



News Release

PIVOTAL THERAPEUTICS: YEAR IN REVIEW AND CEO UPDATE

FOR IMMEDIATE RELEASE

January 22, 2015

Woodbridge, Ontario, January 22, 2015 – Pivotal Therapeutics Inc. (OTCQX:PVTF; CSE:PVO), (“Pivotal” or the “Company”), a specialty pharmaceutical company with a focus on Omega-3 therapies for cardiovascular disease and overall health is pleased to provide you with a summary of the Company’s accomplishments in 2014 and its outlook for 2015 from the CEO, Mr. Eugene Bortoluzzi.

Dear Fellow Shareholders,

We would like to take this opportunity to share with you the Company’s achievements over the past year. In March 2014, the Company completed a series of equity and debt financings with US-based institutional investors led by Crossover Healthcare Fund, LLC which took approximately 20 months from start to finish to complete. Specifically, Pivotal raised approximately \$1.5 million in 2012, \$3.1 million in 2013 and \$5.8 million in 2014. In addition to keeping the business and operations going during the long raise period, these funds have allowed the Company to initiate and further expand the following activities:

1. Intellectual Property - Patents

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**[®]’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.

On October 7, 2014 the Company received notification of patent allowance for U.S. Patent Application serial number 13/584,480 related to a combination product of **VASCAZEN**[®] and statin therapy. The Company received another notification of allowance for U.S. Patent Application serial number 13/584,403 on October 8, 2014 related to a combination product of **VASCAZEN**[®] and a cholesterol absorption inhibitor.

These applications are part of Pivotal’s expanding patent portfolio that protects its unique formulation. The Company has a total of eight (8) patent applications, of which one has been issued and two allowed in the United States. The Company is also pursuing patent applications related to **VASCAZEN**[®]’s formulation in multiple jurisdictions outside the United States. The Company has patents pending on the formulation, composition and combinations with existing cardiovascular drugs around the world. The Company expects the issuance of the above two allowed patents and the allowance of several more patents in 2015.

2. Publication of **VASCAZEN[®]-REVEAL TRIAL**

The publication of the **VASCAZEN**[®]-REVEAL Trial in 2014 has added credence to the concept that an Omega-3 deficiency plays a vital role in cardiovascular disease and that **VASCAZEN**[®] is an effective medical food that can correct this deficiency. According to the study, correcting an Omega-3 deficiency with **VASCAZEN**[®] can increase blood flow, reduce inflammation, promote normal triglyceride levels and have positive effects on blood lipid profile.

The randomized, double blinded, placebo-controlled **VASCAZEN**[®]-REVEAL Trial found that of the 655 CVD patients screened, 89% were Omega-3 deficient. The results of the trial were significant. The **VASCAZEN**[®]-REVEAL Trial was the first to determine levels of Omega-3 in plasma and in red blood cells using the Omega-Score and Omega-Index diagnostics. Omega-Score measures whole blood levels of EPA, DHA and DPA and Omega-Index measures EPA and DHA in red blood cells. **VASCAZEN**[®] was demonstrated to be highly effective in correcting an Omega-3 deficiency in CVD patients with normal and high triglycerides: in eight weeks of treatment with four (4) capsules/day of **VASCAZEN**[®] there was a 121% improvement in the Omega-Score and 112% improvement in Omega-Index in CVD patients with hypertriglyceridemia (200-500 mg/dL). According to the results of the **VASCAZEN**[®]-REVEAL Trial, Omega-3 deficiency was corrected within eight weeks of treatment, and treatment resulted in a 48% reduction of triglycerides, a 30% reduction of very-low-density lipoprotein cholesterol and a 9% increase of HDL (good cholesterol), without adversely affecting LDL (bad cholesterol), in CVD patients with normal and high triglyceride levels. The **VASCAZEN**[®]-REVEAL Trial has been published in the peer-reviewed journal, **Molecular and Cellular Biochemistry**, with open public access at <http://link.springer.com/article/10.1007/s11010-014-2132-1/fulltext.html>, and was presented at various American Heart Association scientific meetings in 2014.

3. US Product Sales

The last quarter of 2014 set a record high for the Company with a 47% increase in sales versus the last quarter of 2013. This demonstrates that healthcare practitioners and patients across the country are acknowledging the Company's medical food strategy and messaging. **VASCAZEN**[®] is selling in 37 states across the U.S. even though sales efforts to date have predominately concentrated on only three states, which further demonstrates the growing awareness, acceptance and adoption of **VASCAZEN**[®] and the concept of Omega-3 deficiency. This is a very positive experience for Pivotal and validates the decision to seek additional financing to expand the in-house sales force and find a co-marketing partner so that the Company can implement the next phase of its commercialization strategy.

4. Point-of-Care (POC) Diagnostic

Capitalizing on its extensive experience in developing innovative POC diagnostics tests, the Company established an in-house research facility to develop a POC diagnostic test to assist healthcare practitioners to easily identify patients that are Omega-3 deficient in their offices, clinics and pharmacies. The POC diagnostic will simplify the current technology to determine Omega-Score and Omega-Index tests which measure the amount of Omega-3 fatty acids in blood. Current practice involves collecting blood samples and sending them to a laboratory for analysis and reporting, which can be a costly and time-consuming process. The POC test will also act as a companion diagnostic to assist with **VASCAZEN**[®] treatment monitoring and patient compliance. During the year, the Company focused its efforts and resources on the development of reagents for the rapid format (POC) test. The Company is targeting a 510(k) submission to the FDA in the latter part of 2015 or early part of 2016.

5. Expansion of Product Pipeline

In 2014 the Company continued to build on its product pipeline that is backed by clinical research that supports the performance of its products. In Canada the commercial development strategy includes the over-the-counter (OTC) professional and direct to retail supplement markets.

- **OMAZEN**[®]: In 2014, the indication of **OMAZEN**[®] was expanded to include a product specifically for heart health and another product for the lowering of triglycerides. **OMAZEN**[®] is Pivotal's second product to market for the maintenance of good health, contains greater than 90% pure, pharmaceutical grade Omega-3 with the optimal 6:1 ratio of EPA to DHA. **OMAZEN**[®]'s dosage is three softgel capsules per day, delivering 2.7 grams of total Omega-3. **OMAZEN**[®] is available for sale and distribution in Canada only and is positioned for the professional OTC market.



- **BeneFishial™** was created as the cornerstone of our new nutraceutical product line, which will include prenatal, children and heart health orientated products. It is specifically 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™** 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.

Another key differentiating benefit of our products is that unlike our OTC counterparts, Pivotal is one of the only companies whose products are backed by clinical data and scientific support.

- **Drug Candidate – PVT-100:** Pivotal introduced **PVT-100** as its first drug candidate. **PVT-100** indication is for the stabilization of vulnerable plaque in patients undergoing carotid endarterectomy. Also during 2014 the Company began the first steps in establishing a Phase IIa clinical trial to be conducted in France. On December 16, 2014, the French FDA in Paris (ANSM: Agence Nationale de la Sécurité du Médicament - French National Agency for Drug Safety) officially cleared the clinical evaluation part of the **VASCAZEN® POMEGA** Phase IIa trial protocol. The **VASCAZEN® POMEGA** Phase IIa clinical trial is a double-blinded placebo controlled study in over 100 patients scheduled to undergo vascular invasive surgery for carotid endarterectomy at the University Hospital of Strasbourg, France. Patients shall be randomized to receive either Pivotal's uniquely formulated drug candidate **PVT-100** or placebo for six consecutive weeks. The composite primary endpoint of the trial consists of histomorphological, biochemical and immunological status of the vascular plaque. The Company looks forward to reporting in 2015 on initiating this Phase IIa trial with its lead drug candidate **PVT-100** in patients with vulnerable plaque.

Looking Ahead

We look forward to building on the momentum we gained in 2014 and to carrying out the objectives we have planned for 2015, including finding the right partners to help achieve some of the objectives we have laid out as well as to help further capitalize the Company.

We would like to take this opportunity to thank all of our shareholders, business partners and employees and to express our gratitude for their continued support and loyalty. We have great programs that were initiated in 2014 and new ones planned for 2015 and we look forward to sharing them with you as they come to fruition and translate into increased shareholder value.

Sincerely,

“Eugene Bortoluzzi”

Chief Executive Officer
Pivotal Therapeutics Inc.

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®** is a pharmaceutical grade Omega-3 providing over 90% pure Omega-3 in each capsule for the maintenance of good health.



OMAZEN® is a patented product available for sale and distribution in Canada. **BeneFishial™** 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.

Disclosure Notice

The information contained in this document is as January 22, 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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