

# Pressure BioSciences and RedShiftBio Demonstrate Potential of Combining Proprietary Technologies to Enable New Tool for Development and Production of Biotherapeutics

Combined Application of PBI's Pressure Cycling Technology and RSB's Microfluidic Modulation Spectroscopy Reveals Accurate Details of Protein Structure, Folding, and Aggregation Critical to Development, Manufacture, and Quality Control of Next Generation Treatments

SOUTH EASTON, Massachusetts, April 16, 2020 /PRNewswire/ -- Pressure BioSciences, Inc. (OTCQB: PBIO) ("PBI" or the "Company"), a leader in the development and sale of broadly enabling, pressure-based instruments, consumables, and platform technology solutions to the worldwide biotechnology, biotherapeutics, and other industries, today announced that the combination of PBI's patented Pressure Cycling Technology ("PCT") with RedShiftBio's proprietary Microfluidic Modulation Spectroscopy ("MMS") resulted in a powerful new platform for biotherapeutic drug development ("PCT-enhanced MMS"). The Company believes combining both platforms enables the rigorous investigation of protein structure and stability in a streamlined and highly efficient workflow that can be critical in drug development.

The global biopharmaceuticals market was valued at \$237 billion in 2018 and is estimated to reach \$389 billion in 2024 (<a href="https://www.mordorintelligence.com/industry-reports/global-biopharmaceuticals-market-industry">https://www.mordorintelligence.com/industry-reports/global-biopharmaceuticals-market-industry</a>). This rapid market growth is attributed to the growing acceptance for biopharmaceuticals based on their ability to treat previously untreatable diseases, resulting in huge market demand. Biopharmaceuticals offer several important benefits, such as highly effective and potent action, fewer side effects, and the potential to cure diseases rather than merely treat the symptoms.

Biopharmaceuticals include vaccines, growth and blood factors, hormones, monoclonal antibodies, and purified proteins. An example of a biopharmaceutical is interferon beta, a protein biologic used alone or in combination with other drugs against a broad spectrum of viral infections, including MERS-CoV (<a href="https://www.nature.com/articles/s41467-019-13940-6">https://www.nature.com/articles/s41467-019-13940-6</a>).

A major challenge in the manufacture of biopharmaceuticals is the development of drug formulations that ensure proteins maintain their activity during shelf life and do not aggregate (stick together), since protein aggregation can result in significant issues in patients, sometimes even severe immune reactions up to anaphylactic shock. The joint development work undertaken by PBI and RedShiftBio offers a workflow that allows scientists to study

mechanisms of protein aggregation and perturb protein structure "on demand" to promote aggregation events for accelerated stability tests. Such an approach would allow biopharmaceutical companies to test specific chemical formulations that stabilize the protein drug and prevent its aggregation. This should result in both faster development of new drugs as well as improvement in the quality of drugs coming onto the market.

Alexander V. Lazarev, Ph.D., Chief Science Officer of PBI, said: "Our collaboration with RedShiftBio takes advantage of our ability to manipulate protein structure with high pressure and RedShiftBio's precise analytical platform that reports subtle changes in the three-dimensional structure of protein molecules that could lead to protein aggregation. Unfortunately, aggregated protein biologics could train a patient's immune system to recognize and eliminate the drug, so finding appropriate formulations to prevent aggregation is a major task in biopharmaceutical drug development. Moreover, MMS will help us to understand protein folding kinetics in our BaroFold platform, which uses high pressure to shape recombinant proteins into their active and stable conformations in biomanufacturing process development."

Julien Bradley, Chief Executive Officer of RedShiftBio, commented: "Accelerated stability studies are an important component of drug development and regulatory submissions. They are commonly performed today using methods that require elevated temperatures to exhibit their propensity to aggregate. However, temperature-sensitive formulations can't be subjected to high temperature-based accelerated stability studies, but must be tested in real time, which significantly prolongs the development process. Since PCT-enhanced MMS high pressure perturbation does not require the use of elevated temperature, accelerated stability testing in formulations development could potentially be reduced to weeks, if not days. Consequently, the PCT-enhanced MMS platform could potentially be used to achieve new drug approvals in significantly less time than required today."

Roxana McCloskey, PBI's Global Director of PCT/BaroFold Sales and Marketing, commented: "This new alliance is an excellent complement to our existing play with other protein analysis tools, such as NMR, EPR, optical spectroscopy, and mass spectrometry, as well as biomanufacturing process development and biopharmaceutical quality control. The PCT-enhanced MMS platform provides yet another powerful method for accelerating the development of protein therapeutics. It also enables PBI to further expand our reach into the large and rapidly growing protein therapeutics market. Together with our colleagues at RedShiftBio, we will be focusing a large amount of sales & marketing efforts in this area during the second half of 2020. We believe this focus will result in both increased sales and new customers for PBI."

The details of the PCT-enhanced MMS workflow are described in an online webinar <u>Click Here</u>) and in a publication in Genetic Engineering and Biotechnology News <u>Click Here</u>).

#### About RedShiftBio.

RedShiftBio® is a provider of innovative analytical instrumentation for the research, development and manufacture of protein therapeutic drugs. The company has developed a powerful new analytical technique, Microfluidic Modulation Spectroscopy (MMS) that enables direct probing of the biophysical structure of proteins. The patented MMS technology provides comprehensive secondary structure information across five key measurements, in a single automated analysis, replacing the requirement to run samples on multiple instruments. For further information, please visit <a href="https://www.redshiftbio.com/">www.redshiftbio.com/</a> or email

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### 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 and other industries. 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 biomolecular interactions (e.g., cell lysis, biomolecule extraction). Our primary focus is in the development of PCT-based products for biomarker and target discovery, drug design and development, biotherapeutics characterization and quality control, soil & plant biology, forensics, and counter-bioterror applications. Additionally, major new market opportunities have emerged in the use of our pressure-based technologies in the following areas: (1) the use of our recently acquired, patented technology from BaroFold, Inc. (the "BaroFold" technology) to allow entry into the bio-pharma contract 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, 2019, 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: <a href="http://www.pressurebiosciences.com">http://www.pressurebiosciences.com</a>

Please visit us on Facebook, LinkedIn, and Twitter.

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