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Pressure BioSciences, Inc. Announces R&D Agreement With the Armed Forces Institute of Pathology (AFIP); Initial Data on Pressure-Enhanced Processing and Analysis of FFPE Tissue Presented at the Symposium on High Pressure at Harvard Medical School

SOUTH EASTON, Mass., May 27, 2010 (GLOBE NEWSWIRE) -- Pressure BioSciences, Inc. (Nasdaq:PBIO) ("PBI" and the "Company") today announced that it has signed a Cooperative Research and Development Agreement ("CRADA") with the Armed Forces Institute of Pathology ("AFIP"), the American Registry of Pathology ("ARP"), and the Department of Veterans Affairs ("VA"). The purpose of the CRADA is to develop pressure-based methods to improve the quality and speed of formalin fixed, paraffin embedded (FFPE) tissue preparations, and to improve the quality and yield of biomolecule extraction (DNA, RNA, Proteins, Lipids, Small Molecules) from archival FFPE tissue samples.

The Company also announced that ARP scientist Dr. Carol Fowler was an invited speaker at a symposium on the Applications of Ultra-high Pressure in Biotechnology, held at Harvard Medical School on May 21st, where she presented significant data on pressure-enhanced processing and analysis of FFPE tissue, including data generated under the CRADA. Dr. Fowler is an American Registry of Pathology employee working at the Armed Forces Institute of Pathology.

Formalin fixation followed by paraffin embedding is the most commonly used technique worldwide for the preservation of tissues for pathology evaluation. Consequently, archival repositories now exist that contain millions upon millions of FFPE tissue samples. Such samples represent an invaluable resource for retrospective studies of disease progression and response to therapy. Because the disease outcome is known, and the therapies associated with that outcome are also known, studies of these samples could accelerate discoveries of new therapies, drugs, and preventive strategies.

Unfortunately, the analysis of FFPE samples is highly problematic, due to the adverse effects of formalin. These effects can lead to the improper fixation of valuable biomolecules in the sample, causing them to be lost from the FFPE tissue over time. They can also cause difficulties in extracting important biomolecules, even those that have been preserved properly.

Timothy J. O'Leary, MD., Ph.D., Deputy Chief Research and Development Officer,

Department of Veterans Affairs, said: "If these effects can be overcome, today's very sensitive and sophisticated analytical techniques could be used to study millions of archived FFPE samples. Importantly, this could result in the discovery of new biomarkers of disease and drug targets, and in the development of new interventions for the diagnosis, treatment, and prevention of cancer, as well as a host of other diseases."

Dr. Jeffrey T. Mason, Chairman of the Biophysics Department at AFIP, commented: "Pressure BioSciences has experience in the development of high pressure instrumentation and knowledge of the behavior of biological materials under pressure. AFIP and the VA have expertise in pathology, as well as years of experience in tissue histology, immunochemistry, and proteomics. We also have access to specialized scientific instrumentation and pathology samples. The research has already paid dividends, as evidenced by the data presented by Dr. Fowler at the Harvard Symposium last week, which showed significant improvements in the front-end processing of FFPE tissues, as well as in the back-end retrieval of proteins from FFPE samples."

Dr. Carol B. Fowler, Senior Research Associate at the ARP, said: "Our preliminary results showed that the application of pressure increased the rate of formalin penetration into the tissue by more than seven-fold, while preserving tissue morphology. These data indicate that the perfusion of formalin and other chemicals by slow pressure cycling might be an effective way to significantly improve the quality of tissue processing in the preparation of FFPE samples."

Dr. Fowler continued: "The data also show that our pressure-based method can extract nearly twice the number of unique proteins from FFPE tissue as current methods that do not use pressure. This is highly significant, since the greater the number of unique proteins found, the greater the likelihood of finding new, until now undiscovered biomarkers and targets for drug discovery."

Mr. R. Wayne Fritzsche, Chairman of the Board of PBI, commented: "We believe that there are millions of new FFPE tissue samples processed each year, and that our pressure-enhanced perfusion method could potentially add a significant increase in quality to the standard fixation process. We also believe that there are hundreds of millions of existing FFPE samples archived in repositories worldwide, that these samples contain invaluable information that might lead to the development of new treatments, cures, and preventive measures for cancer and many other diseases, and that our pressure-enhanced extraction method could potentially become the method of choice for such work, as current data indicate that it can extract nearly twice the number of unique proteins as the best methods available today."

Mr. Richard T. Schumacher, President and CEO of PBI, said: "We have already begun plans to confirm these very provocative and exciting data, with our CRADA partners and with several prestigious research laboratories who asked to participate after reviewing the early findings. We have also begun discussions with outside parties relating to various ways to best take advantage of these very powerful pressure-enhanced perfusion and extraction methods. Because the potential scientific and financial importance of these early findings is so significant, all stakeholders in PBI should be aware that these newly developed pressure-based methods have become a primary focus for PBI going forward."

About Pressure BioSciences, Inc.

Pressure BioSciences, Inc. (PBI) is a publicly traded company focused on the development of a novel, enabling technology called Pressure Cycling Technology (PCT). PCT uses cycles of hydrostatic pressure between ambient and ultra-high levels (up to 35,000 psi and greater) to control bio-molecular interactions. PBI currently holds 14 US and 10 foreign patents covering multiple applications of PCT in the life sciences field, including genomic and proteomic sample preparation, pathogen inactivation, the control of chemical and enzymatic reactions, immunodiagnostics, and protein purification. PBI currently focuses its efforts in the development and sale of PCT-enhanced enzymatic digestion products designed specifically for the mass spectrometry marketplace, as well as sample preparation products for biomarker discovery, soil and plant biology, forensics, histology, and counter-bioterror applications.

Forward Looking Statements

Statements contained in this press release regarding PBI's intentions, hopes, beliefs, expectations, or predictions of the future are "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward looking statements include statements regarding the expected benefits and results of the CRADA with AFIP, ARP, and the VA; and the potential benefits, improvements and results of using PBI pressure-enhanced FFPE perfusion and extraction methods. These statements are based upon the Company's current expectations, forecasts, and assumptions that are subject to risks, uncertainties, and other factors that could cause actual outcomes and results to differ materially from those indicated by these forward-looking statements. These risks, uncertainties, and other factors include, but are not limited to: possible difficulties or delays in the implementation of the Company's strategies that may adversely affect the Company's continued commercialization of PCT and its PCT-dependent products, including its pressure-based FFPE perfusion and extraction methods; changes in customer's needs and technological innovations; other scientists may not achieve the same results with PCT reported by scientists in the past or by the scientists at the Harvard Symposium, including the results presented by Dr. Fowler; and the Company's sales force may not be successful in selling the Company's PCT product line because scientists may not perceive the advantages of PCT over other sample preparation methods, including in the various areas discussed at the Harvard Symposium. Further, the Company expects that it will need additional capital to fund its continuing operations beyond the first quarter of 2011. Additional risks and uncertainties that could cause actual results to differ materially from those indicated by these forward-looking statements are discussed under the heading "Risk Factors" in PBI's Annual Report on Form 10-K for the year ended December 31, 2009, and other reports filed by PBI from time to time with the SEC. PBI undertakes no obligation to update any of the information included in this release, except as otherwise required by law.

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