

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

[X] Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2020 or

[] Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from to

Commission file number 001-38185

PRESSURE BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in its Charter)

Massachusetts	04-2652826
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
14 Norfolk Avenue South Easton, Massachusetts	02375
(Address of Principal Executive Offices)	(Zip Code)

(508) 230-1828
(Registrant’s Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
None	None

Securities registered pursuant to Section 12(g) of the Act:

(Title of Class)
Common Stock, par value \$.01 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes [] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.
Yes [] No [X]

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes [X] No []

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that registrant was required to submit and post such files).
Yes [X] No []

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company or an “emerging growth company”. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer []
Non-accelerated filer [X]

Accelerated filer []
Smaller reporting company [X]
Emerging growth company []

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. []

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. []

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [] No [X].

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2020 was \$7,127,474 based on the closing price of \$2.30 per share of Pressure BioSciences, Inc. common stock as quoted on the OTCQB Marketplace on that date.

As of April 8, 2021, there were 4,321,973 shares of the registrant’s common stock outstanding.

Documents Incorporated by Reference

N/A.

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Introductory Comments

Throughout this Annual Report on Form 10-K, the terms “we,” “us,” “our,” “the Company,” “our Company,” and “PBI,” refer to Pressure BioSciences, Inc., a Massachusetts corporation, and unless the context indicates otherwise, also includes our wholly-owned subsidiary.

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In some cases, forward-looking statements are identified by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements. Such statements include, without limitation, statements regarding:

- our need for, and our ability to raise, additional equity or debt financing on acceptable terms, if at all;
- our need to take additional cost reduction measures, cease operations or sell our operating assets, if we are unable to obtain sufficient additional financing;
- our belief that we will have sufficient liquidity to finance normal operations for the foreseeable future;
- the options we may pursue in light of our financial condition;
- the potential applications for Ultra Shear Technology (*UST*);
- the potential applications of the BaroFold high-pressure protein refolding and disaggregation technology
- the amount of cash necessary to operate our business;
- the anticipated uses of grant revenue and the potential for increased grant revenue in future periods;
- our plans and expectations with respect to our continued operations;
- the expected increase in the number of pressure cycling technology (“*PCT*”) and constant pressure (“*CP*”) based units that we believe will be installed and the expected increase in revenues from the sale of consumable products, extended service contracts, and biopharma contract services;
- our belief that PCT has achieved initial market acceptance in the mass spectrometry and other markets;
- the expected development and success of new instrument and consumables product offerings;
- the potential applications for our instrument and consumables product offerings;
- the expected expenses of, and benefits and results from, our research and development efforts;
- the expected benefits and results from our collaboration programs, strategic alliances and joint ventures;
- our expectation of obtaining additional research grants from the government in the future;
- our expectations of the results of our development activities funded by government research grants;
- the potential size of the market for biological sample preparation, biopharma contract services and Ultra Shear Technology;
- general economic conditions;
- the anticipated future financial performance and business operations of our company;
- our reasons for focusing our resources in the market for genomic, proteomic, lipidomic and small molecule sample preparation;
- the importance of mass spectrometry as a laboratory tool;
- the advantages of PCT over other current technologies as a method of biological sample preparation and protein characterization in biomarker discovery, forensics, and histology, as well as for other applications;
- the capabilities and benefits of our PCT Sample Preparation System, consumables and other products;
- our belief that laboratory scientists will achieve results comparable with those reported to date by certain research scientists who have published or presented publicly on PCT and our other products and services;
- our ability to retain our core group of scientific, administrative and sales personnel; and
- our ability to expand our customer base in sample preparation and for other applications of PCT and our other products and services.

These forward-looking statements are only predictions and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements, expressed or implied, by such forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. Except as otherwise required by law, we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement contained in this Annual Report on Form 10-K to reflect any change in our expectations or any change in events, conditions or circumstances on which any of our forward-looking statements are based. Factors that could cause or contribute to differences in our future financial and other results include those discussed in the risk factors set forth in Part I, Item 1A of this Annual Report on Form 10-K as well as those discussed elsewhere in this Annual Report on Form 10-K. We qualify all of our forward-looking statements by these cautionary statements.

ITEM 1. BUSINESS.

Throughout this document we use the following terms: Barocycler®, and PULSE®, which are registered trademarks of the Company. We also use the terms ProteoSolve™, ProteoSolveLRS™, the Power of PCT™, the PCT Shredder™, HUB440™, HUB880™, micro-Pestle™, PCT-HD™, BaroFold™, Ultra Shear Technology™, and UST™ all of which are unregistered trademarks of the Company.

Overview

We are a leader in the development and sale of innovative, broadly enabling, pressure-based platform solutions for the worldwide life sciences industry. Our solutions 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 has been 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 platform) 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 acceptably preserved using existing non-thermal technologies.

On April 29, 2020, we entered into a binding letter of intent to merge with Cannaworx Holdings, Inc. (Cannaworx), and their portfolio of products and intellectual property (the “Cannaworx LOI” and “Cannaworx merger”). Post-merger, certain Cannaworx products were expected to utilize our proprietary UST platform. Throughout the course of 2020, we entered into four amendments to the Cannaworx LOI, with the last amendment making the LOI mutually non-exclusive and extending the deadline to January 30, 2021 after which it expired. On June 12, 2020, we entered into a one-year Collaboration Agreement with Cannaworx and its parent company, Availa Bio, Inc. on developing UST applications for prospective use in Cannaworx’s products. All parties remain actively engaged in this collaborative effort.

The PCT Platform

a. Description

The instruments, consumables and software used to perform PCT (the “PCT Platform”) use alternating cycles of hydrostatic pressure between ambient and ultra-high levels to safely and reproducibly control bio-molecular interactions (e.g., critical steps performed by hundreds of thousands of scientists worldwide, such as cell lysis and biomolecule extraction). Our primary focus is in making our recently released, GMP-compliant, next generation PCT-based Barocycler 2320 EXT instrument available globally to biopharmaceutical drug manufacturers to accelerate biologics development by streamlining workflows for the design, development, characterization and quality control of biotherapeutic drugs. The PCT Platform is also used in such areas as biomarker and target discovery, soil & plant biology, anti-bioterror, and forensics. We currently have hundreds of PCT instrument systems placed in approximately 200 academic, government, pharmaceutical, and biotech research laboratories worldwide. There are over 120 independent publications highlighting the advantages of using the PCT Platform in scientific research studies, many from key opinion leaders worldwide. The PCT Platform is offered through the Company’s Research Products & Services Group.

We are focused on solving the challenging problems inherent in biological sample preparation, a crucial laboratory step performed by scientists worldwide working in biological life sciences research. Sample preparation is a term that refers to a wide range of activities that precede most forms of scientific analysis. Sample preparation is often complex, time-consuming and, in our belief, one of the most error-prone steps of scientific research. It is a widely-used laboratory undertaking – the requirements of which drive what we believe is a large and growing worldwide market. We have developed and patented a novel, enabling technology platform that can control the sample preparation process. It is based on harnessing the unique properties of high hydrostatic pressure. This process, which we refer to as Pressure Cycling Technology, or PCT, uses alternating cycles of hydrostatic pressure between ambient and ultra-high levels i.e., 20,000 psi or greater to safely, conveniently and reproducibly control the actions of molecules in biological samples, such as cells and tissues from human, animal, plant and microbial sources.

PCT is an enabling platform technology based on a physical process that had not previously been used to control bio-molecular interactions. PCT uses unique instrumentation that is capable of cycling pressure between ambient and ultra-high levels at controlled temperatures and specific time intervals, to rapidly and repeatedly control the interactions of bio-molecules, such as proteins, DNA, RNA, lipids and small molecules. Our laboratory instrument family, the Barocycler®, and our proprietary consumables product line, which include our unique MicroTubes, MicroCaps, MicroPestles, and PULSE® (Pressure Used to Lyse Samples for Extraction) Tubes, and application specific kits (containing consumable products and reagents), together make up our PCT Sample Preparation System (the “PCT SPS”).

In 2015, together with an investment bank, we formed a subsidiary called Pressure BioSciences Europe (“PBI Europe”) in Poland. We have 49% non-controlling ownership interest with the investment bank retaining 51%. Throughout 2020, PBI Europe did not have any operating activities and we cannot reasonably predict when operations will commence.

Sample preparation is widely regarded as a significant impediment to research and discovery and sample extraction is generally regarded as one of the key parts of sample preparation. The process of preparing samples for genomic, proteomic, lipidomic, and small molecule studies includes a crucial step called sample extraction or sample disruption. This is the process of extracting biomolecules such as nucleic acid i.e., DNA and/or RNA, as well as proteins, lipids, or small molecules from the plant or animal cells and tissues that are being studied. The majority of our current sales and marketing efforts are based upon our belief that pressure cycling technology provides a superior solution for sample extraction when compared to other available technologies or procedures, and thus might significantly improve the quality of sample preparation, and thus the quality of the test result.

Within the broad field of biological sample preparation, we focus the majority of our PCT and constant pressure (“CP”) product development efforts in three specific areas: biomarker discovery, precision medicine and forensics. We believe that our existing PCT and CP-based instrumentation and related consumable products fill an important and growing need in the sample preparation market for the safe, rapid, versatile, reproducible and quality extraction of nucleic acids, proteins, lipids, and small molecules from a wide variety of plant, animal, and microbiological cells and tissues.

Biomarker Discovery and Precision Medicine

The most commonly used technique worldwide for the preservation of cancer and other tissues for long-term storage and subsequent pathology evaluation is to process them into formalin-fixed, paraffin-embedded (“FFPE”) samples. We believe that the quality and analysis of FFPE tissues is highly problematic, and that PCT offers significant advantages over current processing methods, including standardization, speed, biomolecule recovery, and safety.

Our customers include researchers at academic laboratories, government agencies, biotechnology companies, pharmaceutical companies and other life science institutions in the United States, Europe, and Asia. Our goal is to continue aggressive market penetration in these target areas. We also believe that there is a significant opportunity to sell and/or lease additional Barocycler® instrumentation to additional laboratories at current customer institutions.

If we are successful in commercializing PCT in applications beyond our current focus area of genomic, proteomic, lipidomic, and small molecule sample preparation, and if we are successful in our attempts to attract additional capital, our potential customer base could expand to include hospitals, reference laboratories, pharmaceutical manufacturing plants and other sites involved in each specific application. If we are successful in forensics, our potential customers could be forensic laboratories, military and other government agencies. If we are successful in biomarker discovery and precision medicine - specifically the extraction of biomolecules from FFPE tissues, our potential customers could be pharmaceutical companies, hospitals, and laboratories focused on drug discovery or differentiation of disease states, subtypes and susceptibility to alternative treatments.

Forensics

The detection of DNA has become a part of the analysis of forensic samples by laboratories and criminal justice agencies worldwide in their efforts to identify the perpetrators of violent crimes and missing persons. Scientists from the University of North Texas and Florida International University have reported improvements in DNA yield from forensic samples (e.g., bone and hair) when using the PCT platform in the sample preparation process. We believe that PCT may be capable of differentially extracting DNA from sperm cells and female epithelial cells captured in swabs collected from rape victims and subsequently stored in rape kits. We also believe that there are many completed rape kits that remain untested for reasons such as cost, time and quality of results. We further believe that the ability to differentially extract DNA from sperm and not epithelial cells could reduce the cost of such testing, while increasing the quality, safety and speed of the testing process.

b. Market

We focus most of our research and development and commercialization efforts on sample preparation and quality control analysis for genomic, proteomic, lipidomic, and small molecule studies. This market is comprised of academic and government research institutions, biotechnology and pharmaceutical companies, and other public and private laboratories that are engaged in studying genomic, proteomic and small molecule material within plant and animal cells and tissues. We elected to initially focus our resources in the market of genomic, proteomic and small molecule sample preparation because we believe it is an area that:

- is a rapidly growing market;
- has a large and immediate need for better technology;
- is comprised mostly of research laboratories, which are subject to minimal governmental regulation;
- is the least technically challenging application for the development of our products;
- is compatible with our technical core competency; and
- we currently have strong patent protection.

We believe that our existing PCT and CP-based instrumentation and related consumable products fill an important and growing need in the sample preparation market for the safe, rapid, versatile, reproducible and quality extraction of nucleic acids, proteins and small molecules from a wide variety of plant and animal cells and tissues.

Biomarker Discovery - Mass Spectrometry

A biomarker is any substance (e.g., protein, DNA) that can be used as an indicator of the presence or absence of a particular disease-state or condition, and/or to predict or measure the progression and effects of therapy. Biomarkers can help in the diagnosis, prognosis, therapy selection and monitoring, prevention, surveillance, control, and cure of diseases and medical conditions.

A mass spectrometer is a laboratory instrument used in the analysis of biological samples, often focused on proteins, in life sciences research. It is frequently used to help discover biomarkers. According to the November 2017 published market report by Markets and Markets “Mass Spectrometry Market by Application (Pharmaceuticals, Biotechnology, Environmental testing), Platform (Single mass spectrometry (Quadrupole, TOF & Ion Trap), Hybrid mass spectrometry (Triple Quadrupole, QTOF & FTMS)) – Global Forecast to 2022, the global mass spectrometry market is expected to grow from USD 3.44 billion in 2016 to USD 5.27 billion by 2022, at a CAGR of 7.4% from 2015 to 2020. We believe PCT and CP-based products offer significant advantages in speed and quality compared with current techniques used in the preparation of samples for mass spectrometry analysis.

Biomarker Discovery – Precision Medicine

Precision medicine is an approach to patient care that allows doctors to select treatments that are most likely to help patients based on a specific biomolecular understanding of their disease. The hope of precision medicine is that treatments will one day be tailored to the unique biomolecular variations specific to each person’s disease.

A significant roadblock in obtaining necessary information to advance precision medicine – specifically in proteogenomics, is sample preparation and the time required using conventional methods. We believe our PCT workflows address this roadblock by providing a rapid, reproducible means of extracting biomarkers from patient samples in a clinically relevant timeframe of 2 hours.

Biomarker Discovery – Cancer and Tumor Microenvironment

The most commonly used technique worldwide for the preservation of cancer and other tissues for subsequent pathology evaluation is formalin-fixation followed by paraffin-embedding, or FFPE. We believe that the quality and analysis of FFPE tissues is highly problematic, and that PCT offers significant advantages over current processing methods, including standardization, speed, biomolecule recovery, and safety.

Biopharmaceutical Quality Control

A critical step in biopharmaceutical manufacturing processes is quality control, involving characterization of the resulting biotherapeutics via peptide mapping and analysis of post-translational modifications. Peptide mapping can be used in drug discovery and throughout the manufacturing process for quality control between batches to produce a unique ‘fingerprint’ of an individual protein and to compare this with the theoretical gene-derived amino acid sequence. Using conventional methods this process can take overnight or more. We believe our PCT workflows offer a significant advantage to this process by offering a significant reduction in time and improvement in reproducibility with a GMP compliant platform. Many protein-based pharmaceuticals undergo specific enzymatic and chemical modifications (such as glycosylation, when specific carbohydrate moieties, glycans, are attached to the protein core, thus helping them remain active longer in the patient’s bloodstream). Similar to peptide mapping, analysis of glycans, also critical quality attributes of biologic drugs, requires tedious sample preparation steps that can be significantly accelerated and rendered more reproducible by PCT workflows.

Our customers include researchers at academic laboratories, government agencies, biotechnology companies, pharmaceutical companies and other life science institutions in the Americas, Europe, Asia, Africa and Australia. Our goal is to continue aggressive market penetration in these target areas. We also believe that there is a significant opportunity to sell and/or lease additional Barocycler® instrumentation to additional laboratories within current customer organizations.

If we are successful in commercializing PCT in applications beyond our current focus area of genomic, proteomic, lipidomic sample preparation, and if we are successful in our attempts to attract additional capital, our potential customer base could expand to include hospitals, reference laboratories, pharmaceutical manufacturing plants and other sites involved in each specific application.

If we are successful in forensics, our potential customers could be forensic laboratories, military and other government agencies.

If we are successful in precision medicine applications supporting diagnostic and prognostic decisions, including the extraction of biomolecules from FFPE tissues, our potential customers could be clinical laboratories, pharmaceutical and biopharmaceutical companies, and laboratories focused on drug discovery or prediction of disease treatment outcomes.

Sample Extraction Process

The process of preparing samples for genomic, proteomic and small molecule studies includes a crucial step called sample extraction or sample disruption. This is the process of extracting nucleic acid i.e., DNA and/or RNA, proteins or small molecules from the plant or animal cells and tissues that are being studied. Sample preparation is widely regarded as a significant impediment to research and discovery and sample extraction is generally regarded as one of the key parts of sample preparation. Our current commercialization efforts are based upon our belief that pressure cycling technology provides a superior solution to sample extraction compared with other available technologies or procedures and can thus significantly improve the quality of sample preparation, and thus the quality of the test result.

c. Products

We believe our PCT and CP products allow researchers to improve scientific research studies in the life sciences field. Our products are developed with the expectation of meeting or exceeding the needs of research scientists while enhancing the safety, speed and quality that is available to them with existing sample preparation methods.

Barocycler® Instrumentation

Our Barocycler® product line consists of laboratory instrumentation that subjects a sample to cycles of pressure from ambient (approximately 14.5 psi) to ultra-high levels (20,000 psi or greater) and then back to ambient, in a precisely controlled manner.

Our instruments (the Barocycler 2320EXT, the HUB440 and the HUB880) use cycles of high, hydrostatic pressure to quickly and efficiently break up the cellular structures of a specimen to release proteins, nucleic acids, lipids and small molecules from the specimen into our consumable processing tubes, referred to as our PULSE® Tubes and MicroTubes. Our instruments have temperature control options (on-board heating via internal heating jacket or heating and chilling via an external circulating water-bath), automatic fill and dispensing valves, and an integrated touchscreen for interfacing with an onboard micro-processor or computer. The microprocessor, computer or laptop computer are capable of saving specific PCT protocols, so the researcher can achieve maximum reproducibility for the preparation of nucleic acids, proteins, lipids, or small molecules from various biological samples. Our Barocycler® instruments, consumable products and application specific kits make up our PCT Sample Preparation System.

Barocycler® 2320EXTREME - The Barocycler® 2320EXT is the flagship of the Company's Barocycler line of PCT-based instruments. It weighs approximately 80lbs, delivers a maximum pressure of 45,000 psi, and can process either up to 16 MicroTubes simultaneously or one PULSE® Tube. The working temperature range is 4 – 95°C and is controlled via an on-board electric heating jacket or external circulating water bath. All tests are entered and recorded on a touch screen interface. Information from each test run (pressure profile, cycle number, and temperature) is recorded and can be stored on the instrument, on a USB drive, or networked into the user's lab computer system. Pressure profiles can be manipulated in a number of ways, including static high pressure holds and pressure ramp programs. The Barocycler® 2320EXT is pneumatic and requires an input air source of only 100psi to achieve and cycle at high pressure.

The Barocycler® 2320EXT was developed to support the PCT-HD/PCT-SWATH application. PCT-HD enables faster, less cumbersome and higher quality processing of biopsy tissues. With homogenization, extraction, and digestion of proteins occurring in a single PCT MicroTube under high pressure, this protocol can yield analytical results in under four hours from the start of tissue processing. PCT-HD was developed by our scientists and engineers in collaboration with Professor Ruedi Aebersold and Dr. Tiannan Guo of the Institute of Molecular Systems Biology, ETH Zurich, and the University of Zurich, both in Zurich, Switzerland. Drs. Aebersold and Guo combined PCT-HD with SCIEX's SWATH-Mass Spectrometry – calling the resulting method "PCT-SWATH".

Barocyler® HUB440 –We believe the Barocyler® HUB440 is the first portable, ready to use, “plug-and-play” high pressure generator for the laboratory bench. The Barocyler® HUB440 is capable of creating and controlling hydrostatic pressure from 500 psi to 58,000 psi and is designed for easy and flexible interfacing with a wide variety of user-specified pressure vessels. It is computer controlled and runs on software that was developed by us to allow data logging and sophisticated algorithms for controlling pressure and temperature. We own the rights and have a license to use the specialty LabVIEW software. We believe that over the coming years, the Barocyler® HUB440 may become one of the main products in our pressure-based instrument line.

Barocyler® HUB880 - The Barocyler® HUB880 is a compact, portable, bench-top, ultra-high pressure generator with vessel interface flexibility similar to the HUB440, that uses an air pressure-to-liquid pressure intensifier allowing the user to generate fluid pressure as high as 90,000 psi with input air pressure of just 126 psi. The HUB880 can be operated through a simple front panel or controlled using an optional external Data Acquisition and Control Module for dynamic pressure control. We believe that the HUB880 will be well accepted by scientists that need to achieve super high pressure, such as those working in the life science research, food safety and vaccine industries.

The Shredder SG3 –The Shredder SG3 is a low shear mechanical homogenization system for use with tough, fibrous and other difficult-to-disrupt tissues and organisms. The Shredder SG3 System uses a variety of Shredder PULSE® Tubes to directly and rapidly grind a biological sample which, when combined with selected buffers, can provide effective extraction of proteins, DNA, RNA, lipids and small molecules from tissues and organisms. The Shredder SG3 is also used to isolate intact and functional mitochondria from tissues. The Shredder SG3 features a three-position force setting lever, which enables the operator to select and apply reproducible force to the sample during the shredding process and eliminates the need for the operator to exert force for long periods when processing one or more samples.

Barocycler® Consumable Products

PCT MicroTubes – PCT MicroTubes are made from a unique fluoropolymer, fluorinated ethylene propylene (FEP). FEP is highly inert and retains its integrity within an extremely wide temperature range (-200°C to 100°C), while providing important limited flexibility behavior for PCT applications. MicroTubes hold a maximum total volume of 150 microliters. PCT MicroTubes must be used with either PCT-MicroCaps or PCT-MicroPestles.

PCT-MicroCaps – PCT MicroCaps are made from polytetrafluoroethylene (PTFE). The PCT MicroCaps are available in three sizes to accommodate total sample volume: 50, 100 and 150uL. 50uL MicroCaps are used with samples ≤50uL, 100uL MicroCaps are used with samples between 50-100uL, and 150uL MicroCaps are used with samples between 100-150uL.

PCT-Micro Pestle - PCT μPestles are made from polytetrafluoroethylene (PTFE), a synthetic fluoropolymer of tetrafluoroethylene, also known as Teflon (by DuPont Co). PTFE is practically inert; the only chemicals known to affect it are certain alkali metals and most highly reactive fluorinating agents. PCT μPestles, in conjunction with PCT MicroTubes, are designed to enhance the extraction of proteins, lipids, DNA, RNA and small molecules from minute amounts (0.5 – 3.0 mg) of solid tissue in extraction reagent volumes as low as 20-30 μL. PCT MicroTubes and PCT μPestles use PCT to effectively disrupt soft tissues and lyse their cells. As a result, the tissue sample trapped between the MicroTube walls and the μPestles shaft is crushed on every pressure cycle. This mechanical action, combined with the extraction ability of the buffer under high pressure, results in highly effective tissue homogenization and extraction.

PCT μPestles and PCT MicroTubes, together with a PBI Barocycler®, comprise the PCT Micro-Pestle System, which provides a fast, safe, and efficient means of extraction from extremely small amounts of solid samples such as soft tissue biopsies. The PCT μPestle System can be used in any PBI Barocycler®.

We believe our development of these various consumable products has helped, and will continue to help, drive the adoption of PCT within the life sciences market.

d. Customers

Our customers include researchers at academic laboratories, government agencies, biotechnology companies, pharmaceutical firms, and other life science institutions throughout the Americas, Europe, Asia, Africa and Australia. Our goal is to continue aggressive market penetration to target groups in these geographical areas. We also believe that there is a significant opportunity to sell and/or lease additional Barocycler® instrumentation to additional laboratories within current customer organizations.

If we are successful in commercializing PCT in applications beyond our current focus area of genomic, proteomic, lipidomic, and small molecule sample preparation, and if we are successful in our attempts to attract additional capital, our potential customer base could expand to include:

- Hospitals
- Reference laboratories
- Government laboratories (e.g., FDA, USDA, NIH, FBI, and police)
- Pharmaceutical/biotech/diagnostic companies
- Laboratories focused on drug discovery, cancer research, and precision medicine

e. Competition

We compete with companies that have existing technologies for the extraction of nucleic acids, proteins, lipids, and small molecules from cells and tissues, including methods such as mortar and pestle grinding, sonication, rotor-stator homogenization, French Press, bead beating, freezer milling, enzymatic digestion, and chemical dissolution. We believe that there are a number of significant issues related to the use of these methods, including: complexity, sample containment, cross-contamination, shearing of biomolecules of interest, limited applicability to different sample types, ease-of-use, reproducibility, and cost. We believe that our PCT Sample Preparation System offers a number of significant advantages over these methods, including:

- | | |
|-----------------------|---------------|
| ● labor reduction | ● versatility |
| ● temperature control | ● efficiency |
| ● precision | ● simplicity |
| ● reproducibility | ● safety |

To be competitive in the industry, we believe we must be able to clearly and conclusively demonstrate to potential customers that our products provide these improved performance capabilities. We strongly believe that our PCT Sample Preparation System is a novel and enabling system for genomic, proteomic, and small molecule sample preparation. As such, many users of current manual techniques will need to be willing to challenge their existing methods of sample preparation and invest time to evaluate a method that could change their overall workflow in the sample preparation process, prior to adopting our technology.

Further, we are aware that the cost of the PCT Sample Preparation System may be greater than the cost of many of the other methods currently employed. Consequently, we are focusing our sales efforts on those product attributes that we believe will be most important and appealing to potential customers; namely versatility, reproducibility, quality, and safety.

f. Manufacturing and Supply

We utilize a contract assembler for our Barocycler® 2320EXT. They provide us with precision manufacturing services that include management support services to meet our specific application and operational requirements. Among the services provided to us are:

- CNC Machining
- Contract Assembly & Kitting
- Component and Subassembly Design
- Inventory Management
- ISO certification

At this time, we believe that outsourcing contract assembly of our Barocycler® 2320EXT is the most cost-effective method for us to obtain ISO Certified, CE and CSA Marked instruments.

We currently manufacture and assemble the Barocycler® HUB440, HUB880, the SHREDDER SG3, and most of our consumables at our South Easton, MA facility. We will regularly reassess the tradeoffs between in-house assembly versus the benefits of outsourced relationships for of the entire Barocycler® product line, and future instruments.

g. Research and Development

Our research and development activities are split into two functional areas: Applications Development and Engineering.

1. *Applications Development R&D*: Our highly educated and trained staff has years of experience in molecular and cellular biology, virology, and proteomics. Our team of scientists focuses on the development and continued improvement of the PCT Sample Preparation System and on PCT-dependent genomic, proteomic, lipidomic, and small molecule sample preparation applications. Dr. Alexander Lazarev, our Chief Science Officer, meets regularly with our sales, marketing, and engineering staff to discuss market needs and trends. Our applications research and development team is responsible for the technical review of all scientific collaborations, for the support of our marketing and sales departments through the generation of internal data in a number of areas of market interest, and in the development of commercially-viable PCT-dependent products.
2. *Engineering R&D*: Our engineering research and development team is focused on the design and development of new and improved instrumentation and consumable products to support the commercialization of PCT. Our engineering department is led by Dr. Edmund Ting, our Senior Vice President of Engineering. The primary focus of our engineering group is to develop and continually improve our line of PCT-based instruments and consumables, ensure seamless production processes, help perform installations and field service, and work with our application scientists to enhance our PCT-based systems for the mass spectrometry and other markets.

Collaboration Program

Our Collaboration Program is an important element of our business strategy. Initiating a collaboration with a researcher involves the installation of a Barocycler® instrument for an agreed upon period of time of approximately three to twelve months, a financial commitment that is beneficial to both the collaborator and PBI, and the execution of an agreed upon work plan. Our primary objectives for entering into a collaboration agreement include:

- the development of a new application for PCT and CP in sample preparation;
- the advancement and validation of our understanding of PCT and CP within an area of life sciences in which we already offer products;
- the demonstration of the effectiveness of PCT and CP by specific research scientists, particularly Key Opinion Leaders (“KOLs”), who we believe can have a positive impact on market acceptance of PCT; and
- the expectation of peer-reviewed publications and/or presentations at scientific meetings by a third party, especially a KOL, on the merits of PCT and CP.

Since we initiated our collaboration program, third party researchers have cited the use of our PCT platform in multiple publications and presentations. We believe that this program has provided and continues to provide us with independent and objective data about PCT from well-respected laboratories in the United States and throughout the rest of the world. We believe this program has been responsible for the sale of multiple Barocycler instruments over the past few years and will continue to help to increase the sales of instrument systems in the future.

Active Collaborations:

- a. RedShiftBio Inc.
- b. Thomas Conrads, Inova Schar Cancer Center
- c. Christine Vogel, NYU
- d. Leica Microsystems, GmbH
- e. Dr. Michael Przybylski, Steinbeis Centre for Biopolymer Analysis and Biological Mass Spectrometry
- f. Dr. V.M. Balasubramaniam, The Ohio State University
- g. University of Delaware
- h. Dr. Jennifer Van Eyk, Cedars Sinai Medical Center

Other Fields of Use and Applications for PCT

Our research and development efforts have shown that, in addition to genomic, proteomic, lipidomic, and small molecule sample preparation, PCT is potentially beneficial in a number of other areas of the life sciences, including pathogen inactivation, protein purification, control of chemical (particularly enzymatic) reactions, and immunodiagnostics. Other applications in the sample preparation market include forensics and histology, as discussed above. Our pursuit of these markets, however, depends on a number of factors, including our success in commercializing PCT in the area of sample preparation, our judgment regarding the investment required to be successful in these areas, the value of these markets to PBI, and the availability of sufficient financial resources. Below is a brief explanation of each of these additional potential applications and a short description of why we believe PCT can be used to improve scientific studies in these areas.

Protein Purification

Many vaccines and drugs are comprised of proteins. These proteins need to be purified from complex mixtures as part of the manufacturing process. Current purification techniques often result in the loss of a significant amount of the protein. Therefore, any method that could increase the amount of protein being recovered in the purification step, could subsequently lead to a reduction in cost to the manufacturer. We believe we have successfully generated proof-of-concept that PCT can satisfy this need. We believe that compared with current purification procedures, a process that uses PCT has the potential to increase protein recovery, increase the quality of the product, and lower production costs. We have been issued U.S. patents in this area.

Pathogen Inactivation

Biological products intended for human use, such as blood, vaccines and drugs, are put through rigorous processing protocols in an effort to minimize the potential of that product to transmit disease. These protocols may include methods to remove infectious materials such as pre-processing testing, filtration or chromatography, or methods to inactivate infectious agents that are not captured in the removal steps such as pasteurization, irradiation and solvent detergent inactivation. Notwithstanding current diligence in both the removal and inactivation steps, significant concern remains that some pathogens (e.g., bacteria, viruses, spores) capable of transmitting infection to recipients may not be removed or inactivated with current procedures. In addition, some removal and inactivation methods may not be useful because of cost, safety, ease-of-use or other practical concerns. To that end, we believe that a superior inactivation method is needed that can safely, rapidly and inexpensively inactivate pathogens in blood, vaccines and drugs without the need for chemical or other potentially toxic additives. We have successfully generated proof-of-concept that PCT can satisfy this need. We believe that compared with current procedures, a process that uses PCT has the potential to increase safety and yield, lower cost and decrease the potential side effects of current methods. We have been issued U.S. patents for this PCT-dependent inactivation technology.

Control of Chemical (Particularly Enzymatic) Reactions

Chemical reactions encompass many important interactions in nature. Methods used to control chemical reactions could have a positive effect on the quality, speed, and overall result of the reaction. The control and detection of chemical reactions is particularly useful in the biotechnology field for synthesizing and characterizing such molecules as nucleic acids and polypeptides. We believe that PCT offers distinct advantages in controlling chemical reactions over current methods, since PCT can provide precise, automated control over the timing and synchronization of chemical reactions, particularly enzymatic reactions. We have been issued U.S. patents in this area.

Immunodiagnosics

Many tests used in the clinical laboratory today are based on the formation of a complex between two proteins, such as an antigen and an antibody. Such “immunodiagnostic” methods are used for the detection of infectious agents such as the human immunodeficiency virus (“HIV”), hepatitis viruses, West Nile virus, and others, as well as for endocrine, drug testing and cancer diagnostics. We have generated proof-of-concept that PCT may be used to control biomolecular interactions between proteins, such as antigens and antibodies. We believe this capability may provide a greater degree of sensitivity and quantitative accuracy in immunodiagnostic testing than that offered by methods that are available today. We have been issued U.S. patents in this area.

Extended Service Contracts

We offer extended service contracts on our laboratory instrumentation to all of our customers. These service contracts allow a customer who purchases a Barocycler® instrument to receive on-site scheduled preventative maintenance, on-site repair and replacement of all worn or defective component parts, and telephone support, all at no incremental cost for the life of the service contract. We offer one-year and four-year extended service contracts to customers who purchase Barocycler® instruments.

The BaroFold Platform

a. Description

The need for the efficient production of recombinant protein biopharmaceuticals has grown rapidly and demand for them will continue to grow as a result of their high specificity and efficacy. Protein drugs are being manufactured in a variety of host organisms. With the rapid growth in biosimilars (less expensive versions of popular biopharmaceuticals that are manufactured and marketed after the expiration of the original patents), expression in bacteria is beginning to play a major role in this industry, particularly when the biological activity of the protein product is not dependent on post-translational modifications. Overexpression of proteins in bacteria often results in the accumulation of the protein product in inactive insoluble deposits inside the cells, called inclusion bodies. Inclusion bodies protect the protein of interest from degradation and present a simple and convenient ways to extract and purify it. Moreover, if the protein of interest is toxic or lethal to the host cell, then inclusion body expression may be the only available production method. However, the challenge of protein production in bacterial systems most often lies in conversion of inactive and misfolded proteins in the inclusion bodies into soluble, properly folded bioactive products. This conversion process is called protein refolding. Traditional methods of protein refolding rely on using high concentrations of chemical denaturants and detergents to unfold misshapen proteins, disentangle inactive aggregated proteins and to dissolve them, followed by up to 100-fold dilution or dialysis to remove interfering chemicals and then letting the proteins refold into their desired active forms. Since chemically-driven unfolding is harsh, it tends to destroy most protein structure, some of which could be beneficial for subsequent refolding. Moreover, dilution- or dialysis-based methods take a long time and produce very low yields of refolded protein, while most of the unfolded protein material tends to get lost into irreversible aggregation. Overall, traditional refolding methods are usually inefficient, include multiple costly steps and have very low recovery yields. Pressure-mediated disaggregation and unfolding and refolding of proteins offers an attractive pathway for achieving much higher yields of correctly folded proteins with desired efficaciousness, produced at much lower cost, versus traditional chemically driven methodologies.

Acquisition of BaroFold’s PreEMT™ high-pressure protein refolding technology in December 2017

Our acquisition of the assets of BaroFold, Inc. have significantly increased PBI’s intellectual property portfolio in high-pressure technologies with the addition of eight issued and several pending patents. These patents give PBI the ability to operate in several important areas for biologics research and manufacturing: protein folding, re-folding and disaggregation. The patents also provide PBI the right to grant licenses to third parties to practice the BaroFold technology in both research laboratories and in biopharmaceutical manufacturing.

Biopharmaceutical products are typically large-molecule protein therapeutics produced via complex biological manufacturing processes that can result in undesirable protein misfolding and aggregation outcomes. Misfolded or aggregated proteins typically lack therapeutic activity and can present health risks to patients, requiring robust remediation within pharmaceutical manufacturing processes. The Barofold technology improves the quality of manufacturing, decreases manufacturing costs (as much as \$2-10M/year per commercial biologic drug), and facilitates achievement of proper activity from difficult-to-manufacture proteins.

Barofold technology utilizes high pressure instead of, or in synergy with, chemical denaturants, offering significantly milder conditions for unfolding and disaggregation of proteins in inclusion bodies. As a result, subsequent refolding can be carried out faster, more efficiently, and in much smaller volumes. Pressure-based unfolding of proteins in inclusion bodies tends to only partially unfold the protein and preserve some beneficial structures that could help to guide the refolding process into the desired outcomes. Consequently, higher yields of active protein and faster manufacturing turn-around further lower the cost of biopharmaceutical production. Moreover, lower requirements for harsh chemical reagents in high pressure refolding process result in decrease or elimination of associated hazardous waste generated from chemical removal processes, leading to further cost reduction and protection of the environment.

The instruments, consumables and software used to practice the BaroFold technology (the “BaroFold Platform”) can be used to significantly lower the cost, boost production yield, and improve the quality of protein therapeutics. It employs high pressure for the disaggregation and controlled refolding of proteins to their native structures at yields and efficiencies not achievable using existing technologies. The BaroFold Platform has been shown to remove protein aggregates in biotherapeutic drug manufacturing, thereby improving product efficacy and safety for both new-drug entities and biosimilar products. The BaroFold Platform can help companies create novel protein therapeutics, accelerate therapeutic protein development, manufacture follow-on biologics, and significantly optimize life-cycle management of protein therapeutics. It is scalable and practical for standard manufacturing processes. This unique technology platform can help protein-based biopharmaceutical companies create and manufacture high quality, novel protein therapeutics and lower the cost of existing formulations. Research and manufacturing licenses are available.

b. Market

The global biopharmaceuticals market was valued at \$237 billion in 2018 and is estimated to be valued at \$389 billion in 2024, witnessing a CAGR of 8.59%. The market growth is attributed to the growing acceptance for biopharmaceuticals due to their ability to treat previously untreatable or poorly managed diseases, resulting in huge market demand for biopharmaceuticals.

We believe that biopharmaceuticals offer several benefits, such as highly effective and potent action, fewer side effects, and the potential to actually cure diseases rather than merely treat the symptoms, which have significantly increased the demand for biopharmaceutical products.

The predominant majority of biopharmaceutical products are recombinant proteins. Typical examples of such proteins are vaccines, monoclonal antibodies (MAbs), growth factors (such as Erythropoietin), hormones (such as insulin or HGH), receptor ligands, recombinant enzymes (Caspase, Cathepsin, etc.), blood factors and other therapeutic and research reagent proteins. Recombinant protein production can be done in bacteria or in cell cultures derived from higher organisms. Due to significant time and cost savings, attention to protein production in bacterial hosts has recently spiked, predominantly driven by rapid growth of biosimilars, antibody-drug conjugates (ADCs) and fusion proteins that are lethal to non-bacterial host cells. A major area of challenge in the biopharmaceuticals industry results from suboptimal folding configurations and/or agglomeration of proteins during production and storage, requiring subsequent remediation via unfolding and controlled refolding of these therapeutic proteins into their optimal configurations. Following initial penetration and acceleration through conversion of market share from traditional chemical methods, the growth of the protein refolding business is expected to follow the growth trajectory of the entire biopharmaceutical market.

Our Barofold platform technology has been shown not only to save manufacturing costs and time, but to boost protein yield and minimize protein immunogenicity, resulting in greater efficacy and safety for the patient.

Moreover, PBI's Barocycler line of products can also be utilized in accelerated protein stability testing to guide biopharmaceutical formulation development. PBI has initiated several collaborations, including a co-marketing agreement with RedShift BioAnalytics, Inc., and a research collaboration with the University of Delaware (see the Research and Development section below).

c. Products

Instruments: Barocycler 2320 EXT - a convenient screening tool for protein refolding optimization

Originally developed within the framework of our PCT platform business as a tool for biological sample preparation (as described above), our Barocycler 2320EXT instrument features a "ramp mode" in its control software that makes it ultimately suitable for performing research-scale experiments for protein refolding and disaggregation on a laboratory bench scale. Each protein molecule is biochemically unique and, while pressure is highly efficient in solubilization of practically any misfolded protein contained within inclusion bodies, a unique chemical environment may be required to persuade each unfolded protein molecule to refold into a stable biologically active state. Therefore, development of protein refolding methods requires screening experiments necessary to determine the most optimal composition of the chemical milieu for each protein of interest. The Barocycler 2320EXT is ideally suited for such experiments, providing researchers with abilities to process up to 12 specimens per batch in varying chemical environments. We believe that availability of this affordable screening tool will promote adoption of the high-pressure refolding approach among biopharmaceutical process development teams and academic researchers involved in development of protein biopharmaceuticals. The same instrument is also uniquely suited for studies of thermodynamics of protein aggregation and accelerated protein stability tests.

BaroFold Contract Services

Our BaroFold contract services can be used to significantly impact and improve the quality of large-molecule protein biotherapeutics. These services employ high pressure manipulations for the disaggregation and unfolding of proteins to their native structural states and then controlled refolding of the proteins to the desired therapeutically active state, at yields and efficiencies not achievable using existing technologies. The Barofold Platform has been shown to eliminate protein aggregation during biotherapeutic drug manufacturing and storage, thereby improving product yield, efficacy and safety for both new-drug entities and biosimilar products. The Barofold platform can help companies create novel protein therapeutics, accelerate therapeutic protein development, manufacture follow-on biologics, and enable life-cycle management of protein therapeutics. It is scalable and practical for standard manufacturing processes. This unique technology platform can help protein-based biopharmaceutical companies create and manufacture high quality, novel protein therapeutics and lower the cost of existing formulations. Research and manufacturing licenses are available.

d. Customers (examples only, not current customers for confidentiality reasons)

Biopharmaceutical companies (Roche, Novartis A.G., Sanofi, Biogen-Idec, Abbvie, Inc., Amgen, Takeda, Pfizer, Merck & Co., etc.)

Biosimilars companies (Teva, Sandoz, Hospira, Mylan, Allergan, Biocon, Momena, etc.)

Biopharmaceutical Contract Development and Manufacturing Organizations (Boehringer-Ingelheim, Lonza, Samsung Biologics, Catalent Pharma Solutions, Thermo Fisher Scientific, Fujifilm, etc.)

Life science research reagent manufacturers (Thermo Scientific, GE Healthcare, Danaher Corporation, Millipore-Sigma, Bio-Techne R&D Systems, etc.)

Academic research laboratories involved in development of protein pharmaceuticals, expression of recombinant proteins, protein structure analysis and biophysical characterization.

e. Competition

Over two decades, Barofold, Inc. built an intellectual property portfolio centered around the use of hydrostatic pressure for protein refolding and disaggregation. Following Barofold's acquisition by PBI in 2017, this portfolio, combined with the PBI patents in adjacent areas, puts PBI in a unique position worldwide to commercialize, practice and license out the right to practice high pressure protein refolding, disaggregation and accelerated stability testing. There is no direct competition to PBI that is using high pressure for these applications. Competing traditional approaches use chemicals for refolding and appear inferior in many aspects, as described above.

f. Manufacturing and Supply

Manufacturing of the Barocycler 2320EXT has been covered above, since this instrument shares its utility with applications of PCT technology platform. The PCT MicroTube consumable line is also shared between these two application areas.

PBI currently develops GMP-compliant, pilot-scale, high-pressure systems for processing of protein batches up to 10L in volume at pressure up to 60,000 psi.

In order to provide access for our customers to manufacturing scale high pressure equipment, PBI is currently in negotiations with several HPP (High Pressure Processing) equipment vendors supplying large pressure systems to food manufacturers. Upon successful feasibility studies conducted by customers themselves, or within the framework of Barofold Contract Services, PBI will act as a contractor to assist protein refolding customers in scaling up the process and identifying, procuring and validating appropriate large-scale equipment for high pressure protein refolding.

g. Research and Development

The PBI team has gained access to a significant body of research data through acquisition of the assets of Barofold, Inc. Barofold has spent over two decades perfecting high-pressure protein refolding applications and produced many publications and patents (see below). Our team's experience in high pressure refolding is being used in Contract Service work currently offered by PBI to our biopharmaceutical customers, as described above. As an equipment vendor, PBI has a goal of taking advantage of these R&D instrument assets and turning a benchtop high pressure protein refolding solution into a convenient, popular and easily accessible workflow for thousands of laboratories worldwide. As the knowledge about this method spreads and feasibility of great economic impact of utilizing this approach at a production scale is demonstrated, PBI plans to license high pressure refolding methods to its biopharmaceutical customers.

Additionally, several new applications of high pressure in biopharmaceutical development are stemming from a combined Barofold and PBI intellectual property portfolio. One of these highly promising applications, namely, pressure-assisted accelerated protein stability testing, is currently being developed by PBI's R&D team in collaboration with the Center for Biomanufacturing Science and Technology of the University of Delaware, headed by Professor Christopher J. Roberts. Many protein biopharmaceuticals must be kept in solution. Any physical factors such as exposure to temperature fluctuations in storage and shipment, mechanical vibration, exposure to light, etc., could promote protein aggregation, if the biotherapeutic protein is stored in a suboptimal chemical environment. Protein aggregates tend to be highly immunogenic, i.e., causing a patient's immune system to recognize protein drug as a foreign object and destroy it, leading to undesired inflammatory response and counteracting the desired therapeutic effect. Each protein drug may require optimization of its chemical environment (formulations development) to guarantee maximal stability and shelf life. Meanwhile, high pressure is a convenient tool for controlled protein unfolding. Partially unfolded proteins tend to aggregate more rapidly. Brief exposure of the protein drug in a specific formulation to a "pressure shock" can be used to promote aggregation, allowing researchers to screen for best formulations that prevent drug aggregation in a matter of only a few days. Conventional approaches for accelerated stability testing utilize exposure to high temperature. Since thermal effects on proteins are stochastic (i.e., random), there is little chance that every protein molecule will follow the same fate after thermal shock. Pressure exerts its effect on all protein molecules of the same type/conformation in exactly the same manner, making the pressure shock more effective in such studies. Our collaborative research program with Professor Roberts's team is directed towards development of validated workflows for high pressure accelerated stability testing.

The UST Platform

a. Description

The UST Platform is based on the use of intense shear forces generated from ultra-high pressure (greater than 20,000 psi) discharged through a controlled nanometer-scale valve orifice. UST has been shown to turn hydrophobic extracts into stable, effectively water-soluble formulations on a small, laboratory scale. The UST Platform offers the potential to produce stable nanoemulsions of oil-like products in water. Such formulations could potentially have enormous success in many markets, including pharmaceuticals, nutraceuticals (such as medically important plant oil extracts like CBD-enriched plant oil soluble in water), cosmetic and personal care products, liquid foods and beverages, agrochemicals, as well as inks, paints, lubricants and other industrial products. We believe that UST has the potential to play a significant role in a number of commercially important areas, including (i) the creation of stable nanoemulsions of otherwise immiscible fluids (e.g., oils and water), and (ii) 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, e.g., dairy products.

UST is an emerging technology that combines intense fluid shear with an instant, short-lived burst of heat achieved by specialized high-pressure equipment that can produce commercially sterile, pumpable, homogeneous fluid products. The UST process can provide energetic cellular disruption that results in the inactivation of bacteria, bacterial spores, viruses, and enzymes. Depending on operating conditions, low nano-scale emulsions (nanoemulsions) of oil and water mixtures can be produced that have been shown to have improved room-temperature shelf stability, and superior sensory profiles (taste, smell, texture and appearance). Of particular importance, oil-based active components delivered in such extreme nano-emulsions in water facilitates greatly improved absorption and bioavailability in the water-based biochemistry of humans, animals and plants, allowing for much lower loading quantities of actives required in manufacture, while ensuring safer and more controlled effective dosing.

The Company has received its first US patent and two patents in China on UST, focused on a low cost, scalable approach for product manufacturing. The Company believes this method can find use in various nanoemulsion applications for pharmaceutical (e.g., drug delivery), biotechnology (e.g., protein recovery, biomolecule extraction), and food (e.g., shelf-stable “clean label” products). We plan to design, develop, manufacture, and market a lab-scale UST-based production instrument that we will license to the life sciences and other industries. We also plan to develop a pilot plant scale UST-based production instrument for larger-scale production demonstrations, in our expectation to license the technology with larger manufacturing scale equipment to food, cosmetics, nutraceuticals, and other companies worldwide.

b. Market

In 2019, we have focused efforts on developing and demonstrating the UST protocol and seeding early adopters, which would provide insights into market, formulation, product development, and ultimately end product requirements. Our initial market focus has been on cannabis extracts, as this market's unmet needs for nanoemulsions solutions offer high visibility and ready access to funding, versus many other important target markets, such as Cosmetics, Food and Beverage, Nutraceutical, Pharmaceutical, and Industrial fluids and lubricants. In 2020, we refined the Ultra Shear Technology™ K45 instrument allowing us to run samples for multiple potential customers, which demonstrated the goal of producing room temperature stable, transparent nanoemulsions. (Transparency is achieved when nanoemulsion droplet sizes are smaller than the wavelength of visible light – an important indicator of achievement of extremely low-scale nanoemulsions.) We secured orders from companies for 15 units, which is the target number for our first production run. We also moved forward in the development of the BaroShear Mini: bench-top, laboratory-based instrument for research, formulation, and small volume processing; and the BaroShear Max; high-volume, industrial-scale, clean-in-place (CIP), production instrument. In 2021, we plan to commercialize both the standard K45 and BaroShear Mini, as well as continue the development of the BaroShear Max.

c. Products

The BaroShear Ultra Shear Technology platform development portfolio is currently comprised of three models for use in research, formulation, and processing of oil and water nanoemulsions.

- BaroShear Mini – bench-top instrument to be used for research, formulation, and small volume processing where budget is a concern. Throughput of 1mL / minute
- BaroShear K45 – pilot scale, floor standing instrument for throughput of at least 1L / hour.
- BaroShear Max – floor standing, fully automated, CIP industrial production system for throughput up to 1L / minute.

d. Customers

Cannabis extracts, cosmetic & personal care products, liquid foods & beverages, nutraceuticals, pharmaceuticals, agrochemicals, inks, paints, lubricants and other industrial products, and researchers and processors interested in developing stable, water-soluble nanoemulsions for any application.

e. Competition - High Pressure

- Avestin / ATA Scientific – Australia
- Bee Int'l, Easton, MA – USA
- DyHydromatics, Maynard, MA - USA
- ELVEFLOW an Elvsys brand, Paris, FRANCE
- Microfluidics an IDEX Corp Company, Westwood, MA – USA

f. Manufacturing and Supply

PBI's current strategy is to have the development handled by PBI's development and engineering team, with manufacturing to be outsourced to a Contract Manufacturing Organization (CMO). Aftermarket service and support will initially be handled by PBI's service and repair staff. As unit placements grow, we will investigate expansion of PBI's service and support organization or augment it with external partners.

g. Research and Development

PBI's UST engineering team is developing a product portfolio consisting of three model instruments with the following research & formulation, pre-production and production models scheduled for launch as follows:

BaroShear K45 mini – bench-top instrument, Q2 2021

BaroShear K45 – floor standing model, Q4 2021

BaroShear Max – floor standing, fully automated, CIP equipment, prototype delivery to Ohio State University – Q2 2020. Commercial release planned for late 2021/2022 timeframe.

Other

a. Sales and Marketing

Our marketing and sales functions are led by Richard T. Schumacher, our Chief Executive Officer. Mr. Schumacher oversees and directs all marketing and sales activities, including trade show attendance and sponsorship, on-line advertising, website maintenance and improvement, search engine optimization, creation and dissemination of newsletters, market research initiatives, the arrangement of on-location seminars, lectures, and demonstrations of instrumentation and consumables capabilities, and the supervision of our sales and marketing personnel. Mr. Schumacher is also responsible for the overall coordination of our collaboration programs, from initial set-up, research plan design, and training, service, and data analysis. Some of these responsibilities are shared with other departments such as Research and Development, but marketing and sales drives the collaborative process. Mr. Schumacher is also responsible for the continued coordination and support of our foreign distribution partners.

Our sales and marketing efforts are centered on using the independent data developed and disseminated by our collaboration partners to help drive the installed base of our PCT Sample Preparation System, BaroFold services, and BaroShear UST platform. The development of scientific data by our partners and our internal researchers provides our sales and marketing staff with additional tools that are essential in selling existing and newly developed paradigm-shifting, high value technologies and services.

Our domestic PCT sales force currently consists of one sales director and one field salesperson. Our sales director is currently responsible for servicing the U.S., excluding New England, as well as all CBD-related UST customers and our field salesperson handles New England and the international distributors.

Our domestic BaroShear UST sales efforts in the non-CBD market is handled by both the sales director and the field salesperson. We believe that partnering with seasoned, capable equipment distribution partners in the cannabis and other laboratory / process markets will drive lead generation and purchase orders faster than if we were to build our own sales force.

b. Marketing Strategy

We recognize that our enabling PCT, BaroFold, and UST pressure platforms are powerful, novel platform technologies. We also recognize that the power of pressure in today’s laboratories is not yet generally known by researchers. Our first goal is to greatly broaden the awareness of pressure and its applications among research scientists and to ensure they know that these technologies exist through our high-pressure instruments, requisite consumables, and unique services. To accomplish this expansion of knowledge about the power of pressure and the subsequent adoption of our pressure-based technology platforms, we have developed and are implementing a multi-faceted approach to marketing our products and services.

Key Opinion Leaders and Publications

To initially reach scientists, we have established collaborations with key opinion leaders (KOL) who recognized early the potential for our pressure-based platforms and who went on to report their discoveries in peer reviewed journals. Among the KOLs working with us is Dr. Ruedi Aebersold (Head of the Department of Biology, ETH, Zurich). Dr. Aebersold, a pioneer in proteomics, worked with our scientists and engineers to develop PCT-SWATH (aka PCT-HD), a superior method for the extraction and preparation of proteins from samples intended for analysis by mass spectrometry. Other KOLs include Dr. Jennifer van Eyk (Director of *Advanced Clinical Biosystems Institute in the Department of Biomedical Sciences* Cedar Sinai, Los Angeles, CA) and Dr. Wayne Hubble (Jules Stein Professor at the University of California, LA). Dr. van Eyk is a recognized expert in the causes of heart disease and is using PCT in her attempt to discover cardiac disease biomarkers. Dr. Hubble, a member of the National Academy of Sciences, is a leader in the field of electron paramagnetic resonance (EPR). He uses PCT in his studies of protein-protein interactions, so very important in the discovery of drug targets and drug design. The publications and presentations of these and other world class scientists have been invaluable in gaining initial entry of PCT in several areas of research. In addition to publications by our numerous KOLs, there are also many additional peer reviewed publications from dozens of other scientists discussing the advantages of the PCT platform in bio-molecule sample preparation, as well as the advantages of our BaroFold technology and our UST platform. To this end, we do all we can to disseminate the work of these scientists in an effort to increase the exposure of PCT, BaroFold, and UST to the worldwide research community.

Broadcasting PCT and Our Products

1. We attend, exhibit, and present at top scientific meetings such as the American Society of Mass Spectrometry (ASMS) and both the US and International meetings of the Human Proteome Organization (HUPO). These meetings are an opportunity to present our technology and to showcase our products to scientists who require sample preparation in their research studies.
2. Routine and timely “blast” emails to scientists in our database. Topics include new PCT-related publications, announcements of meetings, product advertisements, and a quarterly newsletter. The database we use is proprietary, as it has been built from attending scientific meetings and searching the internet for relevant publications and contact information. Pardot Marketing automation software is utilized for routing email campaigns, allowing us to measure customer engagement with our landing pages, articles and emails.
3. We manage our database with Salesforce, a state-of-the-art Customer Relationship Management (CRM) system. Through Salesforce, we employ the marketing automation software Pardot to manage our email blasts. Pardot enables us to assess open rates, levels of interest, and to create automatic and constant contact with potential clients.
4. We use social media platforms like LinkedIn, Twitter and Facebook to broadcast publications, webinars, our presence at scientific meetings, and press releases. We employ LeadForensics and SRAX to amplify our targeting and social media efforts. Social media enables us to easily reach scientists world-wide.
5. We significantly upgraded our website. The upgraded website contains a state-of-the art search engine that enables researchers to rapidly find PCT-related publications and products.
6. The website contains product information, published articles, and videos of our products to foster engagement, product interest, leads, order placement, and learning.
7. Our scientists regularly present their findings and discuss our products at scientific sessions at regional, national, and international scientific conferences, and at corporate, government, and academic laboratories.
8. In addition to electronic advertising, we have used and will continue to use print media to showcase our products.

In 2021, we plan to expand our Sales and Marketing team, in order to support these efforts.

c. Foreign Distribution Network

We have previously established distribution arrangements covering China, Poland, South Korea, Japan, and 24 countries in Western Europe.

In May of 2014, we entered into a three-year distribution agreement with Powertech Technology Co, Ltd., of China, pursuant to which we granted Powertech Technology exclusive distribution rights to all of our PCT products in China. This agreement expired in 2019. We continue to maintain a distribution relationship with Powertech and are in contract renewal discussions.

In February 2016, we entered into a three-year distribution agreement with *Bioanalytic* of Poland, pursuant to which PBI granted *Bioanalytic* exclusive distribution rights to all of our PCT products in Poland. This agreement expired in 2019. We continue to maintain a distribution relationship with *Bioanalytic* and are in contract renewal discussions.

In September of 2016, we entered into a three-year distribution agreement with Vita Co. of Japan, pursuant to which we granted Vita Co. exclusive distribution rights to all of our PCT products in Japan. This agreement expired in 2019. We continue to maintain a distribution relationship with Vita and are in contract renewal discussions.

In September of 2016, we entered into a distribution agreement with I&L GmbH of Germany, pursuant to which we granted I&L exclusive distribution rights to all of our products until March 30, 2018 in the countries designated as Western Europe (Andorra, Austria, Belgium, Denmark, Finland, France, Germany, Gibraltar, Greece, Iceland, Italy, Ireland, Liechtenstein, Luxembourg, Malta, Monaco, Norway, Netherlands, Portugal, San Marino, Spain, Sweden, Switzerland, and the United Kingdom). This agreement expired March 31, 2020. We continue to maintain a distribution relationship with I&L GmbH and are in contract renewal discussions.

In January 2020, we entered into a three-year distribution agreement with SCINCO Co., LTD of South Korea, pursuant to which PBI granted SCINCO exclusive distribution rights to all of our PCT products in South Korea.

Non-Exclusive and Other Distribution Agreements

In November 2011, we entered into a distributor agreement with OROBOROS Instruments Corp. (“*OROBOROS*”) of Austria, pursuant to which we granted OROBOROS non-exclusive world-wide distribution rights to our Shredder SG3 System and related products.

We are also the exclusive distributor, throughout the Americas, for Constant Systems, Ltd.’s (“*CS*”) cell disruption equipment, parts, and consumables. CS, a British company located northwest of London, England, has been providing niche biomedical equipment, related consumable products, and services to a global client base since 1989. CS designs, develops, and manufactures high pressure cell disruption equipment used by life sciences laboratories worldwide, particularly disruption systems for the extraction of proteins. The CS equipment provides a constant and controlled cell disruptive environment, giving the user superior, constant, and reproducible results whatever the application. CS has over 900 units installed in over 40 countries worldwide. The CS cell disruption equipment has proven performance in the extraction of cellular components, such as protein from yeast, bacteria, mammalian cells, and other sample types.

The CS pressure-based cell disruption equipment and our PCT-based instrumentation complement each other in several important ways. While both the CS and our technologies are based on high pressure, each product line has fundamental scientific capabilities that the other does not offer. Our PCT Platform uses certain patented pressure mechanisms to achieve small-scale, molecular level effects. CS’s technology uses different, proprietary pressure mechanisms for larger-scale, non-molecular level processing. In a number of routine laboratory applications, such as protein extraction, both effects can be critical to success. Therefore, for protein extraction and a number of other important scientific applications, we believe laboratories will benefit by using the CS and PBI products, either separately or together.

In June 2013, CS and PBI signed an expanded distribution agreement that made us the exclusive distributor of CS products throughout all of the Americas until the end of 2019. We are in renewal discussions for this agreement.

d. Intellectual Property

We believe that protection of our patents and other intellectual property is essential to our business. Subject to the availability of sufficient financial resources, our practice is to file patent applications to protect technology, inventions, and improvements to inventions that are important to our business development. We also rely on trade secrets, know-how, and technological innovations to develop and maintain our potential competitive position.

To date, we have been awarded 26 total United States and foreign patents related to our PCT technology platform, and one US patent and two additional patents in China related to our Ultra Shear Technology. We also received eight patents with our purchase of the assets of BaroFold in December 2017.

The Company received one US patent and two patents in China for UST, focused on a low-cost scalable approach for product manufacturing. The Company believes this method can find use in various nanoemulsion applications for pharmaceutical (e.g., drug delivery), biotechnology (e.g., protein recovery, biomolecule extraction), and food/beverage (e.g., shelf-stable “clean label”) products. We plan to design, develop, manufacture, and market three different modules of BaroShear UST platform:

1. a bench-top, research / formulation, low throughput instrument that we will license for formulation development;
2. a lab-or pilot scale production instrument that we will license into life science companies and other industries;
3. a production scale UST-based instrument for manufacturing applications that we will license to food, cosmetics, nutraceuticals, and other processors worldwide.

Our issued patents expire between 2021 and 2030. Any failure to obtain and maintain adequate patent protection may adversely affect our ability to enter into, or affect the terms of, any arrangement for the marketing, sale or licensing of any of our products or technology platforms. It may also allow our competitors to duplicate our products without our permission and without compensation.

License Agreements Relating to Pressure Cycling Technology

BioMolecular Assays, Inc.

In 1996, we acquired our initial equity interest in BioSeq, Inc., which at the time was developing our original pressure cycling technology. BioSeq, Inc. acquired its pressure cycling technology from BioMolecular Assays, Inc. under a technology transfer and patent assignment agreement. In 1998, we purchased all of the remaining outstanding capital stock of BioSeq, Inc., and at such time, the technology transfer and patent assignment agreement was amended to require us to pay BioMolecular Assays, Inc., a 5% royalty on our sales of products or services that incorporate or utilize the original pressure cycling technology that BioSeq, Inc. acquired from BioMolecular Assays, Inc. We are also required to pay BioMolecular Assays, Inc. 5% of the proceeds from any sale, transfer or license of all or any portion of the original pressure cycling technology. These payment obligations terminated March 7, 2016.

In connection with our acquisition of BioSeq, Inc., we licensed certain limited rights to the original pressure cycling technology back to BioMolecular Assays, Inc. This license is non-exclusive and limits the use of the original pressure cycling technology by BioMolecular Assays, Inc. solely for molecular applications in scientific research and development and in scientific plant research and development. BioMolecular Assays, Inc. is required to pay us a royalty equal to 20% of any license or other fees and royalties, but not including research support and similar payments, it receives in connection with any sale, assignment, license or other transfer of any rights granted to BioMolecular Assays, Inc. under the license. BioMolecular Assays, Inc. was required to pay us these royalties until the expiration in March 2016 of the patents held by BioSeq, Inc. since 1998. We have not received any royalty payments from BioMolecular Assays, Inc. under this license.

Battelle Memorial Institute

In December 2008, we entered into an exclusive patent license agreement with the Battelle Memorial Institute (“Battelle”). The licensed technology is the subject of a patent application filed by Battelle in 2008 and relates to a method and a system for improving the analysis of protein samples, including through an automated system utilizing pressure and a pre-selected agent to obtain a digested sample in a significantly shorter period of time than current methods, while maintaining the integrity of the sample throughout the preparatory process. In addition to royalty payments on net sales of “licensed products,” we are obligated to make minimum royalty payments for each year that we retain the rights outlined in the patent license agreement and we are required to have our first commercial sale of the licensed products within one year following the issuance of the patent covered by the licensed technology. After re-negotiating the terms of the contract in 2013, the minimum annual royalty was \$1,200 in 2014 and \$2,000 in 2015; the minimum royalties were \$3,000 in 2016, \$4,000 in 2017 and \$5,000 in 2018 and each calendar year thereafter during the term of the agreement.

e. Developments and Accomplishments

We reported a number of accomplishments in 2020:

On January 20, 2021, PBI targets revolution in effectiveness of therapeutics via improved drug delivery and dosing safety; announces collaboration with SinuSys Corp to improve and optimize their lead sinus health product candidate prior to Phase IIb trials.

On December 17, 2020, PBI reports its PCT Platform is at the forefront in generating pivotal findings by diverse COVID-19 research teams in the USA, China, and Europe.

On December 15, PBI announces planned presentation on December 17, 2020 at the Life Sciences Investor Forum: <https://www.lifesciencesinvestorforum.com/>

On November 17, PBI reports Third Quarter 2020 Financial Results – as compared to the Third Quarter of 2019 instrument sales increase 68%, total revenue increases 7%, and operating loss decreases 23%.

On November 11, Company was awarded the first U.S. patent for its revolutionary Ultra Shear Technology™ (UST™) platform.

On October 6, PBI achieved a critical milestone in revolutionary nanoemulsions technology development and entered the production era for commercial system (BaroShear K45) development.

On August 12, PBI was awarded a pivotal U.S. patent for novel, high-pressure enhanced consumable device. The new patent secures and protects PBI’s best-selling PCT Sample Preparation Consumable Product, the PCT MicroPestle.

On June 20, PBI and Leica Microsystems sign worldwide co-marketing alliance: combination of proprietary technologies expected to accelerate cancer R&D with innovative tumor processing workflow

On June 4, PBI announces first manufacturing build completely sold out for revolutionary UST System for processing hemp-derived cannabinoid oil into stable, water-soluble nanoemulsions

On May 14, Pressure BioSciences announced the launch of FDA-registered hand sanitizer as first product developed through pending merger partners.

On April 16, PBI and RedShiftBio demonstrate potential of combining proprietary technologies to enable new tool for development and production of biotherapeutics.

On March 12, PBI announced that it is nearing a complete sellout on its pre-launch offering of game-changing UST Platform for processing CBD Oil into water-soluble nanoemulsions.

On February 27, PBI launched new era in preparation of water-soluble nanoemulsions for CBD and other valuable oils with opening of UST Demonstration Laboratory.

On January 30, PBI announced acceleration of UST Platform rollout for water-soluble CBD with planned release of additional BaroShear product – a benchtop, R&D scale, BaroShear “Mini” instrument.

On January 24, PBI announced significant new order and near sellout on revolutionary nanoemulsification system for water-soluble CBD oil. Company said that additional orders are expected shortly.

On January 17, PBI reported the Company’s UST Platform was featured in a leading North American Cannabis Magazine and that the article highlighted the potential of the UST Platform to play a significant role in multiple billion-dollar markets, such as CBD, nutraceuticals, cosmetics, biopharmaceuticals, and food/beverage.

On January 9, 2020, PBI reported that the number of published scientific papers in 2019 citing the advantages of the Company’s PCT Platform remained strong, with over 20 journal articles for the second straight year.

f. Liquidity

Management has developed a plan to continue operations. This plan includes controlling expenses, streamlining operations, and obtaining capital through equity and/or debt financing. We have been successful in raising cash through debt and equity offerings in the past. We have efforts in place to continue to raise cash through debt and equity offerings.

Although we have successfully completed equity financings and reduced expenses in the past, we cannot assure our investors that our plans to address these matters in the future will be successful. Additional financing may not be available to us on a timely basis or on terms acceptable to us, if at all. In the event we are unable to raise sufficient funds on terms acceptable to us, we may be required to:

- severely limit or cease our operations or otherwise reduce planned expenditures and forego other business opportunities, which could harm our business. The accompanying financial statements do not include adjustments that may be required in the event of the disposal of assets or the discontinuation of the business;
- obtain financing with terms that may have the effect of diluting or adversely affecting the holdings or the rights of the holders of our capital stock; or
- obtain funds through arrangements with future collaboration partners or others that may require us to relinquish rights to some or all of our technologies or products.

g. Regulation

Many of our activities are subject to regulation by governmental authorities within the United States and similar bodies outside of the United States. The regulatory authorities may govern the collection, testing, manufacturing, safety, efficacy, labeling, storage, record keeping, transportation, approval, advertising, and promotion of our products, as well as the training of our employees.

Currently, our PCT commercialization efforts are focused in the area of genomic, proteomic, lipidomic, and small molecule sample preparation. We do not believe that our current Barocycler® products used in sample preparation are considered “medical devices” under the United States Food, Drug and Cosmetic Act (the “*FDA Act*”) and we do not believe that we are subject to the law’s general control provisions that include requirements for registration, listing of devices, quality regulations, labeling and prohibitions against misbranding and adulteration. We also do not believe that we are subject to regulatory inspection and scrutiny. If, however, we are successful in commercializing PCT in applications beyond our current focus area of genomic, proteomic, lipidomic, and small molecule sample preparation, such as protein purification, pathogen inactivation and immunodiagnostics, our products may be considered “medical devices” under the FDA Act, at which point we would be subject to the law’s general control provisions and regulation by the FDA that include requirements for registration listing of devices, quality regulations, labeling, and prohibitions against misbranding and adulteration. The process of obtaining approval to market these devices in the other potential applications of PCT would be costly and time consuming and could possibly prohibit us from pursuing such markets.

Some of our devices may also become subject to the European Pressure Equipment Directive, which requires certain pressure equipment meet certain quality and safety standards. We do not believe that we are currently subject to this directive because our Barocycler® instruments are below the threshold documented in the text of the directive. If our interpretation were to be challenged, we could incur significant costs defending the challenge, and we could face production and selling delays, all of which could harm our business.

We self-certified that our Barocycler® instrumentation was electromagnetically compatible, or “CE” compliant, which means that our Barocycler® instruments meet the essential requirements of the relevant European health, safety and environmental protection legislation. In order to maintain our CE Marking, a requirement to sell equipment in many countries of the European Union, we are obligated to uphold certain safety and quality standards. Due to outsourcing manufacturing to CBM for all Barocycler 2320 EXT instruments currently in inventory or sold in 2020, an ISO certified contract manufacturer, we believe compliance with CE and other required marks and certifications is well controlled.

h. Employees

At December 31, 2020, we had twelve (12) full-time employees. All employees enter into confidentiality agreements intended to protect our proprietary information. We believe that our relations with our employees are good. None of our employees are represented by a labor union. Our performance depends on our ability to attract and retain qualified professional, scientific and technical staff. The level of competition among employers for skilled personnel is high. Subject to our limited financial resources, we attempt to maintain employee benefit plans to enhance employee morale, professional commitment and work productivity and provide an incentive for employees to remain with us.

i. Corporate Information

We were incorporated in the Commonwealth of Massachusetts in August 1978 as Boston Biomedica, Inc. In 1996, Boston Biomedica completed a successful initial public offering and was listed on the NASDAQ market. In September 2004, we completed the sale of Boston Biomedica’s core business units and began to focus exclusively on the development and commercialization of the PCT platform. Following this change in business strategy, we changed our legal name from Boston Biomedica, Inc. to Pressure BioSciences, Inc. We began operations as PBI in February 2005, research and development activities in April 2006, early marketing and selling activities of our Barocycler® instruments in late 2007, and active marketing and selling of our PCT-based instrument platform in 2012.

j. Available Information

Our Internet website address is <http://www.pressurebiosciences.com>. Through our website, we make available, free of charge, reports that we file with the Securities and Exchange Commission (“*SEC*”), which include, but are not limited to, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any and all amendments to such reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These SEC reports can be also accessed through the investor relations section of our website. The information found on our website is not part of this or any other report we file with or furnish to the SEC.

ITEM 1A. RISK FACTORS.

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties, such as statements of our objectives, expectations and intentions. The cautionary statements made in this Annual Report on Form 10-K should be read as applicable to all forward-looking statements wherever they appear in this report. Our actual results could differ materially from those discussed herein. Factors that could cause or contribute to such differences include those discussed below, as well as those discussed elsewhere in this Annual Report on Form 10-K.

RISKS RELATED TO OUR COMPANY

We have received an opinion from our independent registered public accounting firm expressing substantial doubt regarding our ability to continue as a going concern.

The audit report issued by our independent registered public accounting firm on our audited consolidated financial statements for the fiscal year ended December 31, 2020 contains an explanatory paragraph regarding our ability to continue as a going concern. The audit report states that our auditing firm determined that there was substantial doubt in our ability to continue as a going concern due to the risk that we may not have sufficient cash and liquid assets at December 31, 2020 to cover our operating and capital requirements for the next twelve-month period; and if sufficient cash cannot be obtained, we would have to substantially alter, or possibly even discontinue, operations. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Management has developed a plan to continue operations. This plan includes continued control of expenses and obtaining equity or debt financing. Although we have successfully completed equity financings and reduced expenses in the past, we cannot assure you that our plans to address these matters in the future will be successful.

The factors described above could adversely affect our ability to obtain additional financing on favorable terms, if at all, and may cause investors to have reservations about our long-term prospects and may adversely affect our relationships with customers. There can be no assurance that our auditing firm will not issue the same opinion in the future. If we cannot successfully continue as a going concern, our stockholders may lose their entire investment.

Our revenue is dependent upon acceptance of our products by the market. The failure of such acceptance will cause us to curtail or cease operations.

Our revenue comes from the sale of our products. As a result, we will continue to incur operating losses until such time as sales of our products reach a mature level and we are able to generate sufficient revenue from the sale of our products to meet our operating expenses. There can be no assurance that customers will adopt our technology and products, or that businesses and prospective customers will agree to pay for our products. In the event that we are not able to significantly increase the number of customers that purchase our products, or if we are unable to charge the necessary prices, our financial condition and results of operations will be materially and adversely affected.

Our business could be adversely affected if we fail to implement and maintain effective disclosure controls and procedures and internal control over financial reporting.

We concluded that as of December 31, 2020, our disclosure controls and procedures and our internal control over financial reporting were not effective. We have determined that we have limited resources for adequate personnel to prepare and file reports under the Securities Exchange Act of 1934 within the required time periods and that material weaknesses in our internal control over financial reporting exist relating to our accounting for complex equity transactions. If we are unable to implement and maintain effective disclosure controls and procedures and remediate the material weaknesses in a timely manner, or if we identify other material weaknesses in the future, our ability to produce accurate and timely financial statements and public reports could be impaired, which could adversely affect our business and financial condition. We identified a lack of sufficient segregation of duties. Specifically, this material weakness is such that the design over these areas relies primarily on detective controls and could be strengthened by adding preventive controls to properly safeguard assets. In addition, investors may lose confidence in our reported information and the market price of our common stock may decline.

We have a history of operating losses, anticipate future losses and may never be profitable.

We have experienced significant operating losses in each period since we began investing resources in PCT and CP. These losses have resulted principally from research and development, sales and marketing, and general and administrative expenses associated with the development of our PCT business. During the year ended December 31, 2020, we recorded a net loss available to common shareholders of \$17,584,710 or (\$5.32) per share, as compared with \$15,868,083 or (\$7.98) per share, for the corresponding period in 2019. We expect to continue to incur operating losses until sales increase substantially. We cannot be certain when, if ever, we will become profitable. Even if we were to become profitable, we might not be able to sustain such profitability on a quarterly or annual basis.

If we are unable to obtain additional financing, business operations will be harmed and if we do obtain additional financing then existing shareholders may suffer substantial dilution.

We need substantial capital to implement our sales distribution strategy for our current products and to develop and commercialize future products using our pressure cycling technology products and services in the sample preparation area, as well as for applications in other areas of life sciences. Our capital requirements will depend on many factors, including but not limited to:

- the problems, delays, expenses, and complications frequently encountered by early-stage companies;
- market acceptance of our pressure cycling technology products and services for sample preparation;
- the success of our sales and marketing programs; and
- changes in economic, regulatory or competitive conditions in the markets we intend to serve.

We expect the net proceeds from an expected equity offering, along with our current cash position, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 36 months. Thereafter, unless we achieve profitability, we anticipate that we will need to raise additional capital to fund our operations and to otherwise implement our overall business strategy. We currently do not have any contracts or commitments for additional financing. There can be no assurance that financing will be available in amounts or on terms acceptable to us, if at all. Any additional equity financing may involve substantial dilution to then existing shareholders.

If adequate funds are not available or if we fail to obtain acceptable additional financing, we may be required to:

- severely limit or cease our operations or otherwise reduce planned expenditures and forego other business opportunities, which could harm our business;
- obtain financing with terms that may have the effect of substantially diluting or adversely affecting the holdings or the rights of the holders of our capital stock; or
- obtain funds through arrangements with future collaboration partners or others that may require us to relinquish rights to some or all of our technologies or products.

Our financial results depend on revenues from our pressure cycling technology products and services, and from government grants.

We currently rely on revenues from PCT, CP, and CS technology products and services in the sample preparation area and from revenues derived from grants awarded to us by governmental agencies, such as the National Institutes of Health. We have been unable to achieve market acceptance of our product offerings to the extent necessary to achieve significant revenue. Competition for government grants is very intense, and we can provide no assurance that we will continue to be awarded grants in the future. If we are unable to increase revenues from sales of our pressure cycling technology products and services and government grants, our business will fail.

We may be unable to obtain market acceptance of our pressure cycling technology products and services.

Many of the initial sales of our pressure cycling technology products and services have been to our collaborators, following their use of our products in studies undertaken in sample preparation for genomics, proteomics, lipidomics, and small molecules studies. Later sales have been to key opinion leaders. Our technology requires scientists and researchers to adopt a method of sample extraction that is different from existing techniques. Our PCT sample preparation system is also more costly than most existing techniques. Our ability to obtain market acceptance will depend, in part, on our ability to demonstrate to our potential customers that the benefits and advantages of our technology outweigh the increased cost of our technology compared with existing methods of sample extraction. If we are unable to demonstrate the benefits and advantages of our products and technology as compared with existing technologies, we will not gain market acceptance and our business will fail.

Our business may be harmed if we encounter problems, delays, expenses, and complications that often affect companies that have not achieved significant market acceptance.

Our pressure cycling technology business continues to face challenges in achieving market acceptance. If we encounter problems, delays, expenses and complications, many of which may be beyond our control or may harm our business or prospects. These include:

- availability of adequate financing;
- unanticipated problems and costs relating to the development, testing, production, marketing, and sale of our products;
- delays and costs associated with our ability to attract and retain key personnel; and
- competition.

The sales cycle of our pressure cycling technology products is lengthy. We have incurred and may continue to incur significant expenses and we may not generate any significant revenue related to those products.

Many of our current and potential customers have required between three and six months or more to test and evaluate our pressure cycling technology products. This increases the possibility that a customer may decide to cancel its order or otherwise change its plans, which could reduce or eliminate our sales to that potential customer. As a result of this lengthy sales cycle, we have incurred and may continue to incur significant research and development, selling and marketing, and general and administrative expense related to customers from whom we have not yet generated any revenue from our products, and from whom we may never generate the anticipated revenue if a customer is not satisfied with the results of the evaluation of our products or if a customer cancels or changes its plans.

Our business could be harmed if our products contain undetected errors or defects.

We are continuously developing new and improving our existing, pressure cycling technology products in sample preparation and we expect to do so in other areas of life sciences depending upon the availability of our resources. Newly introduced products can contain undetected errors or defects. In addition, these products may not meet their performance specifications under all conditions or for all applications. If, despite internal testing and testing by our collaborators, any of our products contain errors or defects or fail to meet customer specifications, then we may be required to enhance or improve those products or technologies. We may not be able to do so on a timely basis, if at all, and may only be able to do so at considerable expense. In addition, any significant reliability problems could result in adverse customer reaction, negative publicity or legal claims and could harm our business and prospects.

Our success may depend on our ability to manage growth effectively.

Our failure to manage growth effectively could harm our business and prospects. Given our limited resources and personnel, growth of our business could place significant strain on our management, information technology systems, sources of manufacturing capacity and other resources. To properly manage our growth, we may need to hire additional employees and identify new sources of manufacturing capabilities. Failure to effectively manage our growth could make it difficult to manufacture our products and fill orders, as well as lead to declines in product quality or increased costs, any of which would adversely impact our business and results of operations.

Our success is substantially dependent on the continued service of our senior management.

Our success is substantially dependent on the continued service of our senior management, specifically our Chief Executive Officer, Richard T. Schumacher. The loss of the services of any of our senior management could make it more difficult to successfully operate our business and achieve our business goals. In addition, our failure to retain existing engineering, research and development, operations, and marketing/sales personnel could harm our product development capabilities and customer and employee relationships, delay the growth of sales of our products, and result in the loss of key information, expertise, or know-how.

We may not be able to hire or retain the number of qualified personnel, particularly engineering and sales personnel, required for our business, which would harm the development and sales of our products and limit our ability to grow.

Competition in our industry for senior management, technical, sales, marketing, finance and other key personnel is intense. If we are unable to retain our existing personnel, or attract and train additional qualified personnel, either because of competition in our industry for such personnel or because of insufficient financial resources, our growth may be limited. Our success also depends in particular on our ability to identify, hire, train and retain qualified engineering and sales personnel with experience in design, development and sales of laboratory equipment.

Our reliance on a single third party for all of our manufacturing, and certain of our engineering, and other related services could harm our business.

We currently solely rely on CBM Industries, a third-party contract manufacturer, to manufacture our Barocycler 2320EXT instrumentation, provide manufacturing expertise, and manage the majority of our sub-contractor supplier relationships for this instrument. Because of our dependence on one manufacturer, our success will depend, in part, on the ability of CBM to manufacture our products cost effectively, in sufficient quantities to meet our customer demand, if and when such demand occurs, and meeting our quality requirements. If CBM experiences manufacturing problems or delays, or if CBM decides not to continue to provide us with these services, our business may be harmed. While we believe other contract manufacturers are available to address our manufacturing and engineering needs, if we find it necessary to replace CBM, there will be a disruption in our business and we would incur additional costs and delays that would harm our business.

Our failure to manage current or future alliances or joint ventures effectively may harm our business.

We have entered into business relationships with four distribution partners and one co-marketing partner, and we may enter into additional alliances, joint ventures or other business relationships to further develop, market and sell our pressure cycling technology product line. We may not be able to:

- identify appropriate candidates for alliances, joint ventures or other business relationships;
- assure that any candidate for an alliance, joint venture or business relationship will provide us with the support anticipated;
- successfully negotiate an alliance, joint venture or business relationship on terms that are advantageous to us; or
- successfully manage any alliance or joint venture.

Furthermore, any alliance, joint venture or other business relationship may divert management time and resources. Entering into a disadvantageous alliance, joint venture or business relationship, failing to manage an alliance, joint venture or business relationship effectively, or failing to comply with any obligations in connection therewith, could harm our business and prospects.

We may not be successful in growing our international sales.

We cannot guarantee that we will successfully develop our international sales channels to enable us to generate significant revenue from international sales. We currently have four international distribution agreements that cover 24 countries in Europe, Asia and Australia. We have generated limited sales to date from international sales and cannot guarantee that we will be able to increase our sales. As we expand, our international operations may be subject to numerous risks and challenges, including:

- multiple, conflicting and changing governmental laws and regulations, including those that regulate high pressure equipment;
- reduced protection for intellectual property rights in some countries;
- protectionist laws and business practices that favor local companies;
- political and economic changes and disruptions;
- export and import controls;
- tariff regulations; and
- currency fluctuations.

Our operating results are subject to quarterly variation. Our operating results may fluctuate significantly from period to period depending on a variety of factors, including but not limited to the following:

- our ability to increase our sales of our pressure cycling technology products for sample preparation on a consistent quarterly or annual basis;
- the lengthy sales cycle for our products;
- the product mix of the Barocycler® instruments we install in a given period, and whether the installations are completed pursuant to sales, rental or lease arrangements, and the average selling prices that we are able to command for our products;
- our ability to manage our costs and expenses;
- our ability to continue our research and development activities without incurring unexpected costs and expenses; and
- our ability to comply with state and federal regulations without incurring unexpected costs and expenses.

Our instrumentation operates at high pressures and may therefore become subject to certain regulations in the European Community. Regulation of high-pressure equipment may limit or hinder our development and sale of future instrumentation.

Our Barocycler® instruments operate at high pressures. If our Barocycler® instruments exceed certain pressure levels, our products may become subject to the European Pressure Equipment Directive, which requires certain pressure equipment meet certain quality and safety standards. We do not believe that we are subject to this directive because our Barocycler® instruments are currently below the threshold documented in the text of the directive. If our interpretation were to be challenged, we could incur significant costs defending the challenge, and we could face production and selling delays, all of which could harm our business.

We expect that we will be subject to regulation in the United States, such as by the Food and Drug Administration, and overseas, if and when we begin to invest more resources in the development and commercialization of PCT in applications outside of sample preparation for the research field.

Our current pressure cycling technology products in the area of sample preparation for the research field are not regulated by the FDA. Certain applications in which we intend to develop and commercialize pressure cycling technology, such as protein purification, pathogen inactivation and immunodiagnostics, are expected to require regulatory approvals or clearances from regulatory agencies, such as the FDA, prior to commercialization, when we expand our commercialization activities outside of the research field. We expect that obtaining these approvals or clearances will require a significant investment of time and capital resources and there can be no assurance that such investments will receive approvals or clearances that would allow us to commercialize the technology for these applications.

If we are unable to protect our patents and other proprietary technology relating to our pressure cycling technology products, our business will be harmed.

Our ability to further develop and successfully commercialize our products will depend, in part, on our ability to enforce our patents, preserve our trade secrets, and operate without infringing the proprietary rights of third parties. To date, we have been granted 15 United States and foreign patents related to our PCT technology platform, and two additional patents in China related to our Ultra Shear Technology. We also received eight patents with our purchase of the assets of BaroFold in December 2017.

There can be no assurance that (a) any patent applications filed by us will result in issued patents; (b) patent protection will be secured for any particular technology; (c) any patents that have been or may be issued to us will be valid or enforceable; (d) any patents will provide meaningful protection to us; (e) others will not be able to design around our patents; and (f) our patents will provide a competitive advantage or have commercial value. The failure to obtain adequate patent protection would have a material adverse effect on us and may adversely affect our ability to enter into, or affect the terms of, any arrangement for the marketing or sale of any product.

Our patents may be challenged by others.

We could incur substantial costs in patent proceedings, including interference proceedings before the United States Patent and Trademark Office, and comparable proceedings before similar agencies in other countries, in connection with any claims that may arise in the future. These proceedings could result in adverse decisions about the patentability of our inventions and products, as well as about the enforceability, validity, or scope of protection afforded by the patents.

If we are unable to maintain the confidentiality of our trade secrets and proprietary knowledge, others may develop technology and products that could prevent the successful commercialization of our products.

We rely on trade secrets and other unpatented proprietary information in our product development activities. To the extent we rely on trade secrets and unpatented know-how to maintain our competitive technological position, there can be no assurance that others may not independently develop the same or similar technologies. We seek to protect our trade secrets and proprietary knowledge, in part, through confidentiality agreements with our employees, consultants, advisors and contractors. These agreements may not be sufficient to effectively prevent disclosure of our confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure of such information. If our employees, consultants, advisors, or contractors develop inventions or processes independently that may be applicable to our products, disputes may arise about ownership of proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property but may remain the property of those persons or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection, for any reason, could harm our business.

If we infringe on the intellectual property rights of others, our business may be harmed.

It is possible that the manufacture, use or sale of our pressure cycling technology products or services may infringe patent or other intellectual property rights of others. We may be unable to avoid infringement of the patent or other intellectual property rights of others and may be required to seek a license, defend an infringement action, or challenge the validity of the patents or other intellectual property rights in court. We may be unable to secure a license on terms and conditions acceptable to us, if at all. Also, we may not prevail in any patent or other intellectual property rights litigation. Patent or other intellectual property rights litigation is costly and time-consuming, and there can be no assurance that we will have sufficient resources to bring any possible litigation related to such infringement to a successful conclusion. If we do not obtain a license under such patents or other intellectual property rights, or if we are found liable for infringement, or if we are unsuccessful in having such patents declared invalid, we may be liable for significant monetary damages, may encounter significant delays in successfully commercializing and developing our pressure cycling technology products, or may be precluded from participating in the manufacture, use, or sale of our pressure cycling technology products or services requiring such licenses.

We may be unable to adequately respond to rapid changes in technology and the development of new industry standards.

The introduction of products and services embodying new technology and the emergence of new industry standards may render our existing pressure cycling technology products and related services obsolete and unmarketable if we are unable to adapt to change. We may be unable to allocate the funds necessary to improve our current products or introduce new products to address our customers' needs and respond to technological change. In the event that other companies develop more technologically advanced products, our competitive position relative to such companies would be harmed.

We may not be able to compete successfully with others that are developing or have developed competitive technologies and products.

A number of companies have developed, or are expected to develop, products that compete or will compete with our products. We compete with companies that have existing technologies for the extraction of nucleic acids, proteins and small molecules from cells and tissues, including but not limited to methods such as mortar and pestle, sonication, rotor-stator homogenization, French press, bead beating, freezer milling, enzymatic digestion, and chemical dissolution.

We are aware that there are additional companies pursuing new technologies with similar goals to the products developed or being developed by us. Some of the companies with which we now compete, or may compete in the future, have or may have more extensive research, marketing, and manufacturing capabilities, more experience in genomics and proteomics sample preparation, protein purification, pathogen inactivation, immunodiagnostics, and DNA sequencing and significantly greater technical, personnel and financial resources than we do, and may be better positioned to continue to improve their technology to compete in an evolving industry. To compete, we must be able to demonstrate to potential customers that our products provide improved performance and capabilities. Our failure to compete successfully could harm our business and prospects.

We will need to increase the size of our organization and may experience difficulties in managing growth.

We are a small company with a minimal number of employees. We expect to experience a period of expansion in headcount, facilities, infrastructure and overhead and anticipate that further expansion will be required to address potential growth and market opportunities. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate new managers. Our future financial performance and its ability to compete effectively will depend, in part, on its ability to manage any future growth effectively.

Provisions in our articles of organization and bylaws may discourage or frustrate stockholders' attempts to remove or replace our current management.

Our articles of organization and bylaws contain provisions that may make it more difficult or discourage changes in our management that our stockholders may consider to be favorable. These provisions include:

- a classified board of directors;

- advance notice for stockholder nominations to the board of directors;
- limitations on the ability of stockholders to remove directors; and
- a provision that allows a majority of the directors to fill vacancies on the board of directors.

These provisions could prevent or frustrate attempts to make changes in our management that our stockholders consider to be beneficial and could limit the price that our stockholders might receive in the future for shares of our common stock.

The costs of compliance with the reporting obligations of the Exchange Act, and with the requirements of the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Consumer Protection Act, may place a strain on our limited resources and our management’s attention may be diverted from other business concerns.

As a result of the regulatory requirements applicable to public companies, we incur legal, accounting, and other expenses that are significant in relation to the size of our Company. In addition, the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules subsequently implemented by the SEC and OTC Markets Group, Inc., have increased and will continue to increase our legal and financial compliance costs and may make some activities more time-consuming. These requirements have placed and will continue to place a strain on our systems and on our management and financial resources.

Certain of our net deferred tax assets could be substantially limited if we experience an ownership change as defined in the Internal Revenue Code.

Certain of our net operating losses (“NOLs”) give rise to net deferred tax assets. Our ability to utilize NOLs and to offset our future taxable income and/or to recover previously paid taxes would be limited if we were to undergo an “ownership change” within the meaning of Section 382 of the Internal Revenue Code (the “Code”). In general, an “ownership change” occurs whenever the percentage of the stock of a corporation owned by “5 percent shareholders,” within the meaning of Section 382 of the Code, increases by more than 50 percentage points over the lowest percentage of the stock of such corporation owned by such “5 percent shareholders” at any time over the preceding three years.

An ownership change under Section 382 of the Code would establish an annual limitation on the amount of NOLs we could utilize to offset our taxable income in any single taxable year to an amount equal to (i) the product of a specified rate, which is published by the U.S. Treasury, and the aggregate value of our outstanding stock plus; and (ii) the amount of unutilized limitation from prior years. The application of these limitations might prevent full utilization of the deferred tax assets attributable to our NOLs. We may have or will have experienced an ownership change as defined by Section 382 through the sale of equity and, therefore, we will consider whether the sale of equity units will result in limitations of our net operating losses under Section 382 when we start to generate taxable income. However, whether a change in ownership occurs in the future is largely outside of our control, and there can be no assurance that such a change will not occur.

We continue to face risks related to Novel Coronavirus (COVID-19) which could continue to significantly disrupt our research and development, operations, sales, and financial results.

Our business was adversely impacted by the effects of the Novel Coronavirus (COVID-19). In addition to global macroeconomic effects, the Novel Coronavirus (COVID-19) outbreak and any other related adverse public health developments could continue to cause disruption to our operations, research and development, and sales activities. Our third-party manufacturers, third-party distributors, and our customers have been and will be disrupted by worker absenteeism, quarantines and restrictions on employees’ ability to work, office and factory closures, disruptions to ports and other shipping infrastructure, border closures, or other travel or health-related restrictions. Depending on the magnitude of such effects on our activities or the operations of our third-party manufacturers and third-party distributors, the supply of our products will be delayed, which could adversely affect our business, operations and customer relationships. In addition, the Novel Coronavirus (COVID-19) or other disease outbreak will in the short-run and may over the longer term adversely affect the economies and financial markets of many countries, resulting in an economic downturn that will affect demand for our products and impact our operating results. There can be no assurance that any decrease in sales resulting from the Novel Coronavirus (COVID-19) will be offset by increased sales in subsequent periods. Although the magnitude of the impact of the Novel Coronavirus (COVID-19) outbreak on our business and operations remains uncertain, the continued spread of the Novel Coronavirus (COVID-19) or the occurrence of other epidemics and the imposition of related public health measures and travel and business restrictions will adversely impact our business, financial condition, operating results and cash flows. In addition, we have experienced and will experience disruptions to our business operations resulting from quarantines, self-isolations, or other movement and restrictions on the ability of our employees to perform their jobs that may impact our ability to develop and design our products in a timely manner or meet required milestones or customer commitments.

RISKS RELATED TO OWNERSHIP OF OUR SECURITIES

The holders of our Common Stock could suffer substantial dilution due to our corporate financing practices.

The holders of our common stock could suffer substantial dilution due to our corporate financing practices, which, in the past few years, have included private placements and a registered direct offering. As of December 31, 2020, we have issued shares of Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, Series C Convertible Preferred Stock, Series D Convertible Preferred Stock, Series E Convertible Preferred Stock, Series G Convertible Preferred Stock, Series H Convertible Preferred Stock, Series H2 Convertible Preferred Stock, Series J Convertible Preferred Stock, Series K Convertible Preferred Stock and Series AA Convertible Preferred Stock.

As of December 31, 2020, all of the issued shares of Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, Series C Convertible Preferred Stock, and Series E Convertible Preferred Stock had been converted into shares of common stock. As of December 31, 2020, only shares of Series D Convertible Preferred Stock, Series G Convertible Preferred Stock, Series H Convertible Preferred Stock, Series H2 Convertible Preferred Stock, Series J Convertible Preferred Stock, Series K Convertible Preferred Stock and Series AA Convertible Preferred Stock were outstanding. Further, in connection with those private placements and the Series D registered direct offering, we issued warrants to purchase common stock. In addition, as of December 31, 2020, we had issued notes and debentures convertible into common stock at \$2.50 to \$7.50 per common share. If all of the outstanding shares of Series D Convertible Preferred Stock, Series G Convertible Preferred Stock, Series H Convertible Preferred Stock, Series H2 Convertible Preferred Stock, Series J Convertible Preferred Stock, Series K Convertible Preferred Stock and Series AA Convertible Preferred Stock were converted into shares of common stock and all outstanding options and warrants to purchase shares of common stock were exercised and all convertible notes and debentures were converted, each as of December 31, 2020, an additional 28,808,263 shares of common stock would be issued and outstanding. This additional issuance of shares of common stock would cause immediate and substantial dilution to our existing stockholders and could cause a significant reduction in the market price of our common stock.

Sales of a significant number of shares of our common stock in the public market or the perception of such possible sales, could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public markets, which include an offering of our preferred stock or common stock could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity or equity-related securities. We cannot predict the effect that future sales of our common stock or other equity-related securities would have on the market price of our common stock.

Our share price could be volatile and our trading volume may fluctuate substantially.

The price of common stock has been and may in the future continue to be extremely volatile. Many factors could have a significant impact on the future price of our shares of common stock, including:

- our inability to raise additional capital to fund our operations, whether through the issuance of equity securities or debt;
- our failure to successfully implement our business objectives;
- compliance with ongoing regulatory requirements;
- market acceptance of our products;
- technological innovations and new commercial products by our competitors;
- changes in government regulations;
- general economic conditions and other external factors;
- actual or anticipated fluctuations in our quarterly financial and operating results; and
- the degree of trading liquidity in our shares of common stock.

A decline in the price of our shares of common stock could affect our ability to raise further working capital and adversely impact our ability to continue operations.

The relatively low price of our shares of common stock, and a decline in the price of our shares of common stock, could result in a reduction in the liquidity of our common stock and a reduction in our ability to raise capital. Because a significant portion of our operations has been and will continue to be financed through the sale of equity securities, a decline in the price of our shares of common stock could be especially detrimental to our liquidity and our operations. Such reductions and declines may force us to reallocate funds from other planned uses and may have a significant negative effect on our business plans and operations, including our ability to continue our current operations. If the price for our shares of common stock declines, it may be more difficult to raise additional capital. If we are unable to raise sufficient capital, and we are unable to generate funds from operations sufficient to meet our obligations, we will not have the resources to continue our operations.

The market price for our shares of common stock may also be affected by our ability to meet or exceed expectations of analysts or investors. Any failure to meet these expectations, even if minor, may have a material adverse effect on the market price of our shares of common stock.

If we issue additional securities in the future, it will likely result in the dilution of our shares of existing stockholders.

As of December 31, 2020, there were 4,168,324 shares of common stock issued and outstanding. Similarly, at such time, there were no shares of Series A Junior Participating Preferred Stock; Series A Convertible Preferred Stock; Series B Convertible Preferred Stock; Series C Convertible Preferred Stock; and Series E Convertible Preferred Stock. As of December 31, 2020 there were 300 shares of Series D Convertible Preferred Stock issued and outstanding and convertible into 25,000 shares of common stock, 80,570 shares of Series G Convertible Preferred Stock issued and outstanding convertible into 26,857 shares of common stock, 10,000 shares of Series H Convertible Preferred Stock issued and outstanding convertible into 33,334 shares of common stock, 21 shares of Series H2 Convertible Preferred Stock issued and outstanding convertible into 70,000 shares of common stock, 3,458 shares of Series J Convertible Preferred Stock issued and outstanding convertible into 115,267 shares of common stock, 6,880 shares of Series K Convertible Preferred Stock issued and outstanding convertible into 229,334 shares of common stock and 8,043 shares of Series AA Convertible Preferred Stock issued and outstanding convertible into 8,043,000 shares of common stock.

As of December 31, 2020, there were outstanding options and warrants to purchase an aggregate of 15,790,603 shares of common stock; and debt convertible into 4,474,868 shares of common stock. From time to time, we also may increase the number of shares available for issuance in connection with our equity compensation plan, we may adopt new equity compensation plans, and we may issue awards to our employees and others who provide services to us outside the terms of our equity compensation plans. Our board of directors may fix and determine the designations, rights, preferences or other variations of each class or series of preferred stock and may choose to issue some or all of such shares to provide additional financing in the future.

The issuance of any securities for acquisition, licensing or financing efforts, upon conversion of any preferred stock or exercise of warrants, pursuant to our equity compensation plans, or otherwise may result in a reduction of the book value and market price of the outstanding shares of our common stock. If we issue any such additional securities, such issuance will cause a reduction in the proportionate ownership and voting power of all current stockholders. Further, such issuance may result in a change in control of our Company.

Financial Industry Regulatory Authority (“FINRA”) sales practice requirements may also limit a stockholder’s ability to buy and sell our common stock.

FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer’s financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our common stock and have an adverse effect on the market for our shares.

Our Common Stock is subject to the “Penny Stock” rules of the SEC and the trading market in our securities is limited, which makes transactions in our stock cumbersome and may reduce the value of an investment in our stock.

The Securities and Exchange Commission has adopted Rule 15c-9 which establishes the definition of a “penny stock,” for the purposes relevant to us, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

- That a broker or dealer approve a person’s account for transactions in penny stocks; and
- The broker or dealer receives from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person’s account for transactions in penny stocks, the broker or dealer must:

- Obtain financial information and investment experience objectives of the person; and
- Make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the Commission relating to the penny stock market, which, in highlight form:

- Sets forth the basis on which the broker or dealer made the suitability determination; and
- That the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the “penny stock” rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

We have never declared or paid a cash dividend on our common stock and we do not expect to pay cash dividends on our common stock in the foreseeable future.

Our shares of Series D Convertible Preferred Stock are entitled to certain rights, privileges and preferences over our common stock, including a preference upon a liquidation of our Company, which will reduce amounts available for distribution to the holders of our common stock.

The holders of our shares of Series D are entitled to payment, prior to payment to the holders of common stock in the event of liquidation of the Company. If we are dissolved, liquidated or wound up at a time when the Series D Preferred Stock remain outstanding, the holders of the Series D Preferred Stock will be entitled to receive only an amount equal to the liquidation preference (as it may be adjusted from time to time), plus any accumulated and unpaid dividends, to the extent that we have funds legally available. Any remaining assets will be distributable to holders of our other equity securities.

Shares eligible for future sale may adversely affect the market.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act, subject to certain limitations. In general, pursuant to amended Rule 144, non-affiliate stockholders may sell freely after six months subject only to the current public information requirement. Affiliates may sell after six months subject to the Rule 144 volume, manner of sale (for equity securities), current public information and notice requirements. Any substantial sales of our common stock pursuant to Rule 144 may have a material adverse effect on the market price of our common stock.

We currently do not intend to pay dividends on our common stock. As result, your only opportunity to achieve a return on your investment is if the price of our common stock appreciates.

We currently do not expect to declare or pay dividends on our common stock. In addition, in the future we may enter into agreements that prohibit or restrict our ability to declare or pay dividends on our common stock. As a result, your only opportunity to achieve a return on your investment will be if the market price of our common stock appreciates and you sell your shares at a profit.

We could issue additional common stock, which might dilute the book value of our Common Stock.

Our Board of Directors has authority, without action or vote of our shareholders, to issue all or a part of our authorized but unissued shares. Such stock issuances could be made at a price that reflects a discount or a premium from the then-current trading price of our common stock. In addition, in order to raise capital, we may need to issue securities that are convertible into or exchangeable for our common stock. These issuances would dilute the percentage ownership interest, which would have the effect of reducing your influence on matters on which our shareholders vote and might dilute the book value of our common stock. You may incur additional dilution if holders of stock warrants or options, whether currently outstanding or subsequently granted, exercise their options, or if warrant holders exercise their warrants to purchase shares of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not Applicable.

ITEM 2. PROPERTIES.

Our corporate office is currently located at 14 Norfolk Avenue, South Easton, Massachusetts 02375. We are currently paying \$6,950 per month, on a lease extension, signed on December 30, 2020, that expires December 31, 2021, for our corporate office. We expanded our space to include offices, warehouse and a loading dock on the first floor starting May 1, 2017 with a monthly rent increase already reflected in the current payments.

On October 18, 2017 we signed a lease extension for our lab space in Medford, MA. The lease will now expire on December 30, 2023 and requires monthly payments of \$7,282 starting January 1, 2021 subject to annual cost of living increases. The lease shall be automatically extended for additional three years unless either party terminates at least six months prior to the expiration of the current lease term.

ITEM 3. LEGAL PROCEEDINGS.

We are not currently involved in any litigation that we believe could have a material adverse effect on our financial condition or results of operations. There is no action, suit, or proceeding by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the executive officers of our Company or our subsidiary, threatened against or affecting our Company, our common stock, our subsidiary or of our companies or our subsidiary's officers or directors in their capacities as such, in which an adverse decision could have a material adverse effect.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is currently traded on the OTCQB tier of the OTC Markets under the trading symbol “PBIO.”

Authorized Capital

As of December 31, 2020, we were authorized to issue 100,000,000 shares of common stock, \$.01 par value, and 1,000,000 shares of preferred stock, \$.01 par value. Of the 1,000,000 shares of preferred stock, 20,000 shares were designated as Series A Junior Participating Preferred Stock, 313,960 shares as Series A Convertible Preferred Stock, 279,256 shares as Series B Convertible Preferred Stock, 88,098 shares as Series C Convertible Preferred Stock, 850 shares as Series D Convertible Preferred Stock, 500 shares as Series E Convertible Preferred Stock, 240,000 shares as Series G Convertible Preferred Stock, 10,000 shares as Series H Convertible Preferred Stock, 21 shares as Series H2 Convertible Preferred Stock, 6,250 shares as Series J Convertible Preferred Stock, 15,000 shares as Series K Convertible Preferred Stock and 10,000 shares of Series AA Convertible Preferred Stock.

As of December 31, 2020, there were 4,168,324 shares of common stock issued and outstanding. Similarly, at such time, there were no shares of outstanding Series A Junior Participating Preferred Stock; Series A Convertible Preferred Stock; Series B Convertible Preferred Stock; Series C Convertible Preferred Stock; and Series E Convertible Preferred Stock. As of December 31, 2020 there were 300 shares of Series D Convertible Preferred Stock issued and outstanding and convertible into 25,000 shares of common stock, 80,570 shares of Series G Convertible Preferred Stock issued and outstanding convertible into 26,857 shares of common stock, 10,000 shares of Series H Convertible Preferred Stock issued and outstanding convertible into 33,334 shares of common stock, 21 shares of Series H2 Convertible Preferred Stock issued and outstanding convertible into 70,000 shares of common stock, 3,458 shares of Series J Convertible Preferred Stock issued and outstanding convertible into 115,267 shares of common stock, 6,880 shares of Series K Convertible Preferred Stock issued and outstanding convertible into 229,334 shares of common stock and 8,043 shares of Series AA Convertible Preferred Stock issued and outstanding convertible into 8,043,000 shares of common stock.

Approximate Number of Equity Security Holders

As of December 31, 2020, there were approximately 157 stockholders of record. Because shares of our common stock are held by depositaries, brokers and other nominees, the number of beneficial holders of our shares is substantially larger than the number of stockholders of record.

Dividends

We have never declared or paid any cash dividends on common stock and do not plan to pay any cash dividends on common stock in the foreseeable future.

As of December 31, 2020, dividends issued or to be issued on convertible preferred stock for the years ended December 31, 2020 and 2019 are outlined in the table below.

Dividends paid in common stock or cash For The Year Ended December 31,			Dividends Payable As Of December 31,		
	2020	2019		2020	2019
Series D	\$ -	\$ -	Series D	\$ -	\$ -
Series G	-	-	Series G	-	-
Series H	-	-	Series H	-	-
Series H2	-	-	Series H2	-	-
Series J	-	-	Series J	-	-
Series K	-	-	Series K	-	-
Series AA	299,709	205,100	Series AA	3,247,202	2,025,821
	<u>\$ 299,709</u>	<u>\$ 205,100</u>		<u>\$ 3,247,202</u>	<u>\$ 2,025,821</u>

Unregistered Sales of Equity Securities and Use of Proceeds

During the year ended December 31, 2020, we issued securities that were not registered under the Securities Act, and were not previously disclosed in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K as listed below. Except where noted, all of the securities discussed in this Item 5 were issued in reliance on the exemption under Section 4(a)(2) of the Securities Act.

Except where noted, all the securities discussed in this Part II, Item 5 were issued in reliance on the exemption under Section 4(a)(2) of the Securities Act. This Part II, Item 5 does not discuss issuances previously disclosed in Form 8-Ks, Form 10-Qs, or the Form 10-K filed by the Company.

On various dates in the quarter ended December 31, 2020 the Company issued a total of 329,068 shares of restricted common stock at a fair value of \$638,901 to accredited investors. 73,700 shares with a fair value of \$66,644 were issued in conjunction with the signing of new convertible loans; 51,800 shares with a fair value of \$91,114 were issued to investor relations firms for services rendered; 161,521 shares with a fair value of \$389,899 were issued upon the conversion of convertible loans; and 34,617 shares with a fair value of \$78,335 were issued in lieu of cash for the 8% dividend on Series AA Convertible Preferred Stock and 7,430 of the shares with a fair value of \$12,909 were issued for interest payments on debt.

ITEM 6. SELECTED FINANCIAL DATA.

Not Applicable.

ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION.

OVERVIEW

We are a leader in the development & sale of innovative, broadly enabling, pressure-based platform solutions for the worldwide life sciences industry. Our solutions 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 has been 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 platform) 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.

Patents

PBI has 14 United States granted patents and one foreign granted patent (Japan: 5587770, EXTRACTION AND PARTITIONING OF MOLECULES) covering multiple applications of PCT in the life sciences field. PBI also has 19 pending patents in the USA, Canada, Europe, Australia, China, and Taiwan.

Primary Fields of Use and Application for PCT

Sample preparation is widely regarded as a significant impediment to research and discovery and sample extraction is generally regarded as one of the key parts of sample preparation. The process of preparing samples for genomic, proteomic, lipidomic, and small molecule studies includes a crucial step called sample extraction or sample disruption. This is the process of extracting biomolecules such as nucleic acid i.e., DNA and/or RNA, proteins, lipids, or small molecules from the plant or animal cells and tissues that are being studied. Our current commercialization efforts are based upon our belief that pressure cycling technology provides a superior solution for sample extraction when compared to other available technologies or procedures and thus might significantly improve the quality of sample preparation, and thus the quality of the test result.

Within the broad field of biological sample preparation, in particular sample extraction, we focus the majority of our PCT and constant pressure (“CP”) product development efforts in three specific areas: biomarker discovery (primarily through mass spectrometric analysis), forensics, and histology. We believe that our existing PCT and CP-based instrumentation and related consumable products fill an important and growing need in the sample preparation market for the safe, rapid, versatile, reproducible and quality extraction of nucleic acids, proteins, lipids, and small molecules from a wide variety of plant, animal, and microbiological cells and tissues.

Biomarker Discovery and Precision Medicine

The most commonly used technique worldwide for the preservation of cancer and other tissues for long-term storage and subsequent pathology evaluation is to process them into formalin-fixed, paraffin-embedded (“FFPE”) samples. We believe that the quality and analysis of FFPE tissues is highly problematic, and that PCT offers significant advantages over current processing methods, including standardization, speed, biomolecule recovery, and safety.

Our customers include researchers at academic laboratories, government agencies, biotechnology companies, pharmaceutical companies and other life science institutions in the Americas, Europe, Asia, Africa and Australia. Our goal is to continue aggressive market penetration in these target areas. We also believe that there is a significant opportunity to sell and/or lease additional Barocycler® instrumentation to additional laboratories within current customer organizations.

If we are successful in commercializing PCT in applications beyond our current focus area of genomic, proteomic, lipidomic, and small molecule sample preparation, and if we are successful in our attempts to attract additional capital, our potential customer base could expand to include hospitals, reference laboratories, pharmaceutical manufacturing plants and other sites involved in each specific application. If we are successful in forensics, our potential customers could be forensic laboratories, military and other government agencies. If we are successful in biomarker discovery and precision medicine - specifically the extraction of biomolecules from FFPE tissues, our potential customers could be pharmaceutical companies, hospitals, and laboratories focused on drug discovery or differentiation of disease states, subtypes and susceptibility to alternative treatments.

Forensics

The detection of DNA has become a part of the analysis of forensic samples by laboratories and criminal justice agencies worldwide in their efforts to identify the perpetrators of violent crimes and missing persons. Scientists from the University of North Texas and Florida International University have reported improvements in DNA yield from forensic samples (e.g., bone and hair) when using the PCT platform in the sample preparation process. We believe that PCT may be capable of differentially extracting DNA from sperm cells and female epithelial cells captured in swabs collected from rape victims and subsequently stored in rape kits. We also believe that there are many completed rape kits that remain untested for reasons such as cost, time and quality of results. We further believe that the ability to differentially extract DNA from sperm and not epithelial cells could reduce the cost of such testing, while increasing the quality, safety and speed of the testing process.

Going Concern

We have experienced negative cash flows from operations since our inception. As of December 31, 2020, we did not have adequate working capital resources to satisfy our current liabilities and as a result we have substantial doubt about our ability to continue as a going concern. Based on our current projections, including equity financing subsequent to December 31, 2020, we believe we will have the cash resources that will enable us to continue to fund normal operations into the foreseeable future.

The audit report issued by our independent registered public accounting firm on our audited consolidated financial statements for the fiscal year ended December 31, 2020, contains an explanatory paragraph regarding our ability to continue as a going concern. The audit report issued by our independent registered public accounting firm for our financial statements for the fiscal year ended December 31, 2020 states that our auditing firm has substantial doubt in our ability to continue as a going concern due to the risk that we may not have sufficient cash and liquid assets to cover our operating and capital requirements for the next twelve-month period; and, if sufficient cash cannot be obtained, we would have to substantially alter, or possibly even discontinue, operations. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The conditions described above could adversely affect our ability to obtain additional financing on favorable terms, if at all, and may cause investors to have reservations about our long-term prospects, and may adversely affect our relationships with customers. There can be no assurance that our auditing firm will not issue the same opinion in the future. If we cannot successfully continue as a going concern, our stockholders may lose their entire investment in us.

RESULTS OF OPERATIONS

Year Ended December 31, 2020 as compared with December 31, 2019

Products and Services Revenue

Revenue from the sale of products and services was \$1,220,591 in the year ended December 31, 2020 compared with \$1,809,993 in the year ended December 31, 2019, a 33% decrease. This decrease was primarily attributable to the negative impact that the COVID-19 pandemic had on our operations and the operations of our customers. Revenue included sales of both PBI and CS's pressure-based products, and sales of Barofold Contract Services. Sales of instrumentation decreased in 2020 by \$124,287 or 19%, from \$653,630 in 2019 to \$529,343 in 2020. Sales of consumables were \$204,889 for the year ended December 31, 2020 compared to \$298,385 for the same period in 2019, a decrease of \$93,496 or 31%. Sales of Barofold Contract Services decreased from \$380,800 in 2019 to \$160,085 in 2020. Products, Services, and Other Revenue included \$12,663 from non-cash transactions in the current year while the prior year included non-cash transactions of \$59,456. Revenue from non-cash transactions was recognized based on the carrying value of the assets involved per ASC 845.

Cost of Products and Services

The cost of products and services was \$582,854 for the year ended December 31, 2020, compared with \$1,197,061 in 2019. Our overall gross profit margin increased to 52% for the year ended December 31, 2020 from 34% for the year ended December 31, 2019.

Research and Development

Research and development expenses were \$1,143,420 for 2020 compared to \$1,157,222 in 2019, a decrease of \$13,802 or 1%.

Selling and Marketing

Selling and marketing expenses were \$649,783 in 2020 compared to \$680,629 in 2019, a decrease of \$30,846, or 5%.

General and Administrative

General and administrative costs were \$3,430,321 in the year ended December 31, 2020, as compared with \$4,580,615 in 2019, a decrease of \$1,150,294 or 25%. The decrease in General and Administrative expense is attributable to a \$546,000 decrease in stock-based compensation and a \$531,000 decrease in investor relations expense.

Operating Loss

Our operating loss was \$4,585,787 for the year ended December 31, 2020 as compared to \$5,805,534 for the prior year, a decrease of \$1,219,747 or 21%. This decrease in operating loss was due primarily to lower general and administrative expenses.

Interest Expense

Interest expense totaled \$8,344,236 for the year ended December 31, 2020 as compared to interest expense of \$5,281,480 for the year ended December 31, 2019. The increase in interest expense in the year ended December 31, 2020, compared to the corresponding prior period is attributable to the increase in convertible and other debt.

Unrealized gain on investment in equity securities

Unrealized gain on investments in equity securities was \$500,358 for the year ended December 31, 2020 compared to \$4,018 for the year ended December 31, 2019. The reported increase was attributable to the increase in the market price of the Company's investment in Everest.

Loss on extinguishment of liabilities

In connection with payments of interest in common stock and debt extensions, we calculated net losses of \$3,575,878 in the year ended December 31, 2020 and net losses of \$795,089 in the year ended December 31, 2019. The increase is attributable to extension fees incurred and warrants issued for the recent Standstill and forbearance Agreements and other loan extensions and settlements of merchant loans.

Income Taxes

In the year ended December 31, 2020 we recorded a tax benefit of \$0, compared a tax benefit of \$217,168 in the year ended December 31, 2019. The change in the income tax provision in 2020 was attributable to the 2019 recognition of a tax benefit for corporate alternative minimum tax paid in past years.

Net Loss attributable to common stockholders

During the year ended December 31, 2020, we recorded a net loss attributable to common shareholders of \$17,584,710 or (\$5.32) per share, as compared with a net loss available to common shareholders of \$15,868,083 or (\$7.98) per share during the year ended December 31, 2019. This decrease in the loss per share is attributable to the reported \$2.6 million deemed dividend on a beneficial conversion feature and a 66% increase in weighted average shares outstanding in the year ended December 31, 2020.

LIQUIDITY AND FINANCIAL CONDITION

As of December 31, 2020, we did not have adequate working capital resources to satisfy our current liabilities. We have been successful in raising cash through debt and equity offerings in the past. We have efforts in place to continue to raise cash through debt and equity offerings.

We believe our current and projected capital raising plans, and our projected continued increases in revenue, will enable us to extend our cash resources for the foreseeable future. Although we have successfully completed equity and debt financings and reduced expenses in the past, we cannot assure you that our plans to address these matters in the future will be successful.

We believe we will need approximately \$12 million in additional capital to fund our three-pronged operational plan, which was designed to help increase revenues and reach profitability, by:

- A. reducing/eliminating debt and cleaning up the balance sheet;
- B. funding UST development, instrument build and commercialization;
- C. facilitating up-listing PBIO to a major exchange; and
- D. providing a minimum of two years of operational and growth capital

However, if we are unable to obtain such funds through sales, the capital markets or other source of financing on acceptable terms, or at all, we will likely be required to cease our operations, pursue a plan to sell our operating assets, or otherwise modify our business strategy, which could materially harm our future business prospects. These conditions raise substantive doubt about our ability to continue as a going concern.

Net cash used in operating activities was \$4,883,194 for the year ended December 31, 2020 as compared with \$6,327,578 for the year ended December 31, 2019.

Net cash used in investing activities for the year ended December 31, 2020 totaled \$796,663 compared to \$23,375 for the year ended December 31, 2019. Cash capital expenditures in the current year included loan advances to our pending merger partner and purchases of laboratory and technology equipment.

Net cash provided by financing activities for the year ended December 31, 2020 was \$5,668,772 as compared with \$6,277,460 for the year ended December 31, 2019.

In 2020,

- A. \$150,000 in aggregate net proceeds were raised from sale of Series AA Convertible Preferred Stock
- B. Loans in the aggregate amount of \$9,871,039 were received during the year and we made payments on new and existing debt of \$4,352,267.

Our common stock is currently traded on the OTCQB tier of the OTC Markets under the trading symbol "PBIO."

COMMITMENTS AND CONTINGENCIES

Battelle Memorial Institute

In December 2008, we entered into an exclusive patent license agreement with the Battelle Memorial Institute (“*Battelle*”). The licensed technology is described in the patent application filed by Battelle on July 31, 2008 (US serial number 12/183,219). This application includes subject matter related to a method and a system for improving the analysis of protein samples including, through an automated system, utilizing pressure and a pre-selected agent to obtain a digested sample in a significantly shorter period of time than current methods, while maintaining the integrity of the sample throughout the preparatory process. Pursuant to the terms of the agreement, we paid Battelle a non-refundable initial fee of \$35,000. In addition to royalty payments on net sales on “licensed products,” we are obligated to make minimum royalty payments for each year we retain the rights outlined in the patent license agreement; and, we are required to have our first commercial sale of the licensed products within one year following the issuance of the patent covered by the licensed technology. After re-negotiating the terms of the contract in 2013, the minimum annual royalty was \$1,200 in 2014 and \$2,000 in 2015; the minimum royalties were \$3,000 in 2016, \$4,000 in 2017 and \$5,000 in 2018 and each calendar year thereafter during the term of the agreement.

Target Discovery Inc.

In March 2010, we signed a strategic product licensing, manufacturing, co-marketing, and collaborative research and development agreement with Target Discovery Inc. (“*TDI*”), a related party. Under the terms of the agreement, we have been licensed by TDI to manufacture and sell a highly innovative line of chemicals used in the preparation of tissues for scientific analysis (“*TDI reagents*”). The TDI reagents were designed for use in combination with our pressure cycling technology. The respective companies believe that the combination of PCT and the TDI reagents can fill an existing need in life science research for an automated method for rapid extraction and recovery of intact, functional proteins associated with cell membranes in tissue samples. We did not incur any royalty obligation under this agreement in 2017 or 2016. We executed an amendment to this agreement on October 1, 2016 wherein we agreed to pay a monthly fee of \$1,400 for the use of a lab bench, shared space and other utilities, and \$2,000 per day for technical support services as needed. Mr. Jeffrey N. Peterson, the chief executive officer of TDI, has served as a director of the Company since July 2011 and as Chairman of the Board starting in 2012.

Severance and Change of Control Agreements

Each of Mr. Schumacher, Dr. Ting, and Dr. Lazarev, executive officers of the Company, are entitled to receive a severance payment if terminated by us without cause. The severance benefits would include a payment in an amount equal to one year of such executive officer's annualized base salary compensation plus accrued paid time off. Additionally, the officer will be entitled to receive medical and dental insurance coverage for one year following the date of termination.

Pursuant to severance agreements with each of Mr. Schumacher, Dr. Ting, and Dr. Lazarev, each such executive officer is entitled to receive a change of control payment in an amount equal to one year (other than Mr. Schumacher) of such executive officer's annualized base salary compensation, accrued paid time off, and medical and dental coverage, in the event the officer is terminated as a result of a change of control of our Company. In the case of Mr. Schumacher, his payment is equal to two years of annualized base salary compensation, accrued paid time off, and two years of medical and dental coverage.

Pursuant to our equity incentive plans, any unvested stock options held by a named executive officer will become fully vested upon a change in control (as defined in the 2005 Equity Incentive Plan) of our Company.

Lease Commitments

We lease building space under non-cancelable leases in South Easton, MA and lab space in Medford, MA. Rental costs are expensed as incurred. During 2020 and 2019 we incurred \$182,783 and \$181,106, respectively, in rent expense for the use of our corporate office and research and development facilities.

Following is a schedule by years of future minimum rental payments required under operating leases with initial or remaining non-cancelable lease terms in excess of one year as of December 31, 2020:

2021	\$	170,783
2022		87,383
2023		87,383
Thereafter		-
	\$	<u>345,549</u>

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as of December 31, 2020 and December 31, 2019.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Principles of Consolidation

The consolidated financial statements include the accounts of Pressure BioSciences, Inc., and its wholly-owned subsidiary PBI BioSeq, Inc. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

To prepare our consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, we are required to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In addition, significant estimates were made in projecting future cash flows to quantify deferred tax assets, the costs associated with fulfilling our warranty obligations for the instruments that we sell, and the estimates employed in our calculation of fair value of stock options awarded and warrant derivative liability. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from the estimates and assumptions used.

Revenue Recognition

We recognize revenue in accordance with FASB ASC 606, *ASC 606, Revenue from Contracts with Customers*, and *ASC 340-40, Other Assets and Deferred Costs—Contracts with Customers*. Revenue is measured based on a consideration specified in a contract with a customer, and excludes any sales incentives and amounts collected on behalf of third parties. We enter into sales contracts that may consist of multiple distinct performance obligations where certain performance obligations of the sales contract are not delivered in one reporting period. We measure and allocate revenue according to ASC 606-10.

We identify a performance obligation as distinct if both the following criteria are true: the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. Determining the standalone selling price ("SSP") and allocation of consideration from a contract to the individual performance obligations, and the appropriate timing of revenue recognition, is the result of significant qualitative and quantitative judgments. Management considers a variety of factors such as historical sales, usage rates, costs, and expected margin, which may vary over time depending upon the unique facts and circumstances related to each performance obligation in making these estimates. While changes in the allocation of the SSP between performance obligations will not affect the amount of total revenue recognized for a particular contract, any material changes could impact the timing of revenue recognition, which would have a material effect on our financial position and result of operations. This is because the contract consideration is allocated to each performance obligation, delivered or undelivered, at the inception of the contract based on the SSP of each distinct performance obligation.

Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by the Company from a customer, are excluded from revenue.

Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of revenues as consistent with treatment in prior periods.

Our current Barocycler® instruments require a basic level of instrumentation expertise to set-up for initial operation. To support a favorable first experience for our customers, upon customer request, and for an additional fee, will send a highly trained technical representative to the customer site to install Barocyclers® that we sell, lease, or rent through our domestic sales force. The installation process includes uncrating and setting up the instrument, followed by introductory user training. Our sales arrangements do not provide our customers with a right of return. Any shipping costs billed to customers are recognized as revenue.

The majority of our instrument and consumable contracts contain pricing that is based on the market price for the product at the time of delivery. Our obligations to deliver product volumes are typically satisfied and revenue is recognized when control of the product transfers to our customers. Concurrent with the transfer of control, we typically receive the right to payment for the shipped product and the customer has significant risks and rewards of ownership of the product. Payment terms require customers to pay shortly after delivery and do not contain significant financing components.

Revenue from scientific services customers is recognized upon completion of each stage of service as defined in service agreements.

We apply ASC 845, "Accounting for Non-Monetary Transactions", to account for products and services sold through non-cash transactions based on the fair values of the products and services involved, where such values can be determined. Non-cash exchanges would require revenue to be recognized at recorded cost or carrying value of the assets or services sold if any of the following conditions apply:

- a) The fair value of the asset or service involved is not determinable.
- b) The transaction is an exchange of a product or property held for sale in the ordinary course of business for a product or property to be sold in the same line of business to facilitate sales to customers other than the parties to the exchange.
- c) The transaction lacks commercial substance.

We currently record revenue for non-cash transactions at recorded cost or carrying value of the assets or services sold.

We account for lease agreements of our instruments in accordance with ASC 842, *Leases*. We record revenue over the life of the lease term and we record depreciation expense on a straight-line basis over the thirty-six-month estimated useful life of the Barocycler® instrument. The depreciation expense associated with assets under lease agreement is included in the "Cost of PCT products and services" line item in our accompanying consolidated statements of operations. Many of our lease and rental agreements allow the lessee to purchase the instrument at any point during the term of the agreement with partial or full credit for payments previously made. We pay all maintenance costs associated with the instrument during the term of the leases.

Revenue from government grants is recorded when expenses are incurred under the grant in accordance with the terms of the grant award.

Deferred revenue represents amounts received from grants and service contracts for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. Revenue from service contracts is recorded ratably over the length of the contract.

Transaction price allocated to the remaining performance obligations

The following table includes estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied (or partially unsatisfied) at the end of the reporting period.

<i>In thousands of US dollars (\$)</i>	2021	2022	Total
Extended warranty service	47	20	67

All consideration from contracts with customers is included in the amounts presented above.

Contract Costs

The Company recognizes the incremental costs of obtaining contracts as an expense when incurred if the amortization period of the assets that the Company otherwise would have recognized is one year or less. These costs are included in selling, general, and administrative expenses. The costs to obtain a contract are recorded immediately in the period when the revenue is recognized either upon shipment or installation. The costs to obtain a service contract are considered immaterial when spread over the life of the contract so the Company records the costs immediately upon billing.

Intangible Assets

We have classified as intangible assets, costs associated with the fair value of acquired intellectual property. Intangible assets, including patents, are being amortized on a straight-line basis over sixteen years. We perform an annual review of our intangible assets for impairment. When impairment is indicated, any excess of carrying value over fair value is recorded as a loss. As of December 31, 2020 and 2019, the outstanding balance for intangible assets was \$490,385 and \$576,923, respectively.

Long-Lived Assets

The Company’s long-lived assets are reviewed for impairment in accordance with the guidance of the FASB ASC 360-10-05, *Property, Plant, and Equipment*, whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. Through December 31, 2020, the Company had not experienced impairment losses on its long-lived assets. While our current and historical operating losses and cash flow are indicators of impairment, we performed an impairment test at December 31, 2020 and determined that such long-lived assets were not impaired.

Beneficial Conversion Features

In accordance with FASB ASC 470-20, “Debt with Conversion and Other Options” the Company records a beneficial conversion feature (“BCF”) related to the issuance of convertible debt or preferred stock instruments that have conversion features at fixed rates that are in-the-money when issued. The BCF for the convertible instruments is recognized and measured by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital. The intrinsic value is generally calculated at the commitment date as the difference between the conversion price and the fair value of the common stock or other securities into which the security is convertible, multiplied by the number of shares into which the security is convertible. If certain other securities are issued with the convertible security, the proceeds are allocated among the different components. The portion of the proceeds allocated to the convertible security is divided by the contractual number of the conversion shares to determine the effective conversion price, which is used to measure the BCF. The effective conversion price is used to compute the intrinsic value. The value of the BCF is limited to the basis that is initially allocated to the convertible security.

Accounts Receivable and Allowance for Doubtful Accounts

We maintain allowances for estimated losses resulting from the inability of our customers to make required payments. Judgments are used in determining the allowance for doubtful accounts and are based on a combination of factors. Such factors include historical collection experience, credit policy and specific customer collection issues. In circumstances where we are aware of a specific customer’s inability to meet its financial obligations to us (e.g., due to a bankruptcy filing), we record a specific reserve for bad debts against amounts due to reduce the net recognized receivable to the amount we reasonably believe will be collected. We perform ongoing credit evaluations of our customers and continuously monitor collections and payments from our customers. While actual bad debts have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same bad debt rates that we have in the past. A significant change in the liquidity or financial position of any of our customers could result in the uncollectability of the related accounts receivable and could adversely impact our operating cash flows in that period.

Inventories

Inventories are valued at the lower of cost (average cost) or market (sales price). The cost of Barocyclers consists of the cost charged by the contract manufacturer. The cost of manufactured goods includes material, freight-in, direct labor, and applicable overhead. In assessing the ultimate realization of inventories, management judgment is required to determine the reserve for obsolete or excess inventory. Inventory on hand may exceed future demand either because the product is obsolete, or because the amount on hand is more than can be used to meet future needs. We provide for the total value of inventories that we determine to be obsolete or excess based on criteria such as customer demand and changing technologies. We historically have not experienced significant inaccuracies in computing our reserves for obsolete or excess inventory.

Equity Transactions

We evaluate the proper classification of our equity instruments that embody an unconditional obligation requiring the issuer to redeem it by transferring assets at a determinable date or that contain certain conditional obligations, typically classified as equity, be classified as a liability. We record amortized financing costs associated with our capital raising efforts in our consolidated statements of operations. These include amortization of debt issue costs such as cash, common stock and warrants and other securities issued to finders and placement agents, and amortization of debt discount created by in-the-money conversion features on convertible debt and allocates the proceeds amongst the securities based on relative fair values. We based our estimates and assumptions on the best information available at the time of valuation; however, changes in these estimates and assumptions could have a material effect on the valuation of the underlying instruments.

Stock-Based Compensation

We account for employee and non-employee director stock-based compensation using the fair value method of accounting. Compensation cost arising from stock options to employees and non-employee directors is recognized using the straight-line method over the vesting period, which represents the requisite service or performance period. The calculation of stock-based compensation requires us to estimate several factors, most notably the term, volatility and forfeitures. We estimate the option term using historical terms and estimate volatility based on historical volatility of our common stock over the option's expected term. Expected forfeitures based on historical forfeitures are used in calculating the expense related to stock-based compensation associated with stock awards. Our estimates and assumptions are based on the best information available at the time of valuation; however, changes in these estimates and assumptions could have a material effect on the valuation of the underlying instruments.

Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not Applicable

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
Pressure BioSciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Pressure Biosciences, Inc. and its subsidiary (collectively, the “Company”) as of December 31, 2020 and 2019, and the related consolidated statements of operations, changes in stockholders’ deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has a working capital deficit, has incurred recurring net losses and negative cash flows from operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgements. We determined that there are no critical audit matters.

/s/ *MaloneBailey, LLP*

www.malonebailey.com

We have served as the Company’s auditor since 2015.

Houston, Texas

April 15, 2021

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2020 AND 2019

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
<u>ASSETS</u>		
CURRENT ASSETS		
Cash and cash equivalents	\$ 18,540	\$ 29,625
Accounts receivable	131,228	229,402
Inventories, net of \$342,496 reserve at December 31, 2020 and December 31, 2019	592,767	617,716
Prepaid expenses and other current assets	314,936	213,549
Total current assets	<u>1,057,471</u>	<u>1,090,292</u>
Investment in equity securities	517,001	16,643
Property and equipment, net	16,490	55,590
Right of use asset leases	221,432	76,586
Intangible assets, net	490,385	576,923
TOTAL ASSETS	<u>\$ 2,302,779</u>	<u>\$ 1,816,034</u>
<u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u>		
CURRENT LIABILITIES		
Accounts payable	\$ 771,945	\$ 815,764
Accrued employee compensation	417,578	451,200
Accrued professional fees and other	2,037,806	1,658,452
Other current liabilities	6,330,722	2,949,621
Deferred revenue	47,328	23,248
Convertible debt, net of unamortized discounts of \$3,948,167 and \$619,227, respectively	7,545,670	6,121,338
Other debt, net of unamortized discounts of \$0 and \$1,769, respectively	1,135,469	1,675,667
Operating lease liability	65,193	76,586
Other related party debt	166,000	81,500
Total current liabilities	<u>18,517,711</u>	<u>13,853,376</u>
LONG TERM LIABILITIES		
Long term debt	527,039	-
Operating lease liability – long term	156,239	-
Deferred revenue	19,382	18,065
TOTAL LIABILITIES	<u>19,220,371</u>	<u>13,871,441</u>
COMMITMENTS AND CONTINGENCIES (Note 8)		
STOCKHOLDERS' DEFICIT		
Series D Convertible Preferred Stock, \$.01 par value; 850 shares authorized; 300 shares issued and outstanding on December 31, 2020 and 2019, respectively (Liquidation value of \$300,000)	3	3
Series G Convertible Preferred Stock, \$.01 par value; 240,000 shares authorized; 80,570 shares issued and outstanding on December 31, 2020 and 2019, respectively	806	806
Series H Convertible Preferred Stock, \$.01 par value; 10,000 shares authorized; 10,000 shares issued and outstanding on December 31, 2020 and 2019, respectively	100	100
Series H2 Convertible Preferred Stock, \$.01 par value; 21 shares authorized; 21 shares issued and outstanding on December 31, 2020 and 2019, respectively	-	-
Series J Convertible Preferred Stock, \$.01 par value; 6,250 shares authorized; 3,458 shares issued and outstanding on December 31, 2020 and 2019, respectively	35	35
Series K Convertible Preferred Stock, \$.01 par value; 15,000 shares authorized; 6,880 shares issued and outstanding on December 31, 2020 and 2019, respectively	68	68
Series AA Convertible Preferred Stock, \$.01 par value; 10,000 shares authorized; 8,043 and 7,939 shares issued and outstanding on December 31, 2020 and 2019, respectively	81	80
Common stock, \$.01 par value; 100,000,000 shares authorized; 4,168,324 and 2,549,620 shares issued and outstanding on December 31, 2020 and 2019 respectively	41,683	25,496
Warrants to acquire common stock	29,192,471	22,599,177
Additional paid-in capital	50,312,968	44,261,105
Accumulated deficit	(96,465,807)	(78,942,277)
Total stockholders' deficit	<u>(16,917,592)</u>	<u>(12,055,407)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	<u>\$ 2,302,779</u>	<u>\$ 1,816,034</u>

The accompanying notes are an integral part of these consolidated financial statements.

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2020 AND 2019

	For the Year Ended December 31,	
	2020	2019
Revenue:		
Products, services, other	\$ 1,220,591	\$ 1,809,993
Costs and expenses:		
Cost of products and services	582,854	1,197,061
Research and development	1,143,420	1,157,222
Selling and marketing	649,783	680,629
General and administrative	3,430,321	4,580,615
Total operating costs and expenses	<u>5,806,378</u>	<u>7,615,527</u>
Operating loss	(4,585,787)	(5,805,534)
Other (expense) income:		
Interest expense, net	(8,344,236)	(5,281,480)
Unrealized gain on investment in equity securities	500,358	4,018
Loss on extinguishment of liabilities	(3,575,878)	(795,089)
Total other expense	<u>(11,419,756)</u>	<u>(6,072,551)</u>
Income tax benefit	-	217,168
Net loss	<u>\$ (16,005,543)</u>	<u>\$ (11,660,917)</u>
Deemed dividends on beneficial conversion feature	(61,180)	(2,653,344)
Preferred stock dividends	(1,517,987)	(1,553,822)
Net loss attributable to common shareholders	<u>\$ (17,584,710)</u>	<u>\$ (15,868,083)</u>
Net loss per share - basic and diluted	\$ (5.32)	\$ (7.98)
Weighted average common stock shares outstanding used in the basic and diluted net loss per share calculation	3,304,187	1,987,606

The accompanying notes are an integral part of these consolidated financial statements

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2020 AND 2019

	Series D Preferred Stock		Series G Preferred Stock		Series H Preferred Stock		Series H(2) Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
BALANCE, December 31, 2019	300	\$ 3	80,570	\$ 806	10,000	\$ 100	21	\$ -
Stock-based compensation	-	-	-	-	-	-	-	-
Beneficial conversion feature on debt	-	-	-	-	-	-	-	-
Beneficial conversion option on convertible preferred stock	-	-	-	-	-	-	-	-
Deemed dividend-beneficial conversion feature	-	-	-	-	-	-	-	-
Common stock issued for debt settlement	-	-	-	-	-	-	-	-
Conversion of debt and interest for common stock	-	-	-	-	-	-	-	-
Conversion of debt into Series AA convertible preferred stock	-	-	-	-	-	-	-	-
Issuance of common stock for dividends paid-in-kind	-	-	-	-	-	-	-	-
Issuance of common stock for interest paid-in-kind	-	-	-	-	-	-	-	-
Issuance of common stock for services	-	-	-	-	-	-	-	-
Issuance of common stock to settle accrued liabilities	-	-	-	-	-	-	-	-
Preferred Stock offering	-	-	-	-	-	-	-	-
Series AA Preferred Stock dividend	-	-	-	-	-	-	-	-
Common stock issued with debt	-	-	-	-	-	-	-	-
Warrants issued for debt extension	-	-	-	-	-	-	-	-
Warrants issued for debt settlement	-	-	-	-	-	-	-	-
Warrants issued with debt	-	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-
BALANCE, December 31, 2020	300	\$ 3	80,570	\$ 806	10,000	\$ 100	21	\$ -

	Series J Preferred Stock		Series K Preferred Stock		Series AA Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
BALANCE, December 31, 2019	<u>3,458</u>	<u>\$ 35</u>	<u>6,880</u>	<u>\$ 68</u>	<u>7,939</u>	<u>80</u>	<u>2,549,620</u>	<u>\$ 25,496</u>
Stock-based compensation	-	-	-	-	-	-	-	-
Beneficial conversion feature on debt	-	-	-	-	-	-	-	-
Beneficial conversion option on convertible preferred stock	-	-	-	-	-	-	-	-
Deemed dividend-beneficial conversion feature	-	-	-	-	-	-	-	-
Common stock issued for debt settlement	-	-	-	-	-	-	188,778	1,888
Conversion of debt and interest for common stock	-	-	-	-	-	-	871,309	8,712
Conversion of debt into Series AA convertible preferred stock	-	-	-	-	44	-	-	-
Issuance of common stock for dividends paid-in-kind	-	-	-	-	-	-	122,135	1,222
Issuance of common stock for interest paid-in-kind	-	-	-	-	-	-	134,482	1,345
Issuance of common stock for services	-	-	-	-	-	-	76,800	768
Issuance of common stock to settle accrued liabilities	-	-	-	-	-	-	66,500	665
Preferred Stock offering	-	-	-	-	60	1	-	-
Series AA Preferred Stock dividend	-	-	-	-	-	-	-	-
Common stock issued with debt	-	-	-	-	-	-	158,700	1,587
Warrants issued for debt extension	-	-	-	-	-	-	-	-
Warrants issued for debt settlement	-	-	-	-	-	-	-	-
Warrants issued with debt	-	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-
BALANCE, December 31, 2020	<u>3,458</u>	<u>\$ 35</u>	<u>6,880</u>	<u>\$ 68</u>	<u>8,043</u>	<u>\$ 81</u>	<u>4,168,324</u>	<u>\$ 41,683</u>

	Stock Warrants	Additional Paid- In Capital	Accumulated other comprehensive loss	Accumulated Deficit	Total Stockholders' Deficit
BALANCE, December 31, 2019	<u>\$ 22,599,177</u>	<u>\$ 44,261,105</u>	<u>\$ -</u>	<u>\$ (78,942,277)</u>	<u>\$ (12,055,407)</u>
Stock-based compensation	-	488,792	-	-	488,792
Beneficial conversion feature on debt	-	1,756,311	-	-	1,756,311
Beneficial conversion option on convertible preferred stock	-	61,180	-	-	61,180
Deemed dividend-beneficial conversion feature	-	(61,180)	-	-	(61,180)
Common stock issued for debt settlement	-	372,662	-	-	374,550
Conversion of debt and interest for common stock	-	2,211,730	-	-	2,220,442
Conversion of debt into Series AA convertible preferred stock	38,783	71,217	-	-	110,000
Issuance of common stock for dividends paid-in-kind	-	298,487	-	-	299,709
Issuance of common stock for interest paid-in-kind	-	253,914	-	-	255,259
Issuance of common stock for services	-	178,309	-	-	179,077
Issuance of common stock to settle accrued liabilities	-	127,190	-	-	127,855
Preferred Stock offering	69,580	80,419	-	-	150,000
Series AA Preferred Stock dividend	-	-	-	(1,517,987)	(1,517,987)
Common stock issued with debt	-	212,832	-	-	214,419
Warrants issued for debt extension	1,282,560	-	-	-	1,282,560
Warrants issued for debt settlement	338,412	-	-	-	338,412
Warrants issued with debt	4,863,959	-	-	-	4,863,959
Net loss	-	-	-	(16,005,543)	(16,005,543)
BALANCE, December 31, 2020	<u>\$ 29,192,471</u>	<u>\$ 50,312,968</u>	<u>\$ -</u>	<u>\$ (96,465,807)</u>	<u>\$ (16,917,592)</u>

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018

	Series D Preferred Stock		Series G Preferred Stock		Series H Preferred Stock		Series H(2) Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
BALANCE, December 31, 2018	300	\$ 3	80,570	\$ 806	10,000	\$ 100	21	\$ -
Stock-based compensation	-	-	-	-	-	-	-	-
Issuance of common stock for services	-	-	-	-	-	-	-	-
Beneficial conversion feature on Series AA convertible preferred stock	-	-	-	-	-	-	-	-
Series AA Preferred stock dividend	-	-	-	-	-	-	-	-
Issuance of common stock for dividends paid-in-kind	-	-	-	-	-	-	-	-
Beneficial conversion feature on debt	-	-	-	-	-	-	-	-
Deemed dividend-beneficial conversion feature	-	-	-	-	-	-	-	-
Conversion of Series AA convertible preferred stock	-	-	-	-	-	-	-	-
Preferred stock offering	-	-	-	-	-	-	-	-
Conversion of debt and interest for common stock	-	-	-	-	-	-	-	-
Common stock issued for debt extension	-	-	-	-	-	-	-	-
Common stock warrants issued for debt extension	-	-	-	-	-	-	-	-
Common stock issued with debt	-	-	-	-	-	-	-	-
Warrants issued with debt	-	-	-	-	-	-	-	-
Offering costs for issuance of preferred stock	-	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-
BALANCE, December 31, 2019	300	\$ 3	80,570	\$ 806	10,000	\$ 100	21	\$ -

	Series J Preferred Stock		Series K Preferred Stock		Series AA Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
BALANCE, December 31, 2018	3,458	\$ 35	6,880	\$ 68	6,499	\$ 65	1,684,182	\$ 16,842
Stock-based compensation	-	-	-	-	-	-	-	-
Issuance of common stock for services	-	-	-	-	-	-	139,000	1,390
Beneficial conversion feature on Series AA convertible preferred stock	-	-	-	-	-	-	-	-
Series AA Preferred stock dividend	-	-	-	-	-	-	-	-
Issuance of common stock for dividends paid-in-kind	-	-	-	-	-	-	81,767	818
Beneficial conversion feature on debt	-	-	-	-	-	-	-	-
Deemed dividend-beneficial conversion feature	-	-	-	-	-	-	-	-
Conversion of Series AA convertible preferred stock	-	-	-	-	(16)	-	16,000	160
Preferred stock offering	-	-	-	-	1,456	15	-	-
Conversion of debt and interest for common stock	-	-	-	-	-	-	126,200	1,262
Common stock issued for debt extension	-	-	-	-	-	-	422,234	4,222
Common stock warrants issued for debt extension	-	-	-	-	-	-	-	-
Common stock issued with debt	-	-	-	-	-	-	80,237	802
Warrants issued with debt	-	-	-	-	-	-	-	-
Offering costs for issuance of preferred stock	-	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-
BALANCE, December 31, 2019	3,458	\$ 35	6,880	\$ 68	7,939	\$ 80	2,549,620	\$ 25,496

	Stock Warrants	Additional Paid-In Capital	Accumulated other comprehensive loss	Accumulated Deficit	Total Stockholders' Deficit
BALANCE, December 31, 2018	<u>\$ 19,807,247</u>	<u>\$ 39,777,301</u>	<u>\$ -</u>	<u>\$(65,727,538)</u>	<u>\$ (6,125,071)</u>
Stock-based compensation	-	1,117,277	-	-	1,117,277
Issuance of common stock for services	-	397,210	-	-	398,600
Beneficial conversion feature on Series AA convertible preferred stock	-	2,653,344	-	-	2,653,344
Series AA Preferred stock dividend	-	-	-	(1,553,822)	(1,553,822)
Issuance of common stock for dividends paid-in-kind	-	204,282	-	-	205,100
Beneficial conversion feature on debt	-	558,903	-	-	558,903
Deemed dividend-beneficial conversion feature	-	(2,653,344)	-	-	(2,653,344)
Conversion of Series AA convertible preferred stock	-	(160)	-	-	-
Preferred stock offering	1,902,352	1,736,551	-	-	3,638,918
Conversion of debt and interest for common stock	-	355,248	-	-	356,510
Common stock issued for debt extension	-	644,796	-	-	649,018
Common stock warrants issued for debt extension	275,307	-	-	-	275,307
Common stock issued with debt	-	239,073	-	-	239,875
Warrants issued with debt	208,714	-	-	-	208,714
Offering costs for issuance of preferred stock	405,557	(769,376)	-	-	(363,819)
Net loss	-	-	-	(11,660,917)	(11,660,917)
BALANCE, December 31, 2019	<u>\$ 22,599,177</u>	<u>\$ 44,261,105</u>	<u>\$ -</u>	<u>\$(78,942,277)</u>	<u>\$ (12,055,407)</u>

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2020 AND 2019

	For the Year Ended December 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (16,005,543)	\$ (11,660,917)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	76,586	59,799
Common stock issued for interest and extension fees	255,259	-
Depreciation and amortization	127,301	123,596
Inventory reserve	-	68,949
Accretion of discount on loan receivable	(6,250)	-
Accretion of interest and amortization of debt discount	5,436,863	1,353,483
Gain on investment in equity securities	(500,358)	-
Loss on extinguishment of accrued liabilities and debt	1,036,638	795,089
Stock-based compensation expense	488,792	1,117,277
Common stock issued for services	179,077	398,600
Changes in operating assets and liabilities:		
Accounts receivable	98,174	245,428
Inventories	24,949	78,814
Prepaid expenses and other assets	(101,387)	(42,815)
Accounts payable	(43,819)	156,908
Accrued employee compensation	(33,622)	(5,732)
Operating lease liability	(76,586)	(59,799)
Deferred revenue and other accrued expenses	4,160,732	1,043,742
Net cash used in operating activities	<u>(4,883,194)</u>	<u>(6,327,578)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Advance on loan receivable	(795,000)	-
Purchases of property plant and equipment	(1,663)	(23,375)
Net cash used in investing activities	<u>(796,663)</u>	<u>(23,375)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from related party debt	283,700	259,500
Payment on related party debt	(199,200)	(193,000)
Net proceeds from convertible debt	8,296,800	6,585,300
Payments on convertible debt	(2,857,007)	(4,396,485)
Net proceeds from non-convertible debt	1,290,539	2,981,750
Payments on non-convertible debt	(1,296,060)	(2,234,704)
Net proceeds from the issuance of Series AA Convertible Preferred Stock	150,000	3,275,099
Net cash provided by financing activities	<u>5,668,772</u>	<u>6,277,460</u>
NET (DECREASE) IN CASH AND CASH EQUIVALENTS	(11,085)	(73,493)
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	29,625	103,118
CASH AND CASH EQUIVALENTS AT END OF YEAR	<u>\$ 18,540</u>	<u>\$ 29,625</u>
SUPPLEMENTAL INFORMATION		
Interest paid in cash	\$ 764,600	\$ 3,266,399
NON CASH TRANSACTIONS:		
Conversion of debt for Series AA preferred stock	110,000	-
Discount due to beneficial conversion feature	1,756,311	558,903
Discount from warrants issued with debt	4,863,959	208,714
Common stock issued in lieu of cash for dividend	299,709	205,100
Common stock issued with debt	214,419	239,875
Common stock issued to settle accrued liabilities	127,855	-
Common stock issued for debt settlement	374,550	-
Conversion of preferred stock into common stock	-	160
Conversion of debt and interest into common stock	2,220,442	356,510
Preferred stock dividend	1,517,987	1,553,822
Deemed dividend-beneficial conversion feature	61,180	2,653,344
Loan extension fees and interest added to principal	152,552	-
Recognition of right of use asset and liability	221,432	-

The accompanying notes are an integral part of these consolidated financial statements.

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Business Overview

Pressure Biosciences, Inc. (“we”, “our”, “the Company”) develops and sells innovative, broadly enabling, pressure-based platform solutions for the worldwide life sciences industry. Our solutions 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 has been 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.

(2) Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the liquidation of liabilities in the normal course of business. However, we have experienced negative cash flows from operations with respect to our pressure cycling technology business since our inception. As of December 31, 2020, we do not have adequate working capital resources to satisfy our current liabilities and as a result, there is substantial doubt regarding our ability to continue as a going concern. We have been successful in raising cash through debt and equity offerings in the past and as described in Notes 10 and 11, completed debt financing subsequent to December 31, 2020. We have financing efforts in place to continue to raise cash through debt and equity offerings.

Management has developed a plan to continue operations. This plan includes obtaining equity or debt financing. During the year ended December 31, 2020 we received \$9,871,039 net proceeds in additional convertible and non-convertible debt. We also received \$150,000 in net proceeds from the sale of Series AA Preferred Stock during the year. Although we have successfully completed financings and reduced expenses in the past, we cannot assure you that our plans to address these matters in the future will be successful.

Management’s plans to alleviate these conditions that raise substantial doubt regarding the Company’s ability to continue as a going concern include pursuing one or more of the following options to raise additional funding, none of which can be guaranteed or are entirely within the Company’s control:

- Raise funding through the possible additional sales of the Company’s common stock, including public or private equity financings.
- Raise additional loan funding.
- Continue to seek partners to advance the PCT, BaroFold, and UST technology platforms.
- Earn payments pursuant to potential collaboration and license agreements for BaroFold patents.
- Seek strategic direct equity investments from existing multiple partners

There can be no assurance, however, that the Company will receive cash proceeds from any of these potential resources or, to the extent cash proceeds are received, those proceeds would be sufficient to support the Company's operations for at least the next twelve months from the date of filing this Annual Report on Form 10-K.

Generally, management's plans must be approved before the date the financial statements are issued to be considered probable of being effectively implemented. The future receipt of potential funding from the Company's collaborators and other resources is not considered probable at this time because none of the Company's current plans have been finalized at the time of filing this Annual Report on Form 10-K. Accordingly, substantial doubt is deemed to exist about the Company's ability to continue as a going concern within one year after the date these financial statements are issued.

The Company believes that its \$18,540 in cash and cash equivalents at December 31, 2020 and additional debt and equity financings would allow it to fund its planned operations into the first quarter of 2021. This estimate assumes no additional funding from new partnership agreements, and no accelerated repayment of its term loans. Accordingly, the timing and nature of activities contemplated for the remainder of 2021 and thereafter will be conducted subject to the availability of sufficient financial resources.

If the Company is unable to raise capital when needed or on attractive terms, or if it is unable to procure partnership arrangements to advance its programs, the Company would be forced to delay, reduce or eliminate its research and development programs and any future commercialization efforts.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

(3) Summary of Significant Accounting Policies

i. Principles of Consolidation

The consolidated financial statements include the accounts of Pressure BioSciences, Inc., and its wholly-owned subsidiary PBI BioSeq, Inc. All intercompany accounts and transactions have been eliminated in consolidation.

ii. Use of Estimates

To prepare our consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, we are required to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In addition, significant estimates were made in projecting future cash flows to quantify impairment of assets, deferred tax assets, the costs associated with fulfilling our warranty obligations for the instruments that we sell, and the estimates employed in our calculation of fair value of stock options awarded, beneficial conversion features and derivative liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from the estimates and assumptions used.

iii Recent Accounting Pronouncement

In June 2016, the FASB issued ASU 2016-13, Measurement of Credit Losses on Financial Instruments. The standard is effective for the Company for interim and annual periods beginning after December 15, 2022. The Company is evaluating the impact of this standard on its Consolidated Financial Statements.

In December 2019, the FASB, issued ASU 2019-12, Simplifying the Accounting for Income Taxes. The standard is effective for the Company for interim and annual periods beginning after December 15, 2020 for the Company and for annual periods beginning after December 15, 2021 and interim periods beginning after December 15, 2022. The Company is evaluating the impact of this standard on its Consolidated Financial Statements.

In August 2020, the Financial Accounting Standards Board ("FASB") issued ASU 2020-06, Debt with Conversion and Other Options and Derivatives and Hedging - Contracts in Entity's Own Equity. The standard is effective for interim and annual periods beginning after December 15, 2023 for the Company. The Company is evaluating the impact of this standard on its Consolidated Financial Statements.

iv. Revenue Recognition

We recognize revenue in accordance with FASB ASC 606, *Revenue from Contracts with Customers*, and ASC 340-40, *Other Assets and Deferred Costs—Contracts with Customers*. Revenue is measured based on a consideration specified in a contract with a customer, and excludes any sales incentives and amounts collected on behalf of third parties. We enter into sales contracts that may consist of multiple distinct performance obligations where certain performance obligations of the sales contract are not delivered in one reporting period. We measure and allocate revenue according to ASC 606-10.

We identify a performance obligation as distinct if both the following criteria are true: the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. Determining the standalone selling price ("SSP") and allocation of consideration from a contract to the individual performance obligations, and the appropriate timing of revenue recognition, is the result of significant qualitative and quantitative judgments. Management considers a variety of factors such as historical sales, usage rates, costs, and expected margin, which may vary over time depending upon the unique facts and circumstances related to each performance obligation in making these estimates. While changes in the allocation of the SSP between performance obligations will not affect the amount of total revenue recognized for a particular contract, any material changes could impact the timing of revenue recognition, which would have a material effect on our financial position and result of operations. This is because the contract consideration is allocated to each performance obligation, delivered or undelivered, at the inception of the contract based on the SSP of each distinct performance obligation.

Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by the Company from a customer, are excluded from revenue.

Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of revenues as consistent with treatment in prior periods.

Our current Barocycler® instruments require a basic level of instrumentation expertise to set-up for initial operation. To support a favorable first experience for our customers, upon customer request, and for an additional fee, we will send a highly trained technical representative to the customer site to install Barocyclers® that we sell, lease, or rent through our domestic sales force. The installation process includes uncrating and setting up the instrument, followed by introductory user training. Our sales arrangements do not provide our customers with a right of return. Any shipping costs billed to customers are recognized as revenue.

The majority of our instrument and consumable contracts contain pricing that is based on the market price for the product at the time of delivery. Our obligations to deliver product volumes are typically satisfied and revenue is recognized when control of the product transfers to our customers. Concurrent with the transfer of control, we typically receive the right to payment for the shipped product and the customer has significant risks and rewards of ownership of the product. Payment terms require customers to pay shortly after delivery and do not contain significant financing components.

Revenue from scientific services customers is recognized upon completion of each stage of service as defined in service agreements.

We apply ASC 845, "Accounting for Non-Monetary Transactions", to account for products and services sold through non-cash transactions based on the fair values of the products and services involved, where such values can be determined. Non-cash exchanges would require revenue to be recognized at recorded cost or carrying value of the assets or services sold if any of the following conditions apply:

- a) The fair value of the asset or service involved is not determinable.
- b) The transaction is an exchange of a product or property held for sale in the ordinary course of business for a product or property to be sold in the same line of business to facilitate sales to customers other than the parties to the exchange.
- c) The transaction lacks commercial substance.

We recognize revenue for non-cash transactions at recorded cost or carrying value of the assets or services sold.

We account for lease agreements of our instruments in accordance with ASC 842, *Leases*. We record revenue over the life of the lease term and we record depreciation expense on a straight-line basis over the thirty-six-month estimated useful life of the Barocycler® instrument. The depreciation expense associated with assets under lease agreement is included in the "Cost of PCT products and services" line item in our accompanying consolidated statements of operations. Many of our lease and rental agreements allow the lessee to purchase the instrument at any point during the term of the agreement with partial or full credit for payments previously made. We pay all maintenance costs associated with the instrument during the term of the leases.

Revenue from government grants is recorded when expenses are incurred under the grant in accordance with the terms of the grant award.

Deferred revenue represents amounts received from grants and service contracts for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. Revenue from service contracts is recorded ratably over the length of the contract.

Disaggregation of revenue

In the following table, revenue is disaggregated by primary geographical market, major product line, and timing of revenue recognition.

<i>In thousands of US dollars (\$)</i>	Year Ended December 31,	
	2020	2019
Primary geographical markets		
North America	844	1,111
Europe	88	145
Asia	289	554
	<u>1,221</u>	<u>1,810</u>
Major products/services lines	Year Ended December 31,	
	2020	2019
Hardware	568	713
Consumables	205	298
Contract research services	193	543
Sample preparation accessories	116	82
Technical support/extended service contracts	96	116
Shipping and handling	29	41
Other	14	17
	<u>1,221</u>	<u>1,810</u>
Timing of revenue recognition	Year Ended December 31,	
	2020	2019
Transferred at a point in time	978	1,228
Transferred over time	243	582
	<u>1,221</u>	<u>1,810</u>

Contract balances

<i>In thousands of US dollars (\$)</i>	December 31, 2020	December 31, 2019
Receivables, which are included in ‘Accounts Receivable’	131	229
Contract liabilities (deferred revenue)	67	41

Transaction price allocated to the remaining performance obligations

The following table includes estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied (or partially unsatisfied) at the end of the reporting period.

<i>In thousands of US dollars (\$)</i>	2021	2022	Total
Extended warranty service	47	20	67

All consideration from contracts with customers is included in the amounts presented above.

Contract Costs

The Company recognizes the incremental costs of obtaining contracts as an expense when incurred if the amortization period of the assets that the Company otherwise would have recognized is one year or less. These costs are included in selling, general, and administrative expenses. The costs to obtain a contract are recorded immediately in the period when the revenue is recognized either upon shipment or installation. The costs to obtain a service contract are considered immaterial when spread over the life of the contract so the Company records the costs immediately upon billing.

v. Beneficial Conversion Features

In accordance with FASB ASC 470-20, “Debt with Conversion and Other Options” the Company records a beneficial conversion feature (“BCF”) related to the issuance of convertible debt or preferred stock instruments that have conversion features at fixed rates that are in-the-money when issued. The BCF for the convertible instruments is recognized and measured by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital. The intrinsic value is generally calculated at the commitment date as the difference between the conversion price and the fair value of the common stock or other securities into which the security is convertible, multiplied by the number of shares into which the security is convertible. If certain other securities are issued with the convertible security, the proceeds are allocated among the different components. The portion of the proceeds allocated to the convertible security is divided by the contractual number of the conversion shares to determine the effective conversion price, which is used to measure the BCF. The effective conversion price is used to compute the intrinsic value. The value of the BCF is limited to the basis that is initially allocated to the convertible security.

vi. Cash and Cash Equivalents

Our policy is to invest available cash in short-term, investment grade interest-bearing obligations, including money market funds, and bank and corporate debt instruments. Securities purchased with initial maturities of three months or less are valued at cost plus accrued interest, which approximates fair value, and are classified as cash equivalents.

vii. Research and Development

Research and development costs, which are comprised of costs incurred in performing research and development activities including wages and associated employee benefits, facilities, consumable products and overhead costs that are expensed as incurred. In support of our research and development activities we utilize our Barocycler instruments that are capitalized as fixed assets and depreciated over their expected useful life.

viii. Inventories

Inventories are valued at the lower of cost (average cost) or net realizable value. The cost of Barocyclers consists of the cost charged by the contract manufacturer. The cost of manufactured goods includes material, freight-in, direct labor, and applicable overhead. The composition of inventory as of December 31, is as follows:

	2020	2019
Raw materials	\$ 217,682	\$ 167,189
Finished goods	717,581	793,023
Inventory reserve	(342,496)	(342,496)
Total	<u>\$ 592,767</u>	<u>\$ 617,716</u>

ix. Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. For financial reporting purposes, depreciation is recognized using the straight-line method, allocating the cost of the assets over their estimated useful lives of three years for certain laboratory equipment, from three to five years for management information systems and office equipment, and three years for all PCT finished units classified as fixed assets.

x. Intangible Assets

We have classified as intangible assets, costs associated with the fair value of acquired intellectual property. Intangible assets, including patents, are being amortized on a straight-line basis over nine years. We perform an annual review of our intangible assets for impairment. We capitalize any costs to renew or extend the term of our intangible assets. When impairment is indicated, any excess of carrying value over fair value is recorded as a loss. As of December 31, 2020, and 2019, the outstanding balance for intangible assets was \$490,385 and \$576,923, respectively.

xi. Long-Lived Assets

The Company's long-lived assets are reviewed for impairment in accordance with the guidance of the FASB ASC 360-10-05, *Property, Plant, and Equipment*, whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. Through December 31, 2020, the Company had not experienced impairment losses on its long-lived assets.

xii. Concentrations

Credit Risk

Our financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash, cash equivalents and trade receivables. We have cash investment policies which, among other things, limit investments to investment-grade securities. We perform ongoing credit evaluations of our customers, and the risk with respect to trade receivables is further mitigated by the fact that many of our customers are government institutions and university labs. Allowances are provided for estimated amounts of accounts receivable which may not be collected. At December 31, 2020, we determined that no allowance against accounts receivable was necessary.

The following table illustrates the level of concentration of the below two groups within revenue as a percentage of total revenues during the years ended December 31:

	2020	2019
Top Five Customers	33%	41%
Federal Agencies	4%	12%

The following table illustrates the level of concentration of the below two groups within accounts receivable as a percentage of total accounts receivable balance as of December 31:

	2020	2019
Top Five Customers	89%	83%
Federal Agencies	10%	17%

Investment in Equity Securities

As of December 31, 2020, we held 100,250 shares of common stock of Nexity Global SA, (a Polish publicly traded company). On October 23, 2020 Everest Investments S.A. changed its name to Nexity Global S.A. Nexity is and Everest was listed on the Warsaw Stock Exchange.

We had exchanged 33,334 shares of our common stock for the 100,250 shares we had held in Everest (before the Nexity Merger). We account for this investment in accordance with ASC 320 "Investments — Debt and Equity Securities". ASC 320 requires equity investments with readily determinable fair values to be measured at fair value with changes in fair value recognized in net income.

As of December 31, 2020, our consolidated balance sheet reflected the fair value, determined on a recurring basis based on Level 1 inputs, of our investment in Nexity to be \$517,001. We recorded \$500,358 as an unrealized gain during the year ended December 31, 2020 for changes in market value.

xiii. Computation of Loss per Share

Basic loss per share is computed by dividing loss available to common shareholders by the weighted average number of common shares outstanding. Diluted loss per share is computed by dividing loss available to common shareholders by the weighted average number of common shares outstanding plus additional common shares that would have been outstanding if dilutive potential common shares had been issued. For purposes of this calculation, convertible preferred stock, common stock dividends, warrants to acquire preferred stock convertible into common stock, and warrants and options to acquire common stock, are all considered common stock equivalents in periods in which they have a dilutive effect and are excluded from this calculation in periods in which these are anti-dilutive. The following table illustrates our computation of loss per share for the years ended December 31:

	2020	2019
<u>Numerator:</u>		
Net loss attributable to common shareholders	\$ (17,584,710)	\$ (15,868,083)
<u>Denominator for basic and diluted loss per share:</u>		
Weighted average common shares outstanding	<u>3,304,187</u>	<u>1,987,606</u>
Loss per common share - basic and diluted	<u>\$ (5.32)</u>	<u>\$ (7.98)</u>

The following table presents securities that could potentially dilute basic loss per share in the future. For all periods presented, the potentially dilutive securities were not included in the computation of diluted loss per share because these securities would have been anti-dilutive for the years ended December 31:

	2020	2019
Stock options	1,355,901	1,396,302
Convertible debt	4,474,868	2,351,493
Common stock warrants	14,434,702	9,893,034
Convertible preferred stock:		
Series D Convertible Preferred	25,000	25,000
Series G Convertible Preferred	26,857	26,857
Series H Convertible Preferred	33,334	33,334
Series H2 Convertible Preferred	70,000	70,000
Series J Convertible Preferred	115,267	115,267
Series K Convertible Preferred	229,334	229,334
Series AA Convertible Preferred	8,043,000	7,939,000
	<u>28,808,263</u>	<u>22,079,621</u>

xiv. Accounting for Income Taxes

We account for income taxes under the asset and liability method, which requires recognition of deferred tax assets, subject to valuation allowances, and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and income tax purposes. The Company considers many factors when assessing the likelihood of future realization of our deferred tax assets, including recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income or loss, the carry-forward periods available to us for tax reporting purposes, and other relevant factors. A valuation allowance is established if it is more likely than not that all or a portion of the net deferred tax assets will not be realized. If substantial changes in the Company’s ownership should occur, as defined in Section 382 of the Internal Revenue Code, there could be significant limitations on the amount of net loss carry forwards that could be used to offset future taxable income.

Tax positions must meet a “more likely than not” recognition threshold at the effective date to be recognized. At December 31, 2020 and 2019, the Company did not have any uncertain tax positions. No interest and penalties related to uncertain tax positions were accrued at December 31, 2020 and 2019.

xv. Accounting for Stock-Based Compensation

We maintain equity compensation plans under which incentive stock options and non-qualified stock options are granted to employees, independent members of our Board of Directors and outside consultants. We recognize equity compensation expense over the requisite service period using the Black-Scholes formula to estimate the fair value of the stock options on the date of grant. Employee and non employee awards are accounted for under ASC 718 where the awards are valued at grant date.

Determining Fair Value of Stock Option Grants

Valuation and Amortization Method - The fair value of each option award is estimated on the date of grant using the Black-Scholes pricing model based on certain assumptions. The estimated fair value of employee stock options is amortized to expense using the straight-line method over the vesting period, which generally is over three years.

Expected Term - The Company uses the simplified calculation of expected life, described in the FASB ASC 718, *Compensation-Stock Compensation*, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected term. Using this method, the expected term is determined using the average of the vesting period and the contractual life of the stock options granted.

Expected Volatility - Expected volatility is based on the Company’s historical stock volatility data over the expected term of the award.

Risk-Free Interest Rate - The Company bases the risk-free interest rate used in the Black-Scholes valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term.

Forfeitures - As required by FASB ASC 718, *Compensation-Stock Compensation*, the Company records stock-based compensation expense only for those awards that are expected to vest. The Company estimated a forfeiture rate of 5% for awards granted based on historical experience and future expectations of options vesting. We used this historical rate as our assumption in calculating future stock-based compensation expense.

The following table summarizes the assumptions we utilized for grants of stock options to the three sub-groups of our stock option recipients during the year ended December 31, 2019 (there were no option grants in the year ended December 31, 2020):

Assumptions	Non-Employee Board Members	CEO, other Officers and Employees
Expected life	6.0(yrs)	6.0(yrs)
Expected volatility	150.07%	150.07%-157.28%
Risk-free interest rate	1.73%	1.73%-1.79%
Forfeiture rate	5.00%	5.00%
Expected dividend yield	0.0%	0.0%

We recognized stock-based compensation expense of \$488,792 and \$1,117,277 for the years ended December 31, 2020 and 2019, respectively. The following table summarizes the effect of this stock-based compensation expense within each of the line items within our accompanying consolidated statements of operations for the years ended December 31:

	2020	2019
Research and development	\$ 141,202	\$ 171,928
Selling and marketing	34,142	86,319
General and administrative	313,448	859,030
Total stock-based compensation expense	<u>\$ 488,792</u>	<u>\$ 1,117,277</u>

During the years ended December 31, 2020 and 2019, the total fair value of stock options awarded was \$0 and \$817,722, respectively.

As of December 31, 2020, total unrecognized compensation cost related to the unvested stock-based awards was \$304,900, which is expected to be recognized over weighted average period of 1.59 years.

xvi. Advertising

Advertising costs are expensed as incurred. We incurred \$19,572 in 2020 and \$23,797 in 2019 for advertising.

xvii. Fair Value of Financial Instruments

Due to their short maturities, the carrying amounts for cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their fair value. Long-term liabilities include debt with a fair value of \$419,320 (carrying amount \$527,039) and deferred revenue with a carrying value that approximates fair value. The Company has not elected to carry any of its assets or liabilities at fair value, as allowed by the FASB’s statement of Financial Accounting Standards No. 159, “The Fair Value option for Financial Assets and Financial Liabilities.”

xviii. Fair Value Measurements

The Company follows the guidance of FASB ASC Topic 820, “Fair Value Measurements and Disclosures” (“ASC 820”) as it related to financial assets and financial liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis.

The Company generally defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The Company uses a three-tier fair value hierarchy, which classifies the inputs used in measuring fair values. These tiers include: Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company has determined that its financial assets are currently classified within Level 1. The Company does not have any financial liabilities that are required to be measured on a recurring basis at December 31, 2020 and 2019.

The following tables set forth the Company’s financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2020:

		Fair value measurements at December 31, 2020 using:		
		Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
	December 31, 2020			
Equity Securities	\$ 517,001	\$ 517,001	-	-
Total Financial Assets	\$ 517,001	\$ 517,001	\$ -	\$ -

The following tables set forth the Company’s financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2019:

		Fair value measurements at December 31, 2019 using:		
		Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
	December 31, 2019			
Equity Securities	16,643	16,643	-	-
Total Financial Assets	\$ 16,643	\$ 16,643	\$ -	\$ -

(4) Property and Equipment, net

Property and equipment as of December 31, 2020 and 2019 consisted of the following components:

	December 31,	
	2020	2019
Laboratory and manufacturing equipment	\$ 240,670	\$ 240,670
Office equipment	184,763	183,931
Leasehold improvements	25,248	24,417
PCT collaboration, demonstration and leased systems	53,098	53,098
Total property and equipment	503,779	502,116
Less accumulated depreciation	(487,289)	(446,526)
Net book value	\$ 16,490	\$ 55,590

Depreciation expense for the years ended December 31, 2020 and 2019 was \$40,763 and \$37,057, respectively.

(5) Intangible Assets

Intangible assets as of December 31, 2020 reflect the purchase price attributable to patents received in connection with the acquisition of assets of BaroFold Corp. Acquired BaroFold patents are being amortized to expense on a straight line basis at the rate of \$80,000 per year over their estimated remaining useful lives of approximately 9 years. The estimated aggregate amortization expense for each of the five succeeding fiscal years is \$80,000 annually. We performed a review of our intangible assets for impairment. When impairment is indicated, any excess of carrying value over fair value is recorded as a loss. An impairment analysis of intangible assets was performed as of December 31, 2020. We have concluded that there is no impairment of intangible assets. Intangible assets at December 31, 2020 and 2019 consisted of the following:

	December 31,	
	2020	2019
BaroFold Patents	\$ 750,000	\$ 750,000
Less accumulated amortization	(259,615)	(173,077)
Net book value	\$ 490,385	\$ 576,923

Amortization expense for each of the years ended December 31, 2020 and 2019 was \$86,538 and \$86,539, respectively.

(6) Retirement Plan

We provide all of our employees with the opportunity to participate in our retirement savings plan. Our retirement savings plan has been qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the plan through payroll deductions within statutory limitations and subject to any limitations included in the plan. During 2020 and 2019 we contributed \$13,436 and \$15,308, respectively, in the form of discretionary Company-matching contributions.

(7) Income Taxes

Tax positions must meet a “more likely than not” recognition threshold at the effective date to be recognized. At December 31, 2020 and 2019, the Company did not have any uncertain tax positions. No interest and penalties related to uncertain tax positions were accrued at December 31, 2020 and 2019. Our tax returns for fiscal years 2017, 2018 and 2019 are open to examination.

We recorded a \$0 tax benefit for the year ended December 31, 2020 and a \$217,168 income tax benefit for the year ended December 31, 2019 from a corporate alternative minimum tax refund.

Significant items making up the deferred tax assets and deferred tax liabilities as of December 31, 2020 and 2019 are as follows:

	2020	2019
Long term deferred taxes:		
Inventories	\$ 93,570	\$ 93,570
Accrued expenses	156,699	127,186
Other	15,169	15,169
Non-cash, stock-based compensation, nonqualified	1,206,664	1,073,125
Impairment loss on investment	104,609	104,609
Operating loss carry forwards and tax credits	22,062,690	17,872,050
Less: valuation allowance	(23,639,401)	(19,285,709)
Total net deferred tax assets	\$ -	\$ -

A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. Accordingly, a valuation allowance was established in 2020 and 2019 for the full amount of our deferred tax assets due to the uncertainty of realization. We believe that based on our projection of future taxable operating income for the foreseeable future, it is more likely than not that we will not be able to realize the benefit of the deferred tax asset at December 31, 2020.

We have net operating loss carry-forwards for federal income tax purposes of approximately \$76,607,264 as of December 31, 2020. Included in these numbers are loss carry-forwards that were obtained through the acquisition of BioSeq, Inc. and are subject to Section 382 NOL limitations. These net operating loss carry-forwards expire at various dates from 2022 through 2037. Under the Tax Reform Act, NOL’s generated after December 31, 2017 can offset only 80% of a corporation’s taxable income in any year. With limited exceptions, NOL’s generated after 2017 \$34,971,674 cannot be carried back, but they can be carried forward indefinitely.

We have net operating loss carry-forwards for state income tax purposes of approximately \$70,101,768 at December 31, 2020. These net operating loss carry-forwards expire at various dates from 2031 through 2038.

We have research and development tax credit carry-forwards for federal income tax purposes of approximately \$1,238,308 as of December 31, 2020 and research and development tax credit carry-forwards for state income tax purposes of approximately \$306,425 as of December 31, 2020. The federal credit carry-forwards expire at various dates from 2020 through 2039. The state credit carry-forwards expire at various dates from 2023 through 2034.

The following table reconciles the U.S. Federal statutory tax rate to the Company’s effective tax rate:

	2020	2019
Statutory U.S. Federal tax rate	21%	21%
Permanent differences	(0)%	(0)%
State tax expense	0%	0%
Refundable AMT and R&D tax credit	0%	0%
Valuation allowance	(21)%	(22.9)%
Effective tax rate	-%	(1.9)%

(8) Commitments and Contingencies

Operating Leases

The Company accounts for its leases under ASC 842. The Company has elected to apply the short-term lease exception to leases of one year or less.

Our corporate office is currently located at 14 Norfolk Avenue, South Easton, Massachusetts 02375. We are currently paying \$6,950 per month, on a lease extension, signed on December 30, 2020, that expires December 31, 2021, for our corporate office. We expanded our space to include offices, warehouse and a loading dock on the first floor starting May 1, 2017 with a monthly rent increase already reflected in the current payments.

We extended our lease for our space in Medford, MA (the “Medford Lease”) from December 30, 2020 to December 30, 2023. The lease requires monthly payments of \$7,282 subject to annual cost of living increases. The lease shall be automatically extended for additional three years unless either party terminates at least six months prior to the expiration of the current lease term.

The Company accounted for the lease extension of our Medford Lease as a lease modification under ASC 842. At the effective date of modification, the Company recorded an adjustment to the right-of-use asset and lease liability in the amount of \$221,432 based on the net present value of lease payments discounted using an estimated borrowing rate of 12%.

Following is a schedule by years of future minimum rental payments required under operating leases with initial or remaining non-cancelable lease terms in excess of one year as of December 31, 2020:

2021	\$	170,783
2022		87,383
2023		87,383
Total minimum payments required	\$	<u>345,549</u>

Battelle Memorial Institute

In December 2008, we entered into an exclusive patent license agreement with the Battelle Memorial Institute (“*Battelle*”). The licensed technology is the subject of a patent application filed by Battelle in 2008 and relates to a method and a system for improving the analysis of protein samples, including through an automated system utilizing pressure and a pre-selected agent to obtain a digested sample in a significantly shorter period of time than current methods, while maintaining the integrity of the sample throughout the preparatory process. In addition to royalty payments on net sales on “licensed products,” we are obligated to make minimum royalty payments for each year that we retain the rights outlined in the patent license agreement and we are required to have our first commercial sale of the licensed products within one year following the issuance of the patent covered by the licensed technology. After re-negotiating the terms of the contract in 2013, the minimum annual royalty was \$1,200 in 2014 and \$2,000 in 2015; the minimum royalties were \$3,000 in 2016, \$4,000 in 2017 and \$5,000 in 2018 and each calendar year thereafter during the term of the agreement.

Target Discovery Inc.

In March 2010, we signed a strategic product licensing, manufacturing, co-marketing, and collaborative research and development agreement with Target Discovery Inc. (“*TDI*”), a related party. Under the terms of the agreement, we have been licensed by TDI to manufacture and sell a highly innovative line of chemicals used in the preparation of tissues for scientific analysis (“*TDI reagents*”). The TDI reagents were designed for use in combination with our pressure cycling technology. The companies believe that the combination of PCT and the TDI reagents can fill an existing need in life science research for an automated method for rapid extraction and recovery of intact, functional proteins associated with cell membranes in tissue samples. We did not incur any royalty obligation under this agreement in 2020 or 2019.

In April 2012, we signed a non-exclusive license agreement with TDI to grant the non-exclusive use of our pressure cycling technology. We executed an amendment to this agreement on October 1, 2016 wherein we agreed to pay a monthly fee of \$1,400 for the use of a lab bench, shared space and other utilities, and \$2,000 per day for technical support services as needed. The agreement requires TDI to pay the Company a minimum royalty fee of \$50,000 in 2019 and \$60,000 in 2020.

Severance and Change of Control Agreements

Each of Mr. Schumacher, and Drs. Ting, and Lazarev, executive officers of the Company, are entitled to receive a severance payment if terminated by us without cause. The severance benefits would include a payment in an amount equal to one year of such executive officer’s annualized base salary compensation plus accrued paid time off. Additionally, the officer will be entitled to receive medical and dental insurance coverage for one year following the date of termination.

Each of these executive officers, other than Mr. Schumacher, is entitled to receive a change of control payment in an amount equal to one year of such executive officer’s annualized base salary compensation, accrued paid time off, and medical and dental coverage, in the event of their termination upon a change of control of the Company. In the case of Mr. Schumacher, this payment would be equal to two years of annualized base salary compensation, accrued paid time off, and two years of medical and dental coverage. The severance payment is meant to induce the aforementioned executives to remain in the employ of the Company, in general; and particularly in the occurrence of a change in control, as a disincentive to the control change.

(9) Convertible Debt and Other Debt

Convertible Debt

On various dates during the year ended December 31, 2019, the Company issued convertible notes for net proceeds of approximately \$6.6 million which contained varied terms and conditions as follows: a) maturity dates ranging from seven days to 12 months; b) interest rates that accrue per annum ranging from 3% to 15%; c) convertible to the Company's common stock at issuance at a fixed rate of \$2.50 to \$7.50 or convertible at variable conversion rates either after 6 months after issuance or in the event of a default. Certain of these notes were issued with shares of common stock or warrants to purchase common stock that were fair valued at issuance dates. The aggregate relative fair value of the shares of common stock or warrants to purchase common stock issued with the notes of \$448,589 was recorded as a debt discount and amortized over the term of the notes. We have also evaluated our convertible notes (upon issuance or modification) for any beneficial conversion feature ("BCF") and recorded a BCF of \$558,903 as a debt discount with a corresponding credit to additional paid in capital to be amortized over the term of the notes.

On various dates during the year ended December 31, 2020, the Company issued convertible notes for net proceeds of approximately \$8.3 million which contained varied terms and conditions as follows: a) 6-12 month maturity date; b) interest rates of 10-12% per annum c) convertible to the Company's common stock at issuance at a fixed rate of \$2.50. These notes were issued with shares of common stock or warrants to purchase common stock that were fair valued at issuance dates. The aggregate relative fair value of the shares of common stock issued with the notes of \$214,419 was recorded as a debt discount to be amortized over the term of the notes. The aggregate relative fair value of the warrants issued with the notes of \$4.9 million was also recorded as a debt discount to be amortized over the term of the notes. We then computed the effective conversion price of the notes and recorded a BCF of \$1.8 million as a debt discount to be amortized over the term of the notes. Finally, we evaluated our convertible notes for derivative liability treatment on an on-going basis and have determined that all our notes did not qualify for derivative accounting treatment at December 31, 2020. In the year ended December 31, 2020 the amortization of debt discount on convertible notes was \$5,118,222.

The specific terms of the convertible notes and outstanding balances as of December 31, 2020 are listed in the tables below.

Inception Date	Term	Loan Amount	Outstanding balance with OID	Original Issue Discount (OID)	Interest Rate	Conversion Price	Deferred Finance Fees	Discount for conversion feature and warrants/shares
May 17, 2018 (2)	12 months	\$ 380,000	\$ 166,703	\$ 15,200	8%	\$ 2.50	\$ 15,200	\$ 332,407
June 8, 2018 (1) (4)	6 months	\$ 50,000	\$ 50,000	\$ 2,500	2%	\$ 7.50	\$ 2,500	\$ 3,271
October 19, 2018 (1)	6 months	\$ 100,000	\$ 100,000	\$ -	5%	\$ 7.50	\$ -	\$ -
November 13, 2018 (1 (3) (4)	6 months	\$ 200,000	\$ 220,000	\$ -	5%	\$ 2.50	\$ -	\$ 168,634
January 3, 2019 (1) (4)	6 months	\$ 50,000	\$ 50,000	\$ 2,500	24%	\$ 7.50	\$ 2,500	\$ -
February 21, 2019 (2)	12 months	\$ 215,000	\$ 215,000	\$ -	4%	\$ 2.50	\$ 15,000	\$ 107,709
March 18, 2019 (1)	6 months	\$ 100,000	\$ 100,000	\$ -	4%	\$ 7.50	\$ -	\$ 10,762
June 4, 2019 (2)	9 months	\$ 500,000	\$ 302,484	\$ -	8%	\$ 2.50	\$ 40,500	\$ 70,631
June 19, 2019 (2)	12 months	\$ 105,000	\$ 105,000	\$ -	4%	\$ 2.50	\$ 5,000	\$ 2,646
May 20, 2019 (1) (4)	3 months	\$ 100,000	\$ 91,250	\$ -	5%	\$ 2.50	\$ -	\$ 13,439
June 7, 2019 (1) (4)	6 months	\$ 125,000	\$ 110,000	\$ -	5%	\$ 7.50	\$ -	\$ 18,254
July 1, 2019 (2)	12 months	\$ 107,500	\$ 107,500	\$ -	4%	\$ 2.50	\$ 7,500	\$ 85,791
July 19, 2019 (2)	12 months	\$ 115,000	\$ 115,000	\$ -	4%	\$ 2.50	\$ 5,750	\$ 15,460
July 19, 2019 (2)	12 months	\$ 130,000	\$ 130,000	\$ -	6%	\$ 2.50	\$ 6,500	\$ -
August 14, 2019 (1) (4)	6 months	\$ 50,000	\$ 50,000	\$ -	2%	\$ 7.50	\$ -	\$ -
September 27, 2019 (2)	12 months	\$ 78,750	\$ 78,750	\$ -	4%	\$ 2.50	\$ 3,750	\$ 13,759
October 24, 2019 (2)	12 months	\$ 78,750	\$ 78,750	\$ -	4%	\$ 2.50	\$ 3,750	\$ -
November 1, 2019 (2)	12 months	\$ 270,000	\$ 270,000	\$ -	6%	\$ 2.50	\$ 13,500	\$ -
November 15, 2019 (1)	12 months	\$ 385,000	\$ 320,000	\$ 35,000	10%	\$ 2.50	\$ 35,000	\$ 90,917
January 2, 2020 (1)	12 months	\$ 330,000	\$ 330,000	\$ 30,000	10%	\$ 2.50	\$ 30,000	\$ 91,606
January 24, 2020 (1)	12 months	\$ 247,500	\$ 247,500	\$ 22,500	10%	\$ 2.50	\$ 22,500	\$ 89,707
January 29, 2020 (1)	12 months	\$ 363,000	\$ 363,000	\$ 33,000	10%	\$ 2.50	\$ 33,000	\$ 297,000
February 12, 2020 (1)	12 months	\$ 275,000	\$ 275,000	\$ 25,000	10%	\$ 2.50	\$ 25,000	\$ 225,000
February 19, 2020 (1)	12 months	\$ 165,000	\$ 165,000	\$ 15,000	10%	\$ 2.50	\$ 15,000	\$ 135,000
March 11, 2020 (1)	12 months	\$ 330,000	\$ 330,000	\$ 30,000	10%	\$ 2.50	\$ 30,000	\$ 232,810
March 13, 2020 (1)	12 months	\$ 165,000	\$ 165,000	\$ 15,000	10%	\$ 2.50	\$ 15,000	\$ 60,705
March 26, 2020 (1)	12 months	\$ 111,100	\$ 111,100	\$ 10,100	10%	\$ 2.50	\$ 10,100	\$ 90,900
April 8, 2020	12 months	\$ 276,100	\$ 276,100	\$ 25,100	10%	\$ 2.50	\$ 25,000	\$ 221,654
April 17, 2020	12 months	\$ 143,750	\$ 143,750	\$ 18,750	10%	\$ 2.50	\$ -	\$ 96,208
April 30, 2020	12 months	\$ 546,250	\$ 546,250	\$ 71,250	10%	\$ 2.50	\$ 47,500	\$ 427,500
May 6, 2020	12 months	\$ 460,000	\$ 460,000	\$ 60,000	10%	\$ 2.50	\$ 40,000	\$ 360,000
May 18, 2020	12 months	\$ 546,250	\$ 221,250	\$ 46,250	10%	\$ 2.50	\$ 35,500	\$ 439,500
June 2, 2020	12 months	\$ 902,750	\$ 652,750	\$ 92,750	10%	\$ 2.50	\$ 58,900	\$ 708,500
June 12, 2020	12 months	\$ 57,500	\$ 57,500	\$ 7,500	10%	\$ 2.50	\$ 5,000	\$ 45,000
June 22, 2020	12 months	\$ 138,000	\$ 138,000	\$ 18,000	10%	\$ 2.50	\$ 12,000	\$ 108,000
July 7, 2020	12 months	\$ 586,500	\$ 586,500	\$ 76,500	10%	\$ 2.50	\$ 51,000	\$ 400,234
July 17, 2020	12 months	\$ 362,250	\$ 362,250	\$ 47,250	10%	\$ 2.50	\$ 31,500	\$ 185,698
July 29, 2020	12 months	\$ 345,000	\$ 345,000	\$ 45,000	10%	\$ 2.50	\$ 30,000	\$ 241,245
July 21, 2020 (5)		\$ 115,000	\$ 115,000	\$ 15,000	10%	\$ 2.50	\$ 10,000	\$ 24,875

	12 months								
August 14, 2020	12 months	\$ 762,450	\$ 462,450	\$ 69,450	10%	\$ 2.50	\$ 66,300	\$ 580,124	
September 10, 2020	12 months	\$ 391,000	\$ 391,000	\$ 51,000	10%	\$ 2.50	\$ 34,000	\$ 231,043	
September 21, 2020 (5)	12 months	\$ 345,000	\$ 345,000	\$ 45,000	10%	\$ 2.50	\$ 30,000	\$ 66,375	
September 23, 2020 (5)	12 months	\$ 115,000	\$ 115,000	\$ 15,000	10%	\$ 2.50	\$ 10,000	\$ 20,500	
September 25, 2020 (5)	12 months	\$ 115,000	\$ 115,000	\$ 15,000	10%	\$ 2.50	\$ -	\$ 19,125	
December 3, 2020	12 months	\$ 299,000	\$ 299,000	\$ 39,000	10%	\$ 2.50	\$ 26,000	\$ 197,882	
December 21, 2020	6 months	\$ 100,000	\$ 100,000	\$ 5,000	12%	\$ 2.50	\$ 29,964	\$ 24,400	
October 22, 2020 (5)	12 months	\$ 115,000	\$ 115,000	\$ 15,000	10%	\$ 2.50	\$ 10,000	\$ 18,875	
December 23, 2020 (5)	6 months	\$1,000,000	<u>\$ 1,000,000</u>	<u>\$ 100,000</u>	10%	\$ 2.50	<u>\$ -</u>	<u>\$ 833,536</u>	
			<u>\$11,493,837</u>	<u>\$1,113,600</u>			<u>\$889,714</u>	<u>\$ 7,406,682</u>	

- (1) The Note is past due. The Company and the lender are negotiating in good faith to extend the loan.
- (2) As of December 31, 2020 lender entered into a Standstill and Forbearance agreement (as described below). Loan is convertible at \$2.50 until the expiration of the agreement.
- (3) Interest was capitalized and added to outstanding principal.
- (4) During the year ended December 31, 2020 the Company entered into Rate Modification Agreements with these lenders.
- (5) The Company has agreed to issue shares of common stock or warrants to lenders if their notes are not repaid by a defined date.

As of December 31, 2020 one lender holds approximately \$7.2 million of the \$11.5 million convertible notes outstanding.

In the year ended December 31, 2020, the Company issued three loans for \$875,000 to its pending merger partner, Cannaworx who agreed to repay the loans directly to the Company's lender, on the Company's behalf. In the fourth quarter, the Company netted the \$875,000 of the receivables against loans payable to this lender following confirmation of a right of offset agreement.

For the year ended December 31, 2020, the Company recognized amortization expense related to the debt discounts indicated above of \$5,118,222. The unamortized debt discounts as of December 31, 2020 related to the convertible debentures and other convertible notes amounted to \$3,948,167 (net of a \$73,750 discount to the \$875,000 loan receivable). For the year ended December 31, 2019, the Company recognized amortization expense related to the debt discounts indicated above \$1,257,567. The unamortized debt discounts as of December 31, 2019 related to the convertible debentures and other convertible notes amounted to \$619,227.

Standstill and Forbearance Agreements

On December 13, 2019, the Company entered into Standstill and Forbearance Agreements with lenders who hold convertible promissory notes with a total principal of \$2,267,066. Pursuant to the Standstill and Forbearance Agreements, the lenders agreed to not convert any portion of their notes into shares of common stock at a variable rate until either January 30th or January 31st of 2020, and to waive, through January 30th or January 31st of 2020, all of the Company's defaults under their notes including, but not limited to, the late filing of the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019.

On January 31, 2020 and again on March 3, 2020, April 6, 2020, April 30, 2020, May 15, 2020, May 31, 2020, June 15, 2020, June 30, 2020, July 15, 2020, July 31, 2020, August 15, 2020, August 31, 2020, September 15, 2020, September 30, 2020, October 15, 2020, October 31, 2020, November 15, 2020, November 30, 2020, December 15, 2020 and December 31, 2020 the Company extended these Standstill and Forbearance Agreements until dates ranging from November 16, 2020 to January 15, 2021. For the year ended December 31, 2020, the Company incurred fees of approximately \$2.5 million to extend the agreements.

Convertible Loan Modifications and Extinguishments

We refinanced certain convertible loans during the years ended December 31, 2020 and 2019 at substantially the same terms for extensions ranging over a period of three to six months. We amortized any remaining unamortized debt discount as of the modification date over the remaining, extended term of the new loans. We applied ASC 470 of modification accounting to the debt instruments which were modified during the period or those settled with new notes issued concurrently for the same amounts but different maturity dates. The terms such as the interest rate, prepayment penalties, and default rates will be the same over the new extensions. According to ASC 470, an exchange of debt instruments between or a modification of a debt instrument by a debtor and a creditor in a nontroubled debt situation is deemed to have been accomplished with debt instruments that are substantially different if the present value of the cash flows under the terms of the new debt instrument is at least 10 percent different from the present value of the remaining cash flows under the terms of the original instrument. If the terms of a debt instrument are changed or modified and the cash flow effect on a present value basis is less than 10 percent, the debt instruments are not considered to be substantially different and will be accounted for as modifications.

The cash flows of new debt exceeded 10% of the remaining cash flows of the original debt on several loans in 2020 and 2019. We recorded losses on extinguishment of liabilities of \$3,575,878 in 2020 and \$795,089 in 2019. Our gains and losses were measured by calculating the difference of the fair value of the new debt and the carrying value of the old debt.

The following table provides a summary of the changes in convertible debt and revolving note payable, net of unamortized discounts, during 2020:

	2020
Balance at January 1,	\$ 6,121,338
Issuance of convertible debt, face value	10,202,150
Deferred financing cost	(1,905,350)
Beneficial conversion feature on convertible note	(1,756,311)
Debt discount from shares and warrants issued with debt	(4,874,250)
Conversion of debt into equity	(1,701,872)
Payments	(2,857,007)
Accretion of interest and amortization of debt discount to interest expense through December 31	5,118,222
Note receivable netted against loan	(801,250)
Balance at December 31	7,545,670
Less: current portion	7,545,670
Convertible debt, long-term portion	\$ -

Other Notes

On September 9, 2019 and February 28, 2020 we received a total of \$966,500 unsecured non-convertible loans from a private investor with a one-month term. During the year ended December 31, 2020, the Company received net proceeds of \$463,500, issued 150,000 warrants to purchase common stock (five-year term and \$3.50 exercise price) and repaid \$275,000. The relative fair value of \$185,660 of the warrants issued with the note was recorded as a debt discount to be amortized over the term of the notes. As of December 31, 2020 and 2019 the Company owes \$691,500 and \$400,000, respectively on these notes which are past due. The Company and the investor are negotiating in good faith to extend the loans.

On October 1, 2019, the Company and the holder of the \$170,000 non-convertible loan issued in May 2017 agreed to extend the term of the loan to December 31, 2019. The Company agreed to issue 1,200 shares of its common stock per month while the note remains outstanding. The note will continue to earn 10% annual interest. The loan is currently past due and the Company and the investor are negotiating in good faith to extend the loan.

On October 11, 2019 we received a non-convertible loan with a one month term and a 2% interest charge for \$25,000 from a private investor. The loan is past due and the Company and the investor are negotiating in good faith to extend the loan.

Merchant Agreements

During the years ended December 31, 2020 and 2019 we signed various Merchant Agreements which are secured by second position rights to all customer receipts until the loan has been repaid in full and subject to interest rates of 6% - 76%. As illustrated in the following table, under the terms of these agreements, we received the disclosed Purchase Price and agreed to repay the disclosed Purchase Amount, which is collected by the Merchant lenders at the disclosed Daily Payment Rate.

The following table shows our Merchant Agreements as of December 31, 2020:

Inception Date	Purchase Price	Purchased Amount	Outstanding Balance	Daily Payment Rate	Deferred Finance Fees
November 5, 2020	\$ 200,000	\$ 275,800	\$ 163,955	1,724.00	\$ -
November 19, 2020	100,000	137,900	85,013	985.00	-
	<u>\$ 300,000</u>	<u>\$ 413,700</u>	<u>\$ 248,968</u>	<u>\$ 2,709.00</u>	<u>\$ -</u>

The following table shows our Merchant Agreements as of December 31, 2019:

Inception Date	Purchase Price	Purchased Amount	Outstanding Balance	Daily Payment Rate	Deferred Finance Fees
August 5, 2019	\$ 600,000	\$ 816,000	\$ 421,024	4,533.33	\$ 6,000
August 19, 2019	350,000	479,500	272,315	2,664.00	3,000
August 23, 2019	175,000	239,750	132,284	1,410.00	1,750
September 19, 2019	275,000	384,275	256,812	2,137.36	5,000
	<u>\$ 1,400,000</u>	<u>\$ 1,919,525</u>	<u>\$ 1,082,435</u>	<u>\$ 10,744.69</u>	<u>\$ 15,750</u>

We have accounted for the Merchant Agreements as loans under ASC 860 because while we provided rights to current and future receipts, we still had control over the receipts. The difference between the Purchase Amount and the Purchase Price is imputed interest that is recorded as interest expense when paid each day.

We amortized \$318,641 and \$95,916 of debt discounts during the years ended December 31, 2020 and 2019, respectively for all non-convertible notes. The total unamortized discount for all non-convertible notes as of December 31, 2020 and 2019 was \$0 and \$1,769, respectively.

On November 15, 2019 the Company and its Merchant lenders agreed to a temporary reduction in the Daily Payment Rate for the four loans outstanding during 2019 (and as of December 31, 2019). Subsequently, on January 31, 2020, March 2, 2020 and April 6, 2020 the Company and its Merchant lenders agreed to extend the term of the reduction of its Daily Payment Rate, ultimately to April 30, 2020. The Company issued 495,000 warrants to lenders (valued at \$969,745) as compensation for these agreements. The warrants have a three-year life and a \$3.50 exercise Price. During the year ended December 31, 2020 the Company repaid these loans in full for \$970,028 in cash, 112,885 shares of common stock (valued at \$225,770) and 56,442 warrants that have a three year life and a \$3.50 exercise price (valued at \$97,654) and the loss incurred from the settlements is \$58,476.

The new loans with Merchant lenders were executed in November 2020, as illustrated in the table as of December 31, 2020.

Related Party Notes

In June 2018, we received a non-convertible loan of \$15,000 from a private investor. The loan includes a one-year term and 15% guaranteed interest. This loan remains outstanding at December 31, 2020 and is currently past due.

During the year ended December 31, 2020, we received short-term non-convertible loans of \$283,700 from related parties and repaid \$199,200 of related party loans. These notes bear interest ranging from 0% to 15% interest and are due upon demand.

Long term debt

During the year ended December 31, 2020, the Company borrowed \$527,039 through COVID-19 programs that were sponsored by the United States and administered by the Small Business Administration (the “SBA”). The most notable programs were the Payroll Protection Program (or “PPP”) and the Economic Injury Disaster Loan program (or “EIDL”). The Company’s PPP loan, \$377,039, has a two- year term and bears interest at 1% per annum. Under the PPP, the Company can be granted forgiveness for all or a portion of these loans based on the Company’s spending on payroll, mortgage interest, rent and utilities. The Company’s EIDL loan, \$150,000, accrues interest at 3.75% and requires monthly payments of \$731 for principal and interest beginning in June 2021. The balance of the principal will be due in 30 years. In connection with the EIDL loan the Company entered into a security agreement with the SBA, whereby the Company granted the SBA a security interest in all of the Company’s right, title and interest in all of the Company’s assets.

(10) Stockholders’ (Deficit)

Preferred Stock

We are authorized to issue 1,000,000 shares of preferred stock with a par value of \$0.01. Of the 1,000,000 shares of preferred stock:

- 1) 20,000 shares have been designated as Series A Junior Participating Preferred Stock (“*Junior A*”)
- 2) 313,960 shares have been designated as Series A Convertible Preferred Stock (“*Series A*”)
- 3) 279,256 shares have been designated as Series B Convertible Preferred Stock (“*Series B*”)
- 4) 88,098 shares have been designated as Series C Convertible Preferred Stock (“*Series C*”)
- 5) 850 shares have been designated as Series D Convertible Preferred Stock (“*Series D*”)
- 6) 500 shares have been designated as Series E Convertible Preferred Stock (“*Series E*”)
- 7) 240,000 shares have been designated as Series G Convertible Preferred Stock (“*Series G*”)
- 8) 10,000 shares have been designated as Series H Convertible Preferred Stock (“*Series H*”)
- 9) 21 shares have been designated as Series H2 Convertible Preferred Stock (“*Series H2*”)
- 10) 6,250 shares have been designated as Series J Convertible Preferred Stock (“*Series J*”)
- 11) 15,000 shares have been designated as Series K Convertible Preferred Stock (“*Series K*”)
- 12) 10,000 shares have been designated as Series AA Convertible Preferred Stock (“*Series AA*”)

As of December 31, 2020, there were no shares of Junior A, and Series A, B, C, and E issued and outstanding.

Series D Convertible Preferred Stock

On November 11, 2011, we completed a registered direct offering, pursuant to which we sold an aggregate of 843 units for a purchase price of \$1,000 per unit, resulting in gross proceeds to us of \$843,000 (the “*Series D Placement*”). Each unit (“*Series D Unit*”) consisted of (i) one share of Series D Convertible Preferred Stock, \$0.01 par value per share (the “*Series D Convertible Preferred Stock*”) convertible into 84 shares of our common stock, (subject to adjustment for stock splits, stock dividends, recapitalization, etc.) and (ii) one five-year warrant to purchase approximately 21 shares of our common stock at a per share exercise price of \$24.30, subject to adjustment as provided in the Warrants (“*Series D Warrant*”). The Series D Warrants will be exercisable beginning on May 11, 2012 and until the close of business on the fifth anniversary of the initial exercise date.

The Series D Convertible Preferred Stock will rank senior to the Company's common stock with respect to payments made upon liquidation, winding up or dissolution. Upon any liquidation, dissolution or winding up of the Company, after payment of the Company's debts and liabilities, and before any payment is made to the holders of any junior securities, the holders of Series D Convertible Preferred Stock will first be entitled to be paid \$1,000 per share subject to adjustment for accrued but unpaid dividends.

We may not pay any dividends on shares of common stock unless we also pay dividends on the Series D Convertible Preferred Stock in the same form and amount, on an as-if-converted basis, as dividends actually paid on shares of our common stock. Except for such dividends, no other dividends may be paid on the Series D Convertible Preferred Stock.

Each share of Series D Convertible Preferred Stock is convertible into 84 shares of common stock (based upon an initial conversion price of \$19.50 per share) at any time at the option of the holder, subject to adjustment for stock splits, stock dividends, combinations, and similar recapitalization transactions (the "*Series D Conversion Ratio*"). Subject to certain exceptions, if the Company issues any shares of common stock or common stock equivalents at a per share price that is lower than the conversion price of the Series D Convertible Preferred Stock, the conversion price will be reduced to the per share price at which such shares of common stock or common stock equivalents are issued. Each share of Series D Convertible Preferred Stock will automatically be converted into shares of common stock at the Series D Conversion Ratio then in effect if, after six months from the closing of the Series D Placement, the common stock trades on the OTCQB (or other primary trading market or exchange on which the common stock is then traded) at a price equal to at least 300% of the then effective Series D Convertible Preferred Stock conversion price for 20 out of 30 consecutive trading days with each trading day having a volume of at least \$50,000. Unless waived under certain circumstances by the holder of the Series D Convertible Preferred Stock, such holder's Series D Convertible Preferred Stock may not be converted if upon such conversion the holder's beneficial ownership would exceed certain thresholds.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our shares of common stock are converted or exchanged for securities, cash or other property, or we sell, lease, license or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the Series D Convertible Preferred Stock will be entitled to receive upon conversion of the Series D Convertible Preferred Stock the same kind and amount of securities, cash or property which the holders of the Series D Convertible Preferred Stock would have received had they converted the Series D Convertible Preferred Stock immediately prior to such fundamental transaction.

The holders of Series D Convertible Preferred Stock are not entitled to vote on any matters presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), except that the holders of Series D Convertible Preferred Stock may vote separately as a class on any matters that would (i) amend, our Restated Articles of Organization, as amended, in a manner that adversely affects the rights of the Series D Convertible Preferred Stock, (ii) alter or change adversely the powers, preferences or rights of the Series D Convertible Preferred Stock or alter or amend the certificate of designation, (iii) authorize or create any class of shares ranking as to dividends, redemption or distribution of assets upon liquidation senior to, or otherwise *pari passu* with, the Series D Convertible Preferred Stock, or (iv) increase the number of authorized shares of Series D Convertible Preferred Stock.

If, within 12 months of the initial issuance of the Series D Convertible Preferred Stock, we issue any common stock, common stock equivalents, indebtedness or any combination thereof (a "*Subsequent Financing*"), the holders of Series D Convertible Preferred Stock will have the right to participate on a pro-rata basis in up to 50% of such Subsequent Financing.

Series D Warrants

The Series D Warrants originally had an exercise price equal to \$24.30 per share of common stock. In April 2012, the number of Series D Warrants increased by 17,681 to a total of 34,930 and each Series D Warrant had an exercise price reset to \$12.00 per share of common stock. In December of 2013 the number of Series D Warrants increased by 20,958 to a total of 55,887 and each Series D Warrant had an exercise price reset to \$7.50 per share of common stock. The Series D Warrants will be exercisable beginning on the six-month anniversary of the date of issuance and expire five years from the initial exercise date. The Series D Warrants permit the holder to conduct a "cashless exercise" at any time a registration statement registering, or the prospectus contained therein, is not available for the issuance of the shares of common stock issuable upon exercise of the Series D Warrant, and under certain circumstances at the expiration of the Series D Warrants. The exercise price and/or number of shares of common stock issuable upon exercise of the Series D Warrants are subject to adjustment for certain stock dividends, stock splits or similar capital reorganizations, as set forth in the Warrants. The exercise price is also subject to adjustment in the event that we issue any shares of common stock or common stock equivalents at a per share price that is lower than the exercise price for the Series D Warrants then in effect. Upon any such issuance, subject to certain exceptions, the exercise price will be reduced to the per share price at which such shares of common stock or common stock equivalents are issued and number of Series D Warrant shares issuable thereunder shall be increased such that the aggregate exercise price payable thereunder, after taking into account the decrease in the exercise price, shall be equal to the aggregate exercise price prior to such adjustment. Unless waived under certain circumstance by the holder of a Series D Warrant, such holder may not exercise the Series D Warrant if upon such exercise the holder's beneficial ownership of the Company's common stock would exceed certain thresholds.

In the event we consummate a merger or consolidation with or into another person or other reorganization event in which our shares of common stock are converted or exchanged for securities, cash or other property, or we sell, lease, license or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the Series D Warrants will be entitled to receive upon exercise of the Series D Warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the Series D Warrants immediately prior to such fundamental transaction.

On May 10, 2017, we received net proceeds of \$140,214 from the exercise of 19,889 stock purchase warrants from the Series D registered direct offering on November 10, 2011. In consideration for the warrant exercises, we issued to the investors warrants to purchase 39,778 shares of our Common Stock at an exercise price per share equal to \$8.40 per share. The warrants expire on the third year anniversary date. We determined the fair value of \$186,802 for these warrants and recorded the value as other expenses.

Series G Convertible Preferred Stock

On July 6 and November 15, 2012, we completed a private placement, pursuant to which we sold an aggregate of 4,844 units for a purchase price of \$150.00 per unit (the “Series G Purchase Price”), resulting in gross proceeds to us of \$726,600 (the “*Series G Private Placement*”). Each unit (“*Series G Unit*”) consists of (i) one share of Series G Convertible Preferred Stock, \$0.01 par value per share (the “Series G Preferred Stock”) convertible into 1 share of our common stock, (subject to adjustment for stock splits, stock dividends, recapitalization, etc.) and (ii) a three-year warrant to purchase 1 share of our common stock at a per share exercise price of \$15.00 (the “*Series G Warrant*”). The Series G Warrants will be exercisable until the close of business on the third anniversary of the applicable closing date of the Series G Private Placement.

Each share of Series G Preferred Stock will receive a cumulative dividend at the annual rate of (i) four percent (4%) on those shares of Series G Preferred Stock purchased from the Company by an individual purchaser with an aggregate investment of less than \$100,000, (ii) six percent (6%) on those shares of Series G Preferred Stock purchased from the Company by an individual purchaser with an aggregate investment of at least \$100,000 but less than \$250,000, and (iii) twelve percent (12%) on those shares of Series G Preferred Stock purchased from the Company by an individual purchaser with an aggregate investment of at least \$250,000. Dividends accruing on the Series G Preferred Stock shall accrue from day to day until, and shall be paid within fifteen (15) days of, the first anniversary of, the original issue date of the Series G Preferred Stock; provided, however, if any shares of the Company’s Series E Preferred Stock are outstanding at such time, payment of the accrued dividends on the Series G Preferred Stock shall be deferred until no such shares of Series E Convertible Preferred Stock remain outstanding. The Company may pay accrued dividends on the Series G Preferred Stock in cash or in shares of its common stock equal to the volume weighted average price of the common stock as reported by the OTCQB for the ten (10) trading days immediately preceding the Series G’s first anniversary.

At the election of the Company and upon required advanced notice, each share of Series G Preferred Stock will automatically be converted into shares of common stock at the Conversion Ratio then in effect: (i) if, after 6 months from the original issuance date of the Series G Preferred Stock, the common stock trades on the OTCQB (or other primary trading market or exchange on which the common stock is then traded) at a price equal to at least \$22.50, for 7 out of 10 consecutive trading days with average daily trading volume of at least 334 shares, (ii) on or after the first anniversary of the original issuance date of the Series G Preferred Stock or (iii) upon completion of a firm-commitment underwritten registered public offering by the Company at a per share price equal to at least \$22.50, with aggregate gross proceeds to the Company of not less than \$2.5 million. Unless waived under certain circumstances by the holder of the Series G Preferred Stock, such holder’s Series G Preferred Stock may not be converted if upon such conversion the holder’s beneficial ownership would exceed certain thresholds.

The holders of Series G Preferred Stock are not entitled to vote on any matters presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), except as required by law.

Series H Convertible Preferred Stock

On December 28, 2012 the Company amended the Articles of Incorporation to authorize 10,000 shares of Series H Convertible Preferred Stock. On January 4, 2013, the Company reported that it had entered into a securities purchase and exchange agreement with an investor, pursuant to which the Company agreed to exchange 33,334 shares of the Company's common stock, par value \$0.01 per share of common stock held by the investor for an aggregate of 10,000 shares of a newly created series of preferred stock, designated Series H Convertible Preferred Stock, par value \$0.01 per share (the "*Series H Preferred Stock*") in a non-cash transaction. The investor originally purchased the common stock from the Company for \$24.08 per share. The exchange ratio was 4 shares of common stock per share of Series H Preferred Stock at a stated conversion price of \$24.08 per share.

Series H2 Convertible Preferred Stock

On December 23, 2014 the Company amended the Articles of Incorporation to authorize 21 shares of Series H2 Convertible Preferred Stock. On December 23, 2014, the Company reported that it had entered into a securities purchase and exchange agreement with an investor, pursuant to which the Company agreed to exchange 70,000 shares of the Company's common stock, par value \$0.01 per share of common stock held by the investor for an aggregate of 21 shares of a newly created series of preferred stock, designated Series H2 Convertible Preferred Stock, par value \$0.01 per share (the "*Series H2 Preferred Stock*") in a non-cash transaction. The investor originally acquired the common stock from the Company for \$7.50 per share in the warrant reset transaction on December 23, 2014. The exchange ratio was 3,334 shares of common stock per share of Series H2 Preferred Stock at a stated conversion price of \$7.50 per share.

Series J Convertible Preferred Stock

On February 6, March 28 and May 20, 2013, the Company entered into a Securities Purchase with various individuals pursuant to which the Company sold an aggregate of 5,087.5 units for a purchase price of \$400.00 per unit (the "Purchase Price"), or an aggregate Purchase Price of \$2,034,700. Each unit purchased in the initial tranche consists of (i) one share of a newly created series of preferred stock, designated Series J Convertible Preferred Stock, par value \$0.01 per share (the "Series J Convertible Preferred Stock"), convertible into 34 shares of the Company's common stock, par value \$0.01 per share and (ii) a warrant to purchase 34 shares of common stock at an exercise price equal to \$12.00 per share. The warrants expire three years from the issuance date.

From the date of issuance of any shares of Series J Convertible Preferred Stock and until the earlier of the first anniversary of such date, the voluntary conversion of any shares of Series J Convertible Preferred Stock, or the date of any mandatory conversion (solely under the Company's control based upon certain triggering events) of the Series J Convertible Preferred Stock, dividends will accrue on each share of Series J Convertible Preferred Stock at an annual rate of (i) four percent (4%) of the Purchase Price on those shares of Series J Convertible Preferred Stock purchased from the Company pursuant to the Securities Purchase Agreement by an individual purchaser who purchased from the Company shares of Series J Convertible Preferred Stock with an aggregate Purchase Price of less than \$250,000, and (ii) six percent (6%) of the Purchase Price on those shares of Series J Convertible Preferred Stock purchased from the Company pursuant to the Securities Purchase Agreement by an individual purchaser who purchased shares of Series J Convertible Preferred Stock with an aggregate purchase price of at least \$250,000. Dividends accruing on the Series J Convertible Preferred Stock shall accrue from day to day until the earlier of the first anniversary of the date of issuance of such shares of Series J Convertible Stock, the voluntary conversion of any shares of Series J Convertible Preferred Stock, or the date of any mandatory conversion of the Series J Convertible Preferred Stock, and shall be paid, as applicable, within fifteen (15) days of the first anniversary of the original issue date of the Series J Convertible Preferred Stock, within five (5) days of the voluntary conversion of shares of the Series J Convertible Preferred Stock, or within five (5) days of the mandatory conversion of shares of the Series J Convertible Preferred Stock. The Company may pay accrued dividends on the Series J Convertible Preferred Stock in cash or, in the sole discretion of the Board of Directors of the Company, in shares of its common stock in accordance with a specified formula.

Each share of Series J Convertible Preferred Stock is convertible into 34 shares of common stock at the option of the holder on or after the six-month anniversary of the issuance of such share, subject to adjustment for stock splits, stock dividends, recapitalizations and similar transactions (the "Conversion Ratio"). Unless waived under certain circumstances by the holder of Series J Convertible Preferred Stock, such holder's shares of Series J Convertible Preferred Stock may not be converted if upon such conversion the holder's beneficial ownership would exceed certain thresholds.

At the election of the Company and upon required advance notice, each share of Series J Convertible Preferred Stock will automatically be converted into shares of common stock at the Conversion Ratio then in effect: (i) on or after the six-month anniversary of the original issuance date of the Series J Convertible Preferred Stock, the common stock trades on the OTCQB (or other primary trading market or exchange on which the common stock is then traded) at a price per share equal to at least \$24.00 for 7 out of 10 consecutive trading days with average daily trading volume of at least 1,667 shares, (ii) on the first anniversary of the original issuance date of the Series J Convertible Preferred Stock or (iii) within three days of the completion of a firm-commitment underwritten registered public offering by the Company at a per share price equal to at least \$24.00, with aggregate gross proceeds to the Company of not less than \$2.5 million. Unless waived under certain circumstances by the holder of the Series J Convertible Preferred Stock, such holder's Series J Convertible Preferred Stock may not be converted if upon such conversion the holder's beneficial ownership would exceed certain thresholds.

The holders of Series J Convertible Preferred Stock are not entitled to vote on any matters presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), except as required by law.

Series K Convertible Preferred Stock

From the date of issuance of any shares of Series K Convertible Preferred Stock and until the earlier of the first anniversary of such date, the voluntary conversion of any shares of Series K Convertible Preferred Stock, or the date of any mandatory conversion (solely under the Company's control based upon certain triggering events) of the Series K Convertible Preferred Stock, dividends will accrue on each share of Series K Convertible Preferred Stock at an annual rate of (i) four percent (4%) of the Purchase Price on those shares of Series K Convertible Preferred Stock purchased from the Company pursuant to the Securities Purchase Agreement by an individual purchaser who purchased from the Company shares of Series K Convertible Preferred Stock with an aggregate Purchase Price of less than \$100,000, and (ii) six percent (6%) of the Purchase Price on those shares of Series K Convertible Preferred Stock purchased from the Company pursuant to the Securities Purchase Agreement by an individual purchaser who purchased shares of Series K Convertible Preferred Stock with an aggregate purchase price of at least \$100,000. Dividends accruing on the Series K Convertible Preferred Stock shall accrue from day to day until the earlier of the first anniversary of the date of issuance of such shares of Series K Convertible Stock, the voluntary conversion of any shares of Series K Convertible Preferred Stock, or the date of any mandatory conversion of the Series K Convertible Preferred Stock, and shall be paid, as applicable, within fifteen (15) days of the first anniversary of the original issue date of the Series K Convertible Preferred Stock, within five (5) days of the voluntary conversion of shares of the Series K Convertible Preferred Stock, or within five (5) days of the mandatory conversion of shares of the Series K Convertible Preferred Stock. The Company may pay accrued dividends on the Series K Convertible Preferred Stock in cash or, in the sole discretion of the Board of Directors of the Company, in shares of its common stock in accordance with a specified formula.

Each share of Series K Convertible Preferred Stock is convertible into 34 shares of common stock at the option of the holder on or after the six-month anniversary of the issuance of such share, subject to adjustment for stock splits, stock dividends, recapitalizations and similar transactions (the "Conversion Ratio"). Unless waived under certain circumstances by the holder of Series K Convertible Preferred Stock, such holder's shares of Series K Convertible Preferred Stock may not be converted if upon such conversion the holder's beneficial ownership would exceed certain thresholds.

At the election of the Company and upon required advance notice, each share of Series K Convertible Preferred Stock will automatically be converted into shares of common stock at the Conversion Ratio then in effect: (i) on or after the six-month anniversary of the original issuance date of the Series K Convertible Preferred Stock, the common stock trades on the OTCQB (or other primary trading market or exchange on which the common stock is then traded) at a price per share equal to at least \$24.00 for 7 out of 10 consecutive trading days with average daily trading volume of at least 1,667 shares, (ii) on the first anniversary of the original issuance date of the Series K Convertible Preferred Stock or (iii) within three days of the completion of a firm-commitment underwritten registered public offering by the Company at a per share price equal to at least \$24.00, with aggregate gross proceeds to the Company of not less than \$2.5 million. Unless waived under certain circumstances by the holder of the Series K Convertible Preferred Stock, such holder's Series K Convertible Preferred Stock may not be converted if upon such conversion the holder's beneficial ownership would exceed certain thresholds.

The holders of Series K Convertible Preferred Stock are not entitled to vote on any matters presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), except as required by law.

Series AA Convertible Preferred Stock and Warrants

During the year ended December 31, 2019, the Company entered into Securities Purchase Agreements with accredited investors pursuant to which the Company sold an aggregate of 1,456 shares of Series AA Convertible Preferred Stock, each preferred share convertible into 1,000 shares of the Company's common stock, par value \$0.01 per share, for an aggregate Purchase price of approximately \$3.6 million. We issued to the investors warrants to purchase an aggregate 1,455,600 shares of common stock with an exercise price of \$3.50 per share. The placement agent for this transaction received 145,560 warrants with a value of \$405,557 and cash fees of \$363,819 which were recognized as preferred stock offering costs and charged to additional paid in capital.

During the year ended December 31, 2020, the Company entered into Securities Purchase Agreements with accredited investors pursuant to which the Company sold an aggregate of 60 shares of Series AA Convertible Preferred Stock, each preferred share convertible into 1,000 shares of the Company's common stock, par value \$0.01 per share, for an aggregate Purchase price of approximately \$150,000. We issued to the investors warrants to purchase an aggregate 60,000 shares of common stock with an exercise price of \$3.50 per share. The Company did not incur any placement agent fees for this transaction. In this time we also converted \$110,000 of debt into 44 shares of Series AA preferred stock and 44,000 warrants to acquire common stock (five-year term and \$3.50 exercise price). The relative fair value of warrants is \$38,783.

The issuances of our convertible preferred stock and common stock purchase warrants are accounted for under the fair value and relative fair value method.

The warrant is first analyzed per its terms as to whether it has derivative features or not. If the warrant is determined to be a derivative, then it is measured at fair value using the Black Scholes Option Model and recorded as a liability on the balance sheet. The warrant is re-measured at its then current fair value at each subsequent reporting date (it is "marked-to-market").

If the warrant is determined to not have derivative features, it is recorded into equity at its fair value using the Black Scholes option model, however, limited to a relative fair value based upon the percentage of its fair value to the total fair value including the fair value of the convertible preferred stock.

We analyzed these warrants issued in 2019 and determined that they were not considered derivatives and therefore recorded the aggregate relative fair value of \$2,307,909 into equity relating to the 1,455,600 investor warrants and 145,560 broker warrants issued during 2019.

We analyzed the warrants issued in 2020 and determined that they were not considered derivatives and therefore recorded the aggregate relative fair value of \$69,580 into equity relating to the 60,000 investor warrants issued during 2020.

The convertible preferred stock is recorded at its fair value, limited to a relative fair value based upon the percentage of its fair value to the total fair value including the fair value of the warrant. Further, the convertible preferred stock is examined for any intrinsic BCF of which the convertible price of the preferred stock is less than the closing stock price on date of issuance. If the relative fair value method is used to value the convertible preferred stock and there is an intrinsic BCF, a further analysis is undertaken of the BCF using an effective conversion price which assumes the conversion price is the relative fair value divided by the number of shares of common stock the convertible preferred stock is converted into by its terms. The adjusted BCF value of \$61,180 and \$2,653,344 was accounted for as a deemed dividend within equity and was included in the earnings per share calculation for the years ended December 31, 2020 and 2019, respectively.

Common Stock

Stock Options and Warrants

At the Company's December 12, 2013 Special Meeting, the shareholders approved the 2013 Equity Incentive Plan (the "2013 Plan") pursuant to which 3,000,000 shares of our common stock were reserved for issuance upon exercise of stock options or other equity awards. Under the 2013 Plan, we may award stock options, shares of common stock, and other equity interests in the Company to employees, officers, directors, consultants, and advisors, and to any other persons the Board of Directors deems appropriate. As of December 31, 2020, options to acquire 1,355,901 shares were outstanding under the Plan.

All of the outstanding non-qualified options had an exercise price that was at or above the Company's common stock share price at time of issuance.

On December 19, 2019 the Board of Directors approved the re-pricing of 380,630 outstanding stock options with an exercise price of \$3.40 to \$0.69 (the closing market price on December 19, 2019). The vesting schedule and term of these options remained unchanged. The Board also awarded 1,014,240 stock options to officers, employees, contractor and board members based on the annual compensation committee recommendation.

We accounted for these transactions as modifications under ASC 718. Therefore, incremental compensation cost shall be measured as the excess of the fair value of the replacement award or other valuable consideration over the fair value of the cancelled award at the cancellation date. The total compensation cost measured at the date of a cancellation and replacement shall be the portion of the grant-date fair value of the original award for which the requisite service is expected to be rendered (or has already been rendered) at that date plus the incremental cost resulting from the cancellation and replacement. The compensation value created by the repricing of stock options in 2019 and the termination and issuance of new stock options in 2018, as determined under the Black Scholes method, was approximately \$73,355 and \$759,469, respectively, and under ASC 718 results in a non-cash expense in current and future periods not to exceed the vesting periods of the stock options.

As of December 31, 2019, total unrecognized compensation cost related to the unvested stock-based awards was \$761,770, which is expected to be recognized over weighted average period of 2.37 years. The aggregate intrinsic value associated with the options outstanding and exercisable and the aggregate intrinsic value associated with the warrants outstanding and exercisable as of December 31, 2019, based on the December 31, 2019 closing stock price of \$1.25, was \$136,683.

As of December 31, 2020, total unrecognized compensation cost related to the unvested stock-based awards was \$304,900, which is expected to be recognized over weighted average period of 1.59 years. The aggregate intrinsic value associated with the options outstanding and exercisable and the aggregate intrinsic value associated with the warrants outstanding and exercisable as of December 31, 2020, based on the December 31, 2020 closing stock price of \$2.12, was \$1,240,469.

The following tables summarize information concerning options and warrants outstanding and exercisable:

	Stock Options		Warrants		Total	
	Shares	Weighted Average price per share	Shares	Weighted Average price per share	Shares	Exercisable
Balance outstanding, January 1, 2019	366,734	\$ 3.39	7,764,821	\$ 3.50	8,131,555	7,792,570
Granted	1,447,420	0.81	2,153,214	3.50	3,600,634	
Exercised	-	-	-	-	-	
Expired	-	-	(25,001)	14.82	(25,001)	
Forfeited	(417,852)	3.39	-	-	(417,852)	
Balance outstanding, December 31, 2019	1,396,302	\$ 0.71	9,893,034	\$ 3.52	11,289,336	10,148,543
Granted	-	-	4,925,031	3.50	4,925,031	
Exercised	-	-	-	-	-	
Expired	-	-	(383,363)	4.01	(383,363)	
Forfeited	(40,401)	0.78	-	-	(40,401)	
Balance outstanding, December 31, 2020	1,355,901	\$ 0.69	14,434,702	\$ 3.50	15,790,603	15,302,830

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number of Options	Remaining Contractual Life (Years)	Exercise Price	Number of Options	Remaining Contractual Life (Years)	Exercise Price
\$ 0.01 \$ 0.69	1,355,901	8.7	\$ 0.69	867,461	8.6	\$ 0.69
	1,355,901	8.7	\$ 0.69	867,461	8.6	\$ 0.69

Common Stock Issuances

On various dates in the year ended December 31, 2020 the Company issued a total of 1,618,704 shares of restricted common stock at a fair value of approximately \$3,671,311 to accredited investors. 76,800 of the shares with a fair value of \$179,077 were issued for services rendered; 122,135 of the shares with a fair value of \$299,709 were issued in lieu of cash for the 8% dividend on Series AA Convertible Preferred Stock; 871,309 of the shares with a fair value of \$2,220,442 were issued for the conversion of debt and interest for common stock; 323,260 of the shares with a fair value of \$629,809 were issued for debt extension, settlement and interest payments, 66,500 shares with a fair value of \$127,855 were issued to settle an accrued liability and 158,700 of the shares with a fair value of \$214,419 were issued in conjunction with the signing of new convertible loans.

As profiled in the following table, for five loans we are obligated to issue common stock if not paid by defined dates.

Loan	Loan Issuance Date	Loan Principal	Percentage of Loan Principal Issuable	Defined Date	Shares Issuable Frequency
Loan 1	July 21, 2020	\$ 115,000	0.0435%	September 30, 2020	Monthly
Loan 2	September 21, 2020	\$ 345,000	0.0362%	November 16, 2020	Weekly
Loan 3	September 23, 2020	\$ 115,000	0.0652%	December 1, 2020	Weekly
Loan 4	September 25, 2020	\$ 115,000	0.0652%	December 1, 2020	Weekly
Loan 5	October 22, 2020	\$ 115,000	0.0652%	December 1, 2020	Weekly

During the year ended December 31, 2020, the Company accrued \$4,136 in interest expense for these obligations to issue common stock.

For our loan dated December 23, 2020, we are obligated to issue 100,000 warrants if the loan is not repaid before January 23, 2021 and an additional 10,000 shares of common stock if the loan is not repaid before February 23, 2021. We are also obligated to issue 10,000 shares of common stock and 200,000 warrants if the loan is not repaid before March 23, 2021. If the loan is not repaid on March 23, 2021, 10,000 shares of common stock will be issued every 31 days up to the loan's maturity date on June 23, 2021.

On various dates in the year ended December 31, 2019 the Company issued a total of 865,438 shares of restricted common stock at a fair value of approximately \$1,849,103 to accredited investors. 139,000 of the shares with a fair value of \$398,600 were issued for services rendered; 81,767 of the shares with a fair value of \$205,100 were issued in lieu of cash for the 8% dividend on Series AA Convertible Preferred Stock; shareholders converted 16 shares of Series AA Convertible Preferred Stock into 16,000 shares of common stock; 126,200 of the shares with a fair value of \$356,510 were issued for the conversion of debt and interest for common stock; 422,234 of the shares with a fair value of \$649,018 were issued for debt extension and 80,237 of the shares with a fair value of \$239,875 were issued in conjunction with the signing of new convertible loans.

(11) Subsequent Events

From January 1, 2021 through April 11, 2021 the Company received four convertible loans for a total of \$957,500. The Company issued 181,000 warrants (five-year life and \$3.50 strike price) with three of the loans, and in the fourth loan the Company agreed to issue 5,000 shares of common stock each month over the six-month term as fees paid to the lender. These loans have conversion prices of \$2.50, carry interest rates ranging from 10% to 18%, and terms ranging from six to twelve months. In this time, the Company also received \$100,000 on the sale of Series AA shares (issuing 40,000 warrants with a five-year term and strike price of \$3.50), \$85,000 of related party loans, a second Payroll Protection Program ("PPP") loan sponsored by the United States for \$367,037 (1% interest and five-year term), and entered into Merchant Cash lender agreements (collecting \$379,704, \$110,296 of one merchant cash lender loan was used to settle an existing merchant agreement dated November 5, 2020). One of the Merchant Cash lender loans is personally guaranteed by the Company's Chief Executive Officer. Under these agreements, the Company pays \$4,792 each business day to its Merchant Cash lenders until the lenders have received cumulative payments of \$663,460. In this time, the Company's first PPP loan for \$367,039 was forgiven by the United States, and the Company issued 10,000 shares of common stock (valued at \$22,800) to a consultant for Investor Relations services, 24,000 stock options to an employee (10 year term and \$2.17 per share exercise price) and

repaid loans dated May 20, 2019, June 7, 2019 and August 14,2019 for \$193,375 and 23,200 shares of common stock (settling principal, interest and fees).

On April 1, 2021, the Company entered into extensions of its Standstill and Forbearance Agreements with lenders who hold convertible notes with a total principal of \$1.55 million through April 16, 2021.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 filings are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our President and Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and management was necessarily required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of December 31, 2020, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934. Based upon that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective as of December 31, 2020 due to limited resources for adequate personnel to prepare and file reports under the Securities Exchange Act of 1934 within the required periods, and material weaknesses in our internal control over financial reporting relating to our accounting for complex equity transactions as described below under the heading "Report of Management on Internal Control over Financial Reporting". Management plans to remediate this weakness by taking the actions described below.

Report of Management on Internal Control over Financial Reporting

We are responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act, as a process designed by, or under the supervision of our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and disposition of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our internal control system is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

We have assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013).

Based on this assessment, management believes that, as of December 31, 2020, the Company did not maintain effective internal control over financial reporting because of the effect of material weaknesses in our internal control over financial reporting discussed below.

Public Company Accounting Oversight Board Auditing Standard No. 2 defines a material weakness as a significant deficiency, or combination of significant deficiencies, that results in there being a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. Based upon this definition, our management concluded that, as of December 31, 2020, a material weakness existed in our internal control over financial reporting related to accounting for complex equity transactions.

Specifically, we identified material weaknesses in our internal control over financial reporting related to the following matters:

- We identified a lack of sufficient segregation of duties. Specifically, this material weakness is such that the design over these areas relies primarily on detective controls and could be strengthened by adding preventative controls to properly safeguard Company assets.
- Management has identified a lack of sufficient personnel in the accounting function due to our limited resources with appropriate skills, training and experience to perform the review processes to ensure the complete and proper application of generally accepted accounting principles, particularly as it relates to valuation of warrants and other complex debt /equity transactions. Specifically, this material weakness resulted in audit adjustments to the annual consolidated financial statements and revisions to related disclosures.
- Limited policies and procedures that cover recording and reporting of financial transactions.
- Lack of multiple levels of review over the financial reporting process

Our plan to remediate those material weaknesses is as follows:

- Improve the effectiveness of the accounting group by augmenting our existing resources with additional consultants or employees to assist in the analysis and recording of complex accounting transactions, and to simultaneously achieve desired organizational structuring for improved segregation of duties. We plan to mitigate this identified deficiency by hiring an independent consultant once we generate significantly more revenue or raise significant additional working capital.
- Improve expert review and achieve desired segregation procedures by strengthening cross approval of various functions including quarterly internal audit procedures where appropriate.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the fourth quarter of 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors

The following table sets forth information about the individuals who serve as our directors as of December 31, 2020.

Name	Age	Position	Board Committees	Term of office expires:
Richard T. Schumacher	70	President, Chief Executive Officer, Interim Chief Financial Officer, Treasurer, Clerk and Director		2023
Jeffrey N. Peterson	65	Chairman of the Board	Audit, Compensation, Nominating	2021
Dr. Mickey Urdea	68	Director	Scientific Advisory Board	2021
Vito J. Mangiardi	72	Director	Audit, Compensation, Nominating	2022
Kevin A. Pollack	50	Director	Audit, Compensation, Nominating	2022

The following noteworthy experience, qualifications, attributes and skills for each Board member, together with the biographical information for each nominee described below, led to our conclusion that the person should serve as a director in light of our business and structure:

Mr. Richard T. Schumacher, the founder of the Company, has served as a director of the Company since 1978. He has served as the Company’s Chief Executive Officer since April 16, 2004 and President since September 14, 2004, and Interim Chief Financial officer since November 27, 2019. He previously served as Chief Executive Officer and Chairman of the Board of the Company from 1992 to February 2003. From July 9, 2003 until April 14, 2004 he served as a consultant to the Company pursuant to a consulting agreement. He served as President of the Company from August 1978 to August 1999. Mr. Schumacher served as the Director of Infectious Disease Services for Clinical Sciences Laboratory, a New England-based medical reference laboratory, from 1986 to 1988. From 1972 to 1985, Mr. Schumacher was a research scientist and clinical laboratory director at the Center for Blood Research, a nonprofit medical research institute associated with Harvard Medical School. Mr. Schumacher received a B.S. in Zoology from the University of New Hampshire.

Mr. Jeffrey N. Peterson has served as a director of the Company since July 2011 and as Chairman of the Board starting in 2012. Since 1999, he has served as the Chief Executive Officer of Target Discovery, Inc. (“TDI”), a personalized medicine diagnostics (PMDx) and analytical testing solutions company. Mr. Peterson also serves as Chairman and CEO of TDI’s majority-owned subsidiary, Veritomyx, Inc., which is commercializing software tools for more sensitive, complete and accurate identification and characterization of all large and small molecular components of complex samples. Mr. Peterson served as Chairman of the Board of Imaging3 (OTCQB: IGNG), an innovative medical and industrial imaging company, from March 2018 through July 2019. Prior to incorporating and founding TDI, Mr. Peterson served as CEO of Sharpe, Peterson, Ocheltree & Associates, an international business development consulting firm assisting Fortune 500 and many smaller firms in business expansion and strategy. Prior to that, he spent 9 years in key management roles in Abbott Laboratories’ Diagnostics and International (Pharmaceuticals, Hospital Products, Nutritionals, and Consumer) businesses, last serving as CEO and General Manager of Abbott South Africa. Mr. Peterson’s experience prior to Abbott Laboratories included 11 years with General Electric’s Engineered Materials and Plastics businesses, spanning roles in strategic planning, business development, technology licensing, marketing and sales, operations, quality control and R&D. Mr. Peterson holds BSChE and MSChE (Chemical Engineering) degrees from MIT, as well as 6 issued US patents. He served as Chair Emeritus of the BayBio Institute, a non-profit organization serving the life science community, and on the Board of BayBio, a trade association for the life sciences industry in Northern California. He served as a cofounder of the Coalition for 21st Century Medicine, and of BIO’s Personalized Medicine & Diagnostics Working Group. He served on the Board of Advisors for the Center for Professional Development and Entrepreneurship at the University of Texas MD Anderson Cancer Center. He currently serves on the Advisory Board of the California Technology Council.

Mr. Vito J. Mangiardi has served as a director of the Company since July 2012. Mr. Mangiardi is an accomplished senior executive with proven experience as a President, CEO and COO in the Life Sciences and Bio-Energy product and service sectors. He is a strong P&L performer and corporate strategist in General Management, Operations, Sales/Marketing, and Science. Mr. Mangiardi has held positions as a Research Chemist for Bio-Rad Laboratories, Inc.; Sales & Marketing Director for Baxter Travenol, Inc.; Executive VP and COO for Quintiles Transnational Corp.; President and CEO of Diagnostics Laboratories, Inc., Clingenix, Inc., and Bilcare, Inc.; and President of AAI Pharma, Inc. More recently he was the COO/Deputy Director of Operations and Production at the University of California Lawrence Berkeley National Laboratory Joint Genome Institute. Mr. Mangiardi has experience with three start-ups, two midsize, and several mature companies, and has international experience leading and managing organizations on four continents. He has vast experience in leading alliances, acquisitions, due diligence, and post-acquisition assimilation. Mr. Mangiardi has been on the Board of Directors of three companies and has proven success in working with both national and international investment groups to raise funds. Mr. Mangiardi earned a BS in Biology/Chemistry from Eastern Illinois University and two MBA degrees from Golden Gate University - in General Management and in Marketing. Mr. Mangiardi is listed as an inventor in four patents and various publications in protein separation techniques in the area of metabolism, thyroid, anemia/hematology and cancer, and is a member of numerous professional organizations. Mr. Mangiardi is the founding partner, President and CEO of Marin Bay Partners, LLC (MBP), a consulting firm focused on life sciences, pharmaceutical development and clinical diagnostics.

Mr. Kevin A. Pollack has served as a director of the Company since July 2012. From 2017 to 2018, Mr. Pollack served as an advisor to Opiant Pharmaceuticals, Inc. (OPNT-NASDAQ), a pharmaceutical company with a mission to create best-in-class medicines for the treatment of addictions and drug overdose. He previously served as its Chief Financial Officer and as a member of its Board of Directors from 2012 until 2017. He also serves as President of Short Hills Capital LLC. Previously, Mr. Pollack worked in asset management at Paragon Capital LP, focusing primarily on U.S.-listed companies, and as an investment banker at Banc of America Securities LLC, focusing on corporate finance and mergers and acquisitions. Mr. Pollack started his career at Sidley Austin LLP (formerly Brown & Wood LLP) as a securities attorney focusing on corporate finance, and mergers and acquisitions. He served on the Board of Directors of Taronis Fuels, Inc. (TRNF-OTCQB) from 2019 to 2021 and served on the Board of Directors of BBHC, Inc. (TRNX-OTC) from 2012 until 2020. Mr. Pollack graduated *magna cum laude* from the Wharton School of the University of Pennsylvania and received a dual J.D./M.B.A. from Vanderbilt University, where he graduated with *Beta Gamma Sigma* honors.

Dr. Michael S. Urdea has served as a director of the Company since February 8, 2013. Dr. Urdea founded and is a Founder and Partner for Halteres Associates, a biotechnology consulting firm. He also founded and served as Chief Executive Officer of Tethys Bioscience, a proteomics-based diagnostics company involved in preventative personalized medicine. Additionally, Dr. Urdea is a founder and the Chairman of Catalysis Foundation for Health, an organization addressing gaps in global healthcare caused by inefficiencies in disease diagnosis and monitoring. He serves as an expert consultant to the life sciences industry and is on the scientific advisory boards and boards of directors of a number of biotechnology, diagnostics, venture capital and philanthropic organizations. Prior to his current business activities, Dr. Urdea founded the Nucleic Acid Diagnostics group at Chiron Corporation, and with colleagues, invented branched DNA molecules for amplification of signal in nucleic acid complexes. Application of this technology resulted in the first commercial products for quantification of human hepatitis B, hepatitis C, and human immunodeficiency viruses (HBV, HCV, and HIV, respectively). He then became business head of the Molecular Diagnostics Group and Chief Scientific Officer at Bayer Diagnostics. He continues to serve as a diagnostics industry, product development and scientific advisor to the Bill and Melinda Gates Foundation, acted as co-chair of two of the Grand Challenges grant review committees, and served as a member of its Diagnostic Forum. Dr. Urdea is an author on nearly 200 peer-reviewed scientific publications, nearly 300 abstracts and international scientific presentations, and more than 100 issued and pending patents. He received his BS in Biology and Chemistry from Northern Arizona University in Flagstaff and his Ph.D. in Biochemistry from Washington State University.

Executive Officers

Our executive officers are appointed by, and serve at the discretion of, our board of directors. The following table sets forth information about our executive officers.

Name	Age	Position
Richard T. Schumacher	70	President, Chief Executive Officer, Interim Chief Financial Officer, Treasurer, Clerk and Director
Edmund Ting, Ph.D.	67	Senior Vice President of Engineering
Alexander Lazarev, Ph.D.	56	Chief Science Officer

Mr. Richard T. Schumacher – Mr. Schumacher’s biography can be found under the Directors heading.

Dr. Edmund Ting joined us as Senior Vice President of Engineering on April 24, 2006. Prior to joining us, Dr. Ting served as the Chief Research Officer of Avure Technologies, a leading worldwide manufacturer of high pressure hydrostatic processing equipment for the food and materials processing industry, where he worked from 2001 to 2006. From 1990 to 2001, Dr. Ting was employed by Flow International Corporation, a world leader in the ultrahigh pressure waterjet cutting technology market, and the parent company of Avure Technologies until November 2005. Dr. Ting last held the position of Vice President of Engineering Research and Development at Flow International Corporation. From 1984 to 1990, Dr. Ting was a research scientist and then a group leader at Grumman Aerospace Corporation. Dr. Ting earned a Bachelor of Science degree in mechanical engineering from Northeastern University and a Science Doctorate in materials science and engineering from the Massachusetts Institute of Technology.

Dr. Alexander Lazarev has served as our Chief Science Officer since 2019. Prior to that, he serviced as our Vice President of Research and Development since 2007, and he served as our Director of Research and Development, since joining us in 2006. Prior to joining us, Dr. Lazarev worked as a Visiting Scientist at the Barnett Institute of Chemical and Biological Analysis at Northeastern University in 2005, and served as a Director of New Technology Development at Proteome Systems, Inc., where he was involved in research and development of innovative proteomic analysis applications from 2001 until early 2006. From 1998 to 2001, Dr. Lazarev was employed as Senior Scientist at the Proteomics Division of Genomic Solutions, Inc. Prior to his employment at Genomic Solutions, Inc., Dr. Lazarev was employed in an analytical contract service startup company, PhytoChem Technologies, Inc., which was founded as a spin-off from ESA, Inc. in 1997. Previously, Dr. Lazarev held various scientific positions at the Ohio State University School of Medicine and the Uniformed Services University of Health Sciences. Most of his scientific career has been dedicated to development of methods and applications for biochemical analysis. Since 2005, Dr. Lazarev has been elected as an Executive Board member of the MASSEP.org, a non-profit scientific discussion forum dedicated to the promotion and improvement of chromatography and other analytical technologies. Dr. Lazarev earned his undergraduate and graduate degrees at the University of Kazan, Russian Federation.

Section 16(a) Beneficial Ownership Reporting Compliance

Delinquent Section 16(a) Report

Section 16(a) of the Exchange Act requires the Company's executive officers and directors, and persons who own more than 10% of the Company's common stock, to file reports of ownership and changes in ownership on Forms 3, 4 and 5 with the SEC.

Based solely on the Company's review of the copies of such Forms and written representations from certain reporting persons, the Company believes that all filings required to be made by the Company's Section 16(a) reporting persons during the Company's fiscal year ended December 31, 2020 were made on a timely basis.

Code of Ethics

Pursuant to Section 406 of the Sarbanes-Oxley Act of 2002, we have adopted a Code of Ethics for senior financial officers that applies to our principal executive officer, principal financial officer, principal accounting officer, controller, and other persons performing similar functions. A copy of the code of ethics is posted on and may be obtained free of charge from our internet website at <http://www.pressurebiosciences.com>. If we make any amendments to this Code of Ethics or grant any waiver, including any implicit waiver, from a provision of this Code of Ethics to our principal executive officer, principal financial officer, principal accounting officer, controller, or other persons performing similar functions, we will disclose the nature of such amendment or waiver, the name of the person to whom the waiver was granted and the date of waiver in a Current Report on Form 8-K.

Corporate Governance

Term of Office

Our directors are appointed for a three-year term to hold office until the annual general meeting of our shareholders or until removed from office in accordance with our bylaws. Our officers are appointed by our board of directors and hold office until removed by the board.

Audit Committee

The Audit Committee was established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934. Messrs. Pollack (chairman), Mangiardi and Peterson are currently the members of the Audit Committee.

The Board of Directors has determined that Mr. Pollack qualifies as an "audit committee financial expert" as defined in Item 407(d) (5) of Regulation S-K and is "independent" as defined by SEC and OTC Market rules.

The Audit Committee operates pursuant to a written charter (the "*Audit Committee Charter*"), a current copy of which is publicly available on the investor relations portion of the Company's website at www.pressurebiosciences.com. Under the provisions of the Audit Committee Charter, the primary functions of the Audit Committee are to assist the Board of Directors with the oversight of (i) the Company's financial reporting process, accounting functions, and internal controls, and (ii) the qualifications, independence, appointment, retention, compensation, and performance of the Company's independent registered public accounting firm. The Audit Committee is also responsible for the establishment of "whistle-blowing" procedures, and the oversight of other compliance matters.

Compensation Committee

The Board of Directors has a Compensation Committee, consisting of Messrs. Peterson, Pollack and Mangiardi. The Compensation Committee's duties include (i) reviewing and approving our executive compensation, (ii) reviewing the recommendations of the president and chief executive officer regarding the compensation of our executive officers, (iii) evaluating the performance of the president and chief executive officer, (iv) overseeing the administration and approval of grants of stock options and other equity awards under our equity incentive plans, and (v) recommending compensation for our board of directors and each committee thereof for review and approval by the board of directors. The Compensation Committee operates pursuant to a written charter, a current copy of which is publicly available on the investor relations portion of our website at www.pressurebiosciences.com.

Involvement in Certain Legal Proceedings

To the best of our knowledge, none of our directors or executive officers has, during the past ten years:

- been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;
- been found by a court of competent jurisdiction in a civil action or by the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
- been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Except as set forth in our discussion below in “Certain Relationships and Related Transactions,” none of our directors or executive officers has been involved in any transactions with us or any of our directors, executive officers, affiliates or associates which are required to be disclosed pursuant to the rules and regulations of the Commission.

ITEM 11. EXECUTIVE COMPENSATION

Executive Officer Compensation

Summary Compensation Table

The Summary Compensation Table below sets forth the total compensation paid or earned for the fiscal years ended December 31, 2020 and 2019 for: (i) each individual serving as our chief executive officer (“CEO”) or acting in a similar capacity during any part of fiscal 2020; and (ii) the other two most highly paid executive officers (collectively, the “Named Executive Officers”) who were serving as executive officers at the end of fiscal 2020.

Name and Principal Position	Fiscal Year	Salary ⁽¹⁾	Bonus	Stock Awards	Option Awards ⁽²⁾	Non-Qualified Deferred Compensation Earning	All other Compensation ⁽³⁾	Total
Richard T. Schumacher President, CEO	2020	\$308,962	\$ -	\$ -	\$ -	\$ -	\$ 11,631	\$320,593
	2019	308,962	-	-	34,840	-	11,408	355,210
Edmund Ting, Ph.D. Senior Vice President of Engineering	2020	207,480	-	-	-	-	3,106	210,586
	2019	207,480	-	-	7,665	-	2,043	217,188
Alexander Lazarev, Ph.D. Vice President of Research and Development	2020	200,000	-	-	-	-	6,554	206,554
	2019	198,995	-	-	6,968	-	8,310	214,273

(1) Salary refers to base salary compensation paid through our normal payroll process. No bonus was paid to any named executive officer for 2020 or 2019.

(2) Amounts shown do not reflect compensation received by the Named Executive Officers. Instead, the amounts shown are the aggregate grant date fair value as determined pursuant to FASB ASC 718, Compensation-Stock Compensation. Please refer to Note 3, xiii, “Accounting for Stock-Based Compensation” in the accompanying Notes to Consolidated Financial Statements for the fiscal year ended December 31, 2020, for the relevant assumptions used to determine the valuation of stock option grants.

(3) “All Other Compensation” includes our Company match to the executives’ 401(k) contribution and premiums paid on life insurance for the executives. Both of these benefits are available to all of our employees. In the case of Mr. Schumacher, “All Other Compensation” also includes \$8,379 in premiums we paid for a life insurance policy to which Mr. Schumacher’s wife is the beneficiary. “All Other Compensation” for Dr. Lazarev includes \$4,250 paid to Dr. Lazarev in lieu of his participation in the medical benefit plan offered by the Company. “All Other Compensation” for Dr. Ting includes \$1,500 paid to Dr. Ting in lieu of his participation in the medical benefit plan offered by the Company.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth certain information regarding outstanding stock options awards for each of the Named Executive Officers as of December 31, 2020.

Name	Option Awards		Option Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable ⁽¹⁾		
Richard T. Schumacher President, CEO	8,056	1,944	\$ 0.69	7/18/2028
	187,247	235,421	\$ 0.69	12/19/2028
Edmund Y. Ting, Ph.D Senior Vice President of Engineering	17,066	4,119	\$ 0.69	7/18/2028
	31,116	54,439	\$ 0.69	12/19/2028
Alexander V. Lazarev, Ph.D Vice President of Research & Development	14,368	3,467	\$ 0.69	7/18/2028
	26,863	46,642	\$ 0.69	12/19/2028

(1) All unvested stock options listed in this column were granted to the Named Executive Officer pursuant to our 2013 Equity Incentive Plan. On December 19, 2019, all outstanding options were repriced and re-issued pursuant to this plan. All options expire ten years after the date of grant. Unvested stock options become fully vested and exercisable upon a change of control of our company.

Retirement Plan

All employees, including the named executive officers, may participate in our 401(k) Plan. Under the 401(k) Plan, employees may elect to make before tax contributions of up to 60% of their base salary, subject to current Internal Revenue Service limits. The 401(k) Plan does not permit an investment in our common stock. We match employee contributions up to 50% of the first 2% of the employee’s earnings. Our contribution is 100% vested immediately.

Severance Arrangements

Each of Mr. Schumacher, Dr. Ting, Dr. and Lazarev, executive officers of the Company, are entitled to receive a severance payment if terminated by us without cause. The severance benefits would include a payment in an amount equal to one year of such executive officer’s annualized base salary compensation plus accrued paid time off. Additionally, the officer will be entitled to receive medical and dental insurance coverage for one year following the date of termination.

Change-in-Control Arrangements

Pursuant to severance agreements with each of Mr. Schumacher, Dr. Ting, and Dr. Lazarev, each such executive officers, is entitled to receive a change of control payment in an amount equal to one year (other than Mr. Schumacher) of such executive officer’s annualized base salary compensation, accrued paid time off, and medical and dental coverage, in the event of their termination upon a change of control of our Company. In the case of Mr. Schumacher, his payment is equal to two years of annualized base salary compensation, accrued paid time off, and two years of medical and dental coverage.

Pursuant to our equity incentive plans, any unvested stock options held by a named executive officer will become fully vested upon a change in control (as defined in the 2005 Equity Incentive Plan) of our Company.

Director Compensation and Benefits

The following table sets forth certain information regarding compensation earned or paid to our directors during fiscal 2020.

Name	Fees Earned or Paid in Cash (\$) ⁽¹⁾	Stock Awards (\$)	Option Awards (\$)	Total (\$)
Vito J. Mangiardi	70,000	-	-	70,000
Jeffrey N. Peterson	107,500	-	-	107,500
Kevin A. Pollack	72,500	-	-	72,500
Michael S. Urdea, Ph. D.	50,000	-	-	50,000

Our non-employee directors receive the following compensation for service as a director:

(1) Each director currently earns a quarterly stipend of \$10,000 for attending meetings of the full board of directors (whether telephonic or in-person) and fees ranging from \$5,000 to \$20,000 for chairing and attending committee meetings in 2020. Mr. Peterson currently earns \$20,000 per quarter as chairman of the board of directors. There is no limit to the number of board of directors or committee meetings that may be called.

The following table shows the total number of outstanding stock options as of December 31, 2020 that have been issued as director compensation. The Company did not issue any stock options as director compensation in 2020.

Name	Aggregate Number of Stock Options Outstanding
Vito J. Mangiardi	70,408
Jeffrey N. Peterson	120,312
Kevin A. Pollack	70,408
Michael S. Urdea, Ph. D.	52,072

Report from Compensation Committee

General

Messrs. Peterson, Pollack and Mangiardi are currently the members of the Compensation Committee. The Compensation Committee operates pursuant to a written charter, a current copy of which is publicly available on the investor relations portion of our website at www.pressurebiosciences.com. The primary functions of the Compensation Committee include (i) reviewing and approving our executive compensation, (ii) reviewing the recommendations of the president and chief executive officer regarding the compensation of our executive officers, (iii) evaluating the performance of the president and chief executive officer, (iv) overseeing the administration and approval of grants of stock options and other equity awards under our equity incentive plans, and (v) recommending compensation for our board of directors and each committee thereof for review and approval by the board of directors.

The Compensation Committee may form and delegate authority to one or more subcommittees as it deems appropriate from time to time under the circumstances (including (a) a subcommittee consisting of a single member and (b) a subcommittee consisting of at least two members, each of whom qualifies as a “non-employee director,” as such term is defined from time to time in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, and an “outside director,” as such term is defined from time to time in Section 162(m) of the Internal Revenue Code of 1986, as amended, and the rules and regulations there under).

Compensation Objectives

In light of the relatively early stage of commercialization of our products, we recognize the importance of attracting and retaining key employees with sufficient experience, skills, and qualifications in areas vital to our success, such as operations, finance, sales and marketing, research and development, engineering, and individuals who are committed to our short- and long-term goals. The Compensation Committee has designed our executive compensation programs with the intent of attracting, motivating, and retaining experienced executives and, subject to our limited financial resources, rewarding them for their contributions by offering them a competitive base salary, potential for annual cash incentive bonuses, and long-term equity-based incentives, typically in the form of stock options. The Compensation Committee strives to balance the need to retain key employees with financial prudence given our history of operating losses, limited financial resources and the early stage of our commercialization.

Executive Officers and Director Compensation Process

The Compensation Committee considers and determines executive compensation according to an annual objective setting and measurement cycle. Specifically, corporate goals for the year are initially developed by our executive officers and are then presented to our board of directors and Compensation Committee for review and approval. Individual goals are intended to focus on contributions that facilitate the achievement of the corporate goals. Individual goals are first proposed by each executive officer, other than the president and CEO, then discussed by the entire senior executive management team and ultimately compiled and prepared for submission to our board of directors and the Compensation Committee, by the president and chief executive officer. The Compensation Committee sets and approves the goals for the president and chief executive officer. Generally, corporate and individual goals are set during the first quarter of each calendar year. The objective setting process is coordinated with our annual financial planning and budgeting process so our board of directors and Compensation Committee can consider overall corporate and individual objectives in the context of budget constraints and cost control considerations. Annual salary increases, bonuses, and equity awards, such as stock option grants, if any, are tied to the achievement of these corporate and individual performance goals as well as our financial position and prospects.

Under the annual performance review program, the Compensation Committee evaluates individual performance against the goals for the recently completed year. The Compensation Committee’s evaluation generally occurs in the first quarter of the following year. The evaluation of each executive (other than the president and chief executive officer) begins with a written self-assessment submitted by the executive to the president and chief executive officer. The president and chief executive officer then prepares a written evaluation based on the executive’s self-assessment, the president and chief executive officer’s evaluation, and input from others within the Company. This process leads to a recommendation by the president and chief executive officer for a salary increase, bonus, and equity award, if any, which is then considered by the Compensation Committee. In the case of the president and chief executive officer, the Compensation Committee conducts his performance evaluation and determines his compensation, including salary increase, bonus, and equity awards, if any. We generally expect, but are not required, to implement salary increases, bonuses, and equity awards, for all executive officers, if and to the extent granted, by April 1 of each year.

Non-employee director compensation is set by our board of directors upon the recommendation of the Compensation Committee. In developing its recommendations, the Compensation Committee is guided by the following goals: compensation should be fair relative to the required services for directors of comparable companies in our industry and at our Company’s stage of development; compensation should align directors’ interests with the long-term interest of stockholders; the structure of the compensation should be simple, transparent, and easy for stockholders to understand; and compensation should be consistent with the financial resources, prospects, and competitive outlook for the Company.

In evaluating executive officer and director compensation, the Compensation Committee considers the practices of companies of similar size, geographic location, and market focus. In order to develop reasonable benchmark data the Compensation Committee has referred to publicly available sources such as www.salary.com and the BioWorld Survey. While the Compensation Committee does not believe benchmarking is appropriate as a stand-alone tool for setting compensation due to the unique aspects of our business objectives and current stage of development, the Compensation Committee generally believes that gathering this compensation information is an important part of its compensation-related decision making process.

The Compensation Committee has the authority to hire and fire advisors and compensation consultants as needed and approve their fees. No advisors or compensation consultants were hired or fired in fiscal 2020. The Compensation Committee is also authorized to delegate any of its responsibilities to sub committees or individuals as it deems appropriate. The Compensation Committee did not delegate any of its responsibilities in fiscal 2020.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Beneficial Ownership Information

The following table sets forth certain information as of April 8, 2021 concerning the beneficial ownership of common stock for: (i) each director and director nominee, (ii) each Named Executive Officer in the Summary Compensation Table under “Executive Compensation” above, (iii) all executive officers and directors as a group, and (iv) each person (including any “group” as that term is used in Section 13(d)(3) of the Exchange Act) known by us to be the beneficial owner of 5% or more of our common stock. The address for each of the persons below who are beneficial owners of 5% or more of our common stock is our corporate address at 14 Norfolk Avenue, South Easton, MA 02375.

Beneficial ownership has been determined in accordance with the rules of the SEC and is calculated based on 4,321,973 shares of our common stock issued and outstanding as of April 8, 2021. Shares of common stock subject to options, warrants, preferred stock or other securities convertible into common stock that are currently exercisable or convertible, or exercisable or convertible within 60 days of April 8, 2021, are deemed outstanding for computing the percentage of the person holding the option, warrant, preferred stock, or convertible security but are not deemed outstanding for computing the percentage of any other person.

Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own.

Name of Beneficial Owner	Amount and Nature of	
	Beneficial Ownership	Percent of Class (1)
Richard T. Schumacher(2)	310,313	6.8%
Jeffrey N. Peterson(3)	182,026	4.1%
Kevin A. Pollack(4)	132,381	3.0%
Michael S. Urdea(5)	109,978	2.5%
Vito J. Mangiardi(6)	91,903	2.1%
Edmund Y. Ting, Ph.D.(7)	63,821	1.5%
Alexander V. Lazarev, Ph.D.(8)	54,325	1.2%
All Executive Officers and Directors as a Group (9)	944,747	18.3%

- 1) Percentage of ownership is based on 4,321,973 shares of our common stock outstanding as of April 8, 2021.
- 2) Includes (i) 255,393 shares of Common Stock issuable upon exercise of options; (ii) 8,800 shares of Common Stock issuable upon the exercise of warrants and (iii) 8,800 shares of common stock issuable upon conversion of Series AA Convertible Preferred Stock and (iv) 37,320 shares of Common Stock. Does not include 672 shares of Common Stock held by Mr. Schumacher's minor son as Mr. Schumacher's wife exercises all voting and investment control over such shares.
- 3) Includes (i) 120,312 shares of Common Stock issuable upon exercise of options; (ii) 20,000 shares of Common Stock issuable upon the exercise of warrants; (iii) 20,000 shares of common stock issuable upon conversion of Series AA Convertible Preferred Stock; and (iv) 21,714 shares of Common Stock.
- 4) Includes (i) 70,408 shares of Common Stock issuable upon exercise of options; (ii) 20,534 shares of Common Stock issuable upon exercise of warrants; (iii) 20,534 shares of common stock issuable upon conversion of Series AA Convertible Preferred Stock; and (iv) 20,905 shares of Common Stock.
- 5) Includes (i) 52,072 shares of Common Stock issuable upon exercise of options; (ii) 20,200 shares of Common Stock issuable upon exercise of warrants; (iii) 20,200 shares of common stock issuable upon conversion of Series AA Convertible Preferred Stock; and (iv) 17,506 shares of Common Stock.
- 6) Includes (i) 70,408 shares of Common Stock issuable upon exercise of options; (ii) 4,400 shares of Common Stock issuable upon exercise of warrants; (iii) 4,400 shares of common stock issuable upon conversion of Series AA Convertible Preferred Stock; and (iv) 12,695 shares of Common Stock.
- 7) Includes (i) 63,006 shares of Common Stock issuable upon exercise of options and (ii) 815 shares of Common Stock.
- 8) Includes (i) 53,915 shares of Common Stock issuable upon exercise of options and (ii) 410 shares of Common Stock.
- 9) Includes (i) 685,514 shares of Common Stock issuable upon exercise of options; (ii) 73,934 shares of Common Stock issuable upon the exercise of warrants; (iii) 73,934 shares of Common Stock issuable upon conversion of Series AA Convertible Preferred Stock and (iv) 111,365 shares of Common Stock.

Equity Compensation Plan Information

We maintain a number of equity compensation plans for employees, officers, directors and other entities and individuals whose efforts contribute to our success. The table below sets forth certain information as of our fiscal year ended December 31, 2020 regarding the shares of our common stock available for grant or granted under our equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities available for future issuance under equity compensation plans
Equity compensation plan approved by security holders - 2013 Equity Incentive Plan	1,355,901	\$ 0.69	1,644,099

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS; AND DIRECTOR INDEPENDENCE.

The following is a summary of transactions since January 1, 2017 to which we have been or will be a party in which the amount involved exceeded or will exceed \$ (one percent of the average of our total assets at year-end for our last two completed fiscal years) and in which any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock, or any immediate family member of, or person sharing a household with, any of these individuals, had or will have a direct or indirect material interest, other than compensation arrangements that are described under the section captioned “Executive Compensation.”

In March 2010, we signed a strategic product licensing, manufacturing, co-marketing, and collaborative research and development agreement with Target Discovery Inc. (“*TDI*”), a related party. Under the terms of the agreement, we have been licensed by TDI to manufacture and sell a highly innovative line of chemicals used in the preparation of tissues for scientific analysis (“*TDI reagents*”). The TDI reagents were designed for use in combination with our pressure cycling technology. The respective companies believe that the combination of PCT and the TDI reagents can fill an existing need in life science research for an automated method for rapid extraction and recovery of intact, functional proteins associated with cell membranes in tissue samples. We did not incur any royalty obligation under this agreement in 2017 or 2016. We executed an amendment to this agreement on October 1, 2016 wherein we agreed to pay a monthly fee of \$1,400 for the use of a lab bench, shared space and other utilities, and \$2,000 per day for technical support services as needed. Mr. Jeffrey N. Peterson, the chief executive officer of TDI, has served as a director of the Company since July 2011 and as Chairman of the Board starting in 2012.

Related Party Notes

In June 2018, we received a non-convertible loan of \$15,000 from a private investor. The loan includes a one-year term and 15% guaranteed interest. This loan remains outstanding at December 31, 2020 and is currently past due.

During the year ended December 31, 2020, we received short-term non-convertible loans of \$283,700 from related parties. The loans were repaid in full as of December 31, 2020, except for \$151,000.

Board Independence

Our board of directors has reviewed the qualifications of each of Messrs. Peterson, Mangiardi, Pollack, and Dr. Urdea constituting more than a majority of our directors and has affirmatively determined that each individual is “independent” as such term is defined under the current listing standards of the OTC Markets. The board of directors has determined that none of these directors has a material relationship with us that would interfere with the exercise of independent judgment. In addition, each member of the Audit Committee is independent as required under Section 10A(m)(3) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The Audit Committee appointed MaloneBailey LLP, an independent registered public accounting firm, to audit the Company’s consolidated financial statements for the fiscal year ended December 31, 2020.

Independent Registered Public Accounting Fees

The following is a summary of the fees billed to the Company by MaloneBailey LLP, the Company’s independent registered public accounting firm, respectively for the fiscal year ended December 31, 2020 and 2019:

	<u>Fiscal 2020 Fees</u>	<u>Fiscal 2019 Fees</u>
Audit Fees	\$ 155,000	\$ 97,000
Audit-Related Fees	-	-
Tax and Other Fees	-	-
	<u>\$ 155,000</u>	<u>\$ 97,000</u>

Audit Fees. Consists of fees billed for professional services performed for the audit of our annual financial statements, the review of interim financial statements, and related services that are normally provided in connection with registration statements, including the registration statement for our public offering.

Audit-Related Fees. Consists of aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit or review of the Company’s consolidated financial statements and are not reported under “Audit Fees.”

Audit Committee Policy on Pre-Approval of Services

The Audit Committee’s policy is to pre-approve all audit and permissible non-audit services provided by the independent registered public accounting firm. These services may include audit services, audit-related services, tax services, and other services. Pre-approval is generally provided for up to one year. The Audit Committee may also pre-approve particular services on a case-by-case basis.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed or Furnished Herewith
		Form	Exhibit	Filing Date	
3.1	Restated Articles of Organization of the Company.	S-1	3.1	10/08/1996	
3.2	Articles of Amendment to Restated Articles of the Organization of the Company	10-Q	3.1	11/23/2004	
3.3	Articles of Amendment to Restated Articles of the Organization of the Company	8-K	3.1	02/18/2009	
3.4	Articles of Amendment to Restated Articles of the Organization of the Company	8-K	3.1	04/12/2011	
3.5	Articles of Amendment to Restated Articles of the Organization of the Company	8-K	3.1	11/10/2011	
3.6	Articles of Amendment to Restated Articles of the Organization of the Company	8-K	3.1	01/04/2013	
3.7	Articles of Amendment to Restated Articles of the Organization of the Company	8-K	3.1	02/13/2013	
3.8	Articles of Amendment to Restated Articles of the Organization of the Company	8-K	3.1	12/12/2013	
3.9	Articles of Amendment to Restated Articles of the Organization of the Company	8-K	3.1	02/05/2014	
3.10	Articles of Amendment to Restated Articles of the Organization of the Company	8-K	3.1	12/31/2014	
3.11	Articles of Amendment to Restated Articles of the Organization of the Company	8-K	3.1	07/28/2015	
3.12	Amended Certificate of Designation of Series AA Convertible Preferred Stock, filed February 14, 2019.	8-K	3.1	02/15/2019	
3.13	Amendment to Amended and Restated By-Laws of the Company	10-K	3.3	10/08/1996	
3.14	Amendment to Amended and Restated By-Laws of the Company	10-K	3.3	3/31/2003	
4.1	Specimen Certificate for Shares of the Company’s common stock	10-KSB	4.1	04/22/2005	

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Exhibit Number	Exhibit Description	Incorporated by Reference			Filed or Furnished Herewith
		Form	Exhibit	Filing Date	
4.2	Description of securities registered under Section 12 of the Exchange Act of 1934				X
10.1	2013 Equity Incentive Plan.*	S-8	4.1	04/24/2015	
10.2	Economic Injury Disaster Loan Note, dated June 25, 2020, issued to the U.S. Small Business Administration	10-Q	10.3	08/14/2020	
10.3	Security Agreement, dated June 25, 2020, by and between Pressure BioSciences, Inc. and the U.S. Small Business Administration	10-Q	10.4	08/14/2020	
10.4	Paycheck Protection Program Note, dated April 18, 2020, issued to North Easton Savings Bank	10-Q	10.1	06/29/2020	
10.5	Form of Amendment to Standstill and Forbearance Agreement entered into in January, March, April, May and June 2020	10-Q	10.3	06/29/2020	
21.1	List of Subsidiaries				X
23.1	Consent of Independent Registered Public Accounting Firm (Malone Bailey LLP)				X
31.1	Principal Executive Officer Certification Pursuant to Item 601(b) (31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Principal Financial Officer Certification Pursuant to Item 601(b) (31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Principal Executive Officer Certification Pursuant to Item 601(b) (32) of Regulation S-K, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. **				X
32.2	Principal Financial Officer Certification Pursuant to Item 601(b) (32) of Regulation S-K, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. **				X

*Management contract or compensatory plan or arrangement.

**In accordance with SEC Release 33-8238, Exhibit 32.1 is furnished and not filed.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: April 15, 2021

Pressure BioSciences, Inc.

By: /s/ Richard T. Schumacher
Richard T. Schumacher
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacity and on the dates indicated.

Name	Capacity	Date
<u>/s/ Richard T. Schumacher</u> Richard T. Schumacher	President, Chief Executive Officer, Interim Chief Financial Officer, Treasurer, Clerk and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	April 15, 2021
<u>/s/ Jeffrey N. Peterson</u> Jeffrey N. Peterson	Chairman of the Board of Directors	April 15, 2021
<u>/s/ Mickey Urdea</u> Michael S. Urdea, Ph.D.	Director	April 15, 2021
<u>/s/ Vito Mangiardi</u> Vito J. Mangiardi	Director	April 15, 2021
<u>/s/ Kevin Pollack</u> Kevin A. Pollack	Director	April 15, 2021
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**DESCRIPTION OF REGISTRANT’S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934**

Set forth below is the description of the common stock, par value \$0.01 per share (the “Common Stock”) of Pressure BioSciences, Inc. (“we” or “our”). The following description summarizes the most important terms of these securities. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Restated Articles of Organization, as amended (the “Articles”), and our Amended and Restated By-laws, as amended (the “By-laws”), copies of which have been previously filed with the Securities and Exchange Commission and are incorporated by reference into the Annual Report on Form 10-K for the year ended December 31, 2020. You should refer to our Articles, By-laws and the applicable provisions of the Massachusetts General Laws, for a complete description.

The Common Stock is the only class of our securities currently registered under Section 12 of the Securities Exchange Act of 1934. Our Common Stock is quoted on the OTCQB under the symbol “PBIO.”

Authorized Common Stock

Our authorized Common Stock consists of 100,000,000 shares.

Dividend Rights

Subject to limitations under the Massachusetts General Laws and to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our Common Stock are entitled to receive dividends out of funds legally available if our Board of Directors, in its discretion, determines to declare and pay dividends and then only at the times and in the amounts that our Board of Directors may determine.

Voting Rights

Holders of our Common Stock are entitled to one vote for each share held on all matters properly submitted to a vote of stockholders on which holders of Common Stock are entitled to vote. We have not provided for cumulative voting for the election of directors in our Certificate. The directors are elected by a plurality of the outstanding shares entitled to vote on the election of directors. On all other matters the affirmative vote of a majority of the voting power of the shares present or represented by proxy at the meeting and entitled to vote on the subject matter constitutes the act of the stockholders, except as otherwise expressly provided by the Nevada Revised Statutes.

No Preemptive or Similar Rights

Our Common Stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

If we become subject to a liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our Common Stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Transfer Agent and Registrar

Computershare Trust Company NA is the transfer agent and registrar in respect of the common stock.

Pressure BioSciences, Inc. – Subsidiaries

PBI BioSeq, Inc. (U.S.A.)

Pressure BioSciences Europe (Poland)

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 (File No. 333-203609) of our report dated April 15, 2021, with respect to the consolidated financial statements of Pressure BioSciences, Inc., which is included in this Annual Report on Form 10-K for the year ended December 31, 2020. Our report contains an explanatory paragraph regarding the Company’s ability to continue as a going concern.

/s/ Malone Bailey LLP

www.malonebailey.com
Houston, Texas
April 15, 2021

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard T. Schumacher, certify that:

1. I have reviewed this report on Form 10-K of Pressure BioSciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial data; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 15, 2021

By: /s/ Richard T. Schumacher

Name: Richard T. Schumacher

Title: President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard T. Schumacher, certify that:

1. I have reviewed this report on Form 10-K of Pressure BioSciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial data; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 15, 2021

By: /s/ Richard T. Schumacher

Richard T. Schumacher
Interim Chief Financial Officer
(Principal Financial Officer)

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report on Form 10-K of Pressure BioSciences, Inc., a Massachusetts corporation (the “Company”) for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), Richard T. Schumacher, President and Chief Executive Officer, of Pressure BioSciences, Inc., a Massachusetts corporation (the “Company”), do hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) that:

(1) The Report of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 15, 2021

/s/ Richard T. Schumacher

Richard T. Schumacher
President and Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Pressure BioSciences, Inc., and will be retained by Pressure BioSciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report on Form 10-K of Pressure BioSciences, Inc., a Massachusetts corporation (the “Company”) for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), Richard T. Schumacher, Chief Financial Officer, of Pressure BioSciences, Inc., a Massachusetts corporation (the “Company”), do hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) that:

(1) The Report of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 15, 2021

/s/ Richard T. Schumacher
Richard T. Schumacher
Interim Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Pressure BioSciences, Inc., and will be retained by Pressure BioSciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.
