

# Pressure BioSciences, Inc. Announces Commercial Launch of its Unique Biopharmaceuticals Contract Services Business

Proprietary Technology Platform Offers Improved Manufacturing for Protein Therapeutic Candidates and Positions PBI to Service the \$250 Billion Global Biopharmaceuticals Market

**SOUTH EASTON, MA / ACCESSWIRE / January 7, 2019 /**Pressure BioSciences, Inc. (OTCQB: PBIO) ("PBI" and the "Company"), a leader in the development and sale of enabling high pressure-based instruments, consumables, and related services for the worldwide life sciences industry, today announced the commercial launch of its Biopharmaceuticals Contract Services Business. The launch of this new business has been eagerly anticipated following the Company's acquisition of the assets of BaroFold, Inc. in December 2017, including patents, equipment, and other intellectual property relating to Barofold's unique, high pressure-based protein disaggregation and refolding platform.

PBI expects that the unique Barofold technology platform will substantially improve the quality and costs of manufacturing protein therapeutics, by helping to resolve protein aggregation, improving solubility, and refolding complex misfolded protein therapeutic molecules into their desired, therapeutically-optimized conformations for improved drug efficacy and lower immunogenicity.

Protein-based therapeutic drugs are a large and rapidly growing part of the global healthcare industry. There are over 200 therapeutic proteins and peptides approved for clinical use in the U.S. (THPdb database: <a href="http://crdd.osdd.net/raghava/thpdb/">http://crdd.osdd.net/raghava/thpdb/</a>). Protein therapeutics are valued for their more potent and specific therapeutic effectiveness for many diseases, such as cancer and auto-immune disorders. They are also the preferred treatment choices for hormone and growth factor deficiencies. Research and Markets (May 2016) forecasted that the global protein drug market will grow to \$248 billion by 2020.

Dr. Alexander Lazarev, Chief Science Officer of PBI, explained: "The development and manufacture of protein-based drugs can be complex and fraught with difficulty. According to a recent publication from a team of researchers from the U.S. Food and Drug Administration (Lagasse, Feb 2017), producing a typical protein drug may include more than 5,000 critical manufacturing process steps. High on the list of significant problems that can occur during manufacturing and storage of protein drugs are the formation of protein aggregates and the misfolding of the complex protein molecules into configurations that are therapeutically ineffective, undesirable, and even harmful. Our Barofold technology platform offers a unique and cost-effective processing strategy that is expected to be effective in addressing and resolving these expensive manufacturing challenges."

Dr. Lazarev continued: "In May 2018, we began applying the Barofold platform to help resolve a major challenge in the manufacturing process for a key protein drug candidate being developed by an Asian biopharmaceutical company. Based on the successful progress of our Barofold platform to date, this client recently expanded their initial request to now include other variations on their protein drug candidate. In addition, we have recently been approached by another multi-national biopharmaceutical company for help on a similar issue."

Dr. Bradford A. Young, Chief Commercial Officer of PBI, said: "We are excited to announce the launch of our Biopharmaceutical Contract Services Business for the disaggregation and controlled refolding of proteins. For companies involved in protein manufacturing, aggregation of proteins and challenges in achieving and maintaining optimal protein folding conformations are well-known issues that can dramatically reduce a drug's efficacy and shelf-life. Our proprietary, pressure-based Barofold technology platform can help resolve and optimize these outcomes and can enable the development of novel protein therapeutics in both mammalian and non-mammalian systems, which we believe to be a very large and growing market opportunity."

Dr. Young concluded: "We are very pleased to be helping our first client, a publicly-traded biopharma company, in improving their protein manufacturing processes using our proprietary Barofold protocols. The early results were so encouraging in helping our client surmount difficult manufacturing challenges in the production of their protein therapeutic drug candidate, that they have now asked us to extend our Barofold work to include two additional protein drug candidates. In addition, improved pressure-based disaggregation and protein refolding protocols have become exciting new product applications for our core Barocycler™ instrument platforms, which were already being sold into biotechnology and pharmaceutical companies for quality control, as well as for biomarker or drug target characterization purposes. We look forward to building on these successes and growing our Biopharmaceutical Contract Services Business in 2019."

## About the Barofold Technology Platform

The Barofold platform is a patented technology that employs high pressure for the disaggregation and controlled refolding of recombinant proteins into their native structures for desired drug activity. The Barofold technology results in the dissolution of protein aggregates, which may have a significant impact on the quality of protein drugs by improving protein activity, homogeneity, and stability, as well as by reducing undesirable immunogenic properties. The Barofold platform is transformative and practical for biopharmaceutical manufacturing processes, offering substantially reduced production costs due to its increased process yield and throughput at high protein concentrations. The Barofold platform is easily scalable and has been utilized for the cGMP production of phase 1 through phase 3 clinical materials.

#### About Pressure BioSciences, Inc.

Pressure BioSciences, Inc. (OTCQB: PBIO) is a leader in the development and sale of innovative, broadly enabling, pressure-based solutions for the worldwide life sciences industry. Our products are based on the unique properties of both constant (i.e., static) and alternating (i.e., pressure cycling technology, or "PCT") hydrostatic pressure. PCT is a patented enabling technology platform that uses alternating cycles of hydrostatic pressure

between ambient and ultra-high levels to safely and reproducibly control bio-molecular interactions (e.g., cell lysis, biomolecule extraction). Our primary focus is in the development of high pressure-based products for biomarker and target discovery, drug design and development, biotherapeutics characterization and quality control, food science, soil & plant biology, forensics, and counter-bioterror applications. Additionally, PBIO is actively expanding the use of our pressure-based technologies in the following areas: (1) the use of our recently acquired protein disaggregation and refolding technology from BaroFold, Inc. to allow entry into the biologics manufacturing and contract research services sector, and (2) the use of our recently-patented, scalable, high-efficiency, pressure-based Ultra Shear Technology ("UST") platform to (i) create stable nanoemulsions of otherwise immiscible fluids (e.g., oils and water) and to (ii) prepare higher quality, homogenized, extended shelf-life or room temperature stable low-acid liquid foods that cannot be effectively preserved using existing non-thermal technologies.

## **Forward Looking Statements**

This press release contains forward-looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed, implied or inferred by these forwardlooking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "would," "expects," "plans," "intends," "anticipates," "believes," estimates," "predicts," "projects," "potential" or "continue" or the negative of such terms and other comparable terminology. These statements are only predictions based on our current expectations and projections about future events. You should not place undue reliance on these statements. In evaluating these statements, you should specifically consider various factors. Actual events or results may differ materially. These and other factors may cause our actual results to differ materially from any forwardlooking statement. These risks, uncertainties, and other factors include, but are not limited to, the risks and uncertainties discussed under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, and other reports filed by the Company from time to time with the SEC. The Company undertakes no obligation to update any of the information included in this release, except as otherwise required by law.

#### **Investor Contacts:**

Richard T. Schumacher, President & CEO Pressure BioSciences, Inc. Bradford A. Young, Ph.D., SVP and Chief Commercial Officer (508) 230-1828 (T)

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