



**MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS  
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2014**

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**PIVOTAL THERAPEUTICS INC.**  
**(A Development Stage Company)**

**MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS FOR THE THREE AND NINE MONTHS  
ENDED SEPTEMBER 30, 2014**

**DATE AND SUBJECT OF REPORT**

The following Management's Discussion and Analysis ("**MD&A**") of the financial condition and results of operations for Pivotal Therapeutics Inc. (the "**Company**" or "**Pivotal**") is intended to assist in the understanding of the trends and significant changes in the financial condition and results of operations of the Company for the three and nine months ended September 30, 2014, which have been prepared in accordance with International Financial Reporting Standards ("**IFRS**"). The MD&A should be read in conjunction with the audited financial statements and notes thereto for the period ended December 31, 2013. The MD&A has been prepared effective November 28, 2014. All amounts are expressed in Canadian dollars unless otherwise indicated.

**FORWARD-LOOKING STATEMENTS**

The information set forth in this MD&A contains statements concerning future results, future performance, intentions, objectives, plans and expectations that are, or may be deemed to be, forward-looking statements. These statements concerning possible or assumed future results of operations of the Company are preceded by, followed by or include the words 'believes,' 'expects,' 'anticipates,' 'estimates,' 'intends,' 'plans,' 'forecasts,' or similar expressions. Forward-looking statements are not guarantees of future performance. These forward-looking statements are based on current expectations that involve numerous risks and uncertainties, including but not limited to, those identified in the Risks Factors section. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate. These factors should be considered carefully, and readers should not place undue reliance on forward-looking statements. The Company has no intention and undertakes no obligation to update or revise any forward-looking statements, whether written or oral that may be made by or on the Company's behalf.

Further information is available on the SEDAR website, [www.sedar.com](http://www.sedar.com).

## **BUSINESS OVERVIEW**

### **GENERAL AND BUSINESS DEVELOPMENT**

The Company is a specialty pharmaceutical company with expertise in cardiovascular science, focused on cardiovascular disease and overall health. Pivotal's lead prescription-only medical food product, VASCAZEN<sup>®</sup>, is used for the clinical dietary management of cardiovascular disease in patients with documented coronary heart disease and who are deficient in blood Omega-3 fatty acids, Eicosapentaenoic Acid ("EPA") and Docosahexaenoic Acid ("DHA") levels. VASCAZEN<sup>®</sup> is a unique pharmaceutical formulation of EPA:DHA and provides the cornerstone upon which a family of combination products, having efficacy across a broad spectrum of cardiac indications, will be developed, and for which the Company is developing a substantial Intellectual Property portfolio. The Company's strategy is centered on cardio-protection that is administered and overseen by a physician. The Company is commercializing VASCAZEN<sup>®</sup> as a medical food through physician prescription and in combination with a unique monitoring strategy. Based on the Senior Managements internal strengths and track record, the Company is developing a unique rapid format diagnostic test for Omega-3 deficiency.

The Company's operational concept and approach is to participate in areas where it can best create and capture value while minimizing risk. The Company's operational concept and organizational structure was designed to avoid the more costly and asset intensive aspects of the traditional pharmaceutical industry.

At present the Company is funding the following activities through the issuance of securities, including common shares and debt financing:

- Increasing the selling and marketing of VASCAZEN<sup>®</sup> into the North American and International market place;
- Expansion of the VASCAZEN<sup>®</sup> distribution network worldwide;
- Pursuing co-marketing medical food partnership to increase sales footprint and conversion of current sales force to mainly commissioned-based;
- Prosecution and issuance of US and international patent applications;
- Expansion of intellectual property patent portfolio;
- Strategic clinical marketing and registration trials;
- Pursuing licensing opportunities for our unique patented 6:1 EPA:DHA formulation in North America, Europe, East Asia, China and Korea;
- Conducting research and development activities to expand the indication for our unique patented 6:1 EPA: DHA formulation;
- Developing diagnostic reagents and rapid format tests for the identification of Omega-3 deficiency in patients;
- Introducing Benefishial<sup>™</sup> to the over-the-counter (OTC) marketplace and direct to consumer by positioning it for major drugstore chains in the U.S. and Canada;
- Publication of scientific data validating the efficacy of products and expansion of new indications;

- Ongoing investor presentation and promotion in the interest of broadening the Company's shareholder base in North America and in Europe.

## **Listing**

The Company is quoted on the Canadian Securities Exchange ("CSE" formerly "CNSX") under the symbol PVO and trades on the US exchange, OTC Markets QX ("OTCQX") under the symbol PVTTF.

## **CORPORATE UPDATE**

The Company achieved the following milestones between January 1, 2014 and the date of this report, as set out in the following announcements:

- January 29, 2014 – the Company announced having received a notice of allowance for a US Patent on its unique 6:1 EPA:DHA formulation in conjunction with anti-obesity agents for the reduction of body weight in cardiovascular disease patients and diabetics;
- March 4, 2014 – the Company announced the adjustment of terms, expansion and closing of its debt financing, resulting in gross proceeds of \$7,743,580;
- March 10, 2014 – the Company announced the appointment of Mr. James Connolly to the Board of Directors of Pivotal;
- March 14, 2014 – the Company announced the granting of options to acquire 4,075,000 common shares at an exercise price of \$0.20 per share to certain directors, officers, employees and consultants that had been deferred from 2012;
- April 8, 2014 – the Company announced the granting of options to acquire 4,176,000 common shares at an exercise price of \$0.20 per share to certain directors, officers, employees and consultants that had been deferred from 2013;
- April 23, 2014 – the Company announced the resignation of two recently appointed directors who had been nominees of Crossover Healthcare Fund, LLC;
- April 30, 2014 – the Company announced its 2013 financial results;
- May 6, 2014 – the Company announced its presentation at the American Heart Association's Arteriosclerosis, Thrombosis and Vascular Biology 2104 Scientific Sessions in Toronto, Canada;
- May 7, 2014 – the Company announced the issuance of US Patent 8,715,648 for its unique 6:1 EPA:DHA formulation;
- May 13, 2014 – the Company announced that it has engaged Brandkarma LLC., an award winning US-based, healthcare marketing and brand specialist with global expertise;
- May 14, 2014 – the Company announced changes to the Board of Directors appointing independent director John S. Gebhardt as Chairman;
- May 30, 2014 – the Company announced its First Quarter financial results;
- June 11, 2014 – the Company announced the engagement of Kilmer Lucas to provide Canadian and US investor relations and strategic advisory services;

- August 6, 2014 – the Company announced having entered into a Memorandum of Understanding to create a Joint Venture with ACGT Corporation in an effort to explore commercial opportunities in China;
- August 19, 2014 – the Company announced a publication by *PLOS ONE* reporting a study confirming the VASCAZEN<sup>®</sup> formulation was superior to the other existing commercial products in the marketplace in terms of sustained increased blood flow, which is important for patients with Coronary Heart Disease who have compromised coronary vessels;
- August 27, 2014 – the Company announced its Second Quarter financial results;
- September 3, 2014 – announces the presentation of VASCAZEN<sup>®</sup>'s unique Vasoprotective and Antihypertensive effects at the 2104 Annual Meeting of the European Society of Cardiology Congress in Barcelona, Spain;
- September 8, 2014 – the Company announced the appointment of a new Chief Financial Officer;
- September 10, 2014 – the Company announced publication of a clinical trial showing the beneficial effects of VASCAZEN<sup>®</sup> in the correction of Omega-3 deficiency in cardiovascular patients;
- October 7, 2014 – the Company announced notification of patent allowance for U.S. application 13/584,480 related to the combination of VASCAZEN<sup>®</sup> and statin therapy;
- October 8, 2014 – the Company receives notification of allowance for U.S. Patent related to the combination of VASCAZEN<sup>®</sup> and cholesterol absorption inhibitor;
- November 14, 2014 – the Company announced the resignation of the recently appointed Chief Financial Officer.

## **SUBSEQUENT TO COMPLETION OF DEBT FINANCING**

As a result of limited financial resources over the course of 2013 and the first two months of 2014 the Company has had to substantially limit its business development and sales activities. Nevertheless, during 2013, the Company continued its ongoing assessment of its pilot sales force programs performance and developed plans for the expansion of its sales force in an effort to broaden geographic coverage. Pivotal also initiated a Key Opinion Leaders' ("KOL") speaking program for healthcare practitioners to present medical and product information on behalf of the Company and its products. This program was also negatively influenced by the lack of financial resources.

The completion of the \$7,743,580 debt financing, announced on March 4, 2014, allowed the Company to move forward with a number of its business development, sales and marketing and commercialization efforts that had been put on hold. Of the total debt financing of \$7,743,580, completed on March 4, 2014, \$5,362,961 was received subsequent to December 31, 2013. During the nine months ended on September 30, 2014 the use of proceeds comprised of the following activities: \$1,123,901 in sales and marketing; \$636,726 in research and development; \$408,706 in fixed assets, associated with the construction and outfitting of a research laboratory facility; \$61,151 in patent legal fees, loan repayment of \$109,289, financing fees of \$480,544 in connection to the debt financing, legal fees of \$199,252 of which \$117,016 was paid in connection with the

debt financing and in defense of a threatened hostile proxy challenge and the balance of \$1,235,341 for normal operational expenses.

The following is a brief description of the initiatives that began subsequent to March 4, 2014.

The Company has expanded its supply of its product lines. It is anticipated that current inventory levels will satisfy customer requirements for the remainder of 2014 and into 2015.

Pivotal has begun the in-house process of researching and developing an innovative diagnostic test to assist healthcare practitioners in determining Omega-3 deficiency. Current practice involves providing blood samples to a laboratory for analysis and reporting, a lengthy and time-consuming process. In order to conduct the in-house research the Company has built and outfitted a research laboratory that is dedicated to this project and the processing of clinical trial samples. Some of the costs associated with this project have been funded through an Industrial Research and Assistance Program (“IRAP”) grant and a Natural Sciences and Engineering Research Council of Canada (“NSERC”) grant.

Pivotal executed an agreement with a recognized nationwide provider of US sales data. This information is assisting the Company to track the effectiveness of its sales and marketing initiatives in its current limited Geographic area of New York, New Jersey and Pennsylvania. This data is also allowing the Company to identify new opportunities nationally where there is currently no sales representation. Sales of VASCAZEN<sup>®</sup> are reported in 36 states across the country. Physicians are writing prescriptions for VASCAZEN<sup>®</sup> in areas such as Texas, California, Louisiana, Ohio and Florida. The sales data is providing new targeting opportunities and allowing the Company to expand its sales strategy and demonstrates the Company’s readiness for a true national sales partner.

On August 6, 2014 Pivotal announced the execution of a memorandum of understanding that will form the basis for a Joint Venture Distribution agreement with ACGT Corporation “ACGT”. The joint venture’s purpose is to explore commercial opportunities, for Pivotal’s products, in China.

## **GOALS**

The Company continues to work towards the initial goal of commercializing VASCAZEN<sup>®</sup> as a medical food and developing a pipeline of products utilizing VASCAZEN<sup>®</sup>’s unique and patented 6:1 EPA:DHA formulation.

VASCAZEN<sup>®</sup> is currently sold in the United States (“US”) as a prescription-only medical food formulated to meet the dietary Omega-3 deficient needs of patients with cardiovascular disease through elevating EPA and DHA to levels associated with reduced risk of cardiovascular complications.

OMAZEN<sup>®</sup> is being commercialized in Canada for the maintenance of good health through elevating Omega-3 fatty acid levels. The Company is presently looking at expanding the



indication of OMAZEN<sup>®</sup> to include a product specifically for heart health and another product for the lowering of triglycerides. To increase the Company's presence in the OTC direct to retail market and direct to consumer market the Company created a new brand named Benefishial<sup>™</sup>.

The benefits of Omega-3 are well established and endorsed by the American Heart Association for use in the prevention of cardiovascular events in patients with coronary heart disease. Pivotal's medical food strategy is designed to position VASCAZEN<sup>®</sup> as the pre-eminent Omega-3 product, and to differentiate it from the many over-the-counter supplements available and other prescription Omega-3 products. The differentiation will be driven by: (i) VASCAZEN<sup>®</sup>'s unique patented 6:1 EPA:DHA ratio; (ii) its anti-inflammatory properties; (iii) its high purity; (iv) the implementation of a far-reaching intellectual property strategy; (v) the physicians who will be targeted and (vi) the development of a rapid format POC test for monitoring Omega-3 blood levels. Cardiovascular disease has a high inflammatory component. Pivotal's high purity product, enriched with high EPA and a specific level of DHA, is capable of complementing the underlying metabolic processes of the cardiovascular system to restore the proper metabolic balance of inflammatory metabolites to reduce the inflammatory response at the cell membrane level, and thereby promote normal physiologic function and cardiac protection in patients with coronary heart disease.

## STRATEGY

As a result of the information and experience the Company has acquired over the last two years from selling VASCAZEN<sup>®</sup> the Company has developed the following strategy for the commercialization of its lead medical food product:

- Build and expand the sales force;
- Develop a specialized marketing program to create medical food awareness focusing on the correction of an Omega-3 deficiency;
- Create an in-house reimbursement strategy for medical foods;
- Access a specialized medical food pharmacy to increase sales;
- Commercialize a point-of-care diagnostic to identify Omega-3 deficient patients, monitor efficacy and compliance.

In order to achieve significant US market revenues the Company estimates that a minimum of a 100 person sales force would be required. Given the current lack of financial resources the Company is actively seeking a co-marketing partner. The company has developed a strategy to increasing reimbursement levels for medical foods, which will have a positive impact at both the prescriber and patient levels. A specialized medical food pharmacy could facilitate sales to individuals with poor or no third party coverage and make the sales program seamless to all patients. The company is currently developing a rapid format point-of-care (POC) diagnostic test that can easily identify patients that are Omega-3 deficient at the physician's office, clinics and pharmacies.



The Company believes that these are the key components for the successful selling, marketing and positioning of a medical food.

### **Intellectual Property**

The Omega-3 patent field is crowded, with at least one dominant player focused on its own specific EPA:DHA ratio (that differs from the Company's ratio). Based on an extensive patent review, however, Pivotal believes that its unique formulation allows for freedom-to-operate. On February 22, 2012, Pivotal filed five international patent applications under the Patent Cooperation Treaty ("PCT"), directed towards its novel lead product VASCAZEN<sup>®</sup> and combinations thereof with certain cardiovascular treatment agents. A PCT application establishes a filing date in each of the 148 contracted PCT countries that Pivotal designates, including the United States of America, thereby securing patent pending status for VASCAZEN<sup>®</sup>. Pivotal continues to make efforts towards the expansion of its intellectual property portfolio..

On May 7, 2014 the Company announced the issuance of U.S. Patent 8,715,648 for its unique 6:1 EPA:DHA formulation. The issuance of this patent represents an important step in further protecting and advancing the commercial potential of VASCAZEN<sup>®</sup>'s formulation. This patent covers Pivotal's unique formulation in conjunction with anti-obesity agents for the reduction of body weight in patients with cardiovascular disease ("CVD") and diabetics. This patent has terms that expire no earlier than 2031.

On October 7, 2014 the Company received notification of patent allowance for US application serial number 13/584,480 related to a combination product of VASCAZEN<sup>®</sup> and statin therapy. The Company received another notification of allowance for US patent application serial number 13/584,403 on October 8, 2014 related to combination product of VASCAZEN<sup>®</sup> and cholesterol absorption inhibitor.

These applications are part of an expanding patent portfolio for Pivotal protecting its unique formulation with three (3) patent applications now either issued or allowed with the USPTO and over seven (7) additional applications pending in the United States. Pivotal is also pursuing patent applications related to VASCAZEN<sup>®</sup>'s formulation in multiple jurisdictions outside the United States.

### **Development of a Rapid Format POC Test**

This diagnostic test will assist physicians and healthcare professionals in the identification of the desired population, those individuals deficient in EPA and DHA, and permits point-of-care (POC) monitoring of patient Omega-3 levels, compliance and effectiveness of VASCAZEN<sup>®</sup>.

### **Update on VASCAZEN<sup>®</sup>**

Revenues for the three and nine months ended September 30, 2014 are \$72,544 and \$198,867 respectively as compared to \$60,839 for the three months and \$227,670 for the nine months ended September 30, 2013. While sales to date of the US product, VASCAZEN<sup>®</sup>, have been limited, acceptance by healthcare professionals is growing and the increased awareness of VASCAZEN<sup>®</sup> is generating sales in several US states that are not currently serviced by Pivotal sales representatives. While 2013 sales of \$303,530 versus 2012 sales of \$93,637 demonstrated a significant increase, 2014 nine months

results are tracking at slightly below 2013 results. Sales data indicates that our sales representatives are achieving competitive levels of prescriptions written and filled but the limited number of sales and marketing resources is affecting overall financial results. Realizing that current efforts to expand the in house sales team have been hampered by limited financial resources the Company has recently increased its efforts in the identification and contacting of sales groups or companies with a sales network that calls on the same targeted health care practitioners. The Company has also recently set-up a mainly commission-based sales force.

#### **Update on OMAZEN®**

OMAZEN® is a greater than 90% pure, pharmaceutical grade Omega-3 for the maintenance of good health. OMAZEN® has a proprietary formulation delivering optimal levels of Omega-3 that promotes an increase in blood flow, reduced inflammation and positive effects on blood lipids contributing to the maintenance of good health. The Company is currently looking at expanding the indication of OMAZEN® to include a product specifically for heart health and another product for the lowering of triglycerides.

#### **Introduction of Benefishial™**

In an effort to differentiate Pivotal's unique patented 6:1 EPA:DHA formulation with OTC products and to address new market segments Pivotal created Benefishial™. It was specifically designed to be sold in the OTC direct to retail or direct to consumer markets. Benefishial™ is greater than 90% pure and contains the highest content of Omega-3 fatty acids than any other OTC product on the market. It is specifically formulated to give the highest anti-inflammatory properties and the best therapeutic effect for a healthy body and mind. It corrects the imbalance that the typical North American diet high in Omega-6 (pro-inflammatory) creates. Benefishial™'s unique formulation is clinically shown to increase blood levels of Omega-3 and clinical studies conducted determined Benefishial™'s efficacy in maintaining a healthy body and mind. Benefishial™ is third party tested and goes through a five-step purification process to remove all toxins and fillers. It is monitored for freshness throughout the manufacturing process, tested by third parties and is packaged using blister packaging to maintain this freshness. Benefishial™ contains the optimal purity, ratio and dose of any Omega-3. Benefishial™ is a simple solution to a number of health risk factors

#### **PUBLICATOIN OF VASCAZEN®-REVEAL CLINICAL TRIAL**

On May 7, 2013 the Company announced that it had presented positive results from the completion of the VASCAZEN®-REVEAL clinical trial. The results and conclusions derived from this clinical trial were significant. The results were presented on May 3, 2013 at the American Heart Association's Arteriosclerosis, Thrombosis and Vascular Biology ("ATVB") 2013 Scientific Sessions.

The purpose of the VASCAZEN®-REVEAL trial was to demonstrate that CVD patients are nutritionally deficient in Omega-3 fatty acids, and through treatment with VASCAZEN® such deficiency can be corrected, resulting in the improvement of patient lipid profiles and ultimately reducing CVD risk factors. The trial was a double-blind, placebo-controlled study comprised of 110 subjects randomized and stratified by baseline triglyceride levels. The trial analyzed both the placebo (n=54) and VASCAZEN® treated

(n=56) groups at baseline and after eight weeks of treatment. The primary endpoints were the change in the Omega-Score and Omega-Index, with secondary endpoints including the change in serum triglyceride, lipoprotein cholesterol (VLDL, LDL, HDL, ApoB, and subfractions), and hsCRP. The Omega-Score and Omega-Index are proprietary diagnostic tests that measure circulating blood levels of Omega-3 in individuals. The Omega-Score and Omega-Index are independent measures of risk factors for CVD. The levels correlate with the risk of CVD events; patients with low levels of Omega-3 have a higher incidence of CVD events than patients with high levels of Omega-3.

VASCAZEN<sup>®</sup> was demonstrated to be highly effective in correcting an Omega-3 deficiency. In eight weeks of treatment a statistically significant ( $p<0.0001$ ) increase of 121% in the Omega-Score and 112% ( $p<0.0001$ ) in Omega-Index (the blood levels of EPA, DHA and Docosapentaenoic acid, (“DPA”)) was observed in VASCAZEN<sup>®</sup> treated subjects. The VASCAZEN<sup>®</sup>-REVEAL trial confirms Pivotal’s Open Label Study results conducted in 2011 that identified >80% of CVD patients as Omega-3 deficient. The VASCAZEN<sup>®</sup> formulation had a profound effect on correcting an Omega-3 deficiency and positive effect on lipid profiles, mainly the reduction of triglycerides and raising HDL in as little as eight weeks of treatment.

The VASCAZEN<sup>®</sup>-REVEAL trial confirmed that Omega-3 deficiency is prevalent in individuals with CVD, and that such a deficiency can be corrected with VASCAZEN<sup>®</sup>, a 6:1 EPA:DHA Omega-3, resulting in a concomitant and significant placebo-corrected reduction in triglycerides and VLDL, and increase in HDL-C in patients with high triglycerides (200-500mg/dL), without adversely affecting LDL-C.

Of the 110 patients enrolled > 85% were Omega-3 deficient. The VASCAZEN<sup>®</sup>-REVEAL trial is the first to determine dietary levels of Omega-3 in plasma and in red blood cells using the Omega-Score and Omega-Index diagnostics. Improvement after treatment with VASCAZEN<sup>®</sup> and the concomitant beneficial effects on CVD risk factors in patients with high triglycerides (200-500mg/dL) was analyzed.

On September 10, 2014 Pivotal announced the publication of the results of a VASCAZEN<sup>®</sup>-REVEAL study in the peer-reviewed journal Molecular and Cellular Biochemistry. It was a prospective randomized controlled trial in the US that evaluated the effects of VASCAZEN<sup>®</sup> in the correction of Omega-3 deficiency in patients with one or more risk factors associated with CVD and evaluated VASCAZEN<sup>®</sup>’s concomitant effects on these risk factors including triglycerides, VLDL cholesterol, LDL cholesterol, and HDL cholesterol.

The publication titled, “Efficacy of a unique omega-3 formulation on the correction of nutritional deficiency and its effects on cardiovascular disease risk factors in a randomized controlled VASCAZEN<sup>®</sup>-REVEAL Trial,” was authored by Nisar Shaikh, Jason Yantha, Sabah Shaikh, William Rowe, Maggie Laidlaw, Carla Cockerline, Abbas Ali, Bruce Holub and George Jackowski, MolCellBiochem (2014) 396:9-22 with open public access at <http://link.springer.com/article/10.1007/s11010-014-2132-1/fulltext.html>.

## **SELECTED FINANCIAL INFORMATION**

### **TRENDS, RESULTS OF OPERATIONS AND ANNUAL RESULTS**

Since October 1, 2010, the date of incorporation, the Company has concentrated its efforts in the organization, strategic development and financing of the Company and in securing its intellectual property position. On December 8, 2010, Pivotal Therapeutics Inc. (pre-amalgamation) entered into an amalgamation agreement with a reporting issuer, Media Script Marketing Inc., to amalgamate. The parties entered into a definitive agreement whereby the common shares of Pivotal (pre-amalgamation) and Media Script (consolidated shares) were each exchanged for the common shares of the amalgamated entity (the Company) on a one to one basis, after the common shares of Media Script had been consolidated on a two to one basis. This transaction was completed, resulting in the amalgamated entity continuing as the Company, effective April 7, 2011.

The period of three and nine months ended September 30, 2014 represents the Company's fourth year of operation as an amalgamated entity and represents a continuation of Pivotal Therapeutics Inc. (pre-amalgamation) for accounting purposes. Comparative figures are for the three and nine months ended September 30, 2013 and the twelve months ended December 31, 2013.

On March 4, 2014, the Company completed its debt financing, that had been announced in October 2013, resulting in the issuance of 7,744 Convertible Promissory units for gross proceeds of \$7,743,580. Each unit consists of \$1,000 Convertible Promissory Notes ("Notes") and 1,200 common share purchase warrants for a total issuance of 9,292,296 warrants. The maturity of the Notes is two years from the date of issuance. The conversion price of the Notes is \$0.20 for each common share of the Company. The Notes accrue interest at 8% per annum and the warrants may be exercised at any time for a period of 60 months following the date of issuance at an exercise price of \$0.30 per common share. The Company may, at its discretion, pay the interest in either cash or common shares of the Company; valued at the greater of \$0.20 per share and such price as may be allowed under the CSE Policy. The Company incurred financing costs associated with the transaction of \$480,544 and issued an aggregate of 1,641,586 agent warrants. The agent warrants may be exercised at a price of \$0.30 per common share for a period of 60 months. The warrants have an expiry date of March 4, 2019.

The Company's expenses for the three and nine months ended September 30, 2014 increased to \$1,159,402 and \$4,698,592 respectively as compared to \$529,510 and \$2,122,409 for the three and nine months ended September 30, 2013. Expenses for the three and nine months ended September 30, 2014 include \$97,200 and \$1,097,250 respectively, of stock based compensation in recognition of deferred option awards to directors, officers, employees and consultants for 2012 and 2013. Also included in Net Loss are interest of \$156,145 for the three months and \$357,837 for the nine months ended September 30, 2014 on the Notes. Stock based compensation; Interest on long-term debt and Accretion expense account for a total of \$1,944,448 of total net losses of \$5,418,497 reported for the nine months ended September 30, 2014.

Despite the delays in the completion of the Company's financing efforts, many strategic business milestones were achieved by the Company during the twelve months ended December 31, 2013 and the nine months ended September 30, 2014, including: (i) as at April 30, 2013 the completion of the REVEAL clinical trial and presentation of top-line results, (ii) on October 2, 2013, the Company announced the completion of a \$2,741,809 equity financing, (iii) on October 2, 2013 the Company announced a \$5,000,000 debt financing, that resulted in a total of \$7,743,580 having been invested by March 4, 2014, (iv) on May 7, 2014 the Company announced the issuance of US Patent 8,715,648 for its unique 6:1 EPA:DHA formulation, (v) on October 7, 2014 the Company announced notification of patent allowance for US application 13/584,480 related to the combination of VASCAZEN<sup>®</sup> and statin therapy and on October 8, 2014 the Company received notification of allowance for US Patent related to the combination of VASCAZEN<sup>®</sup> and cholesterol absorption inhibitor.

## **Sales**

Product sales for the three and nine months ended September 30, 2014 are \$72,544 and \$198,867 respectively as compared to \$60,839 and \$227,670 for the three and nine months ended September 30, 2013. The nine-month 2014 sales resulted in a 13% decrease when compared to the same period in the previous year. Sales and marketing expenses increased by 31% for the nine months ended September 30, 2014 as compared to the nine months ended September 30, 2013. The reduction of sales and marketing expenses in 2013 had a direct negative impact on product sales for the first nine months of 2014. While sales to date of the US product, VASCAZEN<sup>®</sup>, have been limited, acceptance by healthcare professionals is growing and the increased awareness of VASCAZEN<sup>®</sup> is generating sales in several US states that are not currently serviced by Pivotal sales representatives. While 2013 sales of \$303,530 versus 2012 sales of \$93,637 demonstrated a significant increase, 2014 nine months results are tracking at slightly below 2013 results. Sales data indicates that our sales representative are achieving competitive levels of prescriptions written and filled but the limited number of sales and marketing resources is negatively affecting overall financial results. Realizing that current efforts to expand the in-house sales team have been hampered by limited financial resources the Company has recently increased its efforts in the identification and contacting of sales groups or companies with a sales network that calls on the same targeted health care practitioners.

In an effort to address new market segments Pivotal developed a new product brand, Benefishial<sup>™</sup>, that is being directed towards the over the counter market. Currently the Company is seeking to develop commercial relationships for the US and Canadian market.

Sales and marketing expenses increased by 44% for the three months and by 31% for the nine months ended September 30, 2014 as compared to the three and nine months ended September 30, 2013. Despite the fact that sales and marketing efforts continue to be impacted from the lack of financial resources that first occurred in 2013, we have been able to sell product in 36 states across the US even though our sales efforts to date have concentrated only in three states. This positive experience demonstrates the company's readiness for a true national co-marketing partner.



## **Expenses**

The Company anticipates that expenses will continue to increase commensurate with an increase in sales and marketing activity, business development and expansion of its product portfolio.

During the three and nine months ended September 30, 2014, the Company had stock-based compensation of \$97,200 and \$1,097,250 respectively, as compared to \$Nil for the three and nine months ended September 30, 2013. Stock-based compensation represents the fair value of the options granted during the three and nine months ended September 30, 2014 and was determined using the Black-Scholes option pricing model. The increase reflects the value associated with the issuance of options to acquire 9,251,000 common shares of the Company. The Company had deferred the issuance of 8,251,000 options until it concluded its equity financing. On March 14, 2014, The Company granted previously reserved stock options to certain of its directors, officers, employees and consultants in recognition of awards deferred from 2012. Options to acquire a total of 4,075,000 common shares of the Company were granted in accordance with the provisions of the Company's 2011 stock option plan approved by shareholders on March 10, 2011. The options are exercisable at an exercise price of \$0.20 and will expire five years following the date of the grant. The increase also includes the value attributed to options issued on April 7, 2014. On April 7, 2014 the Company granted previously reserved stock options to certain of its directors, officers, employees and consultants in recognition of awards deferred from 2013. Options to acquire a total of 4,176,000 common shares of the Company were granted in accordance with the provisions of the Company's 2011 stock option plan approved by shareholders on March 10, 2011. Included in the total are 250,000 options granted to Crossover Healthcare Fund, LLC in recognition of services provided. The options are exercisable at an exercise price of \$0.20 and will expire five years following the date of the grant. In addition, on September 15, 2014 the Company announced the granting of 1,000,000 stock options to an officer and consultant. The stock options were granted effective September 12, 2014, are exercisable at an exercise price of \$0.20 and will expire five years following the date of grant.

During the three and nine months ended September 30, 2014, the Company had sales and marketing expenses of \$308,149 and \$1,123,901 as compared to \$213,694 and \$858,507 for the three and nine months ended September 30, 2013, a increase of \$94,455 and \$265,394 respectively. The increase reflects a renewal of selling and marketing efforts that was previously reduced due to the Company's limited financial resources during 2013. With the completion of the recent debt financing, the Company has renewed its selling and marketing efforts leading to an increase in expenditures and a delayed potential increase in revenues. With increased capital resulting from the recent financings, the Company entered into an agreement during the second quarter of 2014 with a sales and marketing branding company to assist in the implementation of the next stage in the Company's commercialization strategy. In addition, Pivotal has entered into agreements to obtain industry retail pharmaceutical sales data to assist in the identification of new selling opportunities and the refining of current efforts. These activities have contributed significantly to the increase in expenses during 2014.

During the three and nine months ended September 30, 2014, the Company had consulting expenses of \$189,135 and \$525,218 as compared to \$133,823 and \$392,514 for the three and nine months ended September 30, 2013. The increase of \$55,312 and \$132,704 for the three and nine months ended September 30, 2014 relates to an increase in activity associated with business development and product sales.

During the three and nine months ended September 30, 2014, the Company had research and development costs of \$263,226 and \$636,726, respectively, as compared to \$93,887 and \$260,670 for the three and nine months ended September 30, 2013. The three month increase of \$169,339 and nine month increase of \$376,056 in research and development costs is directly attributed to the Company having established its own in-house research laboratory. One of the main purposes for the in-house laboratory is to enhance the Company's research capabilities in the development of new products. Research and development cost are planned to continue to increase for the remainder of 2014 in conjunction with an expansion of in-house research staff, the constructing and outfitting of a dedicated research laboratory and the commencement of activities leading to the development of a rapid format point-of-care Omega-3 diagnostic. The Company plans to develop a rapid format diagnostic, which can be used in the physician offices, to provide an analysis of a patient's Omega-3 deficiency levels.

During the three and nine months ended September 30, 2014, the Company had salaries and benefits expenses of \$191,104 and \$639,139 respectively, as compared to \$83,584 and \$285,968 for the three and nine months ended September 30, 2013. The three-month increase of \$107,520 and the six-month increase of \$353,171 reflect an increase in executive compensation to bring compensation levels up to industry comparatives and the addition of the new Chief Financial Officer, effective September 7, 2014.

During the three and nine months ended September 30, 2014, the Company had office and general administration expenses of \$11,048 and \$303,832 respectively, as compared to \$87,599 and \$214,414 for the three and nine months ended June 30, 2013. Included in the nine month increase of \$89,418 are foreign exchange losses of \$37,562.

During the three and nine months ended September 30, 2014, the Company had interest on long term debt of \$156,145 and \$357,837 respectively as compared to \$Nil for the three and nine months ended September 30, 2013. The increase of \$156,145 for the three months and \$357,837 for the nine months ended September 30, 2014 relates to paid and or accrued interest on the Notes.

During the twelve months ended December 31, 2013, the Company was required to provide an inventory impairment provision of \$271,068. No additional amount has been provided for the three and nine months ended September 30, 2014. This provision relates to the possibility that a portion of existing VASCAZEN<sup>®</sup> and OMAZEN<sup>®</sup> inventories will not be distributed or sold prior to the expiration date of the product based on forecasted sales levels. Pivotal had produced sufficient inventory to meet with projected demand resulting from anticipated increase in sales and marketing efforts. The delays in financing for the Company had a serious negative effect on sales and marketing activities for 2013 and the beginning of 2014 resulting in downward revisions to forecasted sales.



During the three and nine months ended September 30, 2014, the Company had professional fees of \$36,413 and \$199,252 respectively, as compared to \$42,405 for the three months and \$157,746 for the nine months ended September 30, 2013, a decrease of \$5,992 for the three months and an increase of \$41,506 for the nine months ended September 30, 2014. The three month decrease reflects a decrease in recent legal fees and the nine month increase relates to an increase in legal fees, incurred in the first half of the year, associated with the recent debt financing.

During the three and nine months ended September 30, 2014, the Company had rent and utilities expenses of \$19,003 and \$57,616 respectively, as compared to \$11,109 for the three months and \$37,924 for the six months ended September 30, 2013, a increase of \$7,894 for the three months and an increase of \$19,692 for the nine months ended September 30, 2014. The increase relates to an expansion of space requirements in connection with the establishment of an in-house research facility.

During the three and nine months ended September 30, 2014, the Company had registration fees of \$16,683 and \$38,288 respectively, as compared to \$10,048 for the three months and \$37,180 for the nine months ended September 30, 2013. An increase of \$6,635 for the three months and a increase of \$1,108 for the nine months ended September 30, 2014. The changes are reflective of timing difference associated with the delays in billings from third party service providers. These costs are associated with the Company being listed on two exchanges, the Canadian Securities Exchange (“CSE”) (formerly “CNSX”) and the OTC Markets QX (“OTCQX”).

During the three and nine months ended September 30, 2014, the Company had amortization of intangible assets expenses of \$9,284 and \$27,010 respectively, as compared to \$6,500 for the three months and \$19,500 for the nine months ended September 30, 2013. This expense pertains to the amortization of intellectual property. Intellectual property had an original carrying value of \$520,000 and has been supplemented by capitalized investment in prosecuting and maintaining the portfolio. Intellectual property expenditures during 2013 resulted in an increase to such intangible assets of \$139,167. In addition expenditures of \$61,151, incurred during the first nine months of 2014 have been added to the carrying value. The amortization of the increase in value explains the increase in amortization expense for the nine months ended September 30, 2014.

During the three and nine months ended September 30, 2014, the Company had depreciation expenses of \$18,157 and \$50,360 respectively as compared to \$5,563 and \$16,688 for the three and nine months ended September 30, 2013. The three month increase of \$12,594 and nine month increase of \$33,672 in depreciation is related to increased purchases of research and development equipment made in connection with the Company expanding its in-house research facility for the purposes of pursuing a rapid-format diagnostic test to assist healthcare practitioners in determining Omega-3 deficiency.

During the nine months ended September 30, 2014, the Company had accretion expense of \$489,361 as compared to \$Nil for the nine months ended September 30, 2013. Accretion expense relates to the Company's Convertible Promissory Notes, as described

in Note 6(b) to the condensed interim consolidated financial statements for the period ended September 30, 2014. This expense reflects the difference, which is recognized as an expense over the life of the Notes, between the face value of the promissory notes and the fair value at which they are reported in the Company's statement of financial position.

## **Trends**

Based on completion of its initial private placements, amalgamation, and warrant exercise, the Company was able to fund its initial growth plan and begin to commercialize its lead product, VASCAZEN<sup>®</sup>.

Effective February 2013, the Company has directly employed its sales force. This action has resulted in a more effective control of the sales force, reduced costs of operation and increased sales. Bringing the sales team in-house has provided greater understanding of the US market. The experiences gained are expected to better enable management to develop and execute a more effective sales and marketing strategy for the future. The Company anticipates that over time positive results will be achieved.

Sales, marketing, product distribution, clinical trials and reimbursement activities undertaken and managed during the twelve months ended December 31, 2013 and the first nine months of 2014, were restricted as the Company made every effort to control costs and preserve financial resources.

On October 2, 2013 the Company announced that the equity portion of its private placement had raised gross proceeds of \$2,741,809, and issued 12,462,768 units at a price of \$0.22 per unit. Each unit consisted of one common share and one-half purchase warrant. Prior to closing, the terms of the purchase warrants were revised from an expiry of 24 months to 60 months and the warrants' exercise price was revised from \$0.50 per common share to \$0.30 per common share. The purchase warrants may be called by the Company at any time after six months following the closing, provided the common shares of the Company have traded at a price of at least \$0.45 for 20 trading days within a 30 day consecutive trading period.

On March 4, 2014, the Company completed its debt financing that had been announced in October 2013, resulting in the issuance of 7,744 Convertible Promissory units for gross proceeds of \$7,743,580. Each unit consists of \$1,000 Convertible Promissory Notes ("Notes") and 1,200 common share purchase warrants for a total issuance of 9,292,296 warrants. The maturity of the Notes is two years from the date of issuance. Subsequent to the year-end, the conversion price of the Notes was amended from \$0.25 to \$0.20 for each common share of the Company, the maximum amount of the offering was increased from \$5,000,000 and the warrant exercise price was reduced from \$0.50 per common share to \$0.30. The Notes accrue interest at 8% per annum due and payable quarterly with the first payment due three months from the date of issuance, (July 1, 2014). The Company may, at its discretion, pay the interest in either cash or common shares of the Company, valued at the greater of \$0.20 per share and such price as may be allowed under the CSE's policy (CNSX policy). As at July 1, 2014 the Company made the first interest payment of \$156,145 in cash. As at October 1, 2014 it issued 780,722 common shares of the Corporation (the "Common Shares") representing payment of interest for the period of June 5, 2014 to September 4, 2014 on its outstanding Convertible Notes.

The warrants may be exercised at any time for a period of 60 months following the date of issuance at an exercise price of \$0.30 per common share. The Company also incurred financing costs associated with the transaction of \$480,544 and issued an aggregate of 1,641,586 agent warrants. The agent warrants may be exercised at a price of \$0.30 for a period of 60 months and have an expiry date of March 4, 2019.

The following tables provide selected financial information that should be read in conjunction with the audited consolidated financial statements and the unaudited condensed interim consolidated financial statements of the Company.

#### **SUMMARY OF SELECTED QUARTERLY RESULTS**

<b>Income Statement Items</b>	<b>Three Months ended September 30, 2014 (unaudited)</b>	<b>Three Months ended June 30, 2014 (unaudited)</b>	<b>Three Months ended March 31, 2014 (unaudited)</b>	<b>Three Months ended December 31, 2013 (unaudited)</b>	<b>Three Months ended September 30, 2013 (unaudited)</b>
Total Net Revenues	\$72,544	\$73,791	\$52,532	\$75,860	\$60,839
Net Loss	\$(1,632,052)	\$(2,172,778)	\$(1,613,667)	\$(964,088)	\$(492,719)
Weighted Average Number of Shares Outstanding	91,916,277	91,916,277	91,916,277	82,526,520	79,453,509
Loss per Common Share	\$(0.02)	\$(0.02)	\$(0.02)	\$(0.01)	\$(0.01)

<b>Statements of Financial Position as at</b>	<b>September 30, 2014 (unaudited)</b>	<b>December 31, 2013 (audited)</b>
<b>Assets</b>		
Current Assets	\$2,088,848	\$1,191,098
Production Advance	\$164,928	\$165,348
Equipment	\$432,714	\$74,368
Intangible Assets	\$614,850	\$580,709
Total Assets	\$3,301,340	\$2,011,523
<b>Liabilities</b>		
Current Liabilities	\$521,950	\$655,682
Long Term Liabilities	\$6,295,027	\$1,967,293
Total Liabilities	\$6,816,977	\$2,622,975
<b>Shareholders' Equity</b>		
Share Capital	\$7,962,346	\$7,962,346
Other Paid-in Capital	\$3,641,190	\$1,458,518
Warrants	\$869,583	\$537,943
Deficit	\$(15,988,756)	\$(10,570,259)
Total Liabilities and Shareholders' Equity	\$3,301,340	\$2,011,523

## LIQUIDITY AND CAPITAL RESOURCES

The financial statements are prepared in accordance with IFRS and on the assumption that the Company will be able to realize the carrying value of its assets and discharge its liabilities in the normal course of operations as a going concern. The Company's ability to discharge its liabilities and realize the carrying value of its assets in the normal course of operations is dependent upon, among other things, being able to raise the required capital amount of debt and/or equity financing for profitable operations to be achieved.

The Company's first private placement occurred through the issuance of a unit ("**Unit**") consisting of one common share and one-half of one common share purchase warrant, with a subscription price of \$0.10 per Unit. As at February 2, 2011 the Company was successful in completing the first private placement resulting in gross proceeds of \$2,378,844.

On July 14, 2011, after having met the conditions of an Accelerated Event, the Company issued a call on the share purchase warrants. Following an extension of the exercise period, Warrant holders of record had until 5:00 pm on September 16, 2011 to exercise their warrants, with each full warrant, at a price of \$0.25 per common share, entitling the holder to purchase one common share in the capital of the Company. The cumulated exercise of 10,466,392 common stock purchase warrants resulted in net proceeds of \$2,616,598.

On June 25, 2012, the Company announced having entered into a subscription agreement for a \$5,000,000 non-brokered private placement with a US Institutional Fund. Pursuant to the subscription agreement, the Company had agreed to issue 22,727,273 units at a price of \$0.22 each. Each unit consisted of one common share and one-half purchase warrant. Each full purchase warrant may be exercised to purchase one common share of the Company upon payment of the exercise price of \$0.50 per common share. Units were to be issued in tranches as funds were received. The purchase warrants were to expire 24 months following the closing of each tranche and may be called by the Company at any time after six months following the closing, provided the common shares of the Company have traded at a price of at least \$0.75 per share for 20 trading days within a 30 day consecutive trading period.

On October 2, 2013 the Company announced that equity portion of the private placement had raised gross proceeds of \$2,741,809 representing 12,462,768 units at a price of \$0.22 per unit. Each unit consist of one common share and one-half purchase warrant. The terms of the purchase warrants were revised from an expiry of 24 months to 60 months. The warrants' exercise price was reduced from \$0.50 per common share to \$0.30 per common share. The purchase warrants may be called by the Company at any time after six months following the closing, provided the commons shares of the Company have traded at a price of at least \$0.45 for 20 trading days within a 30 day consecutive trading period.

On March 4, 2014, the Company completed its debt financing that had been announced in October 2013, resulting in the issuance of 7,744 Convertible Promissory units for gross proceeds of \$7,743,580. Each unit consists of \$1,000 Convertible Promissory Notes

(“Notes”) and 1,200 common share purchase warrants for a total issuance of 9,292,296 warrants. The maturity of the Notes is two years from the date of issuance. Subsequent to the year-end, the conversion price of the Notes was amended from \$0.25 to \$0.20 for each common share of the Company, the maximum amount of the offering was increased from \$5,000,000 and the warrant exercise price was reduced from \$0.50 per common share to \$0.30. The Notes accrue interest at 8% per annum due and payable quarterly with the first payment due three months from the date of issuance, (July 1, 2014). The Company may, at its discretion, pay the interest in either cash or common shares of the Company, valued at the greater of \$0.20 per share and such price as may be allowed under the CSE’s policy (CNSX policy). The warrants may be exercised at any time for a period of 60 months following the date of issuance at an exercise price of \$0.30 per common share. The Company also incurred financing costs associated with the transaction of \$480,544 and issued an aggregate of 1,641,586 agent warrants. The agent warrants may be exercised at a price of \$0.30 for a period of 60 months and have an expiry date of March 4, 2019.

There are currently no defaults or arrears by the Company on:

- i) Dividend payments, lease payments, interest or principal payment on debt;
- ii) Debt covenants; or
- iii) Redemption or retraction or sinking fund payments.

As of the date of this MD&A, the Company did not have any commitments for capital expenditures.

At September 30, 2014, the Company had cash totaling \$1,439,105 compared to \$487,199 at December 31, 2013. The increase in cash that occurred during the three and nine months ended September 30, 2014 is primarily due to an increase in cash resulting from revenues of the sale of VASCAZEN<sup>®</sup> in the US market and the completion of equity and debt financings.

## **WORKING CAPITAL**

Working capital (defined as current assets minus current liabilities) has increased to \$1,566,898 (excluding Production advance of \$164,928) for the nine months ended September 30, 2014 as compared to \$535,416 (excluding Production advance of \$165,348) for the year ended December 31, 2013, mainly as a result of an increase in financing activities, a reduction in cash used for operating activities, and an increase in the acquisition of equipment and intangible asset additions. In order for the Company to sustain operations it will require additional capital. The Company expects to satisfy operating cash requirements over the next twelve months from cash on hand, collection of anticipated revenues resulting from commercialization activities, development or marketing license agreements, through managing operating expenses and additional equity or debt financings. There are no assurances that Pivotal will be able to obtain any new capital on desirable terms or in amounts sufficient to meet its operating needs. The availability of financing for the Company will be affected by, amongst other things, the success of its commercialization efforts, the results of its clinical studies, the market acceptance of its products, the general state of the capital markets, its strategic alliance

agreements and other commercial factors. In the event that Pivotal is unable to obtain additional capital over the next twelve months, there may be substantial doubt about the Company's ability to continue as a going concern and realization of assets and payment of liabilities as they become due.

## **CAPITAL EXPENDITURES**

Total capital expenditures for the nine months ended September 30, 2014 were \$408,706, an increase from the December 31, 2013 amount of \$13,103. Capital expenditures for the nine months ended September 30, 2014 all relate to the purchase and expansion of research equipment and related facilities. Total capital expenditures for the remainder of 2014 are anticipated to increase insignificantly as the majority of planned purchases took place during the nine months ended September 30, 2014. The Company continues to fund 2014 capital expenditures from working capital.

## **CONTRACTUAL OBLIGATIONS**

During the financial year ended December 31, 2011, \$709,326 was provided as a production advance to a supplier under an exclusive supply agreement. Under the revised terms of the supply agreement, \$567,068 of the production advance of \$709,326 was utilized during 2012 as settlement of an outstanding accounts payable obligation. The remaining balance as at September 30, 2014 was \$164,928. The decrease of \$420 between the December 31, 2013 balance of \$165,348 and the September 30, 2014 balance of \$164,928 relates to accrued interest applied and foreign exchange fluctuations between the Euro and Canadian dollar. The advance will be drawn down against future purchases.

In addition, the Company had entered into a lease for office premises, which was scheduled to expire on January 31, 2013, with an option to renew the term of the lease for a further three years. The Company exercised the option for a further three years expiring January 2016. The minimum annual rental payments to the end of the lease term are as follows:

2014: \$39,000  
2015: \$39,000  
2016: \$3,300

On December 1, 2013, the Company entered into a new lease for additional office space, which expires November 30, 2016. The minimum annual rental payments to the end of the lease term are as follows:

2014: \$25,400  
2015: \$25,400  
2016: \$23,283



## **DISCLOSURE CONTROL AND PROCEDURES**

Under the supervision and with the participation of Pivotal's management, including the Chief Executive Officer, Chief Operating Officer and President and Chief Financial Officer, Pivotal has evaluated the effectiveness of its disclosure controls and procedures as at September 30, 2014. Disclosure controls and procedures are designed to ensure that the information required to be disclosed by the Company in the reports it files or submits under securities legislation is recorded, processed, summarized and reported on a timely basis and that such information is accumulated and reported to management, including the Company's Chief Executive Officer, Chief Operating Officer and President and Chief Financial Officer, as appropriate, to allow required disclosures to be made on a timely basis. Based on the evaluation, management has concluded that these disclosure controls and procedures are effective.

## **INTERNAL CONTROL OVER FINANCIAL REPORTING**

The management of the Company is responsible for establishing and maintaining effective internal control over financial reporting.

Internal control over financial reporting include those policies and procedures that establish the following: maintenance of records in reasonable detail, that accurately and fairly reflect the transactions and dispositions of assets; reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with applicable generally accepted accounting principles; receipts and expenditures are only being made in accordance with authorizations of management and the Board of Directors; and reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets.

Management has designed internal controls over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with Canadian generally accepted accounting principles.

Management has concluded that internal control over financial reporting is effective. The design and operation of internal control over financial reporting provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with applicable generally accepted accounting principles.

## **OFF BALANCE SHEET ARRANGEMENTS**

As at November 28, 2014, the Company did not have any off-balance sheet arrangements.

## **PROPOSED TRANSACTIONS**

The Company does not have any proposed transactions to discuss at this time.

## **TRANSACTIONS WITH RELATED PARTIES**

The Company paid a total of \$270,000 in consulting fees to an officer and director of the Company for the nine months ending September 30, 2014, compared to \$180,000 for the nine months period ended September 30, 2013. The Company paid a total of \$480,080 in management compensation for the nine months ending September 30, 2014, compared to \$225,000 for the nine months period ended September 30, 2013. The nine-month increase of \$255,080 reflects an increase in executive compensation to bring compensation levels up to industry comparatives, and includes a \$74,630 performance based compensation payment.

As at September 30, 2014, \$Nil was owing to officers and directors of the Company for unpaid expenses as compared to \$29,205 as at December 31, 2013.

## **CONTINGENCIES**

As at the date of this report, the Company did not have any contingencies outstanding.

## OUTSTANDING SHARE DATA

As at:	September 30, 2014	December 31, 2013
Authorized: Unlimited number of common shares without par value		
Issued and Outstanding:		
Common shares (1)	91,916,277	91,916,277
Common share value	\$7,962,346	\$7,962,346
Common share purchase warrants to be issued	17,165,266	6,231,384
Common share purchase warrants to be issued value	\$5,149,579	\$1,869,415
Stock options exercisable at \$0.10, expiry Jan 11, 2016	600,000	600,000
Stock options exercisable at \$0.10, expiry Feb 7, 2016	200,000	200,000
Stock options exercisable at \$0.10, expiry Mar 10, 2016	899,000	899,000
Stock options exercisable at \$0.45, expiry May 24, 2016	1,600,000	1,600,000
Stock options exercisable at \$0.30, expiry Aug 18, 2016	100,000	100,000
Stock options exercisable at \$0.30, expiry Aug 26, 2016	550,000	650,000
Stock options exercisable at \$0.25, expiry Nov 22, 2016	200,000	200,000
Stock options exercisable at \$0.29, expiry Mar 29, 2017	200,000	200,000
Stock options exercisable at \$0.20, expiry Mar 14, 2019	3,825,000	-
Stock options exercisable at \$0.20, expiry April 7, 2019	3,676,000	-
Stock options exercisable at \$0.20, expiry Sept 12, 2015	1,000,000	-
Total stock options issued and outstanding	12,850,000	4,449,000
Total stock options exercised	1,000	1,000
Total stock options available for issuance	936,441	9,337,441
Total stock option plan (15% of common share issued and outstanding)	13,787,441	13,787,441

## COMMON SHARES

On October 2, 2013, the Company announced that the equity portion of the private placement had raised gross proceeds of \$2,741,809 representing 12,462,768 units at a price of \$0.22 per unit. Each unit consist of one common share and one-half purchase warrant.

## WARRANTS

For the six months ended September 30, 2014 there were 17,165,266 warrants issued and outstanding.

Pursuant to the private placement, the closing of the equity portion, which was announced on October 2, 2013, the Company issued 6,231,384 common share purchase warrants, each of which purchase warrant may be exercised to purchase one common share of the Company upon payment of the exercise price of \$0.30 per common share. The purchase warrants expire 60 months following the closing and may be called by the Company at any time after six months following the closing, provided the common shares of the Company have traded at a price of at least \$0.45 per share for 20 trading days within a 30 day consecutive trading period. To date no warrants issued in connection with this financing have been exercised.

On March 4, 2014, the Company completed its debt financing that had been announced in October 2013, resulting in the issuance of 7,744 Convertible Promissory units for gross proceeds of \$7,743,580. Each unit consisted of \$1,000 Convertible Promissory Notes (“Notes”) and 1,200 common share purchase warrants, for a total issuance of 9,292,296 warrants. The maturity of the Notes is two years from the date of issuance. The Notes may be converted at a price of \$0.20 for each common share of the Company. The warrant exercise price is \$0.30 per common share. The Notes accrue interest at 8% per annum due and payable quarterly with the first payment due three months from the date of issuance, (July 1, 2014). The Company may, at its discretion, pay the interest in either cash or common shares of the Company, valued at the greater of \$0.20 per share and such price as may be allowed under the CSE’s policy (CNSX policy). The warrants may be exercised at any time for a period of 60 months following the date of issuance at an exercise price of \$0.30 per common share. The Company also incurred financing costs associated with the transaction of \$480,544 and issued an aggregate of 1,641,586 agent warrants. The agent warrants may be exercised at a price of \$0.30 for a period of 60 months and have an expiry date of March 4, 2019.

## **STOCK OPTIONS**

No stock options were granted during the year ended December 31, 2013. No options were exercised during the year ended December 31, 2013. On February 1, 2014, 100,000 stock options granted August 26, 2011 to a past employee were not exercised within the required option period following the employee departure and expired. On March 14, 2014, the Company granted previously reserved stock options to certain of its directors, officers, employees and consultants that were deferred from 2012. Options to acquire a total of 4,075,000 common shares of the Company were granted in accordance with the provisions of the Company's 2011 stock option plan approved by shareholders on March 10, 2011. The options are exercisable at an exercise price of \$0.20 and will expire five years following the date of the grant. On April 7, 2014, the Company granted previously reserved stock options to certain of its directors, officers, employees and consultants that were deferred from 2013. Options to acquire a total of 4,176,000 common shares of the Company were granted in accordance with the provisions of the Company's 2011 stock option plan approved by shareholders on March 10, 2011. The options are exercisable at an exercise price of \$0.20 and will expire five years following the date of the grant. In addition, on September 15, 2014 the Company announced the granting of 1,000,000 stock options to an officer and consultant. The stock options were granted effective September 12, 2014 are exercisable at an exercise price of \$0.20 and will expire five years following the date of grant. On July 17, 2014, 250,000 stock options, granted March 14, 2014 to a past director were not exercised within the required option period following the director's departure and expired. On July 17, 2014, 500,000 stock options, granted April 7, 2014 to two past directors were not exercised within the required option period following the directors' departure and expired.

## **SUBSEQUENT EVENTS**

On October 1, 2014, the Company issued 780,722 common shares of the corporation, representing payment of interest for the period of June 5, 2014 to September 4, 2014 on its outstanding Convertible Notes. Interest on the notes, at a rate of 8% per annum, is payable quarterly in either cash or common shares at the option of the Company, valued at the greater of \$0.20 per share and such price as may be allowed under the Canadian Securities Exchange (CSE) policy.

## **SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND ESTIMATES**

Please refer to Note 2 of the Company's December 31, 2013 audited consolidated financial statements.

## **RISK AND UNCERTAINTIES**

The Company is subject to numerous risks and uncertainties as a result of its stage of development. The following risk factors outline some of the risks that may impact the

Company and its business but are not a definitive list of all risk factors associated with the Company and its business.

### **Development Stage Company**

The Company is subject to all the risks inherent in the establishment of a new business enterprise, including the need to develop efficient systems while focusing on the development of new products. The likelihood of success of the Company must be considered in view of the problems, expenses, difficulties and delays frequently encountered in connection with the development of a new business.

### **Strategic and Operational Risks**

Strategic and operational risks are risks that arise if the Company fails to launch its product into the market place on a profitable and timely basis or fails to raise the required capital of debt and/or equity financing for profitable operations to be achieved. The strategic opportunities or threats arise from a range of factors, which might include: (1) competitors actions, (2) regulatory requirements and (3) general economic and political conditions.

### **Fair Value**

The carrying value of cash, accounts receivable, government remittances receivable, accounts payable and accrued liabilities do not materially differ from their fair values given their short-term to maturity.

### **Liquidity Risk**

Liquidity risk is the risk that the Company will not be able to meet its obligations associated with financial liabilities. The Company has a planning and budgeting process in place by which it anticipates and determines the funds required to support normal operation requirements as well as growth and development of its Omega-3 pharmaceutical products. The Company coordinates this planning and budgeting process with its financing activities through the capital management process described in Note 12 of the audited consolidated financial statements for the twelve months ended December 31, 2013.

The Company's financial liabilities are comprised of its accounts payable and accrued liabilities and government remittances payable, for financial liabilities within 90 days or less of \$487,895 and financial liabilities of over 90 days of \$Nil. In the event that Pivotal is unable to obtain additional capital over the next twelve months, there may be substantial doubt about the Company's ability to continue as a going concern and realization of assets and payment of liabilities as they become due.

### **Interest Rate Risk**

The Company's cash and cash equivalents are held in the form of cash deposits and/or term deposits at a Canadian chartered bank. The Company periodically monitors the

investments it makes and is satisfied with the credit ratings of the financial institutions. As at September 30, 2014 and December 31, 2013 the Company has no significant exposure to interest rate risk through its financial instruments.

### **Foreign Currency Risk**

The Company is exposed to currency risk because it makes purchases and sales transacted in US dollars and Euro. At September 30, 2014, a 10% change in the average exchange rate between Canadian dollars and US dollars or Euro would have resulted in a \$19,250 change on reported net loss and comprehensive loss for the year.

### **Credit Risk**

Credit risk is defined as the risk that one party to a financial instrument will cause a financial loss to the other party by failing to discharge an obligation. Substantially all the Company's cash is held with major financial institutions in Canada and management believes the exposure to credit risk with such institutions is not significant. The Company is also exposed to credit risk in the event of non-performance by customers paying outstanding trade receivables. At September 30, 2014 and December 31, 2013 no amounts due from customers were considered past due and no allowance for uncollectible amounts was considered necessary.

### **General and Industry Risks**

The Company's financial success may be dependent upon the extent to which it can develop, market and distribute its lead product, VASCAZEN<sup>®</sup>.

### **Competition**

The pharmaceutical/health care industry is intensely competitive in all of its phases, and the Company will compete with many companies possessing greater financial resources and technical facilities than the Company.

### **Additional Funding Requirement**

The Company will require additional capitalization to further manufacture and market its products, and to continue protection of its intellectual property portfolio. The Company will likely need to raise additional funds to support its long-term product development and commercialization programs. The Company offers no assurance that future funding will be secured or, if secured, will be on reasonable terms.

### **Capital**

The primary source of future funds presently available to the Company is through the sale of equity capital or the assumption of debt. There is no assurance that such sources of financing will be available on acceptable terms, if at all. If the Company seeks additional equity financing, the issuance of additional shares may dilute the interests of their current shareholders. Failure to obtain such additional financings could result in delay or indefinite postponement of the Company's strategic goals.



## **No History of Earnings or Dividends**

To date, the Company has limited history of earnings, and there is no assurance that the Company will generate earnings. The Company has not generated significant revenues from the sale of products and accordingly has not made an operating profit. The accumulated deficit as at September 30, 2014 is \$15,988,756. It is anticipated that the Company will continue to experience operating losses in the short run until significant commercial sales have been achieved. There can be no assurance that the Company will ever achieve significant revenues, profitable operations or provide a return on investment in the future. The Company has no plans to pay dividends for the foreseeable future.

## **Potential Profitability Depends Upon Factors Beyond the Control of the Company**

The potential profitability of the Company is dependent upon many factors beyond the Company's control. Profitability also depends on the costs of operations, including costs of labor, equipment, electricity, regulatory compliance or other production inputs. Such costs will fluctuate in ways the Company cannot predict and are beyond the Company's control, and such fluctuations will impact on profitability and may eliminate profitability altogether. Additionally, events, which cause worldwide economic uncertainty, may make the raising of funds for development difficult. These changes and events may materially affect the financial performance of the Company.

## **Possible Volatility of Securities Prices**

The market price of the Company's securities following the offering may be highly volatile, as has been the case with securities of other companies in emerging industries. Factors such as the Company's operating results and announcements by the Company or its competitors concerning technological innovations or new products may have a significant effect on the market price of the Company's securities. In addition, market prices for securities of many emerging companies have experienced wide fluctuations not necessarily related to the operating or other performance of such companies.

## **Key Personnel and External Collaborators**

Pivotal's product development capacity will depend, to a great extent, on its ability to attract and retain highly qualified staff, as well as to establish and maintain relationships with its collaborators. The competition in this area is very intense. Pivotal's success is highly dependent upon its senior officers, its scientific personnel as well as its consultants and collaborators. The loss of key employees or collaborators, if any, could compromise the pace and success of the Company's product development, commercial and operational success.

## **Government Regulation**

The business of the Company may be subject to government regulation, including the Health Protection Branch of Health Canada, the US Food and Drug Administration ("FDA") and applicable health authorities in other countries, with regard to the development, testing, manufacturing and marketing of the products. Even though the Company's product will be marketed as a Medical Food, a distinct category of FDA

regulated products that do not require FDA premarket approval; there are a number of strict guidelines that must be adhered to. There can be no assurance that any required regulatory approvals will be maintained and/or obtained on a timely basis or at all, or that difficulties or excessive costs will not be encountered by the Company in its efforts to secure necessary approvals, which could delay for a considerable period of time or prevent the Company from marketing its products. Regulatory authorities may impose costly requests upon the Company for additional data, the result of which may be a delay in the marketing of its products. Any such delay in obtaining or failure to obtain such approvals would adversely affect the marketing of the Company's planned products and the ability to earn product revenues.

### **Patents and Proprietary Technology**

The Company's success will depend, in part, on its ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of others. Interpretation and evaluation of biotechnology patent claims present complex and often novel legal and factual questions. Accordingly, there is some question as to the extent to which discoveries and related products and processes can be effectively protected by patents. There can be no assurance that the patent applications assigned to the Company will be issued or that any issued patents will be valid and enforceable if challenged or that any patent will provide the Company with a competitive advantage. In addition, others may have filed patent applications and may have been granted patents or otherwise obtained proprietary rights to technologies potentially useful to the Company. The extent to which the Company may be required to modify its products by reason of the rights asserted by others is also unknown. There is no assurance that the Company's proprietary technology will not be circumvented through adoption of a competitive though non-infringing process or product. The cost of enforcing the Company's patent rights, if any, in lawsuits that the Company may bring against infringers or defending itself against infringement charges by other patent holders may be significant and could limit the Company's operations.

### **Manufacturing Capabilities**

The Company is a development stage company with no existing manufacturing capabilities and is reliant upon entering into supply and manufacturing agreements with third parties for the manufacture of product. There can be no assurance that the Company will be able to manufacture or negotiate agreements to manufacture any products on a cost effective basis.

### **Limited Supply**

There are a limited number of potential suppliers of highly purified Omega-3 for the Company's products. There can be no assurance that the Company will be able to lock up supply from these organizations for any significant length of time nor is there any assurance that the supplier will be able to supply all the oil required by the Company.

### **Dependence on Single Product Line**

Although the Company anticipates developing other products, its operations are currently restricted to the development of its lead product, VASCAZEN<sup>®</sup>. In the event the Company

is unable to market such products for any reason, it would be materially adversely affected.

### **Sales and Marketing**

The Company has no history of selling, marketing or distributing any products. In order to market any of its products, the Company has established a dedicated sales force with expertise in such areas as marketing, sales and customer support in the United States. There can be no assurance that the sales or marketing efforts will be successful.