the Scout® device. The de novo process is generally considered to be appropriate for "novel" medical devices for which there are no legally marketed predicate devices, and whose risk profiles do not warrant the regulatory pathway known as a premarket approval (PMA), which is required of products considered to have the highest risk to public safety (Class III). The Company is of the view that there is no predicate for the Scout® device, and based on the feedback received from FDA the de novo process could provide the appropriate regulatory pathway for marketing clearance in the U.S.

On **May 22, 2015** the Company announced that it has completed all required preparations for the submission of its Scout DS<sup>®</sup> device for product testing in compliance with Chinese Food and Drug Administration (CFDA) requirements. Product testing, which must precede clinical trials in China, relates to a series of safety and operational tests that the CFDA testing center and its engineers decide are suitable for a medical device including electrical testing, biocompatibility testing, mechanical testing, stability testing, integrity testing, and other related tests to verify the device's specified operating parameters.

Product testing is the first major step towards securing regulatory approval for the Scout DS® in China, and the Company has been diligently working with its lead Chinese regulatory consultant, Emergo Global, towards compiling and translating all of the technical documentation required for submission to enable the product testing process to begin.

Preparation for CFDA product testing was significant and included the translation of Scout DS® device engineering drawings, circuitry diagrams, operating manuals, ISO documentation, as well as all of the internationally-recognized electrical, safety, mechanical and related testing and performance documentation that the Company already had on file for the Scout DS® related to its prior clearances in Canada and the European Union.

The Company has also been working with Emergo Global to evolve a comprehensive regulatory strategy in China overall, that additionally includes the development of a study protocol for the Scout DS® clinical trials that will be conducted in China following the successful conclusion of the product testing process.

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



On **June 4, 2015** the Company announced that the 23<sup>rd</sup> World Congress of Dermatology has accepted a scientific poster from a collaboration between Miraculins and Amway Corporation's Open Innovation Team ("Amway"). The World Congress of Dermatology is the world's oldest and continuous international dermatology meeting, and will be held in Vancouver, BC from June 8-13, 2015. The poster, entitled "The Association of Skin Glycation with Facial Skin Aging", concludes that advanced glycation end-products ("AGEs") – as measured by the Scout DS® - are correlated with the visible signs of facial skin aging, and that vitamin supplementation was associated with lower skin AGEs. Miraculins has been reviewing these important pilot findings with Amway to determine the potential next steps in assessing the viability of Scout DS® intellectual property being utilized in a device specifically for the health and beauty segment.

The collaborative study was conducted in the United States on 555 women between the ages of 16 and 82, and was comprised of a mixed race cohort. Subjects were assessed through a crosssectional survey using objective methods and a questionnaire that took into account age, ethnicity, BMI, smoking, sun protection habits, years working outdoors, vitamin supplementation, skin care habits, tanning, history of type 1 or 2 diabetes, kidney, heart and skin disease. Skin AGE's were measured utilizing the Scout DS® device, and facial wrinkling and skin lightness were measured using standardized facial photography and analysis.

On **July 6, 2015** the Company announced that four abstracts featuring Scout® as a tool for the measurement of skin intrinsic fluorescence (SIF), a marker for pre-diabetes and diabetes, were presented at the recent 75th Scientific Sessions of the American Diabetes Association (ADA) from June 5-9 in Boston, MA. The ADA Scientific Sessions bring together scientists and health care professionals from around the world who are involved in diabetes research and care.

All four of the abstracts, presented as either posters or oral presentations, were as a result of investigator initiated studies where the Scout® was selected by leading academic and scientific experts as the device of choice for studies in the flourishing field of research related to skin advanced glycated end products (AGEs) and their role in diabetes.

On **July 30, 2015** the Company announced the execution of a non-binding Letter of Intent (the "LOI") with New Leaf Health Ltd. ("New Leaf"), one of the largest, most experienced workplace wellness providers in the United Kingdom (UK), for the exclusive distribution of the Scout DS® diabetes screen into Britain's workplace wellness segment. New Leaf has a large and growing roster of clients including multi-nationals such as British Airways, Airbus and Volvo and it delivers evidence-based and cost-effective wellness programming throughout the entirety of the UK.

On **August 13, 2015** the Company announced that it has made a supplemental filing with the United States Food and Drug Administration ("FDA") regarding its recent de novo pre-submission for its Scout® device. The additional submission of documentation is part of the Company's ongoing dialogue with the FDA regarding the evaluation of the de novo process as a potential pathway for the marketing clearance of the Scout® device as an aid in the identification of pre-diabetes.

## PreVu® POC Test

No recent news to report.

## **Corporate Developments**

On **December 11, 2014**, the Company announced that it has closed a private placement offering with aggregate gross proceeds to the Company of \$200,000 from the sale of 2,000,000 units at a price of \$0.10 per Unit. Each Unit is comprised of one common share of the Company and one Share purchase warrant.

On **April 22, 2015** the Company closed a non-brokered private placement offering (the "Offering") of 4,000,000 units ("Units") at a price of \$0.10 per Unit for gross proceeds of up to \$400,000. Each Unit is comprised of one common share of the Company (a "Share") and one Share purchase warrant. Each whole warrant (a "Warrant") will entitle the holder to purchase one Share at a price of \$0.15 per Share for a period of 24 months from the date the Warrant is issued.

On **July 14, 2015** the Company closed a non-brokered private placement offering (the "Offering") of 4,375,000 units ("Units") at a price of \$0.08 per Unit for gross proceeds of up to \$350,000. Each Unit is comprised of one common share of the Company (a "Share") and one Share purchase warrant. Each whole warrant (a "Warrant") will entitle the holder to purchase one Share at a price of \$0.10 per Share for a period of 24 months from the date the Warrant is issued.

On **October 26, 2015** the Company announced a private placement offering (the "October 2015 Offering") of up to \$250,000 and closed its first tranche of 2,700,000 units ("Units") at a price of \$0.05 per Unit for gross proceeds of \$135,000. Each Unit is comprised of one common share of the Company (a "Share") and one half of one Share purchase warrant. Each whole warrant (a "Warrant") will entitle the holder to purchase one Share at a price of \$0.08 per Share for a period of 12 months from the date the Warrant is issued.

# **Management's Discussion and Analysis**



A certain person assisted the Company by introducing a subscriber for the October 2015 Offering and was paid a finder's fee of 10% of the total subscription proceeds received from the subscriber introduced to the Company by that person.

#### Preeclampsia/Endoglin

No recent news to report.

#### **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 Coronary Artery Disease ("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. The PreVu® program is currently under strategic review by the Company, and is discussed in further detail later in the MD&A.

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, and executing a major sales and distribution agreement for the sale of up to \$90 million Scout DS® diabetes screening devices in China.

## SCOUT DS® PRODUCT ACQUISITION HIGHLIGHTS

On August 1, 2013 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:

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



- 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:
- 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 TECHNOLOGY**

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, pilot outcomes, and the limited availability of investment funding Miraculins has been recently focusing its attention on capitalizing on the acquisition of its Scout DS® program.

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.

#### 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.

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



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 CE Marked in the European Union, and is also cleared for sale in other markets. 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 February 18, 2015, the Company announced that it had provided pre-submission documentation to the U.S. Food and Drug Administration ("FDA") regarding the de novo classification of its Scout® diabetes device, as a next step towards securing marketing clearance in the United States. There is a three-tier classification system in the U.S. that the FDA has established for medical device clearance based on the risks and types of controls required to assure the public's safety:

- Class I devices are the lowest risk, require only general controls, and typically do not require premarket notification or approval.\*
- Class II devices are moderate risk, require general and special controls, and typically require a 510(k) application. A
  510(k) is a premarket submission that demonstrates that a device is substantially equivalent to a legally marketed device
  that is not subject to premarket approval (called a predicate device).
- Class III devices are considered to have the highest risk and require general controls, special controls, and premarket
  approval. If a low to moderate risk product does not have a predicate device it receives an automatic Class III
  designation.\*

For automatic Class III designations, the FDA amended its de novo classification process in 2012 to provide a pathway to Class I or Class II 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 is of the view that there is no predicate device for the Scout<sup>®</sup>, and that the de novo process could provide the appropriate regulatory pathway for market clearance in the U.S. The de novo process may be less burdensome than would be the case if the Company sought a premarket approval for the Scout<sup>®</sup> device.

On August 13, 2015 the Company announced that it has made a supplemental filing with the United States Food and Drug Administration ("FDA") regarding its recent de novo pre-submission for its Scout® device. The additional submission of documentation is part of the Company's ongoing dialogue with the FDA regarding the evaluation of the de novo process as a potential pathway for the marketing clearance of the Scout® device as an aid in the identification of pre-diabetes.

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; the Centers for Disease Control, in Atlanta, Georgia 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 is working with Pear Healthcare Solutions Inc. ("Pear"), a leading provider of in pharmacy health screening and education services, to evolve distribution models for the Scout DS® to the Canadian retail pharmacy/grocery market. 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<sup>®</sup> technology as part of a series of pharmacy diabetes clinics that were 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.

A patient who's Scout DS® screening result suggests a likelihood of pre diabetes or type 2 diabetes is recommended to see their doctor to have a confirmatory 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.

Six 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.
- Edward L. Hull, PhD et al. Non-invasive skin fluorescence spectroscopy for detection of abnormal glucose tolerance.
   Journal of Clinical & Translational Endocrinology 1 (2014) 92e99

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

Key clinical evidence for Scout DS® includes:

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



- 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® tests ability to correctly identify 93.7% of previously identified diabetic individuals.

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 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® Non-Invasive 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. ("Cachet") has been co-appointed 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<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;

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



- 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<sup>®</sup> devices are sold into the field.

On September 25, 2014, the Company announced that it has received the first payment 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 in 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 upfront payment is refundable under the agreement.

On May 22, 2015 the Company announced that it has completed all required preparations for the submission of its Scout DS<sup>®</sup> device for product testing in compliance with Chinese Food and Drug Administration (CFDA) requirements. Product testing, which must precede clinical trials in China, relates to a series of safety and operational tests that the CFDA testing center and its engineers decide are suitable for a medical device including electrical testing, biocompatibility testing, mechanical testing, stability testing, integrity testing, and other related tests to verify the device's specified operating parameters.

Product testing is the first major step towards securing regulatory approval for the Scout DS® in China, and the Company has been diligently working with its lead Chinese regulatory consultant, Emergo Global, towards compiling and translating all of the technical documentation required for submission to enable the product testing process to begin.

Preparation for CFDA product testing was significant and included the translation of Scout DS® device engineering drawings, circuitry diagrams, operating manuals, ISO documentation, as well as all of the internationally-recognized electrical, safety, mechanical and related testing and performance documentation that the Company already had on file for the Scout DS® related to its prior clearances in Canada and the European Union.

The Company has also been working with Emergo Global to evolve a comprehensive regulatory strategy in China overall, that additionally includes the development of a study protocol for the Scout DS® clinical trials that will be conducted in China following the successful conclusion of the product testing process.

On June 4, 2015 the Company announced that the 23<sup>rd</sup> World Congress of Dermatology has accepted a scientific poster from a collaboration between Miraculins and Amway Corporation's Open Innovation Team ("Amway"). The World Congress of Dermatology is the world's oldest and continuous international dermatology meeting, and will be held in Vancouver, BC from June 8-13, 2015. The poster, entitled "The Association of Skin Glycation with Facial Skin Aging", concludes that advanced glycation end-products ("AGEs") – as measured by the Scout DS® - are correlated with the visible signs of facial skin aging, and that vitamin supplementation was associated with lower skin AGEs. Miraculins has been reviewing these important pilot findings with Amway to determine the potential next steps in assessing the viability of Scout DS® intellectual property being utilized in a device specifically for the health and beauty segment.

The collaborative study was conducted in the United States on 555 women between the ages of 16 and 82, and was comprised of a mixed race cohort. Subjects were assessed through a crosssectional survey using objective methods and a questionnaire that took into account age, ethnicity, BMI, smoking, sun protection habits, years working outdoors, vitamin supplementation, skin care habits, tanning, history of type 1 or 2 diabetes, kidney, heart and skin disease. Skin AGE's were measured utilizing the Scout DS® device, and facial wrinkling and skin lightness were measured using standardized facial photography and analysis.

On July 6, 2015 the Company announced that four abstracts featuring Scout<sup>®</sup> as a tool for the measurement of skin intrinsic fluorescence (SIF), a marker for pre-diabetes and diabetes, were presented at the recent 75th Scientific Sessions of the American Diabetes Association (ADA) from June 5-9 in Boston, MA. The ADA Scientific Sessions bring together scientists and health care professionals from around the world who are involved in diabetes research and care.

All four of the abstracts, presented as either posters or oral presentations, were as a result of investigator initiated studies where the Scout® was selected by leading academic and scientific experts as the device of choice for studies in the flourishing field of research related to skin advanced glycated end products (AGEs) and their role in diabetes.

The ADA abstracts which included the Scout® are as follows:

# **Management's Discussion and Analysis**



#### **Poster Presentations**

- Meta-GWAS Identifies a Second Locus Associated with Skin Intrinsic Fluorescence, PI A. Patterson, The Hospital for Sick Children, Toronto, ON (#1742-P)
- Serum Protein Glucosepane and Skin Intrinsic Fluorescence Are increased in Youth with Type 1 Diabetes, PI RA. Gubitosi-Klug, Case Western Reserve University, Cleveland, OH (#1412-P)
- Skin Advanced Glycation End Products (AGE) Fluorescence Identifies Abnormal Glucose Tolerance Independent of Levels of HbA1c and Soluble Receptor for Advanced Glycation End Products (sRAGE) PI V. Mohan, Madras Diabetes Research Foundation & Dr. Mohan's Diabetes Specialties Centre, Chennai, India (#1566-P)

#### **Oral Presentations**

• Advanced Glycation Endproducts (AGEs) Are Already Elevated in Obese Children at Diagnosis of Type 2 Diabetes (T2D) PI S. Chalew, Louisiana State University Health Sciences Center, New Orleans, LA (#68-OR)

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® manufacturing facility in New Mexico, by successfully
  passing an ISO audit (facility was eventually shut down to facilitate a transition of manufacturing operations see below);
- Subsequently transitioning Scout DS® manufacturing operations under full quality standards from the New Mexico facility to a contract manufacturer in Philadelphia, Pennsylvania;
- Enabling new scientific research studies, with third party collaboration, exploring the potential for new market segments and test utility expansion;
- Working with Pear Healthcare Solutions to evolve distribution models for Scout DS<sup>®</sup> to the Canadian Pharmacy segment;
- Facilitating placement of the Scout DS® into a major Canadian retail/food pharmacy chain pilot program:
- Executing a major Agreement for the sales and distribution Scout DS<sup>®</sup> devices in Mainland China;
- Evaluating previous international Scout DS® distributors to identify opportunities for reappointment;
- Filing pre submission documentation with the FDA regarding the de novo classification of its Scout DS® device, as the next step in securing marketing clearance in the United States.

On July 30, 2015 the Company announced the execution of a non-binding Letter of Intent (the "LOI") with New Leaf Health Ltd. ("New Leaf"), one of the largest, most experienced workplace wellness providers in the United Kingdom (UK), for the exclusive distribution of the Scout DS® diabetes screen into Britain's workplace wellness segment. New Leaf has a large and growing roster of clients including multi-nationals such as British Airways, Airbus and Volvo and it delivers evidence-based and cost-effective wellness programming throughout the entirety of the UK.

Under the LOI, the parties have acknowledged the general terms that will form part of a formalized agreement, including the award of exclusive distribution rights to New Leaf within the UK workplace wellness segment for a designated period of time with options for renewal, and New Leaf's commitment to purchase a minimum number of Scout DS® devices within the first year of screening operations. According to the terms of the LOI, Miraculins is also to receive an ongoing payment for every Scout DS® test conducted in the UK and additional revenue through the provision of branded test consumables.

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 in some models, will involve charging them a percentage of the rental or leasing revenue garnered from their customers, or a per test fee, and possibly fulfilling device servicing as well. In some markets, the Company may lease Scout DS® devices and screening kiosks to retailers directly. Use of the Scout DS® device also requires the additional purchase of proprietary consumable cleaning materials that will generate moderate additional revenue. 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 pre-diabetics or type 2 diabetics, and may involve the payment of upfront, milestone and maintenance fees.

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



#### Primary Sales & Distribution Channels

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

- Retail Pharmacy/Grocery
- Workplace Screenings
- Health and Wellness (not currently active in this channel)
- Medical Clinics/Physicians (not currently active in this segment)

#### Retail Pharmacy/Grocery

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.

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.

Retail pharmacy culture has traditionally offered risk assessment and prevention programs 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 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 turnkey 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 or its distribution partners. 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.

The Company recently concluded such a Scout DS® Diabetes Screening Kiosk pilot in the Lovell Drugs chain in southern Ontario, placing a turn-key kiosk with a Miraculins provided Test Operator in two pharmacies over a 23 day period from mid-February to early March 2015. The pilot was conducted to demonstrate that a stand-alone Scout DS® diabetes screening kiosk set up inside a pharmacy location, had the ability to not only deliver a rapid, non-invasive and superior diabetes screening clinic, but could be additionally purposed to generate a meaningful financial return on investment (ROI) for the pharmacy that would not have otherwise been readily achievable. The Company believes that this latter feature could provide additional encouragement to pharmacies to incorporate Scout DS® into their store clinic programming.

With a proven ROI model that could be easily reproduced in any pharmacy setting (independent as well as national chains), Miraculins can make the business case for pharmacies to lease Scout DS® screening kiosks on a regular basis throughout the calendar year, to both meet the diabetes screening needs of their customers and to generate new retail revenue, including the provision of reimbursable products/services such as annual medication reviews and those related to smoking cessation. The Company believes that the model it is developing could have application for retail pharmacy and pharmacy/grocery operations in North America and for similar retail settings in Europe and other countries as well.

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



The Lovell pilot screened 563 pharmacy customers and identified 258 as being at risk for pre-diabetes or type 2 diabetes. Of these 203 individuals (36%) were identified by Scout DS® as being at risk of pre-diabetes and 55 individuals (10%) were identified as being at risk for type 2 diabetes. Individuals who went on to be diagnosed by their doctor as having type 2 diabetes could represent a potential ongoing revenue stream to the pharmacy of up to \$3,000 annually for medication prescriptions and other diabetes related products such as needles, test strips, sterile dressings, foot creams, bandages etc.¹ In addition, diabetics often have co-morbidities that drive additional spending for conditions that may include high blood pressure, fluid and electrolyte disorders, chronic pulmonary disease, anemia and kidney failure, potentially adding to pharmacy revenue streams.1 Individuals who went on to be diagnosed by their doctor as having pre-diabetes could represent an annual revenue stream to the pharmacy for medication prescriptions and other pre-diabetes related products designed to stop or slow down progression of the disease.¹ 15%-30% of pre-diabetics will develop type 2 diabetes within five years,2 and will be in need of ongoing treatment products and services provided by the pharmacy.¹ Patients will continue to be tracked post pilot in an effort to determine how many followed up with their doctors and went on to be diagnosed accordingly.

The pilot also afforded the collection of other valuable customer metrics, facilitated by customers completing a touch-screen survey while seated for their complimentary Scout DS<sup>®</sup> diabetes test. Customer information is traditionally difficult to procure and the survey was specifically tailored to help identify opportunities for the provision of enhanced healthcare and customer service, while isolating pathways for the pharmacy to potentially increase its revenues related to diabetes care and corresponding lifestyle change management. Both the screening and survey were preceded by participating individuals signing a consent form.

## Information gathered included:

Medication Reviews - 16% (70 individuals from a smaller sampling of 434), indicated they were taking three or more prescription medications, without having had a formal medication review with a Pharmacist within the last year. In most Canadian provinces, these patients can receive a free medication review annually, which the pharmacy is reimbursed for by the provincial government. In Ontario, the reimbursement amount is \$60 per patient (more if they are diabetic), which could represent another potential annual revenue stream to the pharmacy if these customers were confirmed for medication reviews.

<u>New Prescriptions</u> – 40% (226 individuals) indicated they had never had a prescription filled at the pharmacy, underscoring the opportunity for acquiring new prescription business from customers presenting in-store.

<u>Prescription Consolidation</u> – 16% (91 individuals) indicated they had their ongoing prescriptions filled at more than one store, underscoring the opportunity to generate increased revenue by migrating customer prescriptions over from other pharmacies.

<u>Dietary and Fitness Counselling</u> – 53% (300 individuals) indicated they were interested in receiving dietary or fitness counselling in the future, while 74% (416 individuals) indicated they did not have a gym or fitness club membership. These individuals would be candidates for complementary service offerings.

Additional survey findings that underscore the opportunity for the pharmacy to enhance customer healthcare and service, build store traffic, increase its retail revenue, and further strengthen customer loyalty include:

- 16% indicated they were smokers and would be candidates for government reimbursable smoking cessation programs provided in pharmacy, which the Ontario Government pays up to \$125 per qualifying patient;
- 57% indicated they were overweight and would be candidates for supplements, vitamins, and other related products;
- 18% came into the pharmacy specifically for a Scout DS® screen, which can result in pharmacy revenue through convenience purchases while that customer is in-store;
- 97% (projected from a smaller sampling) said they would recommend a Scout DS® screening to family or friends, underscoring significant word-of-mouth potential to increase store traffic;
- 99% (projected from a smaller sampling) planned to see their doctor and make changes to their diet/lifestyles if their Scout DS® scores were elevated, suggesting that Scout DS® can be a tipping point for personal action.

Based upon the willingness of pharmacy pilot customers to complete a survey while being tested, the Scout DS® diabetes screening and consumer survey kiosk may also have the potential to be integrated into retail store operations with large customer bases in other major sectors, as well as into shopping malls, airports and a variety of public settings. Retailers, organizations and marquee brands in North America and abroad highly value actionable consumer information, which in practice is very hard to get. The Company believes these groups could use the Scout DS® kiosk to procure that data and deliver a brand message, while providing an important, complimentary healthcare screen to their customers.

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



As a result of these promising pilot results, the Company plans to continue to develop a business model for the pharmacy sector (adaptable for non-pharmacy applications as well) where retailers could lease the turn-key and fully-staffed Scout DS® diabetes screening and consumer survey kiosks on a weekly, monthly, or longer-term basis. As individuals with normal Scout DS® results are recommended to be re-tested annually, the kiosk has a recurring customer contact and outreach feature built-in. Additional Scout DS® pilots for the pharmacy sector are being planned.

(1) Smart Retailing RX: The Full Value of a Diabetes Patient (February 6, 2012); (2) Centers for Disease Control and Prevention: National Diabetes Statistics Report (2014); (3) Canadian Pharmacists Association: Diabetes Strategy for Pharmacists (2013) \*Designates risk factor for diabetes

#### Workplace Screenings

Generally defined as employer sponsored or endorsed activities aimed at improving health related behaviours, workplace 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.<sup>1</sup>

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.¹ 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.

This market segment involves partnering with established health and wellness service providers to introduce Scout DS® diabetes screening devices into the workplace – through weekly and monthly leasing programs that can be repeated annually - targeting private and public sector companies, as well as large government employers (generally considered to have more than 500 employees).

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 in 2015. The objective will be to make the business case to these companies and their insurance providers that workplace diabetes screenings can delay or prevent the economic impact of employees being affected by diabetes, which includes absenteeism, loss of productivity, co-morbidities and cost of medications².

(1) Workplace Wellness Programs Can Generate Savings; Baicker, Cutler, and Song (2010); (2) Benefits Canada – ROI of One Life: Diabetes Conference Report 2014;

## Health and Wellness

While the Company is not currently active in this market segment, as the Scout DS® technology becomes more widely established and accepted, the placement of Scout DS® diabetes screening devices with other accredited medical and health professionals such as Registered Dieticians and Naturopathic Doctors, may offer additional point-of-care opportunities for testing individuals in the community, while offering these professionals a vehicle to further expand their patient rosters and establish new revenue pathways in their practices.

# Medical Clinics/Physicians

While the Company is not currently active in this market segment, as the Scout DS® technology becomes more widely established and accepted, the placement of Scout DS® diabetes screening devices in physician offices may offer another channel of distribution. While physicians have many tools at their disposal to risk assess and diagnose disease conditions, including the ability to order confirmatory blood tests, a reimbursable screening application in-office, with point-of-care results, could enhance a physician's screening capability. It is expected that reimbursement by government or private insurers will be required to fulfill the commercial potential of this market 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 latest pre submission documentation with the FDA was on August 13, 2015 regarding the de novo classification of its Scout DS® diabetes screening device, as the next 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 of those undiagnosed. In addition, there are an estimated 79 million pre diabetics in the U.S., over 90% of which are unaware of their status.¹ 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.

(1) Centers for Disease Control and Prevention. National diabetes statistics report: estimates of diabetes and its burden in the United States, 2014.

#### 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 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® has previously been cleared 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 will continue to evaluate 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 has established a formal Medical Advisory Board for Scout DS®, and has appointed leading occupational health physician and workplace wellness expert Dr. Alain Sotto, Hon. B.Sc., M.D., CCFP (E.M.), F.C.B.O.M to the same board. Dr. Sotto is the Toronto Transit Commission's Occupational Medical Consultant, Investigative Coroner for York Region, and Director of the Medcan Wellness Clinic, Canada's largest executive healthcare clinic with more than 70 physicians and specialists. He is the former Chief Physician at Ontario Power Generation - Wellness Division, where he was the lead on the utility's corporate health and wellness strategy. He was also the Medical Director at Boeing Toronto for 17 years and the Medical Director for many other large employers in Toronto including Pratt and Whitney, Bombardier and McDonnell-Douglas Canada. Additionally, Dr. Sotto has served as Regional Medical Officer for the Great Lakes region at CN Railways and has been an occupational medical consultant to Stelco and several other companies.

Additionally, Dr. Sotto is a certified specialist in Emergency and Family Medicine and is on staff in Family Medicine at William Osler Hospital in Brampton, where he has worked in the Emergency Department for 19 years. He has also had an active part-time Family Practice in Brampton for the last 26 years. Dr. Sotto serves on numerous medical advisory boards including the Ministry of Health and Long Term Care — Scientific Advisory Council (Ontario), Canadian Board of Occupational Medicine Executive, Benefits Canada, and the Morneau Shepell Mental Health Advisory Board. He also serves on the Sanofi Canada Healthcare Survey Advisory Board (2013, 2014, 2015), which publishes an annual report of the same name that since 1998 has been nationally tracking feedback from Canadians with employer-sponsored health benefit plans to help facilitate industry being more aware and responsive to healthcare issues and needs in the workplace. He is a highly regarded guest speaker, writer, and medical guest commentator and in November 2012, he was the Keynote Speaker at the Annual International Foundation of Employee Benefit Plans (IFEBP) speaking to 1,330 attendees on aging and wellness. The IFEBP is the largest association serving the employee benefits and compensation industry with 33,000 members.

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. In Dr. Sotto's specific case, his extensive experience in developing and managing chronic disease prevention programs for a number of Canada's largest and most recognizable workforces will provide Miraculins with a considerable advantage in accelerating the development of commercial models for the Scout DS® in workplace settings and adapt key wellness concepts to other major market segments.

# 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.

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



## Outsourcing Manufacturing

The Company has transitioned manufacturing of the Scout DS® device from a VeraLight International manufacturing facility in New Mexico, to a contract manufacturing partner in Philadelphia, Pennsylvania. Production with the selected manufacturing partner is expected to achieve full production capabilities by the first quarter of 2016.

# 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.

#### PreVu® Non-Invasive Skin Cholesterol Point-of-Care (POC) Test

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. The PreVu® POC Test had received Health Canada clearance and had been CE Marked for sale within the European Union. In the United States, the PreVu® POC Test had previously been cleared by the FDA.

Over the years there was a significant amount of work that the Company conducted towards advancing and introducing the PreVu® technology, including running retail pilots in both Canada and the U.S. The PreVu® business model was to sell products in key market segments through established distribution companies that would 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 were 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. Additional revenues were anticipated to be derived from territorial licensing or marketing partnerships with corporate or brand partners who would have had 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 was successful in gaining preliminary market exposure for PreVu® POC including negotiating and executing pilots through two Canadian pharmacy brands and one large U.S. supermarket/pharmacy chain in Texas. Through these pilots the Company collected important feedback and data on PreVu® POC that underscored its strength as a point of care technology, generating positive consumer response and support from the pharmacy team members involved, who recognized its value as a new tool to help assess CAD risk. The pilots also underscored challenges that were going to take additional resources and possible further product redevelopment to fully address. These included the system of training new test operators in distant locations; managing logistics issues related to the cold chain requirements of the test reagents; maximizing a restrictive USFDA Indication for Use; and addressing a pharmacy culture in Canada that traditionally offered risk assessment and prevention programs such as PreVu® POC only on an occasional basis, in conflict with the Company's desire for more frequent consumer contact.

As a result of some of the challenging findings and feedback secured through the Company's efforts and market related activities, the Company has decided to conduct a strategic review of its PreVu® POC technology program. This review process includes placing on hold any ongoing initiatives or plans related to PreVu®.

When the Company acquired the PreVu® technology in two testing formats – a point of care version (PreVu® POC) and a Lab Test version (PreVu® LP) it recognized that the technology was innovative, clinically strong, and had been well-received during limited pilots and demonstrations. However, there were aspects of both test platforms that the Company recognized could benefit from being further developed. While the Company invested in controlled pilots of the PreVu® POC, which already had regulatory clearance in Canada and the U.S., in an effort to seed market interest and gather important feedback, it also evaluated opportunities to improve upon both test delivery platforms.

The Company has faced limited capital resources as well, which has impacted its ability to mount and sustain multiple initiatives across various product and technology lines. With further advancement of both PreVu® technologies determined to require significant investment, and with Scout DS® representing greater near-term potential, the Company has decided to concentrate its limited resources on the commercialization of the Scout DS® for the time being.

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



Part of this decision on resource allocation is also based on the increasing view that the best approach for PreVu® may lay in additional product development of the test delivery platform that could possibly offer a faster screening and test result delivery system more comparable to the speed and ease of the Scout DS®. While the next steps have not been decided upon, the Company's strategic review of elements related to its PreVu® technology program has been initiated to best determine what those next steps may be. This could include additional product development of the PreVu® POC test delivery system; further R&D and clinical work on the PreVu® LP format; the exploration of licensing opportunities for both test platforms; development of a Kiosk program as a resolution to certain market issues; or a completely new R & D pathway that could result in the creation of a new streamlined testing system platform for the measurement of skin cholesterol. The Company believes that there is still significant potential in PreVu® and Miraculins continues to be the world leader in technology and know-how related to skin cholesterol as a valuable biomarker for risk of CAD.

The Company believes that the strategic review of its PreVu® technology program and suspension of any further investment in it at this time (directing funding instead to advancing the Scout DS® technology program), will allow management to consider possible options for PreVu®, while focusing Company resources on the Scout DS® diabetes screening technology.

On July 22, 2015 the Company finalized the sale of its rights, title and interest to a third party in a pending claim against a former vendor, that was engaged in manufacturing relating to the Company's PreVu® technology, that had filed for bankruptcy protection and the Company received a payment from the third party in the amount of US\$66,784 (CDN \$87,066). Subject to certain circumstances occurring, an additional amount may be received from the third party. Any payments received may be required to be repaid to the third party if certain conditions occur and as at August 31, 2015, \$87,867 is recorded within accounts payable and accrued liabilities on the Statement of Financial Position in the Company's condensed interim financial statements relating to the funds received from the sale of the claim. Any proceeds from the sale of the claim will be recorded as a reversal of a previous write-down on the PreVu® technology, which was written down to nil during the year ended November 30, 2014 once all conditions have been met regarding the claim.

#### 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 biomarkers, in licensed from Mount Sinai Hospital, involved in the development of the placenta and the biology implicated in the development of preeclampsia. The technology was discovered through pioneering research conducted by Dr. Isabella Caniggia and her collaborators at the Samuel Lunenfeld Research Institute of Mount Sinai Hospital, and the Hospital for Sick Children.

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

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.

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



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.

At present, there are no new market developments to report in this area.

#### **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 other projects 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 out licensing partner, advancing the research independently, or canceling the program.

At present, there are no new market developments to report in this area.

#### **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.

At present, there are no new market developments to report in this area.

#### **OUTLOOK**

The strategic direction of the Company is centered 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. 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. Any increase in expenditures would result from the continued development and commercialization of current technology programs and the potential addition of complementary technologies. The Company has concluded a Scout DS® Diabetes Screening Kiosk pilot with Lovell Drugs in pharmacies in southern Ontario and is planning additional pilots in the sector, as well as pilots surrounding workplace screenings and other potential public applications. The Company also has obligations related to the formal agreement it executed for the sale and distribution of Scout DS® diabetes screening devices in Mainland China. All these aforementioned obligations and market efforts, and others not referenced here, will require additional investment to fulfill.

These condensed interim 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 are material uncertainties that cast significant doubt upon the Company's ability to continue as a going concern as the Company has experienced operating losses and cash outflows from operations since incorporation, has accumulated a deficit of \$21,159,619 as at August 31, 2015 (November 30, 2014 - \$19,239,552), a working capital deficiency of \$2,762,748 as at August 31, 2015 (November 30, 2014 - \$441,263) and currently has limited cash available.

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



Management has forecast that expected expenditure levels and contracted commitments will exceed the Company's net cash inflows and working capital during the fourth quarter of fiscal 2015 unless further financing is obtained. In short, additional sources of funding are required to carry on operations. Subsequent to August 31, 2015, as disclosed in note 8(b), on October 26, 2015 the Company announced a private placement offering of up to \$250,000 and closed its first tranche for gross proceeds of \$135,000. However, additional funding is still required as there is currently limited cash available. The Company's debt has previously been extended and is now due on December 31, 2015. The Company intends to renegotiate the terms of its secured debt and/or seek an additional extension of the maturity date.

The Company's strategy changed in fiscal 2015 with the Company's resources for the foreseeable future being focused on the commercialization of the Scout DS® technology. The Scout DS® technology is approved for commercial sale in Canada and Europe and the Company has launched the product through pharmacy pilots in the Canadian market with nominal revenues expected during fiscal 2015 and 2016. The Company is currently in the early stages in the process of obtaining regulatory approval for sale of the Scout DS® technology in China. Commercialization of the Scout DS® technology in the United States will be dependent on, among other things, available funding to obtain regulatory approval. The Company's future operations including the completion of the commercialization of the Scout DS® technology is dependent upon its ability to secure additional funds, renegotiate the terms and/or obtain an additional extension to the maturity date of the Company's secured debt, obtain regulatory approval in China, 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. No agreements with the lender or other potential lenders or investors have been reached yet and there can be no assurance that such agreements will be reached. Such transactions, if completed, could have a significant dilutive effect on existing shareholders. 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, renegotiate the terms and/or obtain an additional extension to the maturity date of the Company's secured debt, obtain regulatory approval in China, 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, further cost curtailments, delays of product launch and exploring the monetization of certain intangible assets, as well as seeking to outlicense 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 6of the Company's condensed interim financial statements for the three and nine months ended August 31, 2015. 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 significant doubt about the validity of the going concern assumption used in preparing these financial statements. The ability of the Company to execute on its operating plan is contingent on having a collaborative relationship with its lenders. 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.

These condensed interim 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. Subsequent to August 31, 2015, as disclosed in note 8(b), on October 26, 2015 the Company announced a private placement offering of up to \$250,000 and closed its first tranche for gross proceeds of \$135,000. However, additional funding is still required as there is limited cash available. 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.

## **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 earned nominal revenue through 2015 through its commercial market development of the Scout DS<sup>®</sup> 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/or renegotiate the terms and/or obtain an additional
  extension to the maturity date of the secured debt 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 and/or renegotiate the terms and/or obtain an additional extension to the maturity date of the
  secured debt.

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

- The Company is in various stages of development of diagnostic and risk assessment products and, as a result, is
  unable to predict whether it will be able to profitably commercialize its products. There can be no assurance that
  the Company will be able to commercialize its products.
- Failure to protect intellectual property, or infringement on the intellectual property rights of others, may impede the Company's ability to operate freely. There can be no assurance that the Company's intellectual property rights will not be challenged by third parties, that the Company will receive patents it seeks, or that the Company will receive any necessary licenses. The Company could incur substantial costs in enforcing its intellectual property rights or defending its intellectual property rights against claims brought by others. Miraculins views patents and other means of intellectual property protection as essential to the Company's core business by protecting the Company's proprietary technology from infringement by competitors. To that end, patents will be reviewed and continued to be sought in relation to those components or concepts of each of its pre clinical and clinical diagnostic products by management of the Company to ensure the highest level of protection possible given the Company's financial position is obtained. The Company requires all employees, consultants, and parties to collaborative research agreements to execute confidentiality agreements upon the commencement of employment, consulting relationships or a collaboration with the Company. These agreements require that all confidential information developed or made known during the course of the engagement with Miraculins is to be kept confidential. The Company also maintains agreements with scientific staff and all parties contracted in a scientific capacity, providing that all inventions resulting from work performed for Miraculins, using Miraculins' property, or relating to Miraculins' business and conceived or completed during the period covered by the agreement are the exclusive property of the Company. Despite these practices, there can be no assurance that the Company will be able to successfully protect its intellectual property rights.
- The Company's business is subject to significant government regulation and failure to achieve and maintain regulatory approval of diagnostic products would negatively affect its business. The process for obtaining such approval, including clinical trials, varies by country and type of product, and the process can be time consuming and costly.

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



- The Company is dependent on strategic partners, including clinical investigators and contract research organizations, as well as its lenders, 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. As well, there can be no assurance that the Company will continue to meet its debt repayment obligations and/or renegotiate the terms and/or obtain an additional extension to the maturity date of the secured debt.
- The Company may be dependent on others for the manufacture, development and sale of its products. If the Company
  is unable to establish or manage collaborations in the future, or if the Company encounters difficulties with these
  collaborations, there could be a delay in the manufacture, development and sale of products.
- Even if product candidates receive all of the required regulatory approvals, there is no guarantee of market
  acceptance or commercialization of the resulting product candidates, which will be determined by the Company's
  sales, marketing and distribution capabilities and the positioning and competitiveness of its diagnostic products
  compared with any alternatives.
- The Company's ability to successfully market certain diagnostic products may depend in part on the extent to which reimbursement for the cost of such products will be available from government health administration authorities, private health insurers and other organizations. Significant uncertainty exists as to whether newly approved healthcare products will qualify for reimbursement, or the timing by which such reimbursement can be secured. Furthermore, challenges to the price of medical products and services are becoming more frequent. There can be no assurance that adequate third party coverage will be available to establish price levels, which would allow the Company to realize an acceptable return on its investment in product development. Although non reimbursed, user pay models may be available to the Company, uncertainty exists to the degree to which lack of available reimbursement by government health administration authorities, private health insurers and other organizations could limit market adoption of the Company's products. Reimbursement issues and decisions vary country by country as to procedure and time for review and/or reimbursement approval.
- The Company's industry is characterized by intense competition and rapid change and a failure by the Company to
  react to such competition and change could have a material adverse effect on its business. Competitors may
  develop products that are more effective and less costly than those developed by the Company. There can be no
  assurance that developments by others will not cause the Company's products to become noncompetitive.
- 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.

# Management's Discussion and Analysis



- The market price and trading volume of the Company's common shares have been volatile, and may continue to be volatile in the future. Variations in earnings estimates by securities analysts and the market prices of the securities of competitors may also lead to fluctuations in the trading price of the common shares. In addition, the financial markets may experience significant price and volume fluctuations that affect the market price of the Company's common shares that are not related to the Company's operating performance. Broad market fluctuation and economic conditions generally, and in the medical device sector specifically, may adversely affect the market price of the Company's common shares.
- The significant costs that the Company will incur as a result of being a public company in Canada could adversely
  affect its business.



# **SELECTED QUARTERLY FINANCIAL INFORMATION**

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

	c	Q3- 2015	(	Q2- 2015	(	Q1- 2015	(	Q4 - 2014
Revenues	\$	-	\$	1,344	\$	7,802	\$	3,000
Cost of goods sold		-		-		-		162,149
Selling, general and administration expenses		544,040		521,957		541,231		620,560
Research and development expenses		-		-		-		(20,211)
Write-down of intangible assets		-		-		-		696,199
Revaluation of contingent share consideration		-		-		-		153,000
Revaluation of royalty obligation		-		-		-		(1,117,062)
Finance expense, net		102,972		99,959		96,881		155,851
Foreign exchange loss (gain), net		9,335		(866)		13,704		11,143
Loss for the period	\$	656,347	\$	619,706	\$	644,014	\$	658,429
Loss per Share	\$	(0.01)	\$	-	\$	0.02	\$	0.03
	c	Q3 -2014	C	<b>)</b> 2 - 2014	(	Q1 -2014	(	Q4 - 2013
Revenues	\$	3,000	\$	3,000	\$	3,459	\$	19,667
Cost of goods sold								
Cost of goods sold		266		267		356		-
Selling, general and administration expenses		266 578,481		267 607,742		356 602,565		- 843,987
-								- 843,987 22,549
Selling, general and administration expenses		578,481		607,742		602,565		
Selling, general and administration expenses Research and development expenses		578,481 5,259		607,742		602,565		
Selling, general and administration expenses Research and development expenses		578,481 5,259		607,742		602,565		
Selling, general and administration expenses Research and development expenses Write-down of intangible assets		578,481 5,259 52,076		607,742 23,291 -		602,565 23,439 -		
Selling, general and administration expenses Research and development expenses Write-down of intangible assets Revaluation of contingent share consideration		578,481 5,259 52,076 92,000		607,742 23,291 - (246,000)		602,565 23,439 - (618,000)		22,549 - -
Selling, general and administration expenses Research and development expenses Write-down of intangible assets Revaluation of contingent share consideration Revaluation of royalty obligation		578,481 5,259 52,076 92,000 (20,498)		607,742 23,291 - (246,000) 45,560		602,565 23,439 - (618,000) (90,964)		22,549 - - - 194,084
Selling, general and administration expenses Research and development expenses Write-down of intangible assets Revaluation of contingent share consideration Revaluation of royalty obligation Finance expense, net	\$	578,481 5,259 52,076 92,000 (20,498) 65,538	\$	607,742 23,291 - (246,000) 45,560 53,926	\$	602,565 23,439 - (618,000) (90,964) 84,361	\$	22,549 - - 194,084 50,276

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



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 acquisition of the Scout DS® technology and, earlier, the commercialization of the PreVu® Non Invasive Skin Cholesterol Test ("PreVu®"). The increasing losses relate to costs associated with expenditures relating to the acquisition of the Scout DS® on August 1, 2013 and the commercialization of this technology throughout the latter part of 2013, through fiscal 2014 and into fiscal 2015. The reduction in the net loss reported in the first and second quarters and subsequent increase in the net loss in the third and fourth quarters of fiscal 2014 as compared to prior quarters are 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 \$246,000 in the second quarter and an increase of the net loss of \$92,000 in the third quarter and \$153,000 in the fourth quarter. Additionally, the fourth quarter of 2014 is effected by the Company recognizing an impairment totaling \$628,703 relating to the PreVu® technology resulting from a change in strategy. This is offset in the fourth quarter by a decrease in the Company's royalty obligation of \$1,182,964 which is as a result of the change in strategy relating to PreVu®. Additionally, the losses for fourth quarter 2014 to the third quarter 2015 remained consistent, in the range of \$619,000 to \$658,000, as a result of cost reductions undertaken by the Company during the past four quarters.

#### **RESULTS OF OPERATIONS**

#### Revenues

The change in revenues for the nine months ended August 31, 2015 and 2014 is reflected in the following table:

Nine months ended August 31,		August 31, 2015		st 31, 2015 August 31, 201			Increa	se (Decrease)
Revenue	\$	9,146	\$	9,459	\$	(313)		

Revenues for the nine months ended August 31, 2015 is as a result of the US\$150,000 up-front payment the Company received under the contract and the recognition of revenues from this agreement based on the performance of related activities under the contract. This payment, initially recorded as deferred revenue, represents an up-front payment where further services are to be provided by the Company and will be recognized over the period of performance of the related activities.

The Company is currently involved in piloting 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 Company expects limited revenue for the remainder of the 2015 fiscal year and into the 2016 fiscal year.

# **Cost of Goods Sold**

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

The change in cost of goods sold for the nine months ended August 31, 2015 and 2014 are reflected in the following table:

ne months ended August 31, 2015		August 31, 2015		ust 31, 2015 August 31, 2014			Increase	(Decrease)
Cost of goods sold	\$	-	\$	889	\$	(889)		

Cost of goods sold were not material for the nine months ended August 31, 2015 and 2014.

The Company expects limited amounts of cost of goods sold for the remainder of the 2015 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 as well as costs associated with the Scout DS®. In fiscal 2014, selling, general and administration expenses included costs associated with the PreVu® technology. PreVu® related costs year to date in fiscal 2015 and into the 2016 fiscal year will be minimal as a result of the change in focus of the Company.

The changes in selling, general and administration expenditures, including stock based compensation, for the nine months ended August 31, 2015 and 2014 are reflected in the following table:

Nine months ended		August 31, 2015		August 31, 2014		Increase (Decrease)	
Scout DS® technology costs Amortization of Scout DS® intangible assets	\$	232,332 93,846	\$	165,978 88,785	\$	66,354 5,061	
		326,178		254,763		71,415	
PreVu® Non-Invasive Cholesterol test costs Amortization of PreVu® intangible assets		10,228		72,227 144,368		(61,999) (144,368)	
		10,228		216,595		(206,367)	
Compensation related costs Wages, consulting fees, and benefits Stock compensation related costs		667,063		678,882		(11,819)	
Other administration costs		6,600 597,159		196,872 454,084		(190,272) 143,075	
Total selling, general and administration	\$	1,607,228	\$	1,801,196	\$	(193,968)	

The decrease in costs for the nine months ended August 31, 2015 as compared to the nine months ended August 31, 2014 can be attributed to the following factors:

- The decrease in PreVu<sup>®</sup> technology costs as a result of cost reductions experienced throughout fiscal 2014 culminating
  in the decision to reevaluate the technology.
- The decrease in stock-based compensation related costs as a result of fewer stock options issued during the nine months ended August 31, 2015 compared to the nine months ended August 31, 2014.

## Partially offset by:

- The increase in Scout DS<sup>®</sup> costs as a result of the shift in focus of the Company towards the Scout DS<sup>®</sup>.
- The increase in other administration costs is a result higher consulting and investor relations expenses during the nine months ended August 31, 2015 compared to the nine months ended August 31, 2014.

The Company expects a moderate level of Scout DS® technology costs, minimal PreVu® technology costs and a lower level of compensation and other administration costs for the remainder of the 2015 fiscal year and into fiscal 2016 as a result of the implementation of further cost reductions that occurred in the second and third quarter of fiscal 2015.

#### Research and development

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

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



The changes in research and development expenditures for the nine months ended August 31, 2015 and 2014 are reflected in the following table:

Nine months ended	August 31, 2015		nths ended August 31, 2015 August 31, 2014 Ir			Increase	(decrease)
Research and development	\$	-	\$	91,657	\$	(91,657)	

The change in costs for the nine months ended August 31, 2015 as compared to the nine months ended August 31, 2014 can be attributed to the shift in focus of the Company away from research and development and towards the commercialization of the Scout DS® technology.

The Company expects minimal levels of research and development expenditures for the remainder of the 2015 fiscal year as the Scout DS® technology is commercially available for sale and the PreVu® technology is being reevaluated, and as such costs are recorded within selling, general and administration expenses.

# Revaluation of contingent share consideration

The change in the revaluation of contingent share consideration for the nine months ended August 31, 2015 and 2014 is reflected in the following table:

Nine months ended	August 31, 2015		Aug	ust 31, 2014	4 Increase (Decrease)	
Revaluation of contingent share consideration	\$	-	\$	(772,000)	\$	(772,000)

As a result of the amendment to the asset purchase agreement signed on December 23, 2014, which resulted in the settlement of the contingent share consideration that was recorded in November 2014, there was no revaluation of contingent share consideration for the nine months ended August 31, 2015.

The revaluation 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 August 1, 2013. The reduction is the result of the decline in the Company's share price from the time the Scout DS® asset purchase agreement was completed and August 31, 2014.

The Company anticipates no revaluation of contingent share consideration for the remainder of fiscal 2015 as a result of the amendment to the asset purchase agreement resulting in the settlement of the contingent share consideration.

#### Revaluation of royalty obligation

The change in the revaluation of royalty obligation for the nine months ended August 31, 2015 and 2014 is reflected in the following table:

Nine months ended	August 31, 2015		5 August 31, 2014		Increase (Decrease)	
Revaluation of royalty obligation	\$	-	\$	(65,902)	\$	(65,902)

There is no revaluation of royalty obligation for the nine months ended August 31, 2015 due to the Company's change in strategy pertaining to the PreVu® technology resulting in the royalty obligation being written down to nil as at November 30, 2014. The revaluation of royalty obligation for the nine months ended August 31, 2014 was in a recovery position totaling \$65,902 as a result of the change in the fair value of the royalty obligation.

The Company anticipates no revaluation of royalty obligation for the remainder of fiscal 2015 as a result of the reduction in value of the royalty obligation as at November 30, 2014 to nil.



## Finance expense, net

The change in finance expense, net for the nine months ended August 31, 2015 and 2014 is reflected in the following table:

Nine months ended	August 31, 2015		just 31, 2015 August 31, 2014		4 Increase (Decrease)	
Finance expense	\$	299,812	\$	204,025	\$	95,787

Finance expense for the nine months ended August 31, 2015 increased due to increases in interest on the Company's secured debt as a result of higher debt levels as additional debt was incurred during the nine months ended August 31, 2014.

The Company anticipates an increase in finance expense in the remainder of fiscal 2015, and into the 2016 fiscal year due to higher debt levels.

## Loss and comprehensive loss for the period

The loss and comprehensive loss for the nine months ended August 31, 2015 and 2014 is reflected in the following table:

Nine months ended	August 31, 2015			igust 31, 2014	4 Increase (Decrease)		
Loss and comprehensive loss for the period Loss per share	\$	(1,920,067)	\$	(1,255,308)	\$	664,759	
	\$	(0.05)	\$	(0.09)	\$	0.04	

As discussed above, the change in the Company's loss for the nine months ended August 31, 2015 as compared to the nine months ended August 31, 2014 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® as a result of the Company's change in strategy during the nine months ended August 31, 2014.

#### 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, 2015, the Company had unrestricted cash totaling \$7,543 as compared with \$1,161,744 at November 30, 2014.

#### Cash used in operating activities

Cash used in operating activities totaled \$1,614,819 for the nine months ended August 31, 2015 and was higher than the cash used in operating activities of \$1,383,163 for the nine months ended August 31, 2014 due to higher net loss when excluding non-cash items during the nine months ended August 31, 2015 when compared to the nine months ended August 31, 2014.

# **Cash from financing activities**

For the nine months ended August 31, 2015, cash from financing activities totaled \$982,573. Of this amount, \$995,005 resulted from proceeds of private placement financings completed during the period, as well as the exercise of warrants, and was partially offset by net interest paid totaling \$12,432. For the nine months ended August 31, 2014 cash from financing activities was \$1,368,900. Of this amount, \$819,347 resulted from proceeds of private placement financings completed during the period and \$550,000 resulted from proceeds of debt financings completed during the period, as well as \$447 of net interest paid.

**Management's Discussion and Analysis** 



# Cash used in investing activities

Cash used in investing activities totaled \$521,955 for the nine months ended August 31, 2015. Of this amount, \$500,000 was paid to VeraLight as part of the amending agreement entered into on December 23, 2015 and resulted in the elimination of the contingent consideration on the purchase of the Scout DS® technology. Additionally, \$11,135 was for patent and trademark cost and \$10,820 was for the acquisition of property and equipment. During the nine months ended August 31, 2014, cash used in investing activities totaled \$52,034. Of this amount, \$51,708 was paid for patent and trademark costs and \$3,926 was paid for the acquisition of property and equipment, partially offset by \$3,600 received from the sale of property and equipment.

## Shares, options and warrants

On December 23, 2013, the Company announced that it had entered into an amending agreement to extend the maturity date of the \$1,000,000 non convertible secured loan with the 2011 Lender that was originally announced on October 13, 2011 as disclosed in note 6 to the Company's condensed interim financial statements for the three and nine months ended August 31, 2015. As consideration for the extension of the loan, the Company issued 100,000 shares to the 2011 Lender. Additionally, the Company entered into a shares for debt agreement with the 2014 Lender and issued 126,806 shares to satisfy \$63,403 of interest owing on the loan as disclosed in note 6 to the Company's condensed interim financial statements for the three and nine months ended August 31, 2015.

On December 23, 2013, the Company announced that it had arranged a nonconvertible secured loan of up to \$1,000,000 with a third party lender as disclosed in note 6 to the Company's condensed interim financial statements for the three and six months ended May 31, 2015. As consideration for providing the loan, in connection with each issuance 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 issuance of the promissory note. On January 10, 2014, the Company issue 55,600 shares in connection with the closing of the second tranche under the loan agreement and an additional 17,172 common shares were issued subsequently.

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.

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.

Included in share issue costs of \$40,350 is \$2,990 of non-cash compensation recognized from warrants issued related to the July 2014 Offering.

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



On December 11, 2014 the Company closed a private placement offering (the "December 2014 Offering") of 2,000,000 units ("Units") at a price of \$0.10 per unit with aggregate gross proceeds to the Company of \$200,000. 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 \$0.13 at any time within 24 months from the date of issuance of the Warrant. There were 2,000,000 warrants issued within the December 2014 Offering. A fair value of \$99,269, net of warrant issue costs, was assigned to the warrants upon issuance. Share issue costs total \$2,600 related to the December 2015 Offering.

On April 22, 2015 the Company closed a private placement offering (the "April 2015 Offering") of 4,000,000 units ("Units") at a price of \$0.10 per Unit for gross proceeds of up to \$400,000. Each Unit is comprised of one common share of the Company (a "Share") and one Share purchase warrant. Each warrant entitles the holder to purchase one Share at a price of \$0.15 per Share for a period of 24 months from the date the Warrant is issued. There were 4,000,000 warrants issued within the April 2015 Offering. A fair value of \$131,627, net of warrant issue costs, was assigned to the warrants upon issuance. Share issue costs total \$9,464 related to the April 2015 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 24 months from the date of the April 2015 Offering. There were 16,000 Compensation Warrants issued.

On July 14, 2015 the Company closed a private placement offering (the "July 2015 Offering") of 4,375,000 units ("Units") at a price of \$0.08 per Unit for gross proceeds of up to \$350,000. Each Unit is comprised of one common share of the Company (a "Share") and one Share purchase warrant. Each whole warrant (a "Warrant") will entitle the holder to purchase one Share at a price of \$0.10 per Share for a period of 24 months from the date the Warrant is issued. There were 4,375,000 warrants issued within the July 2015 Offering. A fair value of \$88,045, net of warrant issue costs, was assigned to the warrants upon issuance. Share issue costs total \$12,784 related to the July 2015 Offering.

A certain person assisted the Company by introducing potential subscribers for the Offering and was paid a finder's fee of 10% of the total subscription proceeds received from subscribers introduced to the Company by this particular person. Additionally, this person was issued compensation warrants ("Compensation Warrants") equal to 10% of the total number of Units subscribed for by subscribers introduced to the Company by this particular person. Each Compensation Warrant entitles the holder thereof to purchase one Share at a price of \$0.10 per Share for a period of 12 months from the date of the July 2015 Offering. There were 20,000 Compensation Warrants issued.

On December 29, 2014, the Company entered into shares for debt agreements with an officer of the Company and a member of the senior management team pursuant to which, subject to regulatory approval, the Company will issue 133,660 of its common shares to the individuals at a deemed price of \$0.245 per common share to satisfy \$32,747 of outstanding amounts owing to them, which were included in accounts payable and accrued liabilities on the Statement of Financial Position as at November 30, 2014. The shares were issued on January 22, 2015 at a fair value of \$30,742, with a gain of \$2,005 being recorded within selling, general and administration expenses on the Statement of Net Loss and Comprehensive Loss.

During the nine months ended August 31, 2015, 580,000 warrants with exercise prices of \$\$.105 and 0.15 were exercised resulting in the issuance of 580,000 common shares of the Company for gross proceeds to the Company of \$81,150.

The Company was obligated to issue shares in certain circumstances as a part of the acquisition of the Scout DS® technology. On December 23, 2014, the Company executed an amendment to the asset purchase agreement with VeraLight. The amendment eliminated the majority of the Company's remaining obligations and terminated the obligation by the Company to issue the contingent consideration to VeraLight which is described in note 4 to the financial statements for the year ended November 30, 2014 for a one time payment of \$500,000 and 1,000,000 common share purchase warrants with an exercise price of \$0.25 per common share and a fair value of \$131,000. The warrants expire on the fifth anniversary of their issuance. Of these warrants, 450,000 vest immediately and the remaining 550,000 vest upon the earlier of 12 months from the date of issuance of a liquidity event.

Subsequent to August 31, 2015, on October 26, 2015 the Company announced a private placement offering (the "October 2015 Offering") of up to \$250,000 and closed its first tranche of 2,700,000 units ("Units") at a price of \$0.05 per Unit for gross proceeds of \$135,000. Each Unit is comprised of one common share of the Company (a "Share") and one-half of one Share purchase warrant. Each whole warrant (a "Warrant") will entitle the holder to purchase one Share at a price of \$0.08 per Share for a period of 12 months from the date the Warrant is issued.

A certain person assisted the Company by introducing a subscriber for the October 2015 Offering and was paid a finder's fee of 10% of the total subscription proceeds received from the subscriber introduced to the Company by that person.



	October 29, 2015	August 31, 2015	November 30, 2014
Common shares issued and outstanding	50,516,392	47,816,392	36,727,732
Options outstanding	3,407,500	3,442,500	3,454,000
Warrants outstanding	33,281,000	31,931,000	25,989,462

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.

Subsequent to August 31, 2015, as disclosed in note 8(b), on October 26, 2015 the Company announced a private placement offering of up to \$250,000 and closed its first tranche for gross proceeds of \$135,000. However, additional funding is still required. Management has forecast that expected expenditure levels and contracted commitments will exceed the Company's net cash inflows and working capital during the fourth quarter of fiscal 2015 unless further financing is obtained. Additional sources of funding will be required commencing in the fourth quarter of fiscal 2015 to carry on operations. The Company's management is reviewing all financing alternatives including raising additional funds for operations from current stockholders and other potential investors. This disclosure is not an offer to sell, nor a solicitation of an offer to buy the Company's securities. Where the Company opts to pursue such financing, there is no assurance that funding will be available or obtained on favourable terms.

#### **CONTRACTUAL OBLIGATIONS**

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

	Payments due by Period								
Management services agreement Contractual commitments Accounts payable and accrued liabilities Long-term debt including interest		Within 1 year		2 - 3 years		4 - 5 years	Total		
	\$	30,000 11,000 783,813 1,940,807	\$	10,000 \$ - - -	- - -	\$	40,000 11,000 783,813 1,940,807		
	\$	2,765,620	\$	10,000	; -	\$	2,775,620		

As at August 31, 2015 and in the normal course of business, the Company has obligations to make future payments, representing contracts and other commitments that are known and committed.

The aggregate lease and business and administration services fee payable during the years ended November 30, 2015 and 2016 amount to \$41,000 and \$10,000 respectively. There are no contractual commitments beyond fiscal 2016.

Effective January 1, 2015 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 \$120,000 per annum for a period of one year. The agreement can be terminated with 90 days notice.

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



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 during the three and nine months ended August 31, 2015 and 2014.

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, 2015, 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 sub-licenses any rights under the MSH Agreement to a third party, the Company shall pay MSH a stipulated percentage of sub-license fee and sub-license royalty fee. No royalties were paid to MSH during the three and nine months ended August 31, 2015 and 2014.

On October 12, 2011, the Company entered into a non convertible secured loan agreement with a private lender (the "2011 Lender") for \$1,000,000. The promissory note evidencing the loan was issued at a discount for a purchase price of \$950,000 and in addition the 2011 Lender received 142,857 common shares of the Company with a fair value of \$71,428, net of issue costs of \$1,050.

The loan originally matured on April 12, 2014 and bore interest at 12% per annum, payable interest only on a quarterly basis, except in the case of the first interest payment, which was payable on April 12, 2012. Any overdue payments bore additional interest at a rate of 6%, for a combined interest rate of 18% 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.

On December 23, 2013, the Company entered into an amending agreement with the 2011 Lender to extend the \$1,000,000 non convertible secured loan for an additional six months. With this amendment, the loan was to mature on October 14, 2014. The interest rates remained the same. As consideration for the extension of this loan, the Company issued 100,000 common shares of the Company with a fair value of \$45,000 to the 2011 Lender. 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. As consideration for the extension of the loan, the Company intended to issue 500,000 common shares to the 2011 Lender, however the issuance of shares was in excess of the allowed limit and did not receive regulatory approval. The Company has accrued \$70,000 within accounts payable and accrued liabilities at November 30, 2014 in respect of consideration for the extension of the loan. Additionally, the 2011 Lender has agreed to accrue all interest until December 31, 2015.

In July 2013, the Company and the 2011 Lender agreed to defer interest payments. The interest payments of \$30,000 each, due on July 12, 2013 and October 12, 2013 respectively, were included in accrued interest on the Statement of Financial Position as at November 30, 2013. On December 23, 2013, the Company entered into an agreement with the 2011 Lender pursuant to which the Company issued 126,806 common shares of the Company with a fair value of \$57,062 to the 2011 Lender to satisfy \$63,403 of interest accrued on the loan. This settlement includes additional interest on the overdue payments and represents the settlement of the July 12, 2013 and October 12, 2013 interest payments. Interest payable at August 31, 2015 is \$249,552 (November 30, 2014 - \$147,191).

The effective interest rate on this secured debt is 19.9%. Interest expense for the three and nine months ended August 31, 2015 was \$51,333 and \$149,355 (2014 - \$33,659 and \$130,472). The initial value assigned to the secured debt, based on a fair value approach, was \$878,571. As at August 31, 2015, the amortized cost of the secured debt was \$979,076 (November 30, 2014 - \$932,083).

On December 23, 2013, the Company arranged an additional nonconvertible secured loan of up to \$1,000,000 from a third party lender (the "2014 Lender"). Any amounts advanced under this loan will be evidenced by promissory notes purchased by the 2014 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 were originally due and payable on December 31, 2014 and bore interest at 12% per annum, payable quarterly. In addition, any overdue payment bore 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 2014 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 effective interest rate on this secured debt is 30.1%.

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



On January 10, 2014, the Company closed the initial tranche under this loan and received an initial advance of \$250,000 when the 2014 Lender issued a promissory note for \$278,000. As consideration for providing the initial tranche of the loan, the Company issued 55,600 common shares of the Company with a fair value of \$25,020 to the 2014 Lender.

On February 10, 2014, the Company closed the second tranche under this loan and received an additional advance of \$150,000 when the 2014 Lender issued a promissory note for \$166,667. As consideration for providing the second tranche of the loan, the Company issued 50,505 common shares of the Company with a fair value of \$16,667 to the 2014 Lender.

On March 20, 2014, the Company closed the third tranche under this loan and received an additional advance of \$150,000 when the 2014 Lender issued a promissory note for \$166,667. As consideration for providing the third tranche of the loan, the Company issued 75,758 common shares of the Company with a fair value of \$16,667 to the 2014 Lender.

On May 16, 2014, the Company entered into an amending agreement with the 2014 Lender to extend the \$611,334 nonconvertible secured loan. The loan with the 2014 Lender now matures on December 31, 2015. As consideration for the extension of the loan, the Company intended to issue 500,000 common shares to the 2014 Lender, however the issuance of shares was in excess of the allowed limit and did not receive regulatory approval. The Company has accrued \$70,000 within accounts payable and accrued liabilities at November 30, 2014 in respect of consideration for the extension of the loan. Additionally, the 2014 Lender has agreed to accrue all interest until December 31, 2015. Interest payable at August 31, 2015 is \$132,552 (November 30, 2014 - \$65,739).

Interest expense for the three and nine months ended August 31, 2015 was \$47,169 and \$138,025 (2014 – \$28,882 and \$73,106). The initial value assigned to all tranches of the secured debt, based on a fair value approach, was \$491,646. As at August 31, 2015, the amortized cost of the long term debt was \$579,627 (November 30, 2014 - \$508,414).

The Company has the option to request the 2014 Lender to advance additional tranches under this loan, which the 2014 Lender may approve or reject at its sole discretion.

Both loans are secured by a general security interest in favour of the Lenders over all tangible and intangible assets of the Company, excluding the assets relating to the Scout DS® which were acquired on July 31, 2013 until December 23, 2014 as VeraLight had retained a first ranking security interest over the Scout DS® assets. On December 23, 2014, the Company executed an amendment to the asset purchase agreement with VeraLight, which eliminated VeraLight's first ranking security interest over the Scout DS® assets resulting in the assets relating to the Scout DS® being included with the assets secured by a general security interest in favour of the Lenders.

A summary of the Company's contractual obligations may be found in Note 9 of the Company's condensed interim financial statements for the three and nine months ended August 31, 2015.

#### **RELATED PARTY TRANSACTIONS**

On December 29, 2014, the Company entered into shares for debt agreements with an officer of the Company and a member of the senior management team pursuant to which, subject to regulatory approval, the Company will issue 133,660 of its common shares to the individuals at a deemed price of \$0.245 per common share to satisfy \$32,747 of outstanding amounts owing to them, which were included in accounts payable and accrued liabilities on the Statement of Financial Position as at November 30, 2014. The shares were issued on January 22, 2015 at a fair value of \$30,742, with a gain of \$2,005 being recorded within selling, general and administration expenses on the Statement of Net Loss and Comprehensive Loss for the three and nine months ended August 31, 2015.

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, 2015, nil and \$28,455 (2014 - \$22,749 and \$26,082), has been recorded in selling, general and administration expenses on the Statement of Net Loss and Comprehensive Loss relating to this consulting agreement. As at August 31, 2014, \$6,668 was recorded within prepaid expenses relating to amounts paid under this consulting agreement.

# **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, 2015, 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 financial statements for the year ended November 30, 2014:

#### Acquired intellectual property - PreVu®

The Company's accounting policy over acquired intellectual propriety - PreVu® may be found in note 3f(ii) to the Company's financial statements for the year ended November 30, 2014. Costs incurred for acquired intellectual property - PreVu® was being amortized over the estimated period that it was 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 was estimated to be five years.

#### Patents and trademarks

The Company's accounting policy over patents and trademarks may be found in note 3f(iii) to the Company's financial statements for the year ended November 30, 2014. 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.

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



#### **Revenue recognition**

The Company's accounting policy over revenue recognition may be found in note 3c to the Company's financial statements for the year ended November 30, 2014. 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 3d to the Company's financial statements for the year ended November 30, 2014. Inventory consisted of parts to be used in the manufacture of finished PreVu® medical devices that were being held for resale, as well as finished and fully assembled and tested PreVu® medical devices and purchased PreVu® testing kit inventories that were being held for resale. Inventory was recorded based on the first in first out principle and was valued at the lower of cost and net realizable value.

# **Share-based Payment Transactions**

The Company's accounting policy over share-based payment transactions may be found in note 3h(ii) to the Company's financial statements for the year ended November 30, 2014. 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.

Management's Discussion and Analysis



## Impairment of non-financial assets

The Company's accounting policy over impairment of non-financial assets may be found in note 3g(ii) to the Company's financial statements for the year ended November 30, 2014. 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 selling, general and administration expense for commercialized technologies and in research and development expense for technologies that have yet to be commercialized in the statement of net loss and 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, 2014.

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

Certain new standards, interpretations and amendments to existing standards issued by the IASB or the International Financial Reporting Interpretations Committee ("IFRIC") that are not yet effective up to the date of issuance of the Company's financial statements are listed below. The Company is assessing the impact of these pronouncements on its results and financial position. The Company intends to adopt those standards when they become effective.

#### IFRS 9 Financial Instruments: Classification and Measurement

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

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

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

Under IFRS 9, for financial liabilities measured at fair value under the fair value option, changes in fair value attributable to changes in credit risk will be recognized in other comprehensive income ("OCI"), with the remainder of the change recognized in profit and loss. IFRS 9 is effective for annual periods beginning on or after January 1, 2018 and is to be applied retrospectively with some exemptions.

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#### 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 nonfinancial 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 was to be effective for annual periods beginning on or after January 1, 2017; however, the IASB has voted to delay this mandatory application date by one year, with earlier adoption permitted and is to be applied retrospectively. 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 1, Presentation of Financial Statements

On December 18, 2014 the IASB issued amendments to IAS 1 as part of its major initiative to improve presentation and disclosure in financial reports (the "Disclosure Initiative"). The amendments are effective for annual period beginning on or after January 1, 2016. Early adoption is permitted. These amendments will not require any significant change to current practice, but should facilitate improved financial statement disclosures. The Company intends to adopt these amendments in its financial statements for the annual period beginning on January 1, 2016. The extent of the impact of adoption of the amendments has not yet been determined.

#### FORWARD-LOOKING STATEMENTS

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

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

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

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

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

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



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.