

September 8, 2023



# Pressure BioSciences' BaroFold Technology Achieves Pivotal Equipment Sale and Begins Scale-up in Service to Leading Global Contract Devt. & Mfg. Organization

***Patented BaroFold Platform is Critical Enabler for Biopharma Manufacturing and Quality Assurance;***

***Company Believes Future BaroFold Equipment and Recurring Utilization/Support Fees***

***Should Exceed \$100 Million in Annual Revenue***

**SOUTH EASTON, MA / ACCESSWIRE / September 8, 2023** /Pressure BioSciences, Inc. (OTCQB:PBIO) ("PBIO" or the "Company"), a global leader in the development and sale of broadly enabling, high-pressure-based equipment, consumables, and specialty testing services to the worldwide biopharmaceuticals, nutraceuticals, cosmeceuticals, food and beverage, and other industries, today announced a key transition in its collaborations with multiple leaders and innovators in global biopharmaceutical development and commercialization, including preeminent Contract Development and Manufacturing Organizations ("CDMOs"). The Company announced its graduation from serial product development and demonstration research contracts, with a pivotal leap forward into the sale, installation, and qualification of a research level BaroFold™ Protein Refolding Process Development System ("BaroFold System"), the first of which is currently being prepared for shipment to the main research and development site of a leading global CDMO.

Because of their high degree of specificity, proven efficacy, and minimal side effects, proteins have become the therapeutic design of choice. The [global protein therapeutics market](#) is expected to reach US \$487 billion by 2030. Unfortunately, conventional methods of biomanufacturing are very costly and time-consuming, making protein therapeutics inaccessible for most patients in developing countries. While the rapidly growing biosimilars (follow-on or generic versions of biologics) market was meant to reduce the cost of protein therapeutics, the major obstacles to achieving affordability of biosimilars remain unsolved when these molecules are produced in conventional bioreactors using animal and human (mammalian) cell cultures. Alternatively, biopharmaceutical proteins can also be produced in bacterial cultures at a fraction of the mammalian cell culture costs, but protein expression in bacteria often results in misfolded inactive proteins that aggregate and precipitate in the bacteria ("inclusion bodies").

The BaroFold Platform (14 issued patents) can be used to revolutionize biomanufacturing of

proteins in bacterial cultures by disaggregating, unfolding, and facilitating the refolding of protein molecules back to their biologically-active native configurations, thus significantly improving the quality and lowering the production costs of protein therapeutics. The BaroFold platform delicately employs extreme pressure perturbations to achieve this disaggregation and controlled refolding of proteins at yields and efficiencies not achievable using other existing technologies. The BaroFold Platform has repeatedly demonstrated the ability to remove protein aggregates in manufactured biotherapeutic drugs, thereby improving product efficacy, safety, and cost for both new-drug entities and biosimilar products. It is readily scalable and practical for standard manufacturing processes. This unique platform is currently helping start-ups and multi-billion-dollar companies in the design and development of novel protein-based therapeutics that could substantially lower the cost of existing formulations.

Dr. Alexander V. Lazarev, PBIO's Chief Science Officer, commented: "Proteins exhibit unique biophysical behaviors, which require optimization of the physical/chemical environment to gently facilitate the successful unfolding and guided refolding of each protein drug candidate into its desired active native states. We offer specialty equipment and comprehensive process development services based on harnessing the power of patented high-pressure manipulations. Following a year-long pilot project with a world renowned CDMO, we are thrilled that they are now incorporating our initial BaroFold System into their R&D infrastructure. This BaroFold System will accelerate the exploration and optimization of refolding conditions that can be seamlessly transitioned into manufacturing scale with future sales of larger BaroFold equipment that integrate with continuous flow systems and align perfectly with modern modular biomanufacturing facilities, ultimately leading to significantly lower costs for protein biologics and expanded access to these life-changing medications."

Mr. Richard T. Schumacher, President and CEO of PBIO, expanded: "The purchase of a BaroFold System by a leading CDMO is expected to evolve into the commercial scale-up phase, eventually requiring the purchase of one or more custom-made, BaroFold Commercial Scale Manufacturing Systems. We estimate that each BaroFold Manufacturing System would likely generate millions of dollars in contract design, installation, and qualification contracts for PBIO. Moreover, adoption of the BaroFold platform by CDMOs throughout their multi-site organizations would accelerate the demonstration and adoption of BaroFold processing by the CDMO's many biopharmaceutical company clients. As each biopharma client becomes ready to scale up further, we will support the establishment of BaroFold manufacturing sites under expanded licensing and contracting engagements. We anticipate the various BaroFold platform systems and the on-going utilization and support fees associated with installations could eventually grow into annual revenue exceeding \$100M for PBIO."

Mr. Jeffrey N. Peterson, Board Chairman of PBIO, summed up: "We have clearly communicated to investors how PBIO has redirected and reprioritized resources into the development and commercialization of our UltraShear™ platform, enabling a new generation of breakthrough nanoemulsion products for optimized dosing and delivery of myriad oil-soluble active therapeutic and nutritional molecules, in multi-billion dollar growth opportunities spanning nutraceuticals, cosmeceuticals, classical small-molecule pharmaceuticals, agrochemicals, food & beverages, and industrial product markets. Nonetheless, we remain proud of PBIO's initial high pressure platform developments in Pressure Cycling Technology™ (PCT™) and in our BaroFold Technology, and we continue

to welcome exciting breakthrough, revenue-generating successes from our ongoing efforts in support of all of P BIO's valuable patented technology platforms."

### **About Pressure BioSciences, Inc.**

Pressure BioSciences, Inc. (OTCQB:PBIO) is a global leader in providing innovative, broadly enabling, high pressure-based solutions for a range of industries, including biotechnology, pharmaceutical, nutraceutical, cosmeceutical, and agrochemical, as well as food and beverage manufacturing. Our products utilize both constant and alternating pressure. Our patented enabling technology platform, Pressure Cycling Technology (PCT), utilizes alternating cycles of pressure to control bio-molecular interactions (such as cell lysis and biomolecule extraction) safely and reproducibly. PCT-based products are beginning to be widely used for biomarker and target discovery, drug design and development, biotherapeutics characterization and quality control, soil & plant biology, forensics, and counter-bioterrorism applications. We have recently expanded our market opportunities with the acquisition of the BaroFold™ patented technology platform, allowing us to enter the biopharma contract services and GMP manufacturing equipment sector. We have also developed the scalable and high-efficiency pressure-based UltraShear Technology™ (UltraShear™) platform, which allows for the creation of stable nanoemulsions of otherwise immiscible fluids. It also allows for the preparation of higher quality, homogenized, extended shelf-life or room temperature-stable low-acid liquid foods that cannot be effectively preserved using existing non-thermal technologies. Our commitment to innovation and cutting-edge technology has established PBIO as a leader in the high-pressure industry, providing unique and effective solutions to our customers.

### **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 forward-looking 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 many forward-looking statements. 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, 2022, 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.

For more information about PBI and this press release, please click on the following website link:

<http://www.pressurebiosciences.com>

Please visit us on Facebook, LinkedIn, and Twitter.

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