



**(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

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

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  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  No

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer [ ] Accelerated filer [ ]  
Non-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 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 29, 2018 was \$6,045,761 based on the closing price of \$3.94 per share of Pressure BioSciences, Inc. common stock as quoted on the OTCQB Marketplace on that date.

As of April 12, 2019, there were 1,699,243 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®, PULSE®, and BioSeq®, 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™, Barozyme™ and BaroFlex™ Strips, Ultra Shear Technology, and UST™ all of which are unregistered trademarks of the Company.

### Overview

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 internally developed 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 internally developed consumables product line, which include our unique MicroTubes, MicroCaps, MicroPestles, BaroFlex 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% ownership interest with the investment bank retaining 51%. Throughout 2018, PBI Europe did not have any operating activities and we cannot reasonably predict when operations will commence. Therefore, we don’t have control of the subsidiary and did not consolidate them in our financial statements.

### Patents



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, or UST. We have also received eight patents with our purchase of the assets of BaroFold in December 2017. PCT employs a unique approach that we believe has the potential for broad use in a number of established and emerging life sciences areas, which include, but are not limited to:

protein characterization

biological sample preparation – including but not limited to sample extraction, homogenization, and digestion - in such study areas as genomic, proteomic, lipidomic, metabolomic and small molecule;

pathogen inactivation;

protein purification;

control of chemical reactions, particularly enzymatic; and

immunodiagnostics.

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 several hours 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 required 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 our products, either separately or together.

### **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, as well as 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 - Mass Spectrometry*

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

### *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.

### *Histology*

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 histology (extraction of biomolecules from FFPE tissues), our potential customers could be pharmaceutical companies, hospitals, and laboratories focused on drug discovery or correlation of disease states.

### **Developments**

We reported a number of accomplishments in 2018:

On February 14, 2018, the Company announced it had signed a two-year, global co-marketing and distribution agreement with ISS, Inc., a designer and manufacturer of advanced scientific instrumentation.

On May 3, 2018, the Company announced receipt of the first contract utilizing the high-pressure patents and other IP acquired from BaroFold, Inc. in the Company’s December 2017 Asset Acquisition. The contract related to evaluating the ability of the acquired PreEMT™ technology platform to enhance the manufacturing process and improve the quality of a specific protein therapeutic drug candidate of the third-party.

On May 15, 2018, the Company announced the conversion of \$6.39 million of debt into equity.

On June 12, 2018, the Company announced the conversion of an additional \$7.24 million of debt into equity.

On July 12, 2018, The Ohio State University announced the receipt of an \$891,000 grant from the USDA to develop – together with PBI – an innovative manufacturing technology to preserve food and beverages using wholesome, recognizable ingredients, no artificial preservatives, and reduced use of heat.

On July 19, 2018, we announced that we were developing a potential breakthrough processing method – based on our patented Ultra Shear Technology, or UST – for high quality, shelf-stable milk and other dairy products that would not require refrigeration or chemical additives.

On August 30, 2018, we announced the award of a key new U.S. patent entitled “Flow-through High Hydrostatic Pressure Microfluidic Sample Preparation Device and Related Methods Therefor.” This new patent (US 9995661) brings the Company’s Intellectual Property (“IP”) estate up to a total of 21 issued patents.

On September 13, 2018, we announced the sale of the first two instruments from our newest line of high-pressure based instrument systems, the HUB880 Explorer.

On September 21, 2018, we announced that our ultra-high-pressure product line of instruments, methods, and technology platforms was prominently featured at the recent Institute of Food Technologists annual meeting in Chicago, IL. The Company’s Ultra Shear Technology platform, particularly its U.S. Department of Agriculture-funded collaborative program with The Ohio State University’s College of Food, Agricultural, and Environmental Sciences, was discussed during the four-day conference.

On October 3, 2018, we announced an acceleration in the development timetable for our novel UST technology platform, in order to pursue commercialization of the technology into major new markets.

On November 7, 2018, Bradford A. Young, Ph.D., MBA joined PBI as Sr. VP and Chief Commercial Officer, where his strong technical and leadership experience is expected to help drive product adoption and help drive revenue growth.

On November 9, 2018, we announced achievement of the first major milestone in the development of our UST technology platform: development of the first working prototype of the UST System.

On November 15, 2018, we achieved the successful development of a proprietary processing method for high quality, water-soluble oils, which we believed had the potential to open up major new opportunities in multiple markets. We said that the initial focus of this new method would be in the CBD oil and cosmetics markets.

On December 18, 2018, the Children's Medical Research Institute in Australia, a major international cancer research center, reported that our patented PCT platform could play a significant role in improving cancer diagnosis and treatment.

## 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.

## Corporate Information

We were incorporated in the Commonwealth of Massachusetts in August 1978 as Boston Biomedica, Inc. 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.

## Available Information

Our Internet website address is <http://www.pressurebiosciences.com>. Through our website, we make available, free of charge, reports we file with the Securities and Exchange Commission ("SEC"), which include, but are not limited to, our

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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.

The SEC maintains an Internet website that contains reports, proxy and information statements and other information regarding Pressure BioSciences and other issuers that file electronically with the SEC. The SEC's Internet website address is <http://www.sec.gov>.



## **Sample Preparation for Genomic, Proteomic, Lipidomic and Small Molecule Studies**

### *The Market*

Since February 2005, we have focused substantially all of our research and development and commercialization efforts on sample preparation 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 to measure the progression and effects of therapy. Biomarkers can help in the diagnosis, prognosis, therapy, 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.

Our plan is to focus primarily on the application of PCT-enhanced protein extraction and CP-based digestion for the mass spectrometry market and the advantages of PCT and CP in this market, and on the use of PCT and CP in biomarker discovery, soil and plant biology, counter bio-terrorism and tissue pathology applications.

### *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) using PCT in the sample preparation process. We believe that PCT may be capable of differentially extracting DNA from sperm cells and female epithelial cells in swabs collected from rape victims and 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.

### *Histology*

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.

### *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.

### **Company 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 2320EXT, the Barozyme-HT48, the Barocycler® NEP3229, 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 or chilling via internal heating jacket or external circulating water-bath), automatic fill and dispensing valves, and an integrated keypad or 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 and our consumable products 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, has 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”.

Barocycler® NEP3229 – The Barocycler® NEP3229 contains two units – a user interface and a power source – comprised primarily of a 1.5 horsepower motor and hydrolic pump assembly. Combined, the two components of the NEP3229 weigh approximately 350 pounds. The Barocycler® NEP3229 is capable of processing up to three samples simultaneously using our specially designed, single-use PULSE® Tubes and up to 48 samples simultaneously using our specially-designed MicroTubes.

Barozyme HT48 - The Barozyme HT48 is a high throughput, bench-top instrument designed for accelerated enzymatic digestion of proteins at high pressure. A typical protein digestion time using the enzyme trypsin (a common yet important laboratory procedure) can be reduced from often requiring an overnight incubation to achieve completion, to under one hour when the digestion procedure is carried out with PCT. The Barozyme HT48 uses an air-pressure-to-liquid-pressure proprietary intensifier system, with a pressure amplification ratio of 160:1, to reach an output pressure of 20,000 psi. The Barozyme HT48 is capable of processing up to 48 samples at a time in six single-use BaroFlex 8-well Strips in the Barozyme Sample Carrier. This design allows for the 8-well strips to be utilized in standard 48 or 96 well plate formats that are compatible with other high-throughput laboratory automation systems.

Barocycler® HUB440 –We believe the Barocycler® HUB440 is the first portable, ready to use, “plug-and-play” high pressure generator for the laboratory bench. The Barocycler® 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 specially-written by us in LabVIEW (software from National Instruments Corporation). We own the rights and have a license to use the specialty LabVIEW software. We believe that over the coming years, the Barocycler® HUB440 may become the main instrument in our pressure-based instrument line.

Barocycler® HUB880 - The Barocycler® 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 food safety and vaccine industries.

Ultra Shear Technology (UST) – UST is an emerging technology that combines intense fluid shear with an instant, short-lived burst of heat achieved by specialized high pressure equipment to produce commercially sterile, pumpable, homogeneous fluid products. The UST process achieves energetic cellular disruption and results in the inactivation of bacteria, bacterial spores, viruses, and enzymes. Depending on operating conditions, low nano-scale emulsions (nanoemulsions) or oil and water mixtures can be produced that have been shown to have improved shelf stability, flavor, absorption and bioavailability.

The Company received two UST patents in China, 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 sell direct 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 to food, cosmetics, nutraceuticals, and other companies worldwide.

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 (-200oC to +100oC), 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  $\mu$ Pestles 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  $\mu$ Pestles, 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  $\mu$ L. PCT MicroTubes and PCT  $\mu$ Pestles use PCT to effectively disrupt soft tissues and lyse their cells. As a result, the tissue sample trapped between the MicroTube walls and the  $\mu$ Pestles 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  $\mu$ Pestles 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  $\mu$ Pestle System can be used in any PBI Barocycler®.

**BaroFlex 8-well Processing Strips** - BaroFlex 8-well Strips are used in the Barozyme HT48 (for pressure-enhanced enzymatic digestion at 20,000 psi). BaroFlex 8-well Strips are made of special high density polyethylene (HDPE) and hold up to 140 $\mu$ l per well when capped with the BaroFlex Cap Strips or Mats. BaroFlex 8-Cap Strips and BaroFlex 24-Cap Mats are made of silicone. These single-use caps are designed to seal BaroFlex 8-well Strips tightly and to prevent fluid exchange between the sample and the Barozyme chamber fluid during pressure cycling. The silicone caps are available as strips of eight, or mats of 24 caps.

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.

## **Company Services**

### *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.

### *Government Grants and Contracts*

We view federal agency grants to be an important part of our business plan. These types of grants allow us to bill the federal agency for work that we are planning to perform as part of the development and commercialization of our technology. We generally start by submitting initial grant requests that are in response to requests for proposals (“RFPs”) from the federal government through their Small Business Innovation Research (“SBIR”) program. Initial (“SBIR Phase I”) grants are meant to fund approved research projects for six months, and generally have budgets of approximately \$100,000 to \$150,000. Because our work in SBIR Phase I grants has been successful, we have applied, and may in the future apply for larger National Institutes of Health (“NIH”) SBIR Phase II grants. Such larger grants are typically for a two-year period and can offer as much as \$1,000,000 to support significant research projects in areas we would otherwise expect to support with internal funds should SBIR Phase II grants not be awarded. To date, we have been awarded five NIH SBIR Phase I grants and three SBIR Phase II grants. The data on three of the NIH SBIR Phase I grants were the basis for the submission, and subsequent award, of applicable SBIR II grants. Of the three NIH SBIR Phase II grants awarded to us: one was in the approximate amount of \$845,000 in August 2008, the second was in the approximate amount of \$850,000 in September 2011, and the third award was in the approximate amount of \$1,020,000 awarded in November 2014. All five of the NIH SBIR Phase I grants and the August 2008 and September 2011, NIH SBIR Phase II grants have been completed. We received an extension on the SBIR Phase II grant, awarded in November 2014, to utilize unused funds until November 30, 2018.



The 2008 SBIR Phase II grant (2R44GM079059) was awarded to us by the NIH for work in the area of using PCT to extract proteins, sub-cellular molecular complexes, and organelles, with the expectation that these studies might ultimately lead to the release of a new, commercially available PCT-based system, with validated protocols, end-user kits, and other consumables intended for the extraction of clinically important protein biomarkers, sub-cellular molecular complexes, and organelles from human and animal tissues. The 2011 SBIR II contract (W81XWH-10-C-0-175) was awarded to us by the U.S. Army for the development of a universal method for the inactivation, extraction, and enrichment of pathogens in diagnostic samples, including arthropod hosts of military importance. The work covered by this grant was significant in helping us develop the Barozyme HT48 High Throughput System. The 2014 SBIR Phase II grant (2R44HG007136) was awarded to us by the National Human Genome Research Institute of the NIH. Entitled “High Pressure Sample Preparation Instrumentation for DNA Sequencing”, this grant allowed us to develop the Barocycler HUB880, an automated, high-throughput, high pressure system (instrument and consumables), to enable significantly better control of DNA fragmentation - a critical step in the preparation of samples for Next Generation Sequencing platforms. This system was based on significant technological advancements over the classic hydrodynamic DNA shearing approach that has been successfully and widely used in the field of DNA sequencing for many years.

#### *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.

#### **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 immunodiagnosics. 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.

#### *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 and that 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.

#### *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.

#### *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.

### *Immunodiagnostics*

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.

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

BaroFold’s assets 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 and other technologies 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.

### **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 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 histology (extraction of biomolecules from FFPE tissues), our potential customers could be pharmaceutical companies, hospitals, and laboratories focused on drug discovery or correlation of disease states.

## 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.

## **Manufacturing and Supply**

CBM Industries (Taunton, MA) is the manufacturer of the Barocycler® 2320EXT. CBM is ISO 13485:2003 and 9001:2008 Certified. CBM provides us with precision manufacturing services that include management support services to meet our specific application and operational requirements. Among the services provided by CBM to us are:

CNC Machining

Contract Assembly & Kitting

Component and Subassembly Design

Inventory Management

ISO certification

At this time, we believe that outsourcing the manufacturing of our Barocycler® 2320EXT to CBM is the most cost-effective method for us to obtain ISO Certified, CE and CSA Marked instruments. CBM's close proximity to our South Easton, MA facility is a significant asset enabling interactions between our Engineering, R&D, and Manufacturing groups and their counterparts at CBM. CBM was instrumental in helping PBI achieve CE Marking on our Barocycler 2320EXT, as announced on February 2, 2017.

Although we currently manufacture and assemble the Barozyme HT48, Barocycler® HUB440, the SHREDDER SG3, and most of our consumables at our South Easton, MA facility, we plan to take advantage of outsourced manufacturing relationships such as that with CBM and outsource manufacturing of the entire Barocycler® product line, future instrument, and other products to CBM.

The Barocycler® NEP3229, launched in 2008, and manufactured by the BIT Group, will be phased out over the next several years and replaced by the new state-of-the-art Barocycler® HUB and Barozyme HT product lines.

## Research and Development

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

*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.

*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.

### *Product Pipeline*

The following instruments are in our research and development pipeline:

*Barocycler® FFPE Protein Extraction Instrument System* - A PCT-based system offering the enhanced extraction of proteins from FFPE samples using a modified Barocycler® instrument that combines the advantages of pressure cycling, high temperature, and certain reagents.

*XstreamPCT™ HPLC Digestion Module* - For automated, in-line, on-demand PCT-enhanced protein digestion; the first module in our PCT-based HPLC platform.

### **Sales and Marketing**

Our marketing and sales functions are led by Dr. Bradford Young, our Chief Commercial Officer. Dr. Young 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 a PCT newsletter, market research initiatives, the arrangement of on-location seminars, lectures, and demonstrations of PCT capabilities, and the supervision of our two-person sales force. Dr. Young 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. Dr. Young 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. 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 a paradigm-shifting, new technology such as PCT.

### *Sales*

#### Direct US Sales Force

Our domestic sales force currently consists of one sales director and one field salesperson. Our sales director is currently responsible for servicing the eastern half of the U.S. and our field salesperson handles the western half of the U.S. We expect to hire two additional sales and marketing personnel during 2019, with a goal that our sales and marketing department will have a minimum of four by the end of 2019.

### **Marketing Strategy**

We recognize that our enabling pressure cycling technology (PCT) is a powerful, novel platform technology. We also recognize that the power of PCT is not yet generally known by researchers. Our first goal is to greatly broaden the awareness of PCT and its applications among research scientists and to ensure they know that this technology exists through our Barocycler® family of high-pressure instruments and requisite consumables. To accomplish this expansion of knowledge about PCT and the subsequent adoption of our PCT-based products, we have developed and are implementing a multi-faceted approach to marketing the PCT platform.



### *Key Opinion Leaders and Publications*

To initially reach scientists, we have established collaborations with key opinion leaders (KOL) who recognized early the potential for PCT and 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 for the downstream 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 KOLs, there are also many peer reviewed publications from dozens of other scientists discussing the advantages of the PCT platform in bio-molecule sample preparation. To this end, we do all we can to disseminate the work of these scientists in an effort to increase the exposure of PCT 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 monthly 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.

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. 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 videos of our products. In 2016, we contracted with BioCompare to produce a high quality video showing PCT-HD and the uses of our Barocycler® 2320EXT and the MicroTube System.
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 2019, we plan to expand our Marketing team to support these and additional initiatives.

## **Foreign Distributor Network**

### *Exclusive Agreements*

Currently, we have distribution arrangements covering China, Poland, 24 countries in Europe, and Japan.

In May of 2014, we entered into a three-year distribution agreement with Powertech Technology Co, Ltd., of China, pursuant to which we were granted Powertech Technology exclusive distribution rights to all of our PCT products in China. This Agreement has since been extended until the end of 2019. .

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.

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.

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). We recently renewed the Agreement to commence on March 31, 2018 and end on March 31, 2020.

### *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 were granted OROBOROS non-exclusive world-wide distribution rights to our Shredder SG3 System and related products.

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.

## 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 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.

Our issued patents expire between 2018 and 2030. Our 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 or sale of any of our PCT products. 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 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 are \$3,000 in 2016, \$4,000 in 2017 and \$5,000 in 2018 and each calendar year thereafter during the term of the agreement.

## 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, all of our 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, an ISO certified contract manufacturer, we believe compliance with CE and other required marks and certifications is well controlled.

## Employees

At December 31, 2018, we had seventeen (17) full-time employees and six (6) part-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.

## **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, 2018 contains an explanatory paragraph regarding our ability to continue as a going concern. The audit report 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 at December 31, 2018 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, 2018, 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, 2018, we recorded a net loss available to common shareholders of \$23,473,150 of which \$12,881,899 was deemed dividends on a beneficial conversion feature, or (\$15.33) per share, as compared with \$10,715,561, or (\$9.62) per share, of the corresponding period in 2017. We expect to continue to incur operating losses until sales of PCT and CP products 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 immunodiagnosics, 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.

*Significant policy shifts from the Trump Administration could have a material adverse effect on us.*

The Trump Administration has called for substantial change to fiscal and tax policies, regulatory oversight of businesses, and greater restrictions on free trade including significant increases on tariffs on goods imported into the United States, including from China. Proposals espoused by President Trump may result in changes to social, political, regulatory and economic conditions in the United States or in laws and policies affecting the development and investment in countries where we currently conduct business. In addition, these changes could result in negative sentiments towards the United States among non-U.S. customers and among non-U.S. employees or prospective employees. We cannot predict the impact, if any, of these changes to our business. However, it is possible that these changes could adversely affect our business. It is likely that some policies adopted by the new administration will benefit us and others will negatively affect us.

## **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, 2018, 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, 2018, 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, 2018, 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, 2018, we had issued notes and debentures convertible into common stock at \$7.50 to \$8.40 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 fixed rate convertible notes and debentures were converted, each as of December 31, 2018, an additional 15,768,112 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, 2018, there were 1,684,182 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, 2018 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 6,499 shares of Series AA Convertible Preferred Stock issued and outstanding convertible into 6,499,000 shares of common stock,

As of December 31, 2018, there were outstanding options and warrants to purchase an aggregate of 8,131,555 shares of common stock; and fixed rate convertible debt convertible into 637,765 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 28, 2018, that expires December 31, 2019, 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 December 30, 2020 and requires monthly payments of \$6,912 starting January 1, 2018 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, 2018, 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, 2018, there were 1,769,882 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, 2018 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 and 6,499 shares of Series AA Convertible Preferred Stock issued and outstanding convertible into 6,499,000 shares of common stock.

#### **Approximate Number of Equity Security Holders**

As of December 31, 2018, there were approximately 205 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, 2018, dividends issued or to be issued on convertible preferred stock for the years ended December 31, 2018 and 2017 are outlined in the table below.

| <b>Dividends paid in common<br/>stock or cash</b> |             |             | <b>Dividends payable</b>                   |             |             |
|---|-------------|-------------|--|-------------|-------------|
| <b>For The Year Ended December<br/>31,</b>        |             |             | <b>For The Year Ended December<br/>31,</b> |             |             |
|   | <b>2018</b> | <b>2017</b> |  | <b>2018</b> | <b>2017</b> |
| Series D  | \$ -        | \$ -        | Series D                                   | \$ -        | \$ -        |
| Series E  | -           | -           | Series E                                   | -           | -           |
| Series G  | -           | -           | Series G                                   | -           | -           |
| Series H  | -           | -           | Series H                                   | -           | -           |
| Series H2   | -           | -           | Series H2                                  | -           | -           |
| Series J  | -           | -           | Series J                                   | -           | 83,004      |
| Series K  | -           | -           | Series K                                   | -           | 107,478     |
| Series AA   | -           | -           | Series AA                                  | 678,921     |             |
|   | \$-         | \$-         |  | \$678,921   | \$190,482   |

### **Unregistered Sales of Equity Securities and Use of Proceeds**

During the year ended December 31, 2018, 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 2 were issued in reliance on the exemption under Section 4(a)(2) of the Securities Act. This Part II, Item 2 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, 2018 the company issued a total of 137,879 shares of restricted common stock at a fair value of \$389,940 to accredited investors. 29,002 of the shares with a fair value of \$88,348 were issued to existing holders of convertible loans who agreed to extend the terms of the loans for another six months; 24,523 shares with a fair value of \$69,764 were issued in conjunction with the signing of new convertible loans; 20,000 shares with a fair value of \$64,600 were issued to an investor relations firm for services rendered; 44,000 shares with a fair value of \$110,440 were issued upon the conversion of 44 shares of Series AA Convertible Preferred Stock; and 20,354 shares with a fair value of \$56,788 were issued in lieu of cash for the 8% dividend on Series AA Convertible Preferred Stock.

### **ITEM 6. SELECTED FINANCIAL DATA.**

Not Applicable.



## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION.**

### **OVERVIEW**

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 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 internally developed 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 internally developed consumables product line, which include our unique MicroTubes, MicroCaps, MicroPestles, BaroFlex and PULSE® (Pressure Used to Lyse Samples for Extraction) Tubes, and application specific kits (containing consumable products and reagents), together make up our PCT SPS.

In 2015, together with an investment bank, we formed a subsidiary called Pressure BioSciences Europe (“PBI Europe”) in Poland. We have 49% ownership interest with the investment bank retaining 51%. PBI Europe has never had any operating activities and we cannot reasonably predict when operations will commence. Therefore, we don't have control of the subsidiary and did not consolidate them in our financial statements.

### **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 PCT employs a unique approach that we believe has the potential for broad use in a number of established and emerging life sciences areas, which include, but are not limited to:

biological sample preparation – including but not limited to sample extraction, homogenization, and digestion - in such study areas as genomic, proteomic, lipidomic, metabolomic and small molecule;

pathogen inactivation;

protein purification;

control of chemical reactions, particularly enzymatic; and

immunodiagnostics.

We are also the exclusive distributor, throughout the Americas for Constant System's cell disruption equipment, parts, and consumables. CS, a British company located several hours 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 required 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 our products, either separately or together.

## **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 - 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 measure the progression and effects of therapy. Biomarkers can help in the diagnosis, prognosis, therapy, 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 a recently published market report by Transparency Market Research, “Spectrometry Market (Atomic, Molecular and Mass Spectrometry) - Global Scenario, Trends, Industry Analysis, Size, Share & Forecast 2011 – 2017,” the global spectrometry market was worth \$10.2 billion in 2011 and is expected to reach \$15.2 billion in 2017, growing at a compound annual growth rate of 6.9% from 2011 to 2017. In the overall global market, the North American market is expected to maintain its lead position in terms of revenue until 2017 and is expected to have approximately 36.2% of the market revenue share in 2017, followed by Europe. 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.

### *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.

### *Histology*

The most commonly used technique worldwide for the preservation of cancer and other tissues for subsequent pathology evaluation is process them into formalin-fixed, paraffin-embedded (“FFPE”) tissue 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 firms, and other life science institutions in the North, Central, and South America; Europe, and Asia. Our goal is to continue aggressive market penetration in these target groups. 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 histology (extraction of biomolecules from FFPE tissues), our potential customers could be pharmaceutical companies, hospitals, and laboratories focused on drug discovery or correlation of disease states.

### *Going Concern*

We have experienced negative cash flows from operations with respect to our pressure cycling technology business since our inception. As of December 31, 2018, 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, 2018, 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, 2018, 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, 2018 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, 2018 as compared with December 31, 2017

#### Revenue

We had total revenue of \$2,457,871, in the year ended December 31, 2018 as compared with \$2,240,498 in the prior year, a 10% increase. The increase was due to product and services sales growth.

*Products, Services, and Other.* Revenue from the sale of products and services was \$2,200,539 in the year ended December 31, 2018 compared with \$2,065,891 in the year ended December 31, 2017, a 7% increase. Revenue included sales of both PBI and CS's pressure-based products and sales of our new Barofold Contract Services. Sales of instrumentation decreased in 2018 by \$40,595 or 3%, from \$1,459,326 for FY 2017 to \$1,418,731 for FY 2018. Sales of consumables were \$235,132 for the year ended December 31, 2018 compared to \$260,331 for the same period in 2017, a decrease of \$25,199 or 10%. Sales of Barofold Contract Services increased from \$0 for FY2017 to \$118,383 in FY2018. Products, Services, and Other Revenue included \$91,265 from non-cash transactions in the current year while the prior year included non-cash transactions of \$77,088. Revenue from non-cash transactions was recognized on the fair value of the assets involved per ASC 845.

*Grant Revenue.* During 2018, we recorded \$257,332 of grant revenue as compared with \$174,607 in 2017. In December 2014, the Company was awarded a \$1,020,969 SBIR Phase II grant (2R44HG007136) from the National Human Genome Research Institute of the NIH. Entitled "High Pressure Sample Preparation Instrumentation for DNA Sequencing", this grant is helping to fund the development of an automated, high-throughput, high pressure system (instrument and consumables) to enable significantly better control of DNA fragmentation - a critical step in the preparation of samples for Next Generation Sequencing platforms. This system will be based on significant technological advancements over the classic hydrodynamic DNA shearing approach that has been successfully and widely used in the field of DNA sequencing for many years. In March 2018, we received an extension on the SBIR Phase II grant to utilize unused funds until November 30, 2018.

#### Cost of Products and Services

The cost of products and services was \$1,280,270 for the year ended December 31, 2018, compared with \$1,273,354 in 2017. Our overall gross profit margin increased to 48% for FY 2018 from 43% for FY 2017.

Research and Development

Research and development expenses were \$1,208,160 for 2018 compared to \$988,597 in 2017, an increase of \$219,563 or 22%. This increase is primarily from an increase in salaries, medical insurance, laboratory supplies and outside testing services. Research and development expense also included \$120,417 and \$92,055 of non-cash, stock-based compensation in 2018 and 2017, respectively.

Selling and Marketing

Selling and marketing expenses were \$1,009,568 in 2018 compared to \$1,209,334 in 2017, a decrease of \$199,766, or 17%. This decrease is primarily attributed to a decrease in consulting and outside services. Selling and marketing expense included \$49,203 and \$54,404 of non-cash stock based compensation expense in 2018 and 2017, respectively.

General and Administrative

General and administrative costs were \$3,436,956 in the year ended December 31, 2018, as compared with \$3,416,261 in 2017, an increase of \$20,695 or 1%. The increase in General and Administrative expense is primarily attributable to an increase in payroll and health insurance, stock-based compensation and board of director fees offset by a decrease in investor relations and other outside services. During the years ended December 31, 2018 and 2017, general and administrative expense included \$423,037 and \$259,968 of non-cash, stock-based compensation expense, respectively.

Operating Loss

Our operating loss was \$4,477,083 for the year ended December 31, 2018 as compared to \$4,647,048 for the prior year, a decrease of \$169,965 or 4%. This decrease in operating loss was due primarily to increased revenues of \$217,373 offset by an increase in costs and expenses of \$47,408.

Other income (expense), net

*Interest Expense.* Net interest expense totaled \$4,168,214 for the year ended December 31, 2018 as compared to interest expense of \$6,055,420 for the year ended December 31, 2017. Interest expense includes the amortization of deferred finance costs associated with our notes. We are amortizing deferred financing costs and imputed interest against the debt discount on loans. During 2018 \$12,688,385 of convertible notes were converted to Series AA Convertible Preferred Stock. Unamortized deferred finance costs associated with the converted notes were charged to equity as a result of these transactions.

*Other income (expense) net*

We recognized \$15,135 in expense during 2018, compared to \$5,674 of expense in 2017.

*Impairment loss on investment*

The value of our investment in common stock of Everest Investments Holdings S.A. (“Everest”) has declined since the date of receipt of the stock in 2015. We evaluated the decline and considered it as an “other than temporary impairment” reduction. Thus, the impairment loss was recognized as a charge in the consolidated statements of operations. We recorded an impairment loss of \$6,069 in 2017, which represented the reduction in value of these securities.

Gain on extinguishment of debt

In connection with payments of interest in common stock, we calculated net gains of \$260,454 and \$185,452 in the years ended December 31, 2018 and 2017 respectively, on the difference between the stock’s trading price on date of



issuance and the interest payable in cash. The gains were offset by fees paid to extend the terms on short-term loans. The 2018 and 2017 gains were offset by \$237,888 and \$33,000 of loan extension fees recorded as losses on debt modifications.

Income Taxes

We did not record an income tax benefit or provision for the years ended December 31, 2018 or 2017.

Net Loss

During the year ended December 31, 2018, we recorded a net loss available to common shareholders of \$23,473,150 or \$(15.33) per share, as compared with a net loss available to common shareholders of \$10,715,561 or \$(9.62) per share during the year ended December 31, 2017. This increase in net loss is primarily attributable to the \$12,881,899 in deemed dividends on beneficial conversion feature resulting from the conversion of convertible debt to Series AA Convertible preferred Stock.

## LIQUIDITY AND FINANCIAL CONDITION

As of December 31, 2018, 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 \$15 million in additional capital to fund our three-pronged operational plan, which was designed to help increase revenues and reach profitability, by:

- building a “demo lab” at our South Easton facility, where we will be able to demonstrate to potential customers, Key Opinion Leaders (KOLs), collaborators, and potential partners our UST and BaroFold instrument systems, consumables, and various applications;
- developing the next generation of UST instruments and applications for the manufacture of nanoemulsions, for use in multiple large and growing markets, such as cosmetics, nutraceuticals, pharmaceuticals, and lubricants; and
- retaining a small team of sales and marketing personnel to target biopharmaceutical manufacturing facilities, research laboratories, and academic institutions, and to cultivate our current customer list of pharmaceutical, military and paramilitary organizations.

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 \$5,695,904 for the year ended December 31, 2018 as compared with \$3,904,549 for the year ended December 31, 2017.

Net cash used in investing activities for the year ended December 31, 2018 totaled \$0 compared to \$171,825 in the prior period. Cash capital expenditures included BaroFold patents, laboratory equipment and IT equipment.

Net cash provided by financing activities for the year ended December 31, 2018 was \$5,717,989 as compared with \$4,019,044 in the prior year.

In 2018,

A \$2,824,664 in aggregate net proceeds were raised from sale of Series AA Convertible Preferred Stock

B Loans in the aggregate amount of \$8,718,387 were received during the year and we made payments on new and existing debt of \$5,825,065.

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

## COMMITMENTS AND CONTINGENCIES

### *Royalty Commitments*

In 1996, we acquired our initial equity interest in BioSeq, Incorporated (“*BioSeq*”). At the time, BioSeq was developing our original pressure cycling technology. They acquired its pressure cycling technology from BioMolecular Assays, Inc. (“*BMA*”) under a technology transfer and patent assignment agreement. In 1998, we purchased all of the remaining, outstanding capital stock of BioSeq; and, consequently, the technology transfer and patent assignment agreement was amended to require us to pay BMA a 5% royalty on our sales of products or services that incorporate or utilize the original pressure cycling technology that BioSeq acquired from BMA. Similarly, the Company is required to pay BMA 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. During the year ended December 31, 2016, we incurred approximately \$6,963 in royalty expense associated with our obligation to BMA.

In connection with our acquisition of BioSeq, we licensed certain limited rights to the original pressure cycling technology back to BMA. This license is non-exclusive and limits the use of the original pressure cycling technology by BMA solely for molecular applications in scientific research and development, and in scientific plant research and development. BMA 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 BMA under the license. BMA was required to pay us these royalties until the expiration of the patents held by BioSeq in March 2016. We have not received any royalty payments from BMA 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 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 are \$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, Dr. Lazarev, and Dr. Young, 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, Dr. Lazarev and Dr. Young, 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 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 2018 and 2017 we incurred \$167,047 and \$140,783, 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, 2018:

|            |           |
|------------|-----------|
| 2019       | 82,953    |
| 2020       | 82,953    |
| 2021       | -         |
| Thereafter | -         |
|            | \$165,906 |

## **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as of December 31, 2018 and December 31, 2017.

## **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.

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.

The transaction is an exchange of a product or property held for sale in the ordinary course of business for a  
b) 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 its non-cash transactions at recorded cost or carrying value of the assets or services sold.

In accordance with FASB ASC 840, *Leases*, we account for our lease agreements under the operating method. 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.

| In thousands of US dollars (\$) | 2019 | 2020 | 2021 | Total |
|---------------------------------|------|------|------|-------|
| Extended warranty service       | 20   | 20   | 18   | 58    |

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, 2018 and 2017, the outstanding balance for intangible assets was \$663,462 and \$750,000, 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, 2018, 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, 2018 and determined that such long-lived assets were not impaired.

### *Conversion Option Liability*

We have signed convertible notes and have determined that conversion options are embedded in the notes and it is required to bifurcate the conversion option from the host contract under ASC 815 and account for the derivatives at fair value. The estimated fair value of the conversion options was determined using the binomial model. The fair value of the conversion options will be classified as a liability until the debt is converted by the note holders or paid back by the Company. The fair value will be affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. We early adopted ASU 2017-11 and applied the guidance to derivative accounting. Therefore, we reclassified the warrant and conversion option liabilities to equity and stopped fair valuing the instruments in 2017.

### *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. Unless otherwise discussed, 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.

In February 2016, the FASB issued ASU 2016-02, Leases (ASC Topic 842). The new standard requires the recognition of assets and liabilities arising from lease transactions on the balance sheet and the disclosure of key information about leasing arrangements. Accordingly, a lessee will recognize a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. Both the asset and liability will initially be measured at the present value of the future minimum lease payments over the lease term. Subsequent measurement, including the presentation of expenses and cash flows, will depend on the classification of the lease as either finance or an operating lease. Initial costs directly attributable to negotiating and arranging the lease will be included in the asset. Lessees will also be required to provide additional qualitative and quantitative disclosures regarding the amount, timing and uncertainty of cash flows arising from leases. The new standard is effective for fiscal years beginning after December 15, 2018, and interim periods therein. The Company early adopted ASC 842 for 2018.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, which requires restricted cash to be presented with cash and cash equivalents on the statement of cash flows and disclosure of how the statement of cash flows reconciles to the balance sheet if restricted cash is shown separately from cash and cash equivalents on the balance sheet. The guidance is effective for interim and annual periods beginning after December 15, 2017, and early adoption is permitted. The Company early adopted the ASU 2016-18 on December 15, 2017.

In January 2017, the FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, which clarifies the definition of a business to provide additional guidance with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This ASU is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company early adopted the ASU 2016-18 on December 15, 2017 starting with its purchase of BaroFold assets.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) which amended the existing accounting standards for revenue recognition. ASU 2014-09 establishes principles for recognizing revenue upon the transfer of promised goods or services to customers, in an amount that reflects the expected consideration received in exchange for those goods or services. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim reporting periods within those periods). The amendments may be applied retrospectively to each prior period (full retrospective) or retrospectively with the cumulative effect recognized as of the date of initial application (modified retrospective). The Company will adopt ASU 2014-09 in the first quarter of 2018 and apply the modified retrospective approach. The Company's primary source of revenues is from instrument sales which are considered distinct performance obligations and are recognized upon shipment, the Company does not expect the impact on its consolidated financial statements to be material.

Effective January 1, 2018, the Company adopted ASC Topic 606, Revenue from Contracts with Customers, using the modified retrospective method. This guidance supersedes nearly all existing revenue recognition guidance under US GAAP. The core principle of the guidance is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company has drafted its accounting policy for the new standard based on a detailed review of its business and contracts. Based on the new guidance, the Company continues to recognize revenue at a particular point in time for the majority of its contracts with customers, which is generally when products are either shipped or delivered. Therefore, the adoption of ASC 606 did not have a material impact on the consolidated financial statements. The Company expanded its consolidated financial statement disclosures in order to comply with the disclosure requirements of the ASU beginning in the first quarter of 2018.

Effective January 1, 2018, the Company adopted ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities. The standard amends various aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The most significant impact to our consolidated financial statements relates to the recognition and measurement of equity investments at fair value with changes recognized in Net income. The amendment also updates certain presentation and disclosure requirements. The adoption of ASU 2016-01 did not have a material impact on the consolidated financial statements. The adoption of ASU 2016-01 is expected to increase volatility in net income as changes in the fair value of available-for-sale equity investments and changes in observable prices of equity investments without readily determinable fair values will be recorded in net income.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down

Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-Controlling Interests with a Scope Exception. Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity transactions. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable non-controlling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018 with early adoption permitted. The Company early adopted the ASU 2017-11 in the third quarter of 2017.

**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, 2018 and 2017, 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, 2018 and 2017, 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.

*/s/ MaloneBailey, LLP*

[www.malonebailey.com](http://www.malonebailey.com)

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

Houston, Texas

April 16, 2019

**PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS****DECEMBER 31, 2018 AND 2017**

|   | December<br>31, 2018 | December<br>31, 2017 |
|---|----------------------|----------------------|
| <b>ASSETS</b>   |                      |                      |
| <b>CURRENT ASSETS</b>   |                      |                      |
| Cash and cash equivalents   | \$103,118            | \$81,033             |
| Accounts receivable, net of \$0 reserve at December 31, 2018 and December 31, 2017                  | 474,830              | 206,848              |
| Inventories, net of \$273,547 reserve at December 31, 2018 and \$179,600 December 31, 2017          | 765,478              | 857,662              |
| Prepaid income taxes  | -                    | 7,482                |
| Prepaid expenses and other current assets   | 170,734              | 214,676              |
| Total current assets  | 1,514,160            | 1,367,701            |
| Investment in equity securities   | 16,643               | 19,825               |
| Property and equipment, net   | 69,272               | 22,662               |
| Right of use asset leases   | 136,385              | -                    |
| Intangible assets, net  | 663,462              | 750,000              |
| <b>TOTAL ASSETS</b>   | <b>\$2,399,922</b>   | <b>\$2,160,188</b>   |
| <b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>  |                      |                      |
| <b>CURRENT LIABILITIES</b>  |                      |                      |
| Accounts payable  | \$658,856            | \$589,263            |
| Accrued employee compensation   | 456,932              | 368,700              |
| Accrued professional fees and other   | 1,112,995            | 800,620              |
| Other current liabilities   | 1,233,325            | 1,536,507            |
| Deferred revenue  | 20,623               | 263,106              |
| Revolving note payable, net of unamortized debt discounts of \$0 and \$637,030, respectively        | -                    | 3,500,000            |
| Related party convertible debt, net of unamortized debt discounts of \$0 and \$31,372, respectively | -                    | 259,762              |
| Convertible debt, net of unamortized discounts of \$156,180 and \$401,856, respectively             | 4,000,805            | 8,028,014            |
| Other debt, net of unamortized discounts of \$9,118 and \$48,194, respectively                      | 852,315              | 1,379,863            |
| Other related party debt  | 15,000               | -                    |
| Total current liabilities   | 8,350,851            | 16,725,835           |
| <b>LONG TERM LIABILITIES</b>  |                      |                      |
| Right of use asset liability  | 136,385              | -                    |
| Deferred revenue  | 37,757               | 57,149               |
| <b>TOTAL LIABILITIES</b>  | <b>8,524,993</b>     | <b>16,782,984</b>    |
| <b>COMMITMENTS AND CONTINGENCIES (Note 7)</b>   |                      |                      |
| <b>STOCKHOLDERS' DEFICIT</b>  | <b>3</b>             | <b>3</b>             |

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|  |                    |                    |
|--|--------------------|--------------------|
| Series D Convertible Preferred Stock, \$.01 par value; 850 shares authorized; 300 shares issued and outstanding on December 31, 2018 and 2017, respectively (Liquidation value of \$300,000) |                    |                    |
| Series G Convertible Preferred Stock, \$.01 par value; 240,000 shares authorized; 80,570 shares issued and outstanding on December 31, 2018 and 2017, respectively                           | 806                | 806                |
| Series H Convertible Preferred Stock, \$.01 par value; 10,000 shares authorized; 10,000 shares issued and outstanding on December 31, 2018 and 2017, respectively                            | 100                | 100                |
| Series H2 Convertible Preferred Stock, \$.01 par value; 21 shares authorized; 21 shares issued and outstanding on December 31, 2018 and 2017, respectively                                   | -                  | -                  |
| Series J Convertible Preferred Stock, \$.01 par value; 6,250 shares authorized; 3,458 shares issued and outstanding on December 31, 2018 and 2017, respectively                              | 35                 | 35                 |
| Series K Convertible Preferred Stock, \$.01 par value; 15,000 shares authorized; 6,880 shares issued and outstanding on December 31, 2018 and 2017, respectively                             | 68                 | 68                 |
| Series AA Convertible Preferred Stock, \$.01 par value; 10,000 shares authorized; 6,499 and 0 shares issued and outstanding on December 31, 2018 and 2017, respectively                      | 65                 | -                  |
| Common stock, \$.01 par value; 100,000,000 shares authorized; 1,684,182 and 1,342,858 shares issued and outstanding on December 31, 2018 and 2017 respectively                               | 16,842             | 13,429             |
| Warrants to acquire common stock   | 19,807,247         | 9,878,513          |
| Additional paid-in capital   | 39,777,301         | 30,833,549         |
| Accumulated other comprehensive loss   |                    | -                  |
| Accumulated deficit  | (65,727,538)       | (55,349,299)       |
| Total stockholders' deficit  | (6,125,071 )       | (14,622,796)       |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>   | <b>\$2,399,922</b> | <b>\$2,160,188</b> |

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, 2018 AND 2017**

|   | For the Year Ended<br>December 31, |                |
|---|------------------------------------|----------------|
|   | 2018                               | 2017           |
| Revenue:  |                                    |                |
| Products, services, other   | \$2,200,539                        | \$2,065,891    |
| Grant revenue   | 257,332                            | 174,607        |
| Total revenue   | 2,457,871                          | 2,240,498      |
| Costs and expenses:   |                                    |                |
| Cost of products and services   | 1,280,270                          | 1,273,354      |
| Research and development  | 1,208,160                          | 988,597        |
| Selling and marketing   | 1,009,568                          | 1,209,334      |
| General and administrative  | 3,436,956                          | 3,416,261      |
| Total operating costs and expenses  | 6,934,954                          | 6,887,546      |
| Operating loss  | (4,477,083 )                       | (4,647,048 )   |
| Other (expense) income:   |                                    |                |
| Interest expense  | (4,168,214 )                       | (6,055,420 )   |
| Other expense   | (15,135 )                          | (5,674 )       |
| Impairment loss on investment   | -                                  | (6,069 )       |
| Gain on extinguishment of liabilities   | 260,454                            | 185,452        |
| Incentive shares and warrants   | (1,299,340 )                       | (186,802 )     |
| Change in fair value of derivative liabilities  | -                                  | -              |
| Total other (expense) income  | (5,222,235 )                       | (6,068,513 )   |
| Net loss  | \$(9,699,318 )                     | \$(10,715,561) |
| Deemed dividends on down round feature  | (213,012 )                         | -              |
| Deemed dividends on beneficial conversion feature   | (12,881,899)                       | -              |
| Preferred stock dividends   | (678,921 )                         | -              |
| Net loss attributable to common shareholders  | \$(23,473,150)                     | \$(10,715,561) |
| Net loss per share - basic and diluted  | \$(15.33 )                         | \$(9.62 )      |
| Weighted average common stock shares outstanding used in the basic and diluted net loss per share calculation | 1,530,989                          | 1,114,225      |

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, 2018 AND 2017**

|   | Series D<br>Preferred<br>Stock |        | Series G<br>Preferred Stock |        | Series H<br>Preferred Stock |        | Series<br>H(2)Preferred<br>Stock |        |
|---|--------------------------------|--------|-----------------------------|--------|-----------------------------|--------|----------------------------------|--------|
|   | Shares                         | Amount | Shares                      | Amount | Shares                      | Amount | Shares                           | Amount |
| BALANCE, December 31, 2016                          | 300                            | \$ 3   | 86,570                      | \$ 866 | 10,000                      | \$ 100 | 21                               | \$ -   |
| Stock-based compensation                            | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Issuance of common stock for services               | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Warrant revaluation                                 | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Warrant exercise                                    | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Stock exchange with Everest Investments             | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Issuance of warrants for services                   | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Conversion of debt and interest for common stock    | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Issuance of common stock for dividends paid-in-kind | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Conversion of Series G convertible preferred stock  | -                              | -      | (6,000)                     | (60)   | -                           | -      | -                                | -      |
| Conversion of Series convertible preferred stock    | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Common Stock offering                               | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Offering costs for issuance of common stock         | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Stock issued with debt                              | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Warrants issued with debt                           | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Unrealized loss on investments, net of tax          | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Net loss  | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| BALANCE, December 31, 2017                          | 300                            | \$ 3   | 80,570                      | \$ 806 | 10,000                      | \$ 100 | 21                               | \$ -   |
| Early adoption of ASU 2017-11                       | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Stock-based compensation                            | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Issuance of common stock for services               | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Warrant revaluation                                 | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Warrant exercise, net of costs                      | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Stock exchange with Everest Investments             | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Issuance of warrants for services                   | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Conversion of debt and interest for common stock    | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Issuance of common stock for interest paid-in-kind  | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
| Conversion of Series G convertible preferred stock  | -                              | -      | -                           | -      | -                           | -      | -                                | -      |
|   | -                              | -      | -                           | -      | -                           | -      | -                                | -      |

|  |     |      |        |        |        |        |    |      |
|--|-----|------|--------|--------|--------|--------|----|------|
| Conversion of Series J convertible preferred stock |     |      |        |        |        |        |    |      |
| Incentive warrants                                 | -   | -    | -      | -      | -      | -      | -  | -    |
| Offering costs for issuance of common stock        | -   | -    | -      | -      | -      | -      | -  | -    |
| Stock issued for debt extension                    | -   | -    | -      | -      | -      | -      | -  | -    |
| Stock issued with debt                             | -   | -    | -      | -      | -      | -      | -  | -    |
| Common stock for asset purchase                    | -   | -    | -      | -      | -      | -      | -  | -    |
| Warrants issued with debt                          | -   | -    | -      | -      | -      | -      | -  | -    |
| Net loss   | -   | -    | -      | -      | -      | -      | -  | -    |
| BALANCE, December 31, 2018                         | 300 | \$ 3 | 80,570 | \$ 806 | 10,000 | \$ 100 | 21 | \$ - |

|   | Series J<br>Preferred<br>Stock |        | Series K<br>Preferred Stock |        | Series AA<br>Preferred Stock |        | Common Stock |          |
|---|--------------------------------|--------|-----------------------------|--------|------------------------------|--------|--------------|----------|
|   | Shares                         | Amount | Shares                      | Amount | Shares                       | Amount | Shares       | Amount   |
| BALANCE, December 31, 2016                              | 3,521                          | \$ 35  | 6,816                       | \$ 68  | -                            | \$ -   | 1,033,328    | \$10,333 |
| Stock-based compensation                                | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Issuance of common stock for services                   | -                              | -      | 64                          | -      | -                            | -      | 5,667        | 57       |
| Warrant revaluation                                     | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Warrant exercise  | -                              | -      | -                           | -      | -                            | -      | 19,889       | 199      |
| Stock exchange with Everest Investments                 | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Issuance of warrants for services                       | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Conversion of debt and interest for common stock        | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Issuance of common stock for interest paid-in-kind      | -                              | -      | -                           | -      | -                            | -      | 61,307       | 612      |
| Conversion of Series G convertible preferred stock      | -                              | -      | -                           | -      | -                            | -      | 2,000        | 20       |
| Conversion of Series J convertible preferred stock      | (63 )                          | -      | -                           | -      | -                            | -      | 2,100        | 21       |
| Common Stock offering                                   | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Stock issued for debt extension                         | -                              | -      | -                           | -      | -                            | -      | 4,167        | 42       |
| Stock issued with debt                                  | -                              | -      | -                           | -      | -                            | -      | 64,400       | 645      |
| Warrants issued with debt                               | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Common stock for asset purchase                         | -                              | -      | -                           | -      | -                            | -      | 150,000      | 1,500    |
| Net loss  | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| BALANCE, December 31, 2017                              | 3,458                          | \$ 35  | 6,880                       | \$ 68  | -                            | \$ -   | 1,342,858    | \$13,429 |
| Stock-based compensation                                | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Issuance of common stock for services                   | -                              | -      | -                           | -      | -                            | -      | 68,000       | 680      |
| Issuance of common stock for interest paid in kind      | -                              | -      | -                           | -      | -                            | -      | 76,361       | 764      |
| Conversion of debt and interest for preferred stock     | -                              | -      | -                           | -      | 5,075                        | 51     | -            | -        |
| Conversion of Series AA preferred stock to common stock | -                              | -      | -                           | -      | (44 )                        | -      | 44,000       | 440      |
| Issuance of warrants for services                       | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Conversion of debt and interest for common stock        | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Issuance of common stock for interest paid-in-kind      | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Conversion of Series G convertible preferred stock      | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Conversion of Series J convertible preferred stock      | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Series AA Preferred Stock offering                      | -                              | -      | -                           | -      | 1,275                        | 13     | -            | -        |
| Incentive warrants and shares                           | -                              | -      | -                           | -      | 193                          | 1      | -            | -        |
| Offering costs for issuance of common stock             | -                              | -      | -                           | -      | -                            | -      | -            | -        |
| Stock issued for debt extension                         | -                              | -      | -                           | -      | -                            | -      | 64,652       | 646      |



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|                            |       |       |       |       |       |       |           |          |
|----------------------------|-------|-------|-------|-------|-------|-------|-----------|----------|
| Stock issued with debt     | -     | -     | -     | -     | -     | -     | 88,311    | 883      |
| Warrants issued with debt  | -     | -     | -     | -     | -     | -     | -         | -        |
| Net loss                   | -     | -     | -     | -     | -     | -     | -         | -        |
| BALANCE, December 31, 2018 | 3,458 | \$ 35 | 6,880 | \$ 68 | 6,499 | \$ 65 | 1,684,182 | \$16,842 |

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|   | Stock<br>Warrants | Additional<br>Paid -In<br>Capital | Accumulated<br>Deficit | Total<br>Stockholders'<br>Deficit |
|---|-------------------|-----------------------------------|------------------------|-----------------------------------|
| BALANCE, December 31, 2016                                    | \$6,325,102       | \$27,544,264                      | \$(42,264,190)         | \$(8,383,418 )                    |
| Early adoption of ASU 2017-11                                 | 2,636,236         | 1,446,011                         | (2,369,548 )           | 1,712,699                         |
| Stock-based compensation                                      | -                 | 406,427                           | -                      | 406,427                           |
| Issuance of common stock for services                         | -                 | 46,935                            | -                      | 46,992                            |
| Warrant exercise, net of costs                                | -                 | 140,015                           | -                      | 140,214                           |
| Issuance of warrants for services                             | 15,558            | -                                 | -                      | 15,558                            |
| Issuance of common stock for interest paid-in-kind            | -                 | 263,990                           | -                      | 264,602                           |
| Conversion of Series G convertible preferred stock            | -                 | 40                                | -                      | -                                 |
| Conversion of Series J convertible preferred stock            | -                 | (21 )                             | -                      | -                                 |
| Incentive warrants  | 186,802           | -                                 | -                      | 186,802                           |
| Stock issued for debt extension                               | -                 | 19,458                            | -                      | 19,500                            |
| Stock issued with debt  | -                 | 367,929                           | -                      | 368,574                           |
| Common stock for asset purchase                               | -                 | 598,500                           | -                      | 600,000                           |
| Warrants issued with debt                                     | 714,815           | -                                 | -                      | 714,815                           |
| Net loss  | -                 | -                                 | (10,715,561)           | (10,715,561)                      |
| BALANCE, December 31, 2017                                    | \$9,878,513       | \$30,833,549                      | \$(55,349,299)         | \$(14,622,796)                    |
| Stock-based compensation                                      | -                 | 592,477                           | -                      | 592,477                           |
| Issuance of common stock for services                         | -                 | 237,440                           | -                      | 238,120                           |
| Series AA preferred stock dividend                            | -                 | -                                 | (678,921 )             | (678,921 )                        |
| Conversion of debt and interest for preferred stock           | 6,826,710         | 5,861,874                         | -                      | 12,688,635                        |
| Issuance of common stock for dividends paid in kind           | -                 | 257,457                           | -                      | 258,221                           |
| Beneficial conversion option on convertible preferred stock   | -                 | 12,881,899                        | -                      | 12,881,899                        |
| Deemed dividend on convertible preferred stock                | -                 | (12,881,899)                      | -                      | (12,881,899)                      |
| Beneficial conversion option on warrant/debenture             | 213,012           | -                                 | -                      | 213,012                           |
| Deemed dividend – down-round feature                          | (213,012 )        | -                                 | -                      | (213,012 )                        |
| Conversion of Series AA convertible preferred stock           | -                 | (440 )                            | -                      | -                                 |
| Warrant modification  | 49,884            | -                                 | -                      | 49,884                            |
| Series AA Preferred Stock offering                            | 1,730,587         | 1,457,400                         | -                      | 3,188,000                         |
| Incentive shares and warrants                                 | 773,832           | 525,507                           | -                      | 1,299,340                         |
| Offering cost for issuance of preferred stock                 | 385,698           | (749,034 )                        | -                      | (363,336 )                        |
| Contingent beneficial conversion option from convertible note | -                 | 253,000                           | -                      | 253,000                           |
| Stock issued for debt extension                               | -                 | 220,306                           | -                      | 220,952                           |
| Stock issued with debt  | -                 | 287,765                           | -                      | 288,648                           |
| Warrants issued with debt                                     | 162,023           | -                                 | -                      | 162,023                           |
| Net loss  | -                 | -                                 | (9,699,318 )           | (9,699,318 )                      |
| BALANCE, December 31, 2018                                    | \$19,807,247      | \$39,777,301                      | \$(65,727,538)         | \$(6,125,071 )                    |

**PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF CASH FLOWS****FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017**

|   | For the Year Ended<br>December 31, |                |
|---|------------------------------------|----------------|
|   | 2018                               | 2017           |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                |                                    |                |
| Net loss  | \$(9,699,318 )                     | \$(10,715,561) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                    |                |
| Common stock issued for debt extension                                      | 50,108                             | 19,500         |
| Depreciation and amortization   | 94,271                             | 8,576          |
| Provision for bad debts   | -                                  | -              |
| Inventory reserve   | 93,947                             | 159,600        |
| Accretion of interest and amortization of debt discount                     | 1,517,394                          | 4,128,637      |
| Issuance of Incentive shares and common stock warrants                      | 1,299,340                          | 186,802        |
| Gain on settlement of liabilities   | (260,454 )                         | (185,452 )     |
| Stock-based compensation expense  | 592,477                            | 406,427        |
| Warrants issued for service   | -                                  | 15,558         |
| Impairment loss on investment   | 3,182                              | 6,069          |
| Shares issued for services  | -                                  | 31,000         |
| Changes in operating assets and liabilities:                                |                                    |                |
| Accounts receivable   | (267,982 )                         | 74,472         |
| Inventories   | (56,107 )                          | (111,978 )     |
| Prepaid expenses and other assets   | 289,544                            | 59,312         |
| Accounts payable  | 69,593                             | 182,014        |
| Accrued employee compensation   | 88,232                             | 119,104        |
| Accrued interest  | 47,690                             | 898,212        |
| Deferred revenue and other accrued expenses                                 | 442,179                            | 813,159        |
| Net cash used in operating activities                                       | (5,695,904 )                       | (3,904,549 )   |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                |                                    |                |
| Purchases of intangible assets  | -                                  | (150,000 )     |
| Purchases of property plant and equipment                                   | -                                  | (21,825 )      |
| Net cash used in investing activities                                       | -                                  | (171,825 )     |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                |                                    |                |
| Net proceeds from related party debt  | 168,600                            | -              |
| Payment of related party debt   | (103,600 )                         | -              |
| Net proceeds from revolving note payable                                    | 460,000                            | 2,070,000      |
| Net proceeds from convertible debt  | 5,717,798                          | 1,755,850      |
| Payments on convertible debt  | (3,522,000 )                       | (925,541 )     |
| Net proceeds from non-convertible debt                                      | 2,371,992                          | 2,905,752      |
| Payments on non-convertible debt  | (2,199,465 )                       | (1,894,231 )   |

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|   |             |           |
|---|-------------|-----------|
| Net proceeds from warrant exercises   | -           | 140,214   |
| Payments on prepayment penalty  | -           | (33,000 ) |
| Net proceeds from the issuance of Series AA Convertible Preferred Stock                               | 2,824,664   | -         |
| Net cash provided by financing activities   | 5,717,989   | 4,019,044 |
| <br>  |             |           |
| NET (DECREASE) INCREASE IN CASH   | 22,085      | (57,330 ) |
| CASH AT BEGINNING OF YEAR   | 81,033      | 138,363   |
| CASH AT END OF YEAR   | \$103,118   | \$81,033  |
| <br>  |             |           |
| SUPPLEMENTAL INFORMATION  |             |           |
| Interest paid in cash   | \$1,085,743 | \$533,532 |
| NON CASH TRANSACTIONS:  |             |           |
| Convertible debt exchanged for preferred stock  | 12,688,385  | -         |
| Discount due to beneficial conversion feature   | 253,000     | -         |
| Discount due to warrants issued with debt   | 162,023     | 714,815   |
| Common stock issued with debt   | 288,648     | 368,574   |
| Common stock issued to purchase intangible assets   | -           | 600 000   |
| Common stock issued in lieu of cash for interest  | 258,211     | 264,602   |
| Common stock issued for prepaid services  | 238,120     | 15,992    |
| Conversion of preferred stock and accrued dividends into common stock                                 | 440         | 61        |
| Discount from one-time interest   | 209,811     | 225,000   |
| Preferred stock dividend  | 678,921     | -         |
| Reclassification of derivative liabilities to equity and cumulative effect of adoption of ASU 2017-11 | -           | 1,712,699 |
| Deemed dividend-triggered down round feature  | 213,012     | -         |
| Deemed dividend-beneficial conversion feature   | 12,881,899  | -         |

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”) is 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, called pressure cycling technology, or PCT, uses alternating cycles of hydrostatic pressure between ambient and ultra-high levels (35,000 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.

Our pressure cycling technology uses internally developed 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 DNA, RNA, proteins, lipids, and small molecules. Our laboratory instrument, the Barocycler®®, and our internally developed consumables product line, including PULSE® (Pressure Used to Lyse Samples for Extraction) Tubes, other processing tubes, and application specific kits (which include consumable products and reagents) together make up our PCT Sample Preparation System, or PCT SPS.

In 2015, together with an investment bank, we formed a subsidiary called Pressure BioSciences Europe (“PBI Europe”) in Poland. We have 49% ownership interest with the investment bank retaining 51%. As of now, PBI Europe does not have any operating activities and we cannot reasonably predict when operations will commence. Therefore, we do not have control of the subsidiary and did not consolidate in our financial statements. PBI Europe did not have any operations in 2018 or in 2017.

#### ***Reverse Stock Split***

On June 5, 2017, the Company effected a 1-for-30 reverse stock split of its issued and outstanding shares of common stock. All common shares, stock options, and per share information presented in the financial statements have been adjusted to reflect the reverse stock split on a retroactive basis for all periods presented. The ratio by which shares of

preferred stock are convertible into shares of common stock were adjusted to reflect the effects of the reverse stock split.

## **(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, 2018, 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 8 and 9, completed debt financing subsequent to December 31, 2018. 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, 2018 we received approximately \$8.7 million net proceeds, in additional convertible and non-convertible debt. We also received \$2.8 million 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 a partner to advance PCT technology.

Earn payments pursuant to potential collaboration and license agreements for BaroFold patents.

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.

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ("ASU 2015-14"). Under the new standard, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. This standard was adopted by the Company at January 1, 2017.

Generally, under the new accounting standard, management's plans must be approved before the date the financial statements are issued to be considered probable of being effectively implemented. Under the new accounting standard, 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 \$103,118 in cash and cash equivalents at December 31, 2018 would allow it to fund its planned operations into the first quarter of 2019. This estimate assumes no additional funding from new partnership agreements, no additional equity financings, no debt financings, and no accelerated repayment of its term loans. Accordingly, the timing and nature of activities contemplated for the remainder of 2019 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. 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, 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.

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.

The transaction is an exchange of a product or property held for sale in the ordinary course of business for a  
b) 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 its non-cash transactions at recorded cost or carrying value of the assets or services sold.

In accordance with FASB ASC 840, *Leases*, we account for our lease agreements under the operating method. 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.

| In thousands of US dollars (\$)              | Twelve<br>Months Ended<br>December 31, |       |
|--|--|-------|
|  | 2018                                   | 2017  |
| Primary geographical markets                 |  |       |
| North America                                | 1,751                                  | 1,461 |
| Europe                                       | 287                                    | 287   |
| Asia   | 420                                    | 493   |
|  | 2,458                                  | 2,241 |
|  |  |       |
|  | Twelve<br>Months Ended<br>December 31, |       |
| Major products/services lines                | 2018                                   | 2017  |
| Hardware                                     | 1,454                                  | 1,471 |
| Grants                                       | 257                                    | 174   |
| Consumables                                  | 235                                    | 260   |
| Contract research services                   | 202                                    | -     |
| Sample preparation accessories               | 147                                    | 153   |
| Technical support/extended service contracts | 84                                     | 104   |
| Shipping and handling                        | 47                                     | 48    |
| Other  | 32                                     | 31    |
|  | 2,458                                  | 2,241 |
|  |  |       |
|  | Twelve<br>Months Ended<br>December 31, |       |

|   |       |       |
|---|-------|-------|
| Timing of revenue recognition               | 2018  | 2017  |
| Products transferred at a point in time     | 1,999 | 1,980 |
| Products and services transferred over time | 459   | 261   |
|   | 2,458 | 2,241 |

### Contract balances

|  |                      |                      |
|--|----------------------|----------------------|
| In thousands of US dollars (\$)                          | December<br>31, 2018 | December<br>31, 2017 |
| Receivables, which are included in 'Accounts Receivable' | 475                  | 374                  |
| Contract liabilities (deferred revenue)                  | 58                   | 206                  |

### 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.

|                                 |      |      |      |       |
|---------------------------------|------|------|------|-------|
| In thousands of US dollars (\$) | 2019 | 2020 | 2021 | Total |
| Extended warranty service       | 20   | 20   | 18   | 58    |

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.

***iv. 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. Restricted cash is included in cash equivalents.

***v. 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.

***vi. 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 current year allowance was increased by a \$93,947 inventory allowance for the older generation of LCM instruments held in stock, the NEP3229. 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:

|                   | 2018      | 2017      |
|-------------------|-----------|-----------|
| Raw materials     | \$311,158 | \$288,295 |
| Finished goods    | 727,867   | 748,967   |
| Inventory reserve | (273,547) | (179,600) |
| Total             | \$765,478 | \$857,662 |

***vii. 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.

*viii. 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, 2018, and 2017, the outstanding balance for intangible assets was \$663,462 and \$750,000, respectively.

***ix. 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, 2018, the Company had not experienced impairment losses on its long-lived assets.

***x. 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, 2018, we determined that no allowance against accounts receivable was necessary and wrote off the prior year allowance of \$28,169 as unrecoverable.

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:

|                    | 2018 | 2017 |
|--------------------|------|------|
| Top Five Customers | 34 % | 37 % |
| Federal Agencies   | 14 % | 14 % |

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:

|  | 2018 | 2017 |
|--|------|------|
|--|------|------|

|                    |      |      |
|--------------------|------|------|
| Top Five Customers | 54 % | 85 % |
| Federal Agencies   | 5 %  | 1 %  |

### *Investment in Equity Securities*

As of December 31, 2018, we held 100,250 shares of common stock of Everest, a Polish publicly traded company listed on the Warsaw Stock Exchange. We exchanged 33,334 shares of our common stock for the 100,250 shares from Everest. We account for this investment in accordance with ASC 320 “*Investments — Debt and Equity Securities*”. On December 31, 2018, our consolidated balance sheet reflected the fair value of our investment in Everest to be \$16,643, based on the closing price of Everest shares of \$0.1660 per share on that day. The carrying value of our investment in Everest common stock held will change from period to period based on the closing price of the common stock of Everest as of the balance sheet date. The change in market value since the receipt of stock amounting to \$382,933 was determined to be other than temporary and was recorded by us as an impairment loss starting in 2016. We recorded \$3,182 as realized losses in 2018 for the changes in market value.

### *xi. 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:

|   | 2018           | 2017           |
|---|----------------|----------------|
| Numerator:  |                |                |
| Net loss attributable to common shareholders      | \$(23,473,152) | \$(10,715,561) |
| Denominator for basic and diluted loss per share: |                |                |
| Weighted average common shares outstanding        | 1,530,989      | 1,114,225      |
| Loss per common share - basic and diluted         | \$(15.33 )     | \$(9.62 )      |



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:

|                                 | 2018       | 2017      |
|---------------------------------|------------|-----------|
| Stock options                   | 366,734    | 247,692   |
| Convertible debt                | 413,998    | 947,203   |
| Common stock warrants           | 7,764,821  | 899,542   |
| 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 | 6,499,000  | -         |
|                                 | 15,544,345 | 2,594,229 |

### *xii. 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, 2018 and 2017, the Company did not have any uncertain tax positions. No interest and penalties related to uncertain tax positions were accrued at December 31, 2018 and 2017.

### *xiii. 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 awards are accounted for under ASC 718 where the awards are valued at grant date. Awards given to nonemployees are accounted for under ASC 505 where the awards are valued at earlier of commitment date or completion of services.

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, 2018:

| Assumptions             | Non-Employee<br>Board Members | CEO, other<br>Officers and<br>Employees |
|-------------------------|-------------------------------|---|
| Expected life           | 6.0(yrs)                      | 6.0(yrs)                                |
| Expected volatility     | 150.06%-155.38 %              | 151.53%-155.21 %                        |
| Risk-free interest rate | 2.62%-3.03 %                  | 2.62%-2.77 %                            |
| Forfeiture rate         | 5.00 %                        | 5.00 %                                  |
| Expected dividend yield | 0.0 %                         | 0.0 %                                   |

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We recognized stock-based compensation expense of \$592,477 and \$406,427 for the years ended December 31, 2018 and 2017, 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:

|  | 2018      | 2017      |
|--|-----------|-----------|
| Research and development               | \$120,417 | \$92,055  |
| Selling and marketing                  | 49,023    | 54,404    |
| General and administrative             | 423,037   | 259,968   |
| Total stock-based compensation expense | \$592,477 | \$406,427 |

During the years ended December 31, 2018 and 2017, the total fair value of stock options awarded was \$403,053 and \$487,964, respectively.

As of December 31, 2018, total unrecognized compensation cost related to the unvested stock-based awards was \$801,885, which is expected to be recognized over weighted average period of 1.15 years.

*xiv. Advertising*

Advertising costs are expensed as incurred. We incurred \$23,227 in 2018 and \$5,899 in 2017 for advertising.

*xv. 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. Short-term and long-term liabilities are primarily related to liabilities transferred under contractual arrangements with carrying values that approximate fair value.

*xvi. 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 and that its financial liabilities are currently all classified within Level 3 in the fair value hierarchy.

The Company changed its method of accounting for the Debentures and Warrants through the early adoption of ASU 2017-11 during the year ended December 31, 2017 on a modified retrospective basis. Accordingly, the Company reclassified the warrant derivative and conversion option derivative liabilities to additional paid in capital on its January 1, 2017 consolidated balance sheets totaling approximately \$2.6 million, reduced debt discount by

approximately \$0.9 million and recorded the cumulative effect of the adoption to the beginning balance of accumulated deficit of approximately \$2.5 million.

*Adoption of ASU 2017-11*

The Company changed its method of accounting for the Debentures, Debenture Warrants and Series D Warrants through the early adoption of ASU 2017-11 during the year ended December 31, 2017 on a modified retrospective basis. Accordingly, the Company reclassified the warrant derivative and conversion option derivative liabilities to additional paid in capital on its January 1, 2017 consolidated balance sheets totaling approximately \$2.6 million, reduced debt discount by approximately \$0.9 million and recorded the cumulative effect of the adoption to the beginning balance of accumulated deficit of approximately \$2.4 million. This resulted to an increase in stock warrants by \$2.6 million and additional paid-in capital by \$1.4 million. The following table provides a reconciliation of the warrant derivative liability, convertible debt, conversion option derivative liability, stock warrant, additional paid-in capital and accumulated deficit on the consolidated balance sheet as of December 31, 2016:

|   | Convertible debt, current portion | Convertible debt, long term portion | Warrant Derivative Liability | Conversion Option Liability | Warrants to acquire common stock | Additional Paid-in Capital | Accumulated deficit |
|---|-----------------------------------|-------------------------------------|------------------------------|-----------------------------|----------------------------------|----------------------------|---------------------|
| Balance, January 1, 2017 (Prior to adoption of ASU 2017-11)           | \$4,005,702                       | \$ 529,742                          | \$ 1,685,108                 | \$ 951,059                  | \$ 6,325,102                     | \$ 27,544,265              | \$(42,264,190)      |
| Reclassified derivative liabilities and cumulative effect of adoption | 769,316                           | 154,152                             | \$(1,685,108)                | (951,059 )                  | 2,636,236                        | 1,446,011                  | (2,369,548 )        |
| Balance, January 1, 2017 (After adoption of ASU 2017-11)              | \$4,775,018                       | \$ 683,894                          | \$-                          | \$-                         | \$ 8,961,338                     | \$ 28,990,276              | \$(44,633,738)      |

The following tables set forth the Company's financial assets and financial liabilities that were accounted for at fair value on a recurring basis as of December 31, 2018 and December 31, 2017. The development of the unobservable inputs for Level 3 fair value measurements and fair value calculations are the responsibility of the Company's management.

|                        |                      | Fair value measurements at<br>December 31, 2018 using:   |   |  |
|------------------------|----------------------|--|---|--|
|                        | December<br>31, 2018 | Quoted<br>prices in<br>active<br>markets<br>(Level<br>1) | Significant<br>other<br>observable<br>inputs<br>(Level 2) | Significant<br>unobservable<br>inputs<br>(Level 3) |
| Equity Securities      | 16,643               | 16,643   | -   | -  |
| Total Financial Assets | \$ 16,643            | \$ 16,643  | \$ -  | \$ -   |

|                        |                      | Fair value measurements at<br>December 31, 2017 using:   |   |  |
|------------------------|----------------------|--|---|--|
|                        | December<br>31, 2017 | Quoted<br>prices in<br>active<br>markets<br>(Level<br>1) | Significant<br>other<br>observable<br>inputs<br>(Level 2) | Significant<br>unobservable<br>inputs<br>(Level 3) |
| Equity Securities      | 19,825               | 19,825   | -   | -  |
| Total Financial Assets | \$ 19,825            | \$ 19,825  | \$ -  | \$ -   |

#### *Adoption of ASU No. 2016-02*

The Company has early adopted ASU No. 2016-02, Leases (Topic 842). The amendment requires companies to recognize leased assets and liabilities on the balance sheet and to disclose key information regarding lease arrangements. This guidance is effective for annual periods, and interim periods within those annual periods, after December 15, 2018. Early application of this amendment is permitted for all entities. While we do not anticipate that going forward, leases will be material to our balance sheet, we chose to early-adopt as of December 31, 2017. We have one lease that is required to be included on our balance sheet under the new standard. This lease is an operating lease and, therefore, will have no income statement impact resulting from the adoption of this standard.

#### *xvii. Reclassifications*

Certain prior year amounts have been reclassified to conform to our current year presentation.

*xviii. Recently Issued Accounting Standards*

In November 2016, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) No. 2016-18 (ASU 2016-18). ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017. As early adoption of this amendment is permitted, the Company has adopted the update retrospectively to each period presented. The adoption of this guidance did not have a material impact on the company's consolidated Financial Statements.

In March 2016, the FASB issued ASU 2016-09, which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 became effective for the Company on January 1, 2017. The adoption of this guidance did not have a material impact on the Company's consolidated Financial Statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The new standard requires the recognition of assets and liabilities arising from lease transactions on the balance sheet and the disclosure of key information about leasing arrangements. Accordingly, a lessee will recognize a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. Both the asset and liability will initially be measured at the present value of the future minimum lease payments over the lease term. Subsequent measurement, including the presentation of expenses and cash flows, will depend on the classification of the lease as either finance or an operating lease. Initial costs directly attributable to negotiating and arranging the lease will be included in the asset. Lessees will also be required to provide additional qualitative and quantitative disclosures regarding the amount, timing and uncertainty of cash flows arising from leases. The new standard is effective for fiscal years beginning after December 15, 2018, and interim periods therein. The Company chose to early adopt ASC 842 effective January 1, 2018. This new guidance did not have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, which clarifies the definition of a business to provide additional guidance with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This ASU is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company early adopted the ASU 2016-18 on January 1, 2017 starting with its purchase of BaroFold assets.

In May 2017, the FASB issued ASU 2017-09, *Compensation – Stock Compensation (Topic 718) Scope of Modification Accounting*, which clarifies that an entity should account for the effects of a modification unless the fair value, vesting terms and classification as liability or equity of the modified and original awards do not change on the modification date. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal



years. The Company adopted this ASU effective on January 1, 2018, on a prospective basis which did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

Effective January 1, 2018, the Company adopted ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities. The standard amends various aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The most significant impact to our consolidated financial statements relates to the recognition and measurement of equity investments at fair value with changes recognized in Net income. The amendment also updates certain presentation and disclosure requirements. The adoption of ASU 2016-01 did not have a material impact on the consolidated financial statements. The adoption of ASU 2016-01 will result in increased volatility in net income as changes in the fair value of equity investments and changes in observable prices of equity investments without readily determinable fair values will be recorded in net income.

Effective January 1, 2018, the Company adopted ASC Topic 606, Revenue from Contracts with Customers, using the modified retrospective method. This guidance supersedes nearly all existing revenue recognition guidance under US GAAP. The core principle of the guidance is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company updated its accounting policy for the new standard based on a detailed review of its business and contracts. Based on the new guidance, the Company continues to recognize revenue at a point in time for the majority of its contracts with customers, which is generally when products are either shipped or delivered. Therefore, the adoption of ASC 606 did not have a material impact on the consolidated financial statements.

In July 2018, the FASB issued ASU 2018-07, Compensation- Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting as an amendment and update expanding the scope of Topic 718. The amendment specifies that Topic 718 now applies to all share-based payment transactions, even non-employee awards, in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. Under the new guidance, awards to nonemployees are measured on the grant date, rather than on the earlier of the performance commitment date or the date at which the nonemployee's performance is complete. Also, the awards would be measured by estimating the fair value of the equity instruments to be issued, rather than the fair value of the goods or services received or the fair value of the equity instruments issued, whichever can be measured more reliably. In addition, entities may use the expected term to measure nonemployee awards or elect to use the contractual term as the expected term, on an award-by-award basis. The new guidance is effective for the Company in annual periods beginning after December 15, 2018, and interim periods within those annual periods, with early adoption permitted. Based on the new guidance, the Company will measure its nonemployee stock awards at grant date not when the stock awards are vested. This new guidance is not expected to have a material impact on the Company's consolidated financial statements.

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ("ASU 2015-14"). Under the new standard, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. This standard was adopted by the Company at January 1, 2017. See Note 2.

#### **(4) Property and Equipment, net**

Property and equipment as of December 31, 2018 and 2017 consisted of the following components:

|   | December 31, |           |
|---|--------------|-----------|
|   | 2018         | 2017      |
| Laboratory and manufacturing equipment              | \$240,670    | \$240,670 |
| Office equipment                                    | 173,312      | 173,312   |
| Leasehold improvements                              | 8,117        | 8,117     |
| PCT collaboration, demonstration and leased systems | 529,956      | 461,858   |
| Total property and equipment                        | 952,055      | 883,957   |
| Less accumulated depreciation                       | (882,783)    | (861,295) |
| Net book value                                      | \$69,272     | \$22,662  |

Depreciation expense for the years ended December 31, 2018 and 2017 was \$7,733 and \$8,576, respectively.

#### (5) Intangible Assets

Intangible assets as of December 31, 2018 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, 2018. We have concluded that there is no impairment of intangible assets. Intangible assets at December 31, 2018 and 2017 consisted of the following:

|                               | December 31, |           |
|-------------------------------|--------------|-----------|
|                               | 2018         | 2017      |
| BaroFold Patents              | \$750,000    | \$750,000 |
| Less accumulated amortization | (86,538)     | -         |
| Net book value                | \$663,462    | \$750,000 |

Amortization expense for each of the years ended December 31, 2018 and 2017 was \$86,538 and \$0 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 2018 and 2017 we contributed \$15,543 and \$13,587, 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, 2018 and 2017, the Company did not have any uncertain tax positions. No interest and penalties related to uncertain tax positions were accrued at December 31, 2018 and 2017. Our tax returns for fiscal years 2015, 2016 and 2017 are open to examination.

We did not record an income tax benefit or provision for the years ended December 31, 2018 and 2017.

Significant items making up the deferred tax assets and deferred tax liabilities as of December 31, 2018 and 2017 are as follows:

|  | 2018         | 2017         |
|--|--------------|--------------|
| Long term deferred taxes:                        |              |              |
| Inventories                                      | \$74,733     | \$49,067     |
| Accounts receivable allowance                    | -            | -            |
| Other accruals                                   | 75,992       | 75,992       |
| Accelerated tax depreciation                     | 6,252        | 6,945        |
| Non-cash, stock-based compensation, nonqualified | 767,885      | 606,020      |
| Impairment loss on investment                    | 104,609      | 103,748      |
| Goodwill and intangibles                         | -            | -            |
| Operating loss carry forwards and tax credits    | 16,112,934   | 12,196,765   |
| Less: valuation allowance                        | (17,142,405) | (13,038,537) |
| 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 2018 and 2017 for the full amount of our deferred

tax assets due to the uncertainty of realization. We believe 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, 2018.

On December 22, 2017, the U.S. Tax Cuts and Jobs Act (the “Tax Reform Act”) was signed into law by President Trump. The Tax Reform Act significantly revised the U.S. corporate income tax regime by, among other things, lowering the U.S. corporate tax rate from 35% to 21% effective January 1, 2018. Under ASC 740, the tax effects of changes in tax laws must be recognized in the period in which the law was enacted. ASC 740 also requires deferred tax assets and liabilities to be measured at the enacted tax rate expected to apply when temporary differences are to be realized or settled. The Company re-measured its deferred tax assets and liabilities at the 21% federal corporate tax rate. The remeasurement resulted in no change in the Company’s recorded tax provision, as the remeasurement of the company’s deferred tax assets and liabilities resulted in a reduction of approximately \$5,843,000 which was fully offset by a change in the Company’s valuation allowance.

We have net operating loss carry-forwards for federal income tax purposes of approximately \$50,997,000 as of December 31, 2018. 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 2018 through 2038. 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 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 \$44,406,000 at December 31, 2018. These net operating loss carry-forwards expire at various dates from 2030 through 2037.

We have research and development tax credit carry-forwards for federal income tax purposes of approximately \$1,138,000 as of December 31, 2018 and research and development tax credit carry-forwards for state income tax purposes of approximately \$487,000 as of December 31, 2018. The federal credit carry-forwards expire at various dates from 2019 through 2039. The state credit carry-forwards expire at various dates from 2023 through 2034.

In addition, we have federal alternative minimum tax credit carry-forwards for federal income tax purposes of approximately \$217,000 as of December 31, 2018. These credits do not expire.

Our effective income tax (benefit) provision rate was different than the statutory federal income tax (benefit) provision rate as follows for the years ended December 31:

|                                   | 2018   | 2017   |
|-----------------------------------|--------|--------|
| Federal tax provision rate        | 21 %   | 35 %   |
| Permanent differences             | (0 )%  | 0 %    |
| State tax expense                 | 0 %    | 0 %    |
| Refundable AMT and R&D tax credit | 0 %    | 0 %    |
| Net operating loss carry back     | 0 %    | 0 %    |
| Valuation allowance               | (21 )% | (35 )% |
| Effective income tax provision    | 0 %    | 0 %    |

## **(8) Commitments and Contingencies**

### *Operating Leases*

As disclosed in Note 2, the Company early adopted ASC 842 to our existing leases. The Company has elected to apply the short-term lease exception to leases of one year or less. Consequently, as a result of adoption of ASC 842, we recognized an operating liability of \$136,385 with a corresponding Right-Of-Use (“ROU”) asset of the same amount based on present value of the minimum rental payments of the lease which is included in non-current assets and long-term liabilities in the consolidated balance sheet. The discount rate used for leases accounted for under ASC 842 is the Company’s estimated borrowing rate of 25%.

## Edgar Filing: PRESSURE BIOSCIENCES INC - Form 10-K

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 28, 2018, that expires December 31, 2019, 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 to December 30, 2020. The lease requires monthly payments of \$6,912 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.

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, 2018:

|                                 |            |
|---------------------------------|------------|
| 2019                            | 82,953     |
| 2020                            | 82,953     |
| Thereafter                      | -          |
| Total minimum payments required | \$ 165,906 |

### *Government Grants*

We received a \$1.02 million NIH SBIR Phase II Grant in November 2014. Under the grant, the NIH has committed to pay the Company to develop a high-throughput, high pressure-based DNA Shearing System for Next Generation Sequencing and other genomic applications. In March 2018, we received an extension on the SBIR Phase II grant to utilize unused funds until November 30, 2018.

### *Royalty Commitments*

#### 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 on 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 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 are \$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 2018 or 2017.

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 \$40,000 in 2018 and \$50,000 in 2019.

*Severance and Change of Control Agreements*

Each of Mr. Schumacher, and Drs. Ting, Lazarev, and Young, 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 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****Conversion of Notes**

We issued 5,075.40 shares of our Series AA Convertible Preferred Stock in satisfaction of \$12,688,635 of convertible promissory notes, Revolving Note and short-term loans issued:

|  | Debt<br>converted<br>to stock |
|--|-------------------------------|
| Current liabilities                        |                               |
| Convertible Debentures, face value         | \$6,962,635                   |
| Revolving Note with interest               | 4,750,000                     |
| May 19, 2017 Promissory Note with interest | 750,000                       |
| Other Notes with interest                  | 226,000                       |
| Total debt converted during the year 2018  | \$12,688,635                  |

***Senior Secured Convertible Debentures and Warrants***

We entered into Subscription Agreements (the “Subscription Agreement”) with various individuals (each, a “Purchaser”) between July 23, 2015 and March 31, 2016, pursuant to which the Company sold Senior Secured Convertible Debentures (the “Debentures”) and warrants to purchase shares of common stock equal to 50% of the number of shares issuable pursuant to the subscription amount (the “Warrants”) for an aggregate purchase price of \$6,329,549 (the “Purchase Price”).

The Company issued a principal aggregate amount of \$6,962,504 in Debentures which includes a 10% original issue discount on the Purchase Price. The Debenture does not accrue any additional interest during the first year it is outstanding but accrues interest at a rate equal to 10% per annum for the second year it is outstanding. The Debenture has a maturity date of two years from issuance. The Debenture is convertible any time after its issuance date. The Purchaser has the right to convert the Debenture into shares of the Company’s common stock at a fixed conversion price equal to \$8.40 per share, subject to applicable adjustments. In the second year that the Debenture is outstanding, any interest accrued shall be payable quarterly in either cash or common stock, at the Company’s discretion. On September 11, 2017, we notified Debenture holders that their Debentures will be extended 180 days beyond the original maturity date as permitted in the Debenture agreement. We will continue to pay interest on the Debentures until the extended maturity date. We accounted for the Debenture extensions as debt modifications and not extinguishment of debt since the changes in fair value are not substantial in accordance with ASC 470-50. We started amortizing the remaining unamortized discount as of September 11, 2017 over the new term, which extends 180 days

beyond the original maturity date.

In connection with the Debentures issued, the Company issued warrants exercisable into a total of 376,759 shares of our common stock. The Warrants issued in this transaction are immediately exercisable at an exercise price of \$12.00 per share, subject to applicable adjustments including full ratchet anti-dilution if we issue any securities at a price lower than the exercise price then in effect. The Warrants have an expiration period of five years from the original issue date. The Warrants are subject to adjustment for stock splits, stock dividends or recapitalizations and also include anti-dilution price protection for subsequent equity sales below the exercise price.

On May 2, 2018, the Company entered into a Securities Purchase Agreement with an existing shareholder pursuant to which the Company sold an aggregate of 100 shares of Series AA Convertible Preferred Stock for an aggregate Purchase Price of \$250,000. We issued to the shareholder a new warrant to purchase 100,000 shares of common stock with an exercise price of \$3.50 per share.

The Company, pursuant to a price protection provision triggered on May 2, 2018 with the sale of Series AA units, amended the Debentures and Warrants to purchase Common Stock held by the Debenture Holders entered into between July 22, 2015 and March 31, 2016 as first disclosed in the Company's Current Report on Form 8-K filed on July 28, 2015. The fair value of \$207,899 relating to the reduction in exercise price was treated as a deemed dividend and recorded as a charge against additional paid-in capital within equity. The amended Debenture conversion price was exempt from revaluation because a beneficial conversion feature had already been recorded on the Debenture at issuance.

Subject to the terms and conditions of the Warrants, at any time commencing six months from the Final Closing, the Company has the right to call the Warrants for cancellation if the volume weighted average price of its Common Stock on the OTCQB (or other primary trading market or exchange on which the Common Stock is then traded) equals or exceeds three times the per share exercise price of the Warrants for 15 out of 20 consecutive trading days.

In connection with the Subscription Agreement and Debenture, the Company entered into Security Agreements with the Purchasers whereby the Company agreed to grant to Purchasers an unconditional and continuing, first priority security interest in all of the assets and property of the Company to secure the prompt payment, performance and discharge in full of all of Company's obligations under the Debentures, Warrants and the other Transaction Documents. On May 14 and June 11, 2018, the Company signed letter agreements with the Debenture holders as explained below that discharged all of the Company's obligations within the Debenture Agreement

*Conversion of Debentures*

On May 14, 2018, we entered into letter agreements (the “Letter Agreements”) with 22 investors (each a “Debenture Holder” and together the “Debenture Holders”) holding convertible debentures (collectively the “Debentures”) and warrants to purchase common stock (the “Debenture Warrants”) whereby the Debenture Holders agreed to convert a total of \$6,220,500 in principal and original issue discount due them under the Debentures into 2,448.20 shares of Series AA Convertible Preferred Stock with a conversion price of \$2.50 per share. The Debenture Holders were also: (a) issued amended Debenture Warrants such that the exercise price will be \$3.50 per share; and (b) issued a new warrant with an exercise price of \$3.50 per share to purchase 2,448,200 shares of common stock (the number of shares of common stock issuable upon conversion of the Series AA Convertible Preferred Stock shares received as a result of the Debenture conversions). The Debenture Holders also agreed to waive any and all defaults or events of default by the Company with respect to any failure by the Company to comply with any covenants contained in the Debentures. The fair value of \$29,865 relating to the adjustment in exercise price was treated as a loan modification and recorded as a gain toward the extinguishment of debt.

On June 11, 2018, the Company entered into additional Letter Agreements with 15 Debenture Holders whereby the Debenture Holders agreed to convert a total of \$742,135 in principal and original issue discount due them under the Debentures into 296.80 shares of Series AA Convertible Preferred Stock with a conversion price of \$2.50 per share. The Debenture Holders were also: (a) issued amended Debenture Warrants such that the exercise price will be \$3.50 per share; and (b) issued a new warrant with an exercise price of \$3.50 per share to purchase 296,800 shares of common stock (the number of shares of common stock issuable upon conversion of the Series AA Convertible Preferred Stock shares received as a result of the Debenture conversions). The Debenture Holders also agreed to waive any and all defaults or events of default by the Company with respect to any failure by the Company to comply with any covenants contained in the Debentures. The fair value of \$3,155 relating to the adjustment in exercise price was treated as a loan modification and recorded as a gain toward the extinguishment of debt.

In connection with the above Debenture conversions and cancellation of the debt term, the Company recorded the full amount of the remaining unamortized Debenture discounts of \$157,908 as interest expense by June 11, 2018. The Company recorded \$287,676 of the Debenture discounts during 2018 through the cancellation date of June 11, 2018.

On various dates for the year ended December 31, 2017, the Company issued 61,307 shares of common stock based on the 10-day VWAP prior to quarter end to holders of the Debentures in payment of the quarterly interest accrued from the Debentures first anniversary date through June 30, 2017 for an aggregate amount of \$483,054. We recognized a \$218,452 gain on extinguishment of debt by calculating the difference of the shares valued on the issuance date and the amount of accrued interest through June 30, 2017.

On various dates for the year ended December 31, 2018, the Company issued 56,007 shares of common stock based on the 10-day VWAP prior to quarter end to holders of the Debentures in payment of the quarterly interest accrued

from the Debentures first anniversary date through June 11, 2018 for an aggregate amount of \$211,047. We recognized a \$9,615 gain on extinguishment of debt for the year ended December 31, 2018 by calculating the difference of the shares valued on the issuance date and the amount of accrued interest through June 11, 2018.

*Convertible notes*

The Company, pursuant to a price protection provision triggered on May 2, 2018 with the sale of Series AA units, amended the conversion price of a March 12, 2018 loan to \$2.50 per share. The fair value of \$253,000, limited to the face value of the loan, relating to the reset in the conversion price was recorded as a debt discount and amortized as interest expense over the remaining loan term.

On various dates during the year ended December 31, 2018, the Company issued convertible notes for net proceeds of approximately \$5.7 million which contained varied terms and conditions as follows: a) maturity dates ranging from 2 to 12 months; b) interest rates that accrue per annum ranging from 4% to 15%; c) convertible to the Company's common stock at issuance at a fixed rate of \$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 \$450,671 of the shares of common stock or warrants to purchase common stock issued with the notes was recorded as a debt discount and amortized over the term of the notes. We then computed the effective conversion price of the notes, noting that no beneficial conversion feature exists. We also evaluated the convertible notes for derivative liability treatment and determined that the notes did not qualify for derivative accounting treatment as of December 31, 2018.

The specific terms of the convertible notes and outstanding balances as of December 31, 2018 are listed in the tables below.

| Inception Date              | Term      | Loan Amount | Outstanding Balance with OID | Original Issue Discount | Interest Rate | Conversion Price (Convertible at Inception Date) | Deferred Finance Fees | Discount related to fair value of conversion feature and warrants/shares |
|-----------------------------|-----------|-------------|------------------------------|-------------------------|---------------|--|-----------------------|--|
| January 3, 2018             | 12 months | 95,000      | -                            | 4,750                   | 5 %           | -  | 2,000                 | -  |
| January 16, 2018            | 12 months | 131,250     | -                            | -                       | -             | -  | 6,250                 | -  |
| January 19, 2018            | 6 months  | 150,000     | -                            | -                       | 10 %          | \$ 7.50  | 6,000                 | 12,267   |
| February 9, 2018            | 6 months  | 100,000     | -                            | -                       | 15 %          | \$ 7.50  | 23,500                | -  |
| February 15, 2018           | 6 months  | 100,000     | 100,000                      | -                       | 15 %          | \$ 7.50  | 9,000                 | 10,474   |
| March 12, 2018              | 6 months  | 85,000      | -                            | 1,150                   | 5 %           | -  | 4,250                 | 5,183  |
| March 12, 2018              | 6 months  | 253,000     | -                            | 53,000                  | 0 %           | -  | -                     | 28,722   |
| April 11, 2018 <sup>1</sup> | 6 months  | 100,000     | 100,000                      | 4,000                   | 15 %          | \$ 7.50  | 20,000                | 7,218  |
| April 23, 2018              | 6 months  | 103,000     | -                            | -                       | 12 %          | -  | 3,000                 | -  |
| April 24, 2018              | 9 months  | 77,000      | 77,000                       | -                       | 12 %          | \$ 7.50  | 2,000                 | -  |
| April 25, 2018              | 12 months | 105,000     | 105,000                      | -                       | 4 %           | \$ 7.50  | 5,000                 | 4,590  |
| April 25, 2018              | 12 months | 105,000     | 105,000                      | -                       | 4 %           | \$ 7.50  | 5,000                 | 4,590  |
| April 25, 2018              | 12 months | 130,000     | -                            | -                       | 6 %           | \$ 7.50  | 6,500                 | -  |
| April 26, 2018              | 12 months | 65,000      | -                            | 6,500                   | 5 %           | -  | 2,000                 | -  |
| May 9, 2018                 | 12 months | 250,000     | -                            | -                       | 10 %          | \$ 7.50  | 12,500                | 26,466   |
| May 11, 2018 <sup>1</sup>   | 6 months  | 161,250     | 161,250                      | 11,250                  | 15 %          | \$ 7.50  | 10,000                | -  |
| May 14, 2018                | 9 months  | 50,000      | -                            | 2,500                   | 15 %          | \$ 7.50  | 2,500                 | 3,704  |
| May 17, 2018                | 12 months | 380,000     | 380,000                      | 15,200                  | 8 %           | \$ 7.50  | 15,200                | 43,607   |
| May 23, 2018                | 9 months  | 103,000     | -                            | -                       | 12 %          | -  | 3,000                 | -  |
| May 24, 2018                | 9 months  | 52,500      | -                            | 2,500                   | 4 %           | -  | -                     | 2,075  |
| May 25, 2018                | 12 months | 78,750      | -                            | -                       | 4 %           | \$ 7.50  | 3,750                 | 3,112  |
| May 30, 2018                | 2 months  | 150,000     | 150,000                      | -                       | 8 %           | \$ 7.50  | -                     | 6,870  |
| June 4, 2018                | 12 months | 75,000      | 75,000                       | 7,500                   | 5 %           | -  | 2,000                 | 3,869  |
| June 8, 2018 <sup>1</sup>   | 6 months  | 50,000      | 50,000                       | 2,500                   | 15 %          | \$ 7.50  | 2,500                 | 3,271  |
| June 12, 2018               | 6 months  | 100,000     | 100,000                      | -                       | 5 %           | \$ 7.50  | 5,000                 | -  |
| June 14, 2018               | 9 months  | 280,000     | 210,000                      | 25,000                  | 10 %          | -  | 5,000                 | 17,573   |

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|                            |           |             |             |           |    |   |         |           |           |
|----------------------------|-----------|-------------|-------------|-----------|----|---|---------|-----------|-----------|
| June 16, 2018              | 9 months  | 130,000     | 101,500     | -         | 5  | % | -       | -         | -         |
| June 16, 2018 <sup>1</sup> | 6 months  | 110,000     | 101,500     | -         | 5  | % | -       | -         | -         |
| June 26, 2018 <sup>1</sup> | 3 months  | 150,000     | 75,000      | -         | 15 | % | \$ 7.50 | -         | 20,242    |
| June 28, 2018 <sup>1</sup> | 6 months  | 50,000      | 50,000      | -         | 15 | % | \$ 7.50 | -         | 10,518    |
| July 2, 2018               | 12 months | 125,000     | -           | -         | 4  | % | -       | 6,250     | 5,588     |
| July 10, 2018              | 12 months | 95,000      | 95,000      | 6,750     | 5  | % | -       | -         | -         |
| July 13, 2018              | 9 months  | 103,000     | 103,000     | -         | 12 | % | -       | 3,000     | -         |
| July 17, 2018 <sup>1</sup> | 3 months  | 100,000     | 100,000     | 15,000    | 15 | % | \$ 7.50 | -         | 16,944    |
| July 19, 2018              | 12 months | 184,685     | 184,685     | 34,685    | 10 | % | \$ 7.50 | -         | -         |
| July 30, 2018              | 12 months | 80,000      | 80,000      | -         | 6  | % | \$ 7.50 | 4,000     | -         |
| July 31, 2018              | 3 months  | 150,000     | -           | -         | 12 | % | \$ 7.50 | -         | 6,578     |
| August 8, 2018             | 6 months  | 100,000     | -           | -         | 15 | % | \$ 7.50 | -         | -         |
| August 15, 2018            | 4 months  | 100,000     | -           | -         | 15 | % | \$ 7.50 | -         | -         |
| August 28, 2018            | 12 months | 131,250     | 131,250     | -         | 4  | % | -       | 6,250     | 4,443     |
| September 7, 2018          | 6 months  | 85,000      | 85,000      | -         | 5  | % | -       | -         | 4,364     |
| October 1, 2018            | 6 months  | 118,800     | 118,800     | 8,800     | 25 | % | \$ 7.50 | 3,000     |           |
| October 19, 2018           | 6 months  | 100,000     | 100,000     | -         | 5  | % | \$ 7.50 |           |           |
| October 23, 2018           | 6 months  | 103,000     | 103,000     |           | 12 | % | -       | 3,000     |           |
| October 29, 2018           | 6 months  | 77,000      | 77,000      |           | 12 | % | \$ 7.50 | 2,000     |           |
| November 5, 2018           | 6 months  | 105,000     | 105,000     |           | 4  | % | -       | 5,000     | 3,872     |
| November 5, 2018           | 6 months  | 130,000     | 130,000     |           | 6  | % | \$ 7.50 | 6,500     |           |
| November 7, 2018           | 6 months  | 205,000     | 205,000     |           | 4  | % | \$ 7.50 | 5,000     | 17,906    |
| November 13, 2018          | 6 months  | 75,000      | 75,000      | 7,500     | 5  | % | -       | 2,000     | 4,656     |
| November 13, 2018          | 6 months  | 200,000     | 200,000     |           | 15 | % | \$ 7.50 |           | 30,026    |
| November 21, 2018          | 9 months  | 103,000     | 103,000     |           | 12 | % | -       | 3,000     |           |
| November 27, 2018          | 12 months | 70,000      | 70,000      |           | 4  | % | -       | 2,500     | 1,922     |
| December 26, 2018          | 2 months  | 150,000     | 150,000     | 3,750     | 5  | % | \$ 7.50 | 3,750     |           |
|                            |           | \$6,460,485 | \$4,156,985 | \$212,335 |    |   |         | \$211,200 | \$310,650 |

1.) The notes were extended for an additional term.

For the year ended December 31, 2018, the Company recognized amortization expense related to the debt discounts indicated above of \$1,517,394. The unamortized debt discounts as of December 31, 2018 related to the convertible



debentures and other convertible notes amounted to \$156,180.

*Revolving Note Payable and May 19, 2017 Promissory Note*

On October 28, 2016, an accredited investor (the “Investor”) purchased from us a promissory note in the aggregate principal amount of up to \$2,000,000 (the “Revolving Note”) due and payable on the earlier of October 28, 2017 (the “Maturity Date”) or on the seventh business day after the closing of a Qualified Offering (as defined in the Revolving Note). Although the Revolving Note is dated October 26, 2016, the transaction did not close until October 28, 2016, when we received its initial \$250,000 advance pursuant to the Revolving Note. As a result, on the same day and pursuant to the Revolving Note, we issued to the Investor a Common Stock Purchase Warrant to purchase 20,834 shares of our common stock at an exercise price per share equal to \$12.00 per share. The Investor is obligated to provide us with advances of \$250,000 under the Revolving Note, but the Investor shall not be required to advance more than \$250,000 in any individual fifteen (15) day period and no more than \$500,000 in the thirty (30) day period immediately following the date of the initial advance. We received \$3,500,000 pursuant to the Revolving Note as amended of which \$2,070,000 net proceeds was received in 2017 and we issued to the Investor warrants to purchase 291,667 shares of our Common Stock at an exercise price per share equal to \$12.00 per share. The terms of the Warrants are identical except for the exercise date, issue date, and termination date which are based on the advance date.

The Revolving Note was amended on May 2, 2017 to increase the aggregate principal amount to \$3,000,000, to issue 16,667 shares of our Common Stock to the Investor, to decrease the exercise price per share of the warrants to the lower of (i) \$12.00 or (ii) the per share purchase price of the shares of our Common Stock sold in the Qualified Offering, and to change the references in the Revolving Note from “the six (6) month anniversary of October 28, 2016” to “July 25, 2017.” The fair value of the 16,667 shares issued of \$149,018 was accounted for as a note discount and are amortized to interest expense over the life of the loan. We evaluated the accounting impact of the Revolving Note amendment and deemed that the amendment did not have a material impact on our consolidated financial statements.

The Revolving Note was amended on August 18, 2017 to increase the aggregate principal amount to \$3,500,000 with all other terms unchanged. The Revolving Note, previously amended, was further amended on January 30, 2018 to increase the aggregate principal amount to \$4,000,000 with all other terms unchanged.

In the event that a Qualified Offering had occurred after July 25, 2017, but prior to the Maturity Date, within seven (7) Business Days of the closing of the Qualified Offering, the Company was to pay a cash fee equal to five percent (5%) of the total outstanding amount owed by the Company to the Holder as of the closing date of the Qualified Offering or, at the option of the Company, issue to the Holder a number of restricted shares of the Company’s common stock equal to (x) five percent (5%) of the total outstanding amount owed by the Company to the Holder as of the closing date of the Qualified Offering divided by (y) the purchase price provided by the documents governing the Qualified Offering. A Qualified Offering means the completion of a public offering of the Company’s securities pursuant to which the Company receives aggregate gross proceeds of at least Seven Million United States Dollars (US\$7,000,000) in consideration of the purchase of its securities and resulting in, pursuant to the effectiveness of the registration statement for such offering, the Company’s common stock being traded on the NASDAQ Capital Market, NASDAQ Global Select Market or the New York Stock Exchange. A Qualified Offering did not occur on or prior to the Maturity

Date.

Interest on the principal balance of the Revolving Note shall be paid in full on the Maturity Date, unless otherwise paid prior to the Maturity Date. Interest shall be assessed as follows: (i) a one-time interest of 10% on all principal amounts advanced prior to April 28, 2017; (ii) the foregoing and 4% on any amount remaining outstanding if the principal amount is repaid between April 28, 2017 and July 28, 2017; or (iii) both of the foregoing and 4% on any amount remaining outstanding if the principal amount is repaid between July 28, 2017 and October 28, 2017.

Broker fees amounting to \$336,500, the one-time interest of \$400,000 and the relative fair value of the 333,334 warrants issued to the Investor amounting to \$1,266,691 were recorded as debt discounts and amortized over the term of the revolving note. The unamortized debt discounts related to the Revolving Note were fully amortized as of December 31, 2017. The finance costs from advances after December 31, 2017 were charged to interest expense directly because the maturity date had passed.

On May 19, 2017, we received a 45-day non-convertible loan of \$630,000 from the Investor. The loan provided guaranteed interest of \$63,000 and had an origination fee of \$32,000. We paid a broker \$31,500 in connection with this loan.

#### **Conversion of October 26, 2016 Revolving Note and May 19, 2017 Promissory Note**

On June 11, 2018, the Company entered into a Letter Agreement with the Investor to convert a total of \$5,500,000 in principal and interest due to the Investor pursuant to the Revolving Note and the May 19, 2017 promissory note into 2,200 shares of Series AA Convertible Preferred Stock with a conversion price of \$2.50 per share. The Company also amended the Line of Credit Warrants held by the Investor. The Company lowered the Line of Credit Warrants' exercise price from \$12.00 per share to \$3.50 per share. The fair value of \$82,904 relating to the reduction in exercise price was treated as a loan modification and recorded as a charge against the extinguishment of debt.

The Company also issued a new warrant to the Investor with an exercise price of \$3.50 per share to purchase 2,200,000 shares of common stock (the number of shares of common stock issuable upon conversion of the Series AA Convertible Preferred Stock shares received as a result of the conversion of a total of \$5,500,000). In connection with the Letter Agreement, the Investor also waived \$520,680 of interest and fees owed as of September 30, 2018. We recognized \$520,680 as a gain on extinguishment of debt.

**Convertible Loan Modifications and Extinguishments**

We refinanced certain convertible loans during the year ended December 31, 2018 at substantially the same terms for extensions of 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 quarter 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 eleven loans. We recorded losses on debt extinguishment of \$237,888 on these eleven loans by calculating the difference of the fair value of the new debt and the carrying value of the old debt. The loss was primarily from the fair value of common stock issued in connection with these refinancings. The fees paid to the lenders which formed part of the \$217,488 loss on debt extinguishment included the aggregate fair value of \$150,438 for the shares issued with the new debt, the write-down of \$5,883 for unamortized discounts remaining on the original debt and cash fees of \$61,167.

The following table provides a summary of the changes in convertible debt and revolving note payable, net of unamortized discounts, during 2018:

|   | 2018         |
|---|--------------|
| Balance at January 1,   | \$11,787,776 |
| Issuance of convertible debt, face value  | 6,625,800    |
| Deferred financing cost   | (448,002 )   |
| Debt discount related to one-time interest charge   | (187,311 )   |
| Contingent beneficial conversion feature on convertible note                                      | (253,000 )   |
| Debt discount from warrants issued with debt  | (162,023 )   |
| Debt discount from shares issued with the notes   | (288,648 )   |
| Conversion of debt into equity  | (10,962,634) |
| Payments  | (3,522,000 ) |
| Accretion of interest and amortization of debt discount to interest expense through September 30, | 1,410,847    |
| Balance at December 31,   | 4,000,805    |
| Less: current portion   | 4,000,805    |
| Convertible debt, long-term portion   | \$-          |

#### *Other Notes*

On March 21, 2017, we received an eight-month, non-convertible loan of \$170,000 from an accredited investor. The loan earns an annual interest rate of 10% and includes a 10% original issue discount. We also agreed to issue the investor 5,667 shares of restricted common stock. We recorded the fair value of the shares amounting to \$35,079 as a debt discount that will be amortized to interest expense during the term of the loan. The loan still remains outstanding as of December 31, 2018 with a balance of \$170,000. The lender extended the term to December 31, 2017 and further to March 31, 2018 in exchange for a total of 9,500 shares of common stock with a fair value of \$28,490 recorded as interest expense. The lender further extended the term to April 30, 2018 then to September 30, 2018 in exchange for an aggregate of 7,200 shares of company stock. We fully amortized \$52,079 of the original debt discount in the year ended December 31, 2017. We recorded a loss of \$20,400 on extinguishment of debt relating to the fair value of common stock issued for the September 30 extension. The note was extended from September 30, 2018 to December 31, 2018 and the lender will receive 3,600 shares of Company common stock. The note was subsequently extended to June 30, 2019 and the lender will receive an additional 3,500 shares of Company common stock for each quarter the loan is outstanding.

On August 1, 2017, we signed a non-convertible installment loan with a lender. Under the agreement we received a loan of \$75,000 with a weekly repayment of \$3,500 until payment in full. The loan includes \$18,750 representing an original issue discount, interest and fees resulting in a total payable of \$93,750. The loan was paid off entirely as of December 31, 2018.

On September 12, 2017, we received a 9-month non-convertible loan of \$225,000 from a privately-held investment firm. The loan earns an annual interest rate of 10%. The Company paid total fees of \$25,000 including original issue discount and other costs related to this loan. We agreed to issue 3,333 shares at closing. We recorded the fair value of the shares as a debt discount that will be amortized to interest expense during the term of the loan. We amortized the entire debt discount of \$38,000 as of December 31, 2018. In the event of default and at the option of the holder, the loan is convertible into common stock at a 35% discount to the average of the two lowest daily volume weighted average closing stock price for the 20 trading days prior to conversion. The loan was paid off entirely as of December 31, 2018.

In March 2018, we received non-convertible loans totaling \$150,000 from private investors. The loans include one-year term and 10% guaranteed interest. We converted these loans into Series AA Units. See below.

In April 2018, we received a non-convertible loan for \$10,000 from a private investor. The loan includes a one-year term and 10% guaranteed interest. We converted this loan into Series AA Units. See below.

On July 16, 2018 we signed a Merchant Agreement with a lender. Under the agreement we received \$180,000, of which \$103,450 was used to pay off the outstanding balance on a previous loan dated April 11, 2018 from this lender, in exchange for rights to all customer receipts until the lender is paid \$246,600, which is collected at the rate of \$1,790.00 per business day. The \$66,600 imputed interest will be recorded as interest expense when paid each day. Fees of \$3,600 were deducted from the initial advance. The payments were secured by second position rights to all customer receipts until the loan has been paid in full. We accounted for the Merchant Agreement as a secured loan under ASC 860 because while we provided rights to current and future receipts, we still had control over the receipts.

On August 8, 2018, we received a non-convertible loan of \$50,000 from a private investor. The loan does not charge interest and was repaid entirely on October 3, 2018.

In September 2018, we received a non-convertible loan of \$67,000 from a private investor. The loan does not charge interest and was repaid entirely in October 2018.

On September 14, 2018, we received a short-term non-convertible loan of \$350,000 from an accredited investor. The loan was repaid entirely on September 18, 2018. We paid \$20,000 in interest on this loan which includes a \$15,000 original issue discount.

### Conversion of Non-Convertible Notes

On June 11, 2018, the Company entered into Letter Agreements with certain private investors to convert a total of \$176,000 in principal and interest due to the private investors pursuant to certain loan documents into 70.4 Series AA Units representing 70.4 shares of Series AA Convertible Preferred Stock with a conversion price of \$2.50 per share and warrants to purchase 70,400 shares of common stock.

### *Merchant Agreements*

We have signed various Merchant Agreements which entitle the lenders to our customer receipts. We 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. Certain of these loans are guaranteed by an officer of the Company. The following table shows our Merchant Agreements as of December 31, 2018.

| Inception Date    | Purchase Price | Purchased Amount | Outstanding Balance | Daily Payment | Deferred Finance Fees |
|-------------------|----------------|------------------|---------------------|---------------|-----------------------|
| February 27, 2018 | 110,000        | 147,400          | -                   | 921.25        | 1,650                 |
| April 11, 2018    | 140,000        | 187,600          | -                   | 1,275.00      | 2,800                 |
| May 11, 2018      | 180,000        | 243,000          | -                   | 1,518.75      | 2,599                 |
| May 15, 2018      | 180,000        | 244,800          | -                   | 1,530.00      | 3,600                 |
| June 29, 2018     | 140,000        | 190,400          | -                   | 1,269.33      | 2,100                 |
| July 16, 2018     | 180,000        | 246,600          | -                   | 1,790.00      | 3,600                 |
| October 18, 2018  | 550,000        | 725,800          | 447,839             | 3,630.00      | 5,500                 |

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|                   |             |             |            |          |          |
|-------------------|-------------|-------------|------------|----------|----------|
| December 18, 2018 | 250,000     | 335,000     | 243,593    | 1,675.00 | 3,912    |
|                   | \$1,730,000 | \$2,320,600 | \$ 691,432 |          | \$25,761 |

We amortized \$112,429 and \$312,870 of debt discounts during the year ended December 31, 2018 and 2017, respectively for all non-convertible notes. The total unamortized discount for all non-convertible notes as of December 31, 2018 was \$9,118.

*Related Party Notes*

On March 14, 2018, we received a one-year, non-convertible loan of \$50,000 from a related party (a member of the Company's Board of Directors). This loan is included in net proceeds from non-convertible debt in the Statement of Cash Flows. The amount of \$50,000 was converted on June 11, 2018 into 20 shares of Series AA Convertible Preferred Stock and a Warrant to purchase 20,000 shares of common stock. The \$7,500 guaranteed interest on the loan was recorded as a debt discount and amortized over the term of the debt. The interest is outstanding as of December 31, 2018.

On May 31, 2018, we received two short-term loans of \$46,500 and \$5,600 from two members of the Company's Board of Directors, respectively. We repaid both loans in full during June 2018 and paid interest of \$6,975.

On June 11, 2018, the Company entered into a Letter Agreement with one non-employee member of the Board, to convert \$50,000 in principal due to the board member pursuant to a certain loan document into 20 Series AA Units representing 20 shares of Series AA Convertible Preferred Stock with a conversion price of \$2.50 per share and warrants to purchase 20,000 shares of common stock.



In June 2018, we received a non-convertible loan of \$15,000 from a private investor. The loan includes a one-year term and 10% guaranteed interest.

On August 6, 2018 and on September 28, 2018, we received two short-term loans of \$6,500 and \$7,500 from an employee and an officer of the Company, respectively. We repaid both loans in full in August and October 2018, respectively. There was no interest charged on these loans.

On October 26, 2018 we received a short-term loan of \$30,000 from an officer of the Company. The loan was repaid on October 29, 2018. There was no interest charged on this loan.

#### **(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, 2018, 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**

On May 2, 2018, the Company entered into a Securities Purchase Agreement with an existing shareholder pursuant to which the Company sold an aggregate of 100 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 \$250,000. Each share of Series AA Convertible Preferred Stock will receive a cumulative dividend at the annual rate of eight percent (8%) payable quarterly commencing on September 30, 2018 on those shares of Series AA Convertible Preferred Stock purchased from the Company.

We issued to the shareholder a new warrant to purchase 100,000 shares of common stock with an exercise price of \$3.50 per share. The Warrant will expire on the fifth-year anniversary after issuance. 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 AA 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.

On May 14, 2018, we entered into Letter Agreements with 22 Debenture Holders holding Debentures and Debenture Warrants whereby the Debenture Holders agreed to convert a total of \$6,220,500 in principal and original issue discount due them under the Debentures into 2,448.20 shares of Series AA Convertible Preferred Stock with a conversion price of \$2.50 per share. The Debenture Holders were also: (a) issued amended Debenture Warrants such that the exercise price will be \$3.50 per share; and (b) issued a new warrant with an exercise price of \$3.50 per share to purchase 2,448,200 shares of common stock (the number of shares of common stock issuable upon conversion of the Series AA Convertible Preferred Stock shares received as a result of the Debenture conversions).

On June 1, 2018, the Company entered into a Securities Purchase Agreement with accredited investors pursuant to which the Company sold an aggregate of 20 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 \$50,000. We issued to the shareholders a new warrant to purchase 20,000 shares of common stock with an exercise price of \$3.50 per share.

On June 11, 2018, the Company entered into additional Letter Agreements with 15 Debenture Holders whereby the Debenture Holders agreed to convert a total of \$742,134 in principal and original issue discount due them under the

Debentures into 296.80 shares of Series AA Convertible Preferred Stock with a conversion price of \$2.50 per share. The Debenture Holders were also: (a) issued amended Debenture Warrants such that the exercise price will be \$3.50 per share; and (b) issued a new warrant with an exercise price of \$3.50 per share to purchase 296,800 shares of common stock (the number of shares of common stock issuable upon conversion of the Series AA Convertible Preferred Stock shares received as a result of the Debenture conversions).

On June 11, 2018, the Company entered into a Letter Agreement with an accredited investor in which we agreed to issue 110.8 additional shares of Series AA Convertible Preferred Stock at \$2,500 per share to the investor. The fair value was recorded as other charge of \$340,257. We also issued 110,833 additional warrants with an exercise price of \$3.50 and an expiration period of five years from the original issue date. The fair value was recorded as other charges of \$312,637. The Company also amended 29,167 Warrants held by the Investor. The Company lowered the Warrants' exercise price from \$15.00 per share to \$3.50 per share. The fair value of \$10,236 relating to the reduction in exercise price was treated as an equity modification and recorded as a charge to other expenses.

During the quarter ended September 30, 2018, the Company entered into Securities Purchase Agreements with accredited investors pursuant to which the Company sold an aggregate of 460 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 \$1,150,000. We issued to the investors warrants to purchase an aggregate 460,000 shares of common stock with an exercise price of \$3.50 per share.

During the quarter ended December 31, 2018, the Company entered into Securities Purchase Agreements with accredited investors pursuant to which the Company sold an aggregate of 695 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 \$1,738,000. We issued to the investors warrants to purchase an aggregate 695,000 shares of common stock with an exercise price of \$3.50 per share. In addition, in accordance with Letter Agreements with two investors, the Company issued an additional 83 shares of Series AA Convertible Preferred Stock and 82,333 warrants with a value of \$358,932. The placement agent for this transaction received 148,160 warrants with a value of \$277,277.

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 and determined that they were not considered derivatives and therefore recorded the aggregate relative fair value of \$9,928,734 into equity relating to the 6,877,728 warrants and 274,660 broker warrants issued.

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 beneficial conversion feature ("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 \$12,881,899 was accounted for as a deemed dividend within equity and was included in the earnings per share calculation.

#### *Common Stock*

Stock Options and Warrants

Our stockholders approved our amended 2005 Equity Incentive Plan (the “Plan”) pursuant to which an aggregate of 1,800,000 shares of our common stock were reserved for issuance upon exercise of stock options or other equity awards made under the Plan. Under the 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. The Plan has expired and on July 18, 2018, the outstanding options to acquire 32,605 shares were transferred as discussed below to one of the other plans.

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, 2018, options to acquire 366,734 shares were outstanding under the Plan with 2,633,266 shares available for future grant under the 2013 Plan.

On November 29, 2015 the Company’s Board of Directors adopted the 2015 Nonqualified Stock Option Plan (the “2015 Plan”) pursuant to which 5,000,000 shares of our common stock were reserved for issuance upon exercise of non-qualified stock options under the 2015 Plan. Under the Plan, we may award non-qualified stock options in the Company to employees, officers, directors, consultants, and advisors, and to any other persons the Board of Directors deems appropriate.

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 July 18, 2018, the Board of Directors approved the immediate termination of 244,467 outstanding stock options held by current officers, employees and board members (32,605 stock options under the 2005 Plan, 81,925 stock options under the 2013 Plan, and 129,937 stock options under the 2015 Plan) and the issuance of new stock options to the same holders with an exercise price of \$3.40 per share equal to the closing market price on July 18, 2018 and an expiration date of July 18, 2028. The new stock options for board members will vest 1/12th per month for 12 months. The new stock options for officers and employees will vest 1/36th per month for 36 months. The 2005 Plan expired in 2015 so of the 32,605 terminated stock options, 16,641 stock options were issued under the 2013 Plan and 15,964 stock options were issued under the 2015 Plan (in addition to the reissuance of 81,925 stock options under the 2013 Plan, and 129,937 stock options under the 2015 Plan). The Board of Directors also awarded 101,267 stock options to officers, employees and board members separately based on the annual compensation committee recommendation. Of the 101,267 stock options issued, 51,934 stock options were issued under the 2013 Plan and 49,333 stock options were issued under the 2015 Plan.

On November 5, 2018 the Board of Directors approved the closing of the 2015 Plan and moved the 203,734 options outstanding in the 2015 Plan into the 2013 Plan which was then the only option plan still active. The unamortized expense related to this transfer is \$108,400 which will be amortized over the remaining life of the options.

On November 5 The Board of Directors also awarded 25,000 options to an officer separately based on the annual compensation committee recommendation. These options have an exercise price of \$3.40 and value of \$3.07 as determined under a Black Scholes method.

We evaluated this exchange and concluded that it was a modification under ASU 2017-09. Under ASU 2017-09, a cancelled equity award accompanied by the concurrent grant of (or offer to grant) a replacement award or other valuable consideration shall be accounted for as a modification of the terms of the cancelled award. 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 in accordance with paragraph ASC 718-20-35-3. 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 termination and issuance of new stock options, as determined under the Black Scholes method, was approximately \$759,469 and under ASU 2017-09 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, 2018, total unrecognized compensation cost related to the unvested stock-based awards was \$801,885, which is expected to be recognized over weighted average period of 1.15 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, 2018, based on the December 31, 2018 closing stock price of \$2.25, was \$0.





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, 2017   | 175,642       | \$ 12.60                         | 881,989    | \$ 12.00                         | 1,057,631  | 991,032     |
| Granted                                | 87,198        | 8.40                             | 245,661    | 11.14                            | 332,859    |             |
| Exercised                              | -             | -                                | (19,889 )  | 7.50                             | (19,889 )  |             |
| Expired                                | (3,202 )      | 30.00                            | (208,219 ) | 11.46                            | (211,421 ) |             |
| Forfeited                              | (11,946 )     | 9.82                             | -          | -                                | (11,946 )  |             |
| Balance outstanding, December 31, 2017 | 247,692       | \$ 10.95                         | 899,542    | \$ 12.03                         | 1,147,234  | 1,073,850   |
| Granted                                | 574,468       | 3.39                             | 6,877,948  | 3.50                             | 7,452,416  |             |
| Exercised                              | -             | -                                | -          | -                                | -          |             |
| Expired                                | (334 )        | 30.00                            | (12,669 )  | 12.00                            | (13,003 )  |             |
| Forfeited                              | (455,092)     | 7.49                             | -          | -                                | (455,092 ) |             |
| Balance outstanding, December 31, 2018 | 366,734       | \$ 3.39                          | 7,764,821  | \$ 3.50                          | 8,131,555  | 7,792,570   |

| Range of Exercise Prices | Options Outstanding |   |                | Options Exercisable |   |                |
|--------------------------|---------------------|---|----------------|---------------------|---|----------------|
|                          | Number of Options   | Weighted Average Remaining Contractual Life (Years) | Exercise Price | Number of Options   | Weighted Average Remaining Contractual Life (Years) | Exercise Price |
| \$2.00 - \$3.40          | 366,734             | 9.8   | \$ 3.40        | 69,292              | 9.8   | \$ 3.40        |
| \$2.00 - \$3.40          | 366,734             | 9.8   | \$ 3.40        | 69,292              | 9.8   | \$ 3.40        |

The loans from November 13, 2017 and May 17, 2018 included Warrants that contains a price protection provision such that if we issue a warrant with any term more favorable to the holder of such warrant that was not similarly provided in these loans, then we shall notify the lender of such additional or more favorable term and such term, shall become a part of the loan agreements. The fair value of the reduction in exercise price was recorded as a deemed dividend of \$5,113 in additional paid in capital.

The Company, pursuant to a price protection provision triggered on May 2, 2018 with the sale of Series AA units, amended the Debentures and Warrants to purchase Common Stock held by the Debenture Holders entered into between July 22, 2015 and March 31, 2016 as first disclosed in the Company's Current Report on Form 8-K filed on July 28, 2015. The fair value of \$207,899 relating to the reduction in exercise price was treated as a deemed dividend and recorded as a charge against additional paid-in capital within equity. The amended Debenture conversion price was exempt from revaluation because a beneficial conversion feature had already been recorded on the Debenture at issuance.

Common Stock Issuances

On various dates in the year ended December 31, 2018 the Company issued a total of 341,324 shares of restricted common stock at a fair value of \$1,005,941 to accredited investors. 64,652 of the shares with a fair value of \$220,952 were issued to existing holders of convertible loans who agreed to extend the terms of the loans for another six months; 88,311 shares with a fair value of \$288,648 were issued in conjunction with the signing of new convertible loans; 68,000 shares with a fair value of \$238,120 were issued for services rendered; 44,000 shares were issued upon the conversion of 44 shares of Series AA Convertible Preferred Stock; and 76,361 shares with a fair value of \$258,221 were issued in lieu of cash for the 8% dividend on Series AA Convertible Preferred Stock.

**(11) Subsequent Events**

From December 31, 2018 through March 1, 2019 the Company has issued fourteen Convertible notes for a total of \$1,677,063. The notes carry interest at rates ranging from 4% to 18% and are for terms of six to twelve months. The Company also extended the maturity dates of loans due January 19, 2019 to July 19, 2019, loans due February 1, 2019 to May 1, 2019, loans due February 8, 2019 to August 8, 2019, loans due February 26, 2019 to May 26, 2019 and loans due March 15, 2019 to September 15, 2019. On March 1, 2019 the Company entered into a merchant loan agreement for \$600,000.

From December 31, 2018 through March 28, 2019 the Company issued 560 shares of Series AA Convertible Preferred Stock at \$2,500 per share and received \$1,260,000 net of \$140,000 of broker fees. Each share of Series AA Convertible Preferred Stock carries 1,000 warrants to purchase Common Stock at \$3.50 per share and is convertible into 1,000 shares of Common Stock.

**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, 2018, 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, 2018 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, 2018. 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, 2018, 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, 2018, 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 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION.**

None.

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**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, 2018.

| Name                  | Age | Position   | Board Committees                | Term of office expires: |
|-----------------------|-----|--|---------------------------------|-------------------------|
| Richard T. Schumacher | 68  | President, Chief Executive Officer, Interim Chief Financial Officer, Treasurer, Clerk and Director |                                 | 2020                    |
| Jeffrey N. Peterson   | 63  | Chairman of the Board  | Audit, Compensation, Nominating | 2021                    |
| Dr. Mickey Urdea      | 66  | Director   | Scientific Advisory Board       | 2021                    |
| Vito J. Mangiardi     | 70  | Director   | Audit, Compensation, Nominating | 2019                    |
| Kevin A. Pollack      | 48  | Director   | Audit, Compensation, Nominating | 2019                    |

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, President since September 14, 2004, and Interim Chief Financial Officer since February 13, 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) company. Mr. Peterson also serves as Chairman and CEO of TDI’s majority-owned subsidiary, Veritomyx, Inc., which is completing development and commercialization of software tools for accurate peptide, protein and isoform identification and characterization. Prior to incorporating and joining 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 specialty pharmaceutical company developing pharmacological treatments for substance use, addictive, and eating disorders. 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, where he provides a range of services. 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 currently sits on the Board of Directors of MagneGas Corporation (MNGA-NASDAQ), the developer of a technology that converts liquid waste into a hydrogen-based metal-working fuel and natural gas alternative. 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. "Mickey" 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.

| <b>Name</b>               | <b>Age</b> | <b>Position</b>   |
|---------------------------|------------|---|
| Richard T. Schumacher     | 68         | President, Chief Executive Officer, Treasurer, Clerk and Director |
| Edmund Ting, Ph.D.        | 65         | Senior Vice President of Engineering                              |
| Nathan P. Lawrence, Ph.D. | 64         | Vice President of Marketing                                       |
| Alexander Lazarev, Ph.D.  | 54         | Vice President of Research and Development                        |
| Joseph L. Damasio, Jr.    | 44         | Vice President of Finance, Chief Financial Officer                |
| Bradford A. Young         | 50         | Chief Commercial 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. Nathan P. Lawrence** was appointed as our Vice President of Marketing and Sales on April 1, 2006. Dr. Lawrence joined Pressure BioSciences Inc. in 2005, serving as Director of Research and Development until his promotion to Vice President of Marketing in 2006. Dr. Lawrence was responsible for the development of protocols based on Pressure Cycling Technology (PCT). From 2004 through 2005, Dr. Lawrence worked for 454 Life Sciences Inc. in product development. Prior to 454 Life Sciences, Dr. Lawrence was Director of Research and Development for Boston Biomedica, Inc. from 1998 to 2004. He was primarily responsible for the development of PCT, as well as the development of nucleic acid-based diagnostic assays. Prior to joining Boston Biomedica, Inc., Dr. Lawrence held several positions with increasing responsibility in Research and Development and manufacturing at Becton Dickinson and Gene Trak Systems. Dr. Lawrence holds a BA from the University of Miami, an M.S. from Southern Connecticut State University, and a Ph.D. from Yale University.

**Dr. Alexander Lazarev** has served as our Vice President of Research and Development since 2007. Prior to that, 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.

**Dr. Bradford A. Young** joined us as Senior Vice-President and Chief Commercial Officer in November 2018. Prior to joining the Company, Dr. Young provided executive level consulting and leadership roles to biomedical technology, diagnostic and pharmaceutical companies for strategic planning, product development and commercialization. Dr. Young's background includes entrepreneurial experience as the Founder and CEO of AddisonField Corporation, a biotechnology company developing and commercializing consumer health products, and as Vice President of Business Development for Nodality, a pharmaceutical services company providing disease and drug profiling services in oncology and autoimmune diseases. Prior to Nodality, Dr. Young served as Director of Market and Business Development for Quest Diagnostics, a leading clinical reference laboratory, and as Head of Market Development for Celera, a pioneer in personalized medicine. Dr. Young serves on the Board of Directors of Liquid Biotech, Inc., a circulating tumor cell diagnostic company and on the Selection Committee for SPADA, the Stanford Predictives and Diagnostics Accelerator program. Dr. Young earned his Ph.D. from the University of Maryland, School of Medicine and his M.B.A. from the University of California, Berkeley, Haas School of Business.

## **Section 16(a) Beneficial Ownership Reporting Compliance**

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, 2018 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](http://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](http://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, 2018 and 2017 for: (i) each individual serving as our chief executive officer (“CEO”) or acting in a similar capacity during any part of fiscal 2018; 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 2018.

| <b>Name and Principal Position</b>  | <b>Fiscal Year</b> | <b>Salary<sup>(1)</sup></b> | <b>Bonus</b> | <b>Stock Awards</b> | <b>Option Awards<sup>(2)</sup></b> | <b>Non-Qualified Deferred Compensation Earning</b> | <b>All other Compensation<sup>(3)</sup></b> | <b>Total</b> |
|---|--------------------|-----------------------------|--------------|---------------------|------------------------------------|--|---|--------------|
| Richard T. Schumacher<br>President, CEO   | 2018               | \$310,954                   | \$ -         | \$ -                | \$ 34,840                          | \$ -   | \$ 11,469                                   | \$357,263    |
|   | 2017               | 300,583                     | -            | -                   | 142,285                            | -  | 11,079                                      | 453,947      |
| Edmund Ting, Ph.D.<br>Senior Vice President of<br>Engineering                   | 2018               | 207,580                     | -            | -                   | 7,665                              | -  | 1,227                                       | 216,472      |
|   | 2017               | 207,100                     | -            | -                   | 31,303                             | -  | 1,227                                       | 239,630      |
| Alexander Lazarev,<br>Ph.D.<br>Vice President of<br>Research and<br>Development | 2018               | 173,915                     | -            | -                   | 6,968                              | -  | 7,754                                       | 188,637      |
|   | 2017               | 173,880                     | -            | -                   | 28,457                             | -  | 7,739                                       | 210,076      |

(1) Salary refers to base salary compensation paid through our normal payroll process. No bonus was paid to any named executive officer for 2018 or 2017.

(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 2, xiii, “Accounting for Stock-Based Compensation” in the accompanying Notes to Consolidated Financial Statements for the fiscal year ended December 31, 2018, 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 \$6,000 paid to Dr. Lazarev 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, 2018.

| Name   | Option Awards   |   | Option Exercise Price (\$) | Option Expiration Date |
|--|---|---|----------------------------|------------------------|
|  | Number of Securities Underlying Unexercised Options Exercisable | Number of Securities Underlying Unexercised Options Unexercisable |                            |                        |
| Richard T. Schumacher<br>President, CEO                                | 1,389   | 8,611   | \$ 3.40                    | 7/18/2028              |
|  | 13,633  | 84,534  | \$3.40                     | 12/19/2028             |
| Edmund Y. Ting, Ph.D<br>Senior Vice President of Engineering           | 2,942   | 18,243  | \$3.40                     | 7/18/2028              |
|  | 764   | 4,736   | \$3.40                     | 12/19/2028             |
| Alexander V. Lazarev, Ph.D<br>Vice President of Research & Development | 2,475   | 18,526  | \$3.40                     | 7/18/2028              |
|  | 694   | 4,306   | \$3.40                     | 12/19/2028             |

All unvested stock options listed in this column were granted to the Named Executive Officer pursuant to our (1) 2013 Equity Incentive Plan. On July 18, 2018 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. Lazarev, and Dr. Young, 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, Dr. Lazarev and Dr. Young, 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 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 2018.

| Name                     | Fees<br>Earned<br>or Paid<br>in Cash<br>(\$) <sup>(1)</sup> | Stock<br>Awards<br>(\$) <sup>(1)</sup> | Option Awards<br>(\$) <sup>(2)(3)</sup> | Total (\$) |
|--------------------------|---|--|---|------------|
| Vito J. Mangiardi        | 70,000  | -                                      | 6,129                                   | 76,129     |
| Jeffrey N. Peterson      | 107,500   | -                                      | 10,216                                  | 117,716    |
| Kevin A. Pollack         | 72,500  | -                                      | 6,129                                   | 78,629     |
| Michael S. Urdea, Ph. D. | 50,000  | -                                      | 3,859                                   | 53,859     |

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 2018. 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.

(2) Amounts shown do not reflect compensation received by the directors. 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 2, xiii, "Accounting for Stock-Based Compensation" in the accompanying Notes to the Consolidated Financial Statements for the fiscal year ended December 31, 2018, for the relevant assumptions used to determine the valuation of stock option grants.

(3) The following table shows the total number of outstanding stock options as of December 31, 2018 that have been issued as director compensation.

| <b>Name</b>              | <b>Aggregate<br/>Number of<br/>Stock<br/>Options<br/>Outstanding</b> |
|--------------------------|--|
| Vito J. Mangiardi        | 17,602   |
| Jeffrey N. Peterson      | 30,078   |
| Kevin A. Pollack         | 17,602   |
| Michael S. Urdea, Ph. D. | 13,018   |

*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](http://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](http://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 2018. 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 2018.

## **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 12, 2019 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 1,699,243 shares of our common stock issued and outstanding as of April 12, 2019. 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 12, 2019, 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<br>and<br>Nature of<br>Beneficial<br>Ownership | Percent<br>of<br>Class |
|---|---|------------------------|
| Richard T. Schumacher(1)                            | 81,486  | 4.79 %                 |
| Jeffrey N. Peterson(2)                              | 79,389  | 4.67 %                 |
| Kevin A. Pollack(3)                                 | 73,756  | 4.34 %                 |
| Michael S. Urdea(4)                                 | 66,541  | 3.92 %                 |
| Vito J. Mangiardi(5)                                | 34,399  | 2.02 %                 |
| Edmund Y. Ting, Ph.D.(6)                            | 7,487   | .44 %                  |
| Alexander V. Lazarev, Ph.D.(7)                      | 6,120   | .33 %                  |
| All other officers                                  | 9,722   | .53 %                  |
| All Executive Officers and Directors as a Group (8) | 358,900   | 17.04 %                |



Includes (i) 27,042 shares of Common Stock issuable upon exercise of options; (ii) 9,991 shares of Common Stock issuable upon the exercise of warrants and (iii) 8,800 shares of common stock issuable upon conversion of Series 1) AA Convertible Preferred Stock and (iv) 35,653 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.

Includes (i) 22,458 shares of Common Stock issuable upon exercise of options; (ii) 22,500 shares of Common 2) 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) 14,431 shares of Common Stock.

Includes (i) 13,142 shares of Common Stock issuable upon exercise of options; (ii) 23,278 shares of Common 3) Stock issuable upon exercise of warrants; (iii) 20,500 shares of common stock issuable upon conversion of Series AA Convertible Preferred Stock; and (iv) 16,001 shares of Common Stock.

Includes (i) 9,728 shares of Common Stock issuable upon exercise of options; (ii) 22,939 shares of Common Stock 4) issuable upon exercise of warrants; (iii) 20,200 shares of common stock issuable upon conversion of Series AA Convertible Preferred Stock; and (iv) 13,674 shares of Common Stock.

Includes (i) 13,142 shares of Common Stock issuable upon exercise of options; (ii) 4,996 shares of Common Stock 5) issuable upon exercise of warrants; (iii) 4,400 shares of common stock issuable upon conversion of Series AA Convertible Preferred Stock; and (iv) 11,861 shares of Common Stock.

Includes (i) 6,672 shares of Common Stock issuable upon exercise of options and (ii) 815 shares of Common 6) Stock.

Includes (i) 5,710 shares of Common Stock issuable upon exercise of options and (ii) 410 shares of Common 7) Stock.

Includes (i) 106,852 shares of Common Stock issuable upon exercise of options; (ii) 83,704 shares of Common 8) Stock issuable upon the exercise of warrants; (iii) 73,900 shares of Common Stock issuable upon conversion of Series AA Convertible Preferred Stock and (iv) 94,444 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, 2018 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 | Weighted-average exercise price of outstanding options | Number of securities available for future |
|---------------|--|--|---|
|---------------|--|--|---|

|  | exercise of<br>outstanding<br>options |         | issuance<br>under equity<br>compensation<br>plans |
|--|---------------------------------------|---------|---|
| Equity compensation plan approved by security holders - 2013 Equity Incentive Plan | 366,734                               | \$ 3.40 | 2,633,266   |

### **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.

On June 11, 2018, the Company entered into additional Letter Agreements with 15 Debenture Holders whereby the Debenture Holders agreed to convert a total of \$742,134 in principal and original issue discount due them under the Debentures into 296.80 shares of Series AA Convertible Preferred Stock with a conversion price of \$2.50 per share. The Debenture Holders were also: (a) issued amended Debenture Warrants such that the exercise price will be \$3.50 per share; and (b) issued a new warrant with an exercise price of \$3.50 per share to purchase 296,800 shares of common stock (the number of shares of common stock issuable upon conversion of the Series AA Convertible Preferred Stock shares received as a result of the Debenture conversions). The Debenture Holders also agreed to waive any and all defaults or events of default by the Company with respect to any failure by the Company to comply with any covenants contained in the Debentures. The fair value of \$3,155 relating to the adjustment in exercise price was treated as a loan modification and recorded as a gain toward the extinguishment of debt.

#### *Related Party Notes*

On March 14, 2018, we received a one-year, non-convertible loan of \$50,000 from a related party (a member of the Company's Board of Directors). This loan is included in net proceeds from non-convertible debt in the Statement of Cash Flows. The amount of \$50,000 was converted on June 11, 2018 into 20 shares of Series AA Convertible

Preferred Stock and a Warrant to purchase 20,000 shares of common stock. The \$7,500 guaranteed interest on the loan was recorded as a debt discount and amortized over the term of the debt. The interest is outstanding as of December 31, 2018.

On May 31, 2018, we received two short-term loans of \$46,500 and \$5,600 from two members of the Company's Board of Directors, respectively. We repaid both loans in full during June 2018 and paid interest of \$6,975.

On June 11, 2018, the Company entered into a Letter Agreement with one non-employee member of the Board, to convert \$50,000 in principal due to the board member pursuant to a certain loan document into 20 Series AA Units representing 20 shares of Series AA Convertible Preferred Stock with a conversion price of \$2.50 per share and warrants to purchase 20,000 shares of common stock.

In June 2018, we received a non-convertible loan of \$15,000 from a private investor. The loan includes a one-year term and 10% guaranteed interest.

On August 6, 2018 and on September 28, 2018, we received two short-term loans of \$6,500 and \$7,500 from an employee and an officer of the Company, respectively. We repaid both loans in full in August and October 2018, respectively. There was no interest charged on these loans.

On October 26, 2018 we received a short-term loan of \$30,000 from an officer of the Company. We repaid the loan in full on October 29, 2018. There was no interest charged on this loan.

## 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, 2018.

### 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, 2018 and 2017:

|                    | Fiscal<br>2018<br>Fees | Fiscal<br>2017<br>Fees |
|--------------------|------------------------|------------------------|
| Audit Fees         | \$132,170              | \$118,549              |
| Audit-Related Fees | -                      | -                      |
| Tax and Other Fees | -                      | -                      |
|                    | \$132,170              | \$118,549              |

*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. Included in the 2017 Audit Fees is an aggregate of \$26,500 of fees billed in connection with 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 |  | Incorporated by Reference |         |             | Filed or<br>Furnished<br>Herewith |
|---------|--|---------------------------|---------|-------------|-----------------------------------|
| Number  | Exhibit Description  | Form                      | Exhibit | Filing Date |                                   |
| 3.1     | <u>Restated Articles of Organization of the Company.</u>   | S-1                       | 3.1     | 10/08/1996  |                                   |
| 3.2     | <u>Articles of Amendment to Restated Articles of the Organization of the Company</u>                         | 10-Q                      | 3.1     | 11/23/2004  |                                   |
| 3.3     | <u>Articles of Amendment to Restated Articles of the Organization of the Company</u>                         | 8-K                       | 3.1     | 02/18/2009  |                                   |
| 3.4     | <u>Articles of Amendment to Restated Articles of the Organization of the Company</u>                         | 8-K                       | 3.1     | 04/12/2011  |                                   |
| 3.5     | <u>Articles of Amendment to Restated Articles of the Organization of the Company</u>                         | 8-K                       | 3.1     | 11/10/2011  |                                   |
| 3.6     | <u>Articles of Amendment to Restated Articles of the Organization of the Company</u>                         | 8-K                       | 3.1     | 01/04/2013  |                                   |
| 3.7     | <u>Articles of Amendment to Restated Articles of the Organization of the Company</u>                         | 8-K                       | 3.1     | 02/13/2013  |                                   |
| 3.8     | <u>Articles of Amendment to Restated Articles of the Organization of the Company</u>                         | 8-K                       | 3.1     | 12/12/2013  |                                   |
| 3.9     | <u>Articles of Amendment to Restated Articles of the Organization of the Company</u>                         | 8-K                       | 3.1     | 02/05/2014  |                                   |
| 3.10    | <u>Articles of Amendment to Restated Articles of the Organization of the Company</u>                         | 8-K                       | 3.1     | 12/31/2014  |                                   |
| 3.11    | <u>Articles of Amendment to Restated Articles of the Organization of the Company</u>                         | 8-K                       | 3.1     | 07/28/2015  |                                   |
| 3.12    | <u>Amended Certificate of Designation of Series AA Convertible Preferred Stock, filed February 14, 2019.</u> | 8-K                       | 3.1     | 02/15/2019  |                                   |
| 3.13    | <u>Amendment to Amended and Restated By-Laws of the Company</u>  | 10-K                      | 3.3     | 10/08/1996  |                                   |
| 3.14    | <u>Amendment to Amended and Restated By-Laws of the Company</u>  | 10-K                      | 3.3     | 3/31/2003   |                                   |
| 4.1     | <u>Specimen Certificate for Shares of the Company's common stock</u>   | 10-KSB                    | 4.1     | 04/22/2005  |                                   |

| <b>Exhibit</b> |  | <b>Incorporated by</b> | <b>Filed or</b>  |
|----------------|--|------------------------|------------------|
| <b>Number</b>  | <b>Exhibit Description</b>   | <b>Reference</b>       | <b>Furnished</b> |
|                |  | <b>Form Exhibit</b>    | <b>Herewith</b>  |
|                |  | <b>Filing Date</b>     |                  |
| 4.2            | <u>Form of Debenture</u>   | 8-K 4.1                | 07/28/2015       |
| 4.3            | <u>Form of Warrant</u>   | 8-K 4.2                | 07/28/2015       |
| 4.4            | <u>Form of Debenture</u>   | 8-K 4.1                | 4/24/2017        |
| 4.5            | <u>Form of Warrant issued in connection with debt conversion</u>   | 8-K 4.1                | 06/15/2018       |
| 10.1           | <u>Technology Transfer and Patent Assignment Agreement dated</u><br><u>October 7, 1996, between Bioseq, Inc. and BioMolecular</u><br><u>Assays, Inc.</u>             | 10-K 10.11             | 03/27/2008       |
| 10.2           | <u>Amendment to Technology Transfer and Patent Assignment</u><br><u>Agreement dated October 8, 1998 between Bioseq, Inc. and</u><br><u>BioMolecular Assays, Inc.</u> | 10-K 10.12             | 03/27/2008       |
| 10.3           | <u>Nonexclusive License Agreement dated September 30, 1998</u><br><u>between Bioseq, Inc. and BioMolecular Assays, Inc.</u>  | 10-K 10.13             | 03/27/2008       |
| 10.4           | <u>Subscription Agreement</u>  | 8-K 10.1               | 07/28/2015       |
| 10.5           | <u>Security Agreement</u>  | 8-K 10.2               | 07/28/2015       |
| 10.6           | <u>Promissory Note, dated October 26, 2016</u>   | 8-K 10.1               | 11/03/2016       |
| 10.7           | <u>2005 Equity Incentive Plan.*</u>  | S-8 99.1               | 09/26/2005       |
| 10.8           | <u>Amendment No. 1 to 2005 Equity Incentive Plan*</u>  | 8-K 10.1               | 09/29/2008       |
| 10.9           | <u>Description of Compensation for Certain Directors*</u>  | 10-K 10.5              | 03/27/2008       |
| 10.10          | <u>Severance Agreement between the registrant and Richard T.</u><br><u>Schumacher*</u>   | 10-K 10.6              | 03/27/2008       |
| 10.11          | <u>Form of Severance Agreement including list of officers to</u><br><u>whom provided*</u>  | 10-K 10.7              | 03/27/2008       |
| 10.12          | <u>2013 Equity Incentive Plan.*</u>  | S-8 4.1                | 04/24/2015       |
| 10.13          | <u>2015 Nonqualified Stock Option Plan.*</u>   | 10-K 10.13             | 03/22/2017       |
| 10.14          | <u>Securities Purchase Agreement</u>   | 10-Q 10.1              | 11/14/2016       |
| 10.15          | <u>Securities Purchase Agreement, dated March 14, 2017</u>   | 8-K 10.1               | 04/24/2017       |
| 10.16          | <u>Letter Agreement, dated April 19, 2017</u>  | 8-K 10.2               | 04/24/2017       |
| 10.17          | <u>Amendment to the July 1, 2016 \$200,000 Convertible Note</u><br><u>between Vision Capital and Pressure BioSciences, Inc.</u>                                      | 10-Q 10.1              | 05/15/2017       |
| 10.18          | <u>Securities Purchase Agreement dated March 14, 2017</u>  | 10-Q 10.2              | 05/15/2017       |
| 10.19          | <u>Amendment Number 1 to October 26 Promissory Note, dated</u><br><u>May 2, 2017</u>   | 8-K 10.1               | 05/26/2017       |
| 10.20          | <u>Promissory Note, dated May 19, 2017</u>   | 8-K 10.2               | 05/26/2017       |
| 10.21          | <u>Asset Purchase Agreement between Pressure BioSciences, Inc.</u><br><u>and BaroFold, Inc., dated December 12, 2017.</u>  | 8-K 10.1               | 12/18/2017       |
| 10.22          | <u>Amendment Number 2 to October 26 Promissory Note, dated</u><br><u>May 2, 2017</u>   | 10-K 10.22             | 04/02/2018       |
| 10.23          | <u>Amendment Number 3 to October 26 Promissory Note, dated</u><br><u>January 30, 2018</u>  | 10-Q 10.1              | 05/15/2018       |
| 10.24          | <u>Form of Letter Agreement to Convert May 2017 Promissory</u><br><u>Note</u>  | 8-K 10.1               | 06/15/2018       |
| 10.25          | <u>Form of Letter Agreement to Convert Debentures</u>  | 8-K 10.2               | 06/15/2018       |
| 10.26          | <u>Form of Letter Agreement to Convert Line of Credit</u>  | 8-K 10.3               | 06/15/2018       |
| 21.1           | <u>List of Subsidiaries</u>  |                        | 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.
- 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.\*\*
- 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.\*\*

\*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 16, 2019 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           |
|---|---|----------------|
| <i>/s/ Richard T. Schumacher</i><br>Richard T. Schumacher | President, Chief Executive Officer, Interim Chief Financial Officer, Treasurer, Clerk and Director<br>(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer) | April 16, 2019 |
| <i>/s/ Jeffrey N. Peterson</i><br>Jeffrey N. Peterson     | Chairman of the Board of Directors  | April 16, 2019 |
| <i>/s/ Mickey Urdea</i><br>Michael S. Urdea,<br>Ph.D.     | Director  | April 16, 2019 |
| <i>/s/ Vito Mangiardi</i><br>Vito J. Mangiardi            | Director  | April 16, 2019 |
| <i>/s/ Kevin Pollack</i><br>Kevin A. Pollack              | Director  | April 16, 2019 |

