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# Pressure BioSciences Ultra Shear Technology Nanoemulsions Platform Targets Revolution in Effectiveness of Therapeutics via Improved Drug Delivery and Dosing Safety

## PBI Announces Collaboration to Improve and Optimize SinuSys Corp's Lead Sinus Health Product Candidate for Commencement of Phase IIb Clinical Study

SOUTH EASTON, Mass., Jan. 20, 2021 /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 services to the worldwide biotechnology, biotherapeutics, and other industries, today announced a collaboration with SinuSys Corporation. The primary goal of the collaboration is to evaluate the feasibility of PBI's innovative Ultra Shear Technology™ ("UST™") platform to improve the effectiveness of SinuSys Corp's lead product candidate Restora. If successful, SinuSys intends to license PBI's UST platform for use in Restora on its continued path to FDA approval in a Phase IIb clinical study later in 2021.

SinuSys reports that chronic sinusitis affects more than 31 million people in the United States and that it is more prevalent than heart disease or asthma and has a greater impact on patients' quality of life than chronic back pain or congestive heart failure. The majority of patients with chronic sinusitis are treated with oral antibiotics and/or nasal steroids, which can increase the risk of antibiotic resistance and cause unwanted side effects such as nose bleeds, nasal ulcers, and nasal and oral infections. The most effective sinusitis treatment is Functional Endoscopic Sinus Surgery (FESS) with rapid balloon dilation at high pressures, which is known to cause significant patient discomfort and is conducted in a surgical suite under general anesthesia or IV sedation. Annually, it is estimated that [\\$11 billion](#) is spent in the U.S. alone on improving the health of patients with sinus conditions.

SinuSys Corporation, a medical device company focused on developing new therapies to improve the sinus health of patients, is led by co-founder and CEO Thomas A. Schreck. Prior to SinuSys, Mr. Schreck was the founding Chairman and CEO of AcelRx, as well as the founding CEO and President, CFO, and Director of DURECT Corporation. He has also held various investment banking positions in the San Francisco Bay area and London and has raised over \$300 million for medical device and biotechnology companies throughout his career.

Mr. Schreck explained: "In the post-FESS patient population, drug-eluting spacers or stents

are typically inserted into the surgically revised sinus opening to deliver steroids locally for reduction of inflammation, scarring and adhesions. Traditional spacers or stents are designed to slowly degrade and be bio-absorbed in place, but their polymer scaffolds can degrade unevenly, causing inflammation and requiring surgical removal of remnants and damaged tissue. Our lead product candidate Restora infuses the desired steroid via a bio-inert and non-inflammatory matrix material that is long-proven with exemplary safety profiles in humans, and that is simply and painlessly inserted and then fully removed by the physician after treatment."

Mr. Schreck continued: "We believe that PBI's patented UST platform for the preparation of nanoemulsions is a compelling transformational technology for therapeutics. Its use is expected to require loading less of the active steroid into the Restora device, while optimizing controlled dosing delivery with minimized risk of overdose exposure to the patient. We are excited to work with PBI's outstanding team of scientists and innovators on this opportunity to improve and optimize our lead compound with their next-generation, UST-based nanoemulsion technology, which we believe will enhance the probability for a successful Restora Phase IIb trial later this year."

Dr. Alexander V. Lazarev, PBI's Chief Science Officer, commented: "Our patented UST platform is a unique breakthrough for nanoemulsification processing designed to resolve multiple substantive problems facing manufacturers of therapeutic drugs, nutraceuticals, and other products containing hydrophobic (water repelling) active ingredients that are at best poorly soluble in water. Poor water solubility results in lower absorption rates and requires much higher loading of the active compounds into products to achieve targeted dosing and bioavailability of active ingredients for the patient. Unfortunately, poor water solubility also carries overdosing risks in conventional emulsions due to oil and water phases further separating and leading to non-uniform drug distribution. Scientific publications have demonstrated that hydrophobic active ingredients manufactured into high quality nanoemulsions with droplet sizes of less than 100 nanometers can facilitate increased absorption and bioavailability while lowering doses and improving controlled release. This should result in better quality products and treatment experiences for the patient, with overall reduction in product costs."

In the post-surgical nasal drug delivery markets, two companies that stand out at present are [Intersect ENT](#) and [Lyra Therapeutics](#). Intersect is a medical technology company with existing products on the market, including mini drug-releasing implants for patients undergoing sinus surgery to treat chronic sinusitis. Lyra is a clinical-stage company developing drugs and new treatment options targeting ears, nose, and throat ("ENT") conditions.

Mr. Richard T. Schumacher, President & CEO of PBI, provided context on these opportunities: "We believe the therapeutics applications for our uniquely enabling UST nanoemulsions technology platform will be transformational across a wide swath of pharmaceutical, biopharmaceutical, nutraceutical, cosmeceutical, dermatological, medical device, and many other applications and markets. We are at an exciting moment in PBI's development when our new, proprietary UST technology platform is soon to be commercially released (mid to late 2021) and initial collaborations are being both announced and commenced. We have recently been approached by several other companies with therapeutics applications. We anticipate multiple additional collaboration and licensing

announcements soon, all of which we believe could add significantly to our revenue in 2021, and beyond."

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

Pressure BioSciences, Inc. (OTCQB: P BIO) 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 control bio-molecular interactions safely and reproducibly (e.g., cell lysis, biomolecule extraction). Our primary focus is 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 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 any forward-looking 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:

<http://www.pressurebiosciences.com>

Please visit us on Facebook, LinkedIn, and Twitter.

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