



# News Release

## PIVOTAL THERAPEUTICS ANNOUNCES 2014 FINANCIAL RESULTS

FOR IMMEDIATE RELEASE

APRIL 30, 2015

Woodbridge, Ontario, April 30, 2015 - Pivotal Therapeutics Inc. (OTCQX: PVTTF) (CSE: PVO), a specialty pharmaceutical company with a focus on Omega-3 therapies for cardiovascular disease (CVD) and overall health, announced its operational highlights and financial results for the fiscal year ended December 31, 2014. All dollar amounts referenced herein are in Canadian dollars unless otherwise stated.

"Pivotal's accomplishments in 2014 have been significant, with the right strategic partners and additional capitalization in 2015, investors can look forward to a more realistic valuation of the Company," stated Mr. Eugenio Bortoluzzi, Pivotal's CEO and CFO.

### Highlights from 2014

- Received Notice of Allowance 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;
- Announced the adjustment of terms, expansion and closing of a debt financing, resulting in gross proceeds of CDN \$7,743,580;
- Presented two posters discussing Omega-3 deficiency and **VASCAZEN**<sup>®</sup>'s unique formulation to correct the deficiency at the American Heart Association's Arteriosclerosis, Thrombosis and Vascular Biology (ATVB) 2014 Scientific Sessions in Toronto, Canada;
- Issuance of U.S. Patent **8,715,648** titled "Formulations Comprising Omega-3 Fatty Acids and Anti-Obesity Agent for the Reduction of Body Weight in CVD Patients and Diabetics";
- Entered into a Memorandum of Understanding to create a Joint Venture with ACGT Corporation in an effort to explore commercial opportunities in China;
- Publication by *PLOS ONE* reporting a study confirming that the **VASCAZEN**<sup>®</sup> formulation is superior to the other existing commercial products in the marketplace in terms of sustained coronary vasodilation (increase of blood flow), which is important for patients with Coronary Heart Disease who have compromised coronary vessels;
- Presented a poster indicating that the chronic intake of **VASCAZEN**<sup>®</sup>'s 6:1 EPA:DHA formulation prevented the development of hypertension and endothelial dysfunction in a rodent model at the 2014 Annual Meeting of the European Society of Cardiology Congress in Barcelona, Spain;
- Publication of the **VASCAZEN**<sup>®</sup>-REVEAL trial showing the positive effects of **VASCAZEN**<sup>®</sup> in the correction of an Omega-3 deficiency in cardiovascular patients is available in the peer-reviewed journal titled *Molecular and Cellular Biochemistry* (MCB) with open public access at <http://link.springer.com/article/10.1007/s11010-014-2132-1/fulltext.html>;
- Received Notice of Allowance for U.S. Patent Application 13/584,480 titled "Statin and Omega-3 Fatty Acids for Reduction of Apolipoprotein-B Levels";
- Received Notice of Allowance for U.S. Patent Application Number 13/584,403 titled "Cholesterol Absorption Inhibitor and Omega-3 Fatty Acids for the Reduction of Cholesterol and for the Prevention or Reduction of Cardiovascular, Cardiac and Vascular Events";



- Announced the creation of a new product line **BeneFishial™** specifically to be sold in the OTC direct to retail or direct to consumer markets. **BeneFishial™** differentiates itself from other OTC products as it is greater than 90% pure and has a unique formulation that is backed by clinical data.
- Announced R&D efforts and resources used to develop reagents for 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
- Announced clearance by the French FDA of the clinical evaluation part of the **POMEGA Phase IIa** trial protocol;

### **Subsequent to Year End**

- Received final approval to conduct the **POMEGA Phase IIa** clinical trial with its **PVT-100** drug candidate. **PVT-100** uses **VASCAZEN®**'s proprietary formulation for the stabilization of vulnerable plaque in patients undergoing carotid endarterectomy, a surgical procedure to remove material accumulated in the arteries to reduce the risk of stroke;
- Issuance of two patents, that were allowed during Q4 2014, U.S. Patent Number **8,951,514** related to the combination of **VASCAZEN®** with key cholesterol lowering agents (statins) and U.S. Patent Number **8,952,000** related to the combination of **VASCAZEN®** with cholesterol absorption inhibitors;
- Received Notice of Allowance for U.S. Patent Application Number 13/584,428 related to a kit for the dietary management of cardiovascular patients that includes **VASCAZEN®** and an Omega-3 fatty acid diagnostic assay;
- Executed a memorandum of understanding with Korea Animal Medical Science Institute (KAMSI) and its newly created affiliate for the exclusive sales and distribution of the **BeneFishial™** family of products in Korea;
- Received Health Canada approval to expand the indication of **OMAZEN®** to include products with claims to maintain and support cardiovascular health and normal triglyceride levels.

### **2014 Financial Review**

For the twelve months ended December 31, 2014 the Company reported a loss of \$5.4 million, or \$0.06 per common share, compared with a loss of \$3.0 million, or \$0.04 per common share for the twelve months ended December 31, 2013. Major items contributing to the loss are increases in selling and marketing expenses of \$1,395,593 versus \$1,097,913 in the previous year, stock based compensation of \$1,037,294 versus \$Nil in the previous year and research and development expenses of \$788,316 versus \$454,443.

Sales for the three and twelve months ended December 31, 2014 are \$107,728 and \$306,596 respectively as compared to \$75,859 and \$303,530 for the three and twelve months ended December 31, 2013. While annual sales increased slightly compared to the previous year, fourth quarter sales achieved an increase of 42% compared to the previous year.

The audited consolidated financial statements, accompanying notes thereto and Management's Discussion and Analysis for the year ended December 31, 2014, will be accessible on SEDAR [www.sedar.com](http://www.sedar.com), CSE [www.cnsx.ca](http://www.cnsx.ca) under the symbol "PVO" and OTCQX [www.otcqx.com](http://www.otcqx.com) under the symbol "PVTTF".

### **About Pivotal Therapeutics Inc.**

Pivotal Therapeutics is a publicly traded (**OTCQX:PVTTF; CSE:PVO**), specialty pharmaceutical company with a focus on cardiovascular disease and overall health. Pivotal Therapeutics' lead product **VASCAZEN®** is a prescription only medical food formulated to meet the dietary Omega-3 deficient needs of patients with

cardiovascular disease through elevating Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA) to levels associated with reduced risk of cardiovascular complications. **OMAZEN**<sup>®</sup> is a pharmaceutical grade Omega-3 providing over 90% pure Omega-3 in each capsule for the maintenance of good health. **OMAZEN**<sup>®</sup> is a patented product available for sale and distribution in Canada for the professional market. **BeneFishial**<sup>™</sup> is the first product in Pivotal's new nutraceutical product line, which has been specifically designed to be sold in the OTC direct to retail or direct to consumer markets.

#### **About VASCAZEN**<sup>®</sup>

**VASCAZEN**<sup>®</sup> is currently available in the U.S. as a prescription only medical food specifically formulated for the dietary management of an Omega-3 deficiency in cardiovascular patients. **VASCAZEN**<sup>®</sup> is a >90% pure Omega-3 with a proprietary 6:1 EPA:DHA fatty acid formulation, protected by a series of both U.S. and foreign patents.

**VASCAZEN**<sup>®</sup> has been clinically shown to correct an Omega-3 deficiency within eight weeks of treatment with positive concomitant effects on the lipid profiles, mainly a 48% reduction of triglycerides and an increase of HDL without negative impact on the LDL-C lipid profile.

#### **About OMAZEN**<sup>®</sup>

**OMAZEN**<sup>®</sup> is Pivotal's second commercial product to market and is available for sale and distribution for the professional over the counter (OTC) market in Canada. **OMAZEN**<sup>®</sup> contains greater than 90% pure, pharmaceutical grade Omega-3 with a unique ratio of EPA to DHA for the maintenance of good health. **OMAZEN**<sup>®</sup>, like all of Pivotal's products, is backed by clinical data and scientific support providing a superior alternative to what is currently available on the market.

#### **About BeneFishial**<sup>™</sup>

**BeneFishial**<sup>™</sup> was created as the cornerstone of our new nutraceutical product line, which will include prenatal, children, heart and animal health orientated products. **BeneFishial**<sup>™</sup> is designed to be sold as a nutraceutical in the OTC direct to retail or direct to consumer markets in both the U.S. and in Canada. **BeneFishial**<sup>™</sup> contains the highest content of Omega-3 fatty acids of any other OTC product on the market. It is specifically formulated to give the highest purity, highest anti-inflammatory properties and the best therapeutic effect for a healthy body and mind. It contains the optimal purity, ratio and dose of Omega-3 and is a simple solution to a number of health risk factors.

#### **Disclosure Notice**

*The information contained in this document is as of April 30, 2015. This press release contains forward-looking statements. Such forward-looking statements are subject to a number of risks, assumptions and uncertainties that could cause Pivotal's actual results to differ materially from those projected in such forward-looking statements. These statements can be identified by the use of words such as "will", "anticipate", "estimate", "expect", "project", "forecast", "intend", "plan", "believe", "project", "potential", and similar expressions with any discussion of future operating or financial performance or events. In particular, factors that could cause actual results to differ materially from those in forward looking statements include the following: Pivotal's inability to obtain additional financing on acceptable terms; growth in costs and expenses; inability to compete with others who provide comparable products; risk that the Company's products will not gain widespread market acceptance; risks relating to the Company's ability to maintain its CSE listing. Forward-looking statements speak only as of the date made and are not guarantees of future performance. The Company undertakes no obligation to publicly update or revise any forward-looking statements contained in this document as a result of new information or future events or developments. The CSE has not reviewed and does not accept responsibility for the adequacy or accuracy of this information.*



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