PRESSURE BIOSCIENCES INC
Form 10-K
April 05, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015 or

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

For the transition period from _____ to _____

Commission file number 000-21615

PRESSURE BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

(Title of Class)
None

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $.01 per share	**OTC Markets Group, Inc.**
Preferred Share Purchase Rights	

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes [ ] No [X]

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that registrant was required to submit and post such files.

Yes [X] No [ ]

Indicate by check mark 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 [ ] (Do not check if smaller reporting company)	Smaller reporting company [X]

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2015 was $4,249,932 based on the closing price of $0.23 per share of Pressure BioSciences, Inc. common stock as quoted on the OTC Markets QB exchange on that date.

As of April 1, 2016, there were 23,209,898 shares of the registrant’s common stock outstanding.

Documents Incorporated by Reference

N/A.

TABLE OF CONTENTS

Introductory Comment

Throughout this Annual Report on Form 10-K, the terms "we," "us," "our," "the Company" and "our Company" refer to Pressu 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 si 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 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 installed and the increase in revenues from the sale of consumable products and extended service contracts;
- 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;
- 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 in biomarker discovery, forensics, and histology and 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;
- 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.

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™, ProteoSolve$_{LRS}$™, the Power of PCT™, the PCT Shredder™, HUB440™, HUB880™, micro-Pestle™, PCT-HD™, Barozyme™ and BaroFlex™ Strips, 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, called pressure cycling technology, or PCT, uses alternating cycles of hydrostatic pressure between ambient and ultra-high levels i.e., 35,000 pounds per square inch ("*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 deoxyribonucleic acid ("*DNA*"), ribonucleic acid ("*RNA*"), proteins, lipids and small molecules. Our laboratory instrument, the Barocycler®, and our internally developed consumables product line, which include our Pressure Used to Lyse Samples for Extraction ("*PULSE*") tubes, and other processing tubes, and application specific kits such as consumable products and reagents, together make up our PCT Sample Preparation System ("*PCT SPS*").

We hold 14 United States and 10 foreign patents covering multiple applications of PCT in the life sciences field. Our pressure cycling technology 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:

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 all of the Americas for the Constant Systems cell disruption equipment, parts, and consumables. Constant Systems, Ltd. (“CS”), a British company located about 90 minutes 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 the PBI PCT-based instrumentation complement each other in several important ways. While both the CS and PBI technologies are based on high pressure, each product line has fundamental scientific capabilities that the other does not offer. PBI’s PCT Platform uses certain patented pressure mechanisms to achieve small-scale, molecular level effects. CS’s technology uses different, proprietary pressure mechanisms for larger-scale, non-molecular level processing. In a number of routine laboratory applications, such as protein extraction, both effects can be critical to success. Therefore, for protein extraction and a number of other important scientific applications, we believe laboratories will benefit by using the CS and PBI products, either separately or together.

Within the broad field of biological sample preparation, we focus the majority of our PCT and constant pressure ("CP") product development efforts in three specific areas: biomarker discovery (primarily through mass spectrometric analysis at the present time), forensics and histology.

Biomarker Discovery - Mass Spectrometry. A biomarker is any substance (e.g., protein, DNA) that can be used (i) as an indicator of the presence or absence of a particular disease-state or condition, (ii) to measure disease progression, and (iii) to measure the 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 one of the laboratory instruments used in the analysis of biological samples, primarily proteins, in life sciences research. It is frequently used to help discover biomarkers. According to a recently published market report by marketing firm Transparency Market Research (www.transparencymarketresearch.com) "*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 that both PCT and CP-based products offer significant advantages in speed and quality compared to current techniques used in the preparation of samples for mass spectrometric 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, using PCT in the sample preparation process. We believe PCT may be capable of differentially extracting DNA from sperm and female epithelial cells in swabs collected from rape victims and stored in rape kits. According to the Joyful Arts Foundation's website, an organization focused on bringing justice to all victims of rape cases that remain unsolved (http://endthebacklog.org/whatisthebacklog.htm), "Experts in the federal government estimate that there are hundreds of thousands of untested rape kits in police and crime lab storage facilities throughout the United States." We believe this backlog exists for reasons such as cost, processing time, and quality of results. We further believe that the ability to differentially extract DNA from the sperm cells while not extracting DNA from the female 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 biopsies of cancer and other tissues for subsequent pathology evaluation is formalin-fixation followed by paraffin-embedding ("*FFPE*"). We believe that the quality and analysis of FFPE tissues is highly problematic. We believe PCT offers significant advantages over current processing methods. These advantages include standardization, speed, biomolecule recovery, and safety.

Our customers include researchers at academic laboratories, government agencies, biotechnology, pharmaceutical and other life sciences companies in the United States, and distribution partners in foreign countries.

We have experienced negative cash flows from operations with respect to our business since inception. As of December 31, 2015, we did not have adequate working capital resources to satisfy our current liabilities. Based on our current projections, including equity and debt financing subsequent to December 31, 2015, we believe our current and projected cash resources will enable us to extend our cash resources for 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, 2015, 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, 2015 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.

Developments

We reported a number of accomplishments during 2015 including:

December 31, we closed on two additional subscriptions totaling $155,000 in our $5 Million PIPE transaction, bringing the total to $4,910,000.

December 15, we reported the close of an additional $730,000 in our $5 Million PIPE transaction, bringing the total to $4,755,000. We also reported the repayment of 100% of the floorless loans previously owed by PBI.

November 12, we announced Q3 2015 financial results, including record revenue for the quarter and nine-month periods ended September 30, a 55% increase in total revenue compared to the same quarter in 2014, and a 13.4% decrease in operating loss for the third quarter of 2015.

October 16, the Company announced a collaboration agreement with Florida International University to co-develop an improved rape kit test method, based on the Company’s patented PCT platform. With a backlog of untested rape kits estimated at approximately 400,000, and with an estimated 180,000 new sexual assaults each year, an improved testing method is vitally needed.

September 1, we announced that a recent publication in a peer-reviewed journal indicated that PBI’s PCT platform could play a significant role in personalized/precision medicine, including cancer tissue biopsies.

August 17, we announced Q2 2015 financial results, including increases in all major revenue categories for the second quarter, and record total revenue for the six month period ended June 30, 2015.

August 14, DM WDM, a small cap investment bank, announced the exchange of 1M shares of PBI (valued at $0.50/share) for 601,500 shares of Everest Investments Holdings, the formation of Pressure BioSciences Europe, and $250,000 of market support for PBI by WDM.

July 23, we announced the close of a $2.18M initial tranche of a $5 Million Private Placement.

July 15, we announced that PCT was a key workflow component in a study to discover potential biomarkers and underlying pathways in the emergence and progression of COPD-associated lung cancer.

July 13, we reported that Chinese and Swiss researchers suggested a workflow that included the PCT platform that they believed could potentially accelerate the discovery of new biomarkers for the early diagnosis and prediction of complications in diabetes.

July 7, we announced promising results when our PCT Platform was incorporated in a new method for improving the extraction of DNA from rape kits and other forensic samples.

June 29, we announced that scientists from the Institute of Molecular Systems Biology in Zurich, Switzerland presented data on an improved method for the proteomic profiling and classification of prostate cancer tissue biopsy samples at an important international scientific conference.

May 4, we announced the publication of three scientific articles that show key advantages of the PCT platform in drug discovery & design, cancer detection, and in the analysis of microbial communities in soil.

April 30, we announced that scientists from Northwestern University had successfully extracted cotinine (metabolite of nicotine) from dried blood spots and theorized that the Company’s new Barozyme High-throughput system might also improve the extraction of other chemical toxins and carcinogens as well.

April 14, we announced a collaboration agreement with Southern University at New Orleans for improving and extending applications of the PCT platform for DNA detection in forensic samples.

March 31, we announced FY 2014 financial results, including an almost 30% increase in products and services revenue compared to FY 2013.

March 12, we released PCT-HD, “the Next Generation Protein Preparation System” in two separate presentations at a major international scientific meeting in Tempe, Arizona.

February 19, we announced the award of a $1 million NIH SBIR Phase II Grant to develop a high-throughput, high pressure-based DNA Shearing System for Next Generation Sequencing (“NGS”).

February 10, we received the first Purchase Order for our Barozyme HT48 High-Throughput System.

January 21, we announced the receipt of over $1.16 million during the past two months from equity investments, and that we planned to expand our marketing, sales, and operations capabilities.

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 and as described in this annual report. We closed $4,910,000 of a $5 million PIPE through December 31, 2015, and have closed additional subscriptions subsequent to December 31, 2015. 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. ("*PBI*"). 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 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 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.

You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also 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 a recently published market report by Transparency Market Research (www.transparencymarketresearch.com) “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 till 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.

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.

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, 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 on the merits of PCT and CP.

Since we initiated our collaboration program in June 2005, 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.

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 (35,000 psi or greater) and then back to ambient; all in a precisely controlled manner. Our instruments (the Barocycler NEP3229, the Barocycler NEP2320, and the HUB440) use cycles of high, hydrostatic pressure to quickly and efficiently break up the cellular structures of a specimen to release nucleic acids, proteins, lipids and small molecules from the specimen into our consumable processing tube, referred to as our PULSE Tubes and MicroTubes. Our Barocycler instrumentation is designed to fit on a laboratory bench top, inside a biological safety cabinet, or on the shelf of a laboratory cold room. Our instruments have an external chiller hook-up (to control temperature during the PCT process), automatic fill and dispensing valves, and an integrated micro-processor keypad or a laptop computer. The microprocessor 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 current PCT Sample Preparation System (see below).

Barocycler NEP3229 – The Barocycler NEP3229 contains two units – a user interface and a power source – comprised primarily of a 1.5 horsepower motor and pump assembly (hydraulic). 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.

Barocycler NEP2320 – The Barocycler NEP2320 is a smaller, more compact version of our NEP3229 unit. It weighs approximately 80 pounds (with accessories) and works on compressed air (pneumatic) instead of hydraulics like the larger NEP3229 unit. Because this instrument is pneumatic, the NEP2320 can be easily attached by an air hose to a typical 85-psi air compressor found in most scientific laboratories, as well as to many consumer-sold portable compressors or even to bottled gas. This instrument is used by our sales staff as a demonstration instrument and is marketed as a second instrument alternative to our PCT SPS. The Barocycler NEP2320 is capable of processing one sample at a time using our specially designed, single-use PULSE Tubes and up to 16 samples simultaneously using our specially-designed MicroTubes.

Barocycler HUB440 – The Barocycler HUB440 was introduced to collaborators in the electron paramagnetic resonance ("EPR") market in 2011 for testing in a laboratory environment, and to elicit feedback from research scientists on performance and capabilities. The Barocycler HUB440 is capable of creating and controlling hydrostatic pressure from 500 psi to 58,000 psi. It is computer controlled, and runs on software that was specially-written by PBI in LabVIEW (software from National Instruments Corporation). PBI owns the rights and has a license to use the specialty LabVIEW software. The Barocycler HUB440 is the first portable, ready to use pressure generator for the laboratory bench. We believe that over the coming years, the Barocycler HUB440 may become the main instrument in the Company's pressure-based instrument line.

PCT MicroTube Adapter Kit – The PCT MicroTube Adapter Kit includes an ergonomically designed, space-saving Workstation, PCT MicroTubes and MicroCaps, and specialized tools to enable the user to process up to forty-eight samples simultaneously in our PCT SPS, as compared to three with the Barocycler NEP3229.

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 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 HUB880 - The Barocycler HUB880 is a new instrument expected to be available for sale during the second half of 2016. It is a compact, portable, bench-top, ultra-high pressure generator 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 and vaccine industries.

Barozyme HT48 - The Barozyme HT48 is a high throughput bench-top instrument designed for accelerated enzymatic digestion of proteins at high pressure. The Barozyme HT48 uses an air-pressure-to-liquid-pressure 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. Typical trypsin digestion times can be reduced from hours to minutes.

BaroFlex 8-well Processing Strips - Baroflex 8-well Strips are used in the Barozyme HT48 (See Specification Sheet) 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 140µl 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 8, or mats of 24 caps.

PCT-HD - The PCT-HD System combines two of the Company's unique products: the recently released, patent-pending µPestle consumable with an enhanced Barocycler NEP2320 instrument. This combination enables faster, less cumbersome and higher quality homogenization, extraction, and digestion of proteins. PCT-HD was developed by the Company's 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 AB SCIEX's SWATH-Mass Spectrometry – calling the resulting method "PCT-SWATH". This protocol can yield analytical results within 12 hours from the start of processing tissue. Although Drs. Aebersold and Guo developed protocols for the combination of PCT-HD with SWATH-MS, the PCT-HD System is not limited to any specific mass spectrometer or method of data analysis. Subsequently, we believe the PCT-HD System can provide most researchers with unprecedented speed and reproducibility for biomarker discovery.

Cell Disruption Instrumentation

We are also the exclusive distributor throughout all of the Americas for the Constant Systems cell disruption equipment, parts, and consumables. Constant Systems, Ltd ("CS"), a British company located about 90 minutes 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 the PBI PCT instrumentation complement each other in several important ways. While both the CS and PBI technologies are based on high pressure, each product line has fundamental scientific capabilities that the other does not offer. PBI's PCT Platform uses certain patented pressure mechanisms to achieve small-scale, molecular level effects. CS's technology uses different, proprietary pressure mechanisms for larger-scale, non-molecular level processing. In a number of routine laboratory applications, such as protein extraction, both effects can be critical to success. Therefore, for protein extraction and a number of other important scientific applications, we believe laboratories will benefit by using the CS and PBI products, either separately or together.

Barocycler Consumable Products

PULSE Tubes (FT500) – The FT500 PULSE Tube is a specially-designed, plastic, single-use, processing container with two chambers separated by a small disk with small holes. This small disk is referred to as a Lysis Disk. PULSE Tubes transmit the power of PCT from the Barocycler instrument to the sample. In sample extraction, the specimen is placed on the Lysis Disk. Buffers are added to the PULSE tube and the PULSE Tube is capped and placed in the pressure chamber of the Barocycler instrument. The pressure chamber fluid then is added and pressurization begins. As pressure increases, a small moveable piston pushes the specimen from the top (sample) chamber, through the Lysis Disk and into the bottom (fluid retention) chamber. When pressure is released, the sample, which is now partially homogenized, is pulled back through the Lysis Disk by the receding ram. The combination of physical passage through the Lysis Disk, rapid pressure changes and other biophysical mechanisms related to cycled pressure break up the cellular structures of the specimen to quickly and efficiently release nucleic acids, proteins, lipids and small molecules.

Non-Disk PULSE Tubes (FT500-ND) – The FT500-ND PULSE Tube is a specially-designed, plastic, single-use, processing container with one chamber. The FT500-ND is similar to the FT500 in look and feel, except there is no

Lysis Disk separating the body of the processing container into two chambers, as in the FT500. The design change was based on market demand for a PCT consumable for the rapid and reproducible processing of solutions and suspensions that do not require partial homogenization by passage through a Lysis Disk and for a consumable that could accept smaller sample volumes. The FT500-ND offers variable sample volumes with a range five times that of the existing FT500.

ProteoSolve - SB – (ProteoSolve for Systems Biology) is a PCT-dependent method for the simultaneous extraction, isolation and fractionation of nucleic acids (DNA and RNA), proteins and lipids from animal and plant samples routinely used in laboratory research. This patent-pending kit contains proprietary reagents, consumable processing containers (PULSE Tubes) and instructions for use. It is intended to be used with our patented PCT Sample Preparation System. The kit is based on an approach to a “systems biology” sample preparation method that was first unveiled during early 2008 in collaboration with Dr. Alexander Ivanov, who was then with the Harvard School of Public Health.

ProteoSolve - CE – (ProteoSolve for Conventional Extraction) is a PCT-dependent kit for the extraction of proteins from a variety of samples using optimized detergent-based reagent system compatible with two-dimensional electrophoresis or two-dimensional chromatographic separation for proteomic analysis. The kit contains the reagents and instructions necessary for the extraction of either denatured or non-denatured proteins, which can then be used for the analysis of protein structure and function.

Mitochondria Isolation Kits – These kits contain the chemical ingredients necessary for a scientist to extract mitochondria from skeletal muscle and lung tissue for subsequent analysis. Mitochondria play a major role in generating the energy required to power most cell processes and are involved in other important cell functions. Mitochondria have been implicated in several human diseases, including heart disease, stroke, Parkinson’s disease, cancer and other mitochondrial diseases.

Micro-Pestle (µPestles) - PCT µPestles, in conjunction with PCT MicroTubes, are designed to enhance the extraction of protein, DNA, RNA and small molecules from minute amounts (0.5 – 3.0 mg) of solid tissue in extraction reagent volumes as low as 20-30 µL. PCT MicroTubes and PCT µPestles use Pressure Cycling Technology (PCT) to effectively disrupt soft tissues and lyse their cells. As a result, the tissue sample trapped between the MicroTube end and the µPestles tip is crushed on every pressure cycle. This mechanical action, combined with the extraction ability of the buffer under high pressure, result in effective homogenization and extraction.

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

PCT µPestles are made from Polytetrafluoroethylene (PTFE), a synthetic fluoropolymer of tetrafluoroethylene, also known as Teflon (by DuPont Co). PTFE is practically inert; the only chemicals known to affect it are certain alkali metals and most highly-reactive fluorinating agents.

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

Company Services

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 the three NIH SBIR Phase II grants awarded to us: one was in the approximate amount of $850,000 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 three of the NIH SBIR Phase I grants and the August 2008 and September 2011, NIH SBIR Phase II grants have been completed.

The 2008 SBIR Phase II grant (2R44GM079059) was awarded to us by the NIH for work in the area of using PCT to extract protein biomarkers, 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 recently released 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 National Institutes of Health (“NIH”). Entitled “High Pressure Sample Preparation Instrumentation for DNA Sequencing”, this grant will help 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.

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 Applications of Pressure Cycling Technology

PCT is an enabling, platform technology based on a physical process that had not previously been used to control bio-molecular interactions. During its early development, under the legacy business of Boston Biomedica, Inc., our scientists were researching and developing applications of pressure cycling technology in many areas of the life sciences, including genomic, proteomic and small molecule sample preparation. The data generated during these early years, combined with the data generated since we began focusing on PCT operations in February 2005, form the basis of knowledge that we believe will allow us to successfully commercialize PCT both within and outside of the sample preparation market.

Our research and development efforts have shown that, in addition to genomic, proteomic and small molecule sample preparation, PCT is potentially beneficial in a number of other areas of the life sciences, including pathogen inactivation, protein purification, control of chemical (particularly enzymatic) reactions, and immunodiagnostics. Other applications in the sample preparation market include forensics and histology, as we discuss 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 our Company, 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 manufactured 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 materials 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 bacteria and viruses 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 new inactivation method is needed that can safely, rapidly and inexpensively inactivate pathogens in blood, vaccines and drugs without the need for chemical or other potentially toxic additives. We believe 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., European, and Japanese 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. and European 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. and European 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. and European patents in this area.

Customers

Our customers include researchers at academic laboratories, government agencies, biotechnology companies, pharmaceutical companies and other life science institutions in the United States. Our customers also include a number of foreign distribution partners. Our goal is to continue our market penetration in these target groups and releasing products in our publicized product pipeline. 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, 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, blood banks and transfusion centers, plasma collection centers, pharmaceutical manufacturing plants and other sites involved in each specific application. If we are successful in forensics, our potential customers could be laboratories, military and other government agencies. If we are successful in histology, 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 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, and 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

BIT Group USA, formerly Source Scientific, LLC, currently provides all of the manufacturing and assembly services for our Barocycler NEP2320 and Barocycler NEP3229 instrumentation products under an informal, unwritten understanding. We currently manufacture and assemble the Barocycler HUB440, the Shredder SG3, and the MicroTubes at our South Easton facility. We plan to continue to utilize BIT Group USA as our primary assembler and contract manufacturer of our current, and future, Barocycler NEP 2320 and 3229 instruments. Until we develop a broader network of manufacturers and subcontractors, obtaining alternative sources of supply or manufacturing services could involve significant delays and other costs and challenges, and may not be available to us on reasonable terms, if at all. The failure of a supplier or contract manufacturer to provide sufficient quantities, acceptable quality and timely products at an acceptable price, or an interruption of supplies from such a supplier could harm our business and prospects.

Research and Development

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

1. *Applications Research and Development*: 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 of our PCT Sample Preparation System and further commercialization of PCT-dependent genomic, proteomic, and small molecule sample preparation methods. Dr. Alexander Lazarev, our vice president of Research & Development, meets regularly with our sales, marketing, and engineering staff to discuss market needs and trends. Our applications research and development team is responsible for the technical review of all scientific collaborations, for the support of our marketing and sales departments through the generation of internal data in a number of areas of market interest, and in the development of commercially-viable PCT-dependent products.

2. *Engineering Research and Development:* 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 ensure seamless production processes, perform installations and field service, and work with our application scientists to complete the development of a high throughput sample processing system for the mass spectrometry market.

Product Pipeline

The following instruments are in our research and development pipeline:

Barocycler NEP2320 Extreme – we have designed a major upgrade to our number one selling Barocycler unit, the NEP2320. The NEP2320 Extreme will use a laptop computer (instead of the current microprocessor), will be able to reach 45,000 psi on a routine basis (compared to 35,000 psi for the NEP2320), will have a larger pressure chamber, better temperature and pressure control, and better ergonomics (compared to the NEP2320).

Barocycler FFPE Protein Extraction Instrument System - A PCT-based system offering the enhanced extraction of proteins from formalin-fixed, paraffin-embedded ("*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 PBI's PCT-based HPLC platform.

Sales and Marketing

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 new technology such as PCT.

Sales

Direct US Sales Force

Our domestic sales force currently consists of one full-time sales director and one part-time salesperson. We believe that hiring seasoned sales professionals with significant industry experience will allow us to penetrate the market more effectively than with a small, focused sales force. We may increase the number of sales professionals if our financial resources permit and if we believe that doing so will accelerate our commercialization efforts.

Foreign Distributor Network

Currently, we have multiple distribution arrangements covering countries in Europe, Asia and Australia. In June 2008, we entered into a distribution agreement with Veritas Corporation ("*Veritas*") of Tokyo, Japan pursuant to which we granted Veritas exclusive distribution rights to all of our products in Japan. This agreement terminated on December 31, 2015. We are currently interviewing new companies who have indicated an interest in distributing our products in Japan. In October 2011, we entered into a distribution agreement with IUL Instruments GmbH ("*IUL*") of Germany pursuant to which we granted IUL exclusive distribution rights to all of our products in Germany and Switzerland through March 31, 2014. IUL currently distributes PBI products through our agreement with Constant Systems. In November 2011, we entered into a distributor agreement with Oroboros Instruments Corp. ("*Oroboros*") of Austria pursuant to which we granted Oroboros non-exclusive world-wide distribution rights to the PBI Shredder SG3 System and related products through December 31, 2015. We are currently negotiating an extension to the Oroboros agreement. In March and July 2012, we entered into a distribution agreement with six companies pursuant to which we granted non-exclusive distribution rights to certain PCT products in six European and Asian countries and Australia through December 2013. Currently all six companies distribute PBI products through our agreement with Constant Systems. In October 2012, we entered into a supply agreement with Cole Parmer Corporation pursuant to which we granted Cole Parmer non-exclusive, worldwide distribution rights to our PBI Shredder SG3 System and related consumables through December 2014. This supply agreement has now expired. In November 2012, we entered into a distribution agreement with UK-based Constant Systems ("*CS*"), pursuant to which we granted Constant Systems non-exclusive distribution rights to certain of our PCT SPS product line in 12 European and Asian countries. In June 2013, CS and PBI signed an expanded Distribution Agreement that made PBI the exclusive distributor of CS products throughout all of the Americas. Both of these agreements were extended to May 31, 2017. We expect these agreements will be extended for a minimum of two additional years.

Marketing and Sales

Our marketing and sales function is led by Dr. Nathan Lawrence, our vice president of Marketing and Sales. Dr. Lawrence oversees and directs marketing and sales activities such as 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. Lawrence 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 PBI departments such as Research and Development, but marketing and sales drives the collaborative process. Dr. Lawrence is also responsible for the continued coordination and support of our foreign and domestic distribution partners.

In January 2016, SCIEX, a global leader in life science analytical technologies, announced an exclusive two-year co-marketing agreement with PBI. In their press release, SCIEX stated that the relationship with PBI will uniquely position SCIEX to address a major challenge in complex sample preparation by marketing a complete solution to

increase the depth, breadth, and reproducibility of protein extraction, digestion, and quantitation in all tissue types, including challenging samples like tumors. Under the agreement, PBI and SCIEX will promote PCT Sample Preparation Systems such as PCT-HD with SWATH® Acquisition-based next generation proteomics, TripleTOF® Systems, QTRAP® Systems, and Triple Quad Systems. This focus on improved sample preparation, a crucial step performed in research laboratories worldwide, will enable scientists to extract more proteins reproducibly from complex sample types, potentially yielding superior biological insights and discoveries.

In January and May 2012, we entered into co-marketing/selling and research and development agreements with Digilab, a provider of products for life sciences, analytical chemistry and diagnostic markets, and LEAP Technologies, a provider of automation equipment for the genomic and proteomic industries. These agreements have recently ended.

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 14 United States and 10 foreign patents. Our issued patents expire between 2015 and 2027. 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 terminate in 2016. During the years ended December 31, 2015 and 2014, we incurred approximately $31,301 and $31,835, respectively, in royalty

expense associated with our obligation to BioMolecular Assays, Inc.

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. must pay us these royalties until the expiration in 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 and $2,900 for the years ended 2015 and 2014, respectively.

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.

All of our commercialization efforts to date are focused in the area of genomic, proteomic 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 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 U.S. Food and Drug Administration (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 prohibit us from pursuing such markets.

We 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.

Employees

At December 31, 2015, we had eleven (11) full-time employees and three (3) 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.

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, 2015 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, 2015 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 in us.

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, 2015, our disclosure controls and procedures and our internal control over financial reporting were not effective. As described in Item 9A of this Annual Report on Form 10-K, 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 will need a greater amount of additional capital than we currently expect to need if we experience unforeseen costs or expenses, unanticipated liabilities or delays in implementing our business plan, developing our products and achieving commercial sales.

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.

To satisfy our potential capital requirements to cover the cost of implementing our sales distribution strategy for our current products and services and to develop and commercialize future products and services using our pressure cycling technology relating to sample preparation and other life science applications, we need to raise additional funds in the public or private capital markets. We may seek to raise any necessary additional funds through the issuance of warrants, equity or debt financings or executing collaborative arrangements with corporate partners or other sources,

which may be dilutive to existing stockholders or otherwise have a material effect on our current or future business prospects. Additional financing may not be available to us on a timely basis, if at all, or on terms acceptable to us. 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 actual results and performance, including our ability to raise additional capital, may be adversely affected by current economic conditions.

Our actual results and performance could be adversely affected by the current economic conditions in the global economy, which continue to pose a risk to the overall demand for our products from our customers who may elect to defer or cancel purchases of, or decide not to purchase, our products in response to continuing tightness in the credit markets, negative financial news and general uncertainty in the economy. In addition, our ability to obtain additional financing, on acceptable terms, if at all, may be adversely affected by the uncertainty in the current economic climate.

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, 2015, we recorded a net loss applicable to common shareholders of $7,438,492, or ($0.36) per share, as compared with $6,251,726, or ($0.44) per share, of the corresponding period in 2014. We expect to continue to incur operating losses until sales of our 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.

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

We currently rely on revenues from our PCT and CP 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 our 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 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 than existing techniques. Our PCT sample preparation system is also more costly than 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. We do not have long-term employment agreements with our key employees. The loss of the services of any of our senior management has made, and 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 and sales personnel could harm our product development capabilities and customer and employee relationships, delay the growth of sales of our products and could 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 rely on BIT Group USA ("*BIT Group*"), a third party contract manufacturer, to manufacture our PCT instrumentation, provide engineering expertise, and manage the majority of our sub-contractor supplier relationships. Because of our dependence on one manufacturer, our success will depend, in part, on the ability of BIT Group 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 BIT Group experiences manufacturing problems or delays, or if BIT Group 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 BIT Group, 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 11 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 11 international distribution agreements that cover 22 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 the Food and Drug Administration, and overseas, if and when we begin to invest more resources in the development and commercialization of PCT in applications outside of sample preparation for the research field.

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

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

Our ability to further develop and successfully commercialize our products will depend, in part, on our ability to enforce our patents, preserve our trade secrets, and operate without infringing the proprietary rights of third parties. We currently have 14 United States and 10 foreign patents. The patents expire between 2015 and 2027.

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 minimal 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 required changes in corporate governance and financial disclosure practices

of public companies, some of which are currently applicable to us and others will or may become applicable to us in the future. These rules and regulations 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.

Risks Related to Share Ownership:

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, 2015, 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 and Series K Convertible Preferred Stock.

As of December 31, 2015, all of the 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, 2015 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 and Series K 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, 2015, the Company has issued notes convertible into common stock at prices ranging from $0.28 to $0.45 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 and Series K 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 notes were converted, each as of December 31, 2015, an additional 88,113,929 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, with the sale price fluctuating from a low of $0.13 to a high of $0.78 since January 1, 2014. 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.

Our restated articles of organization, as amended, currently authorize the issuance of up to 65,000,000 shares of common stock and 1,000,000 shares of preferred stock. As of March 31, 2016, we had 23,209,898 shares of common stock issued and outstanding; 300 units of Series D issued and outstanding (convertible into 750,000 shares of common stock); 86,750 shares of Series G Convertible Preferred Stock (convertible into 865,700 shares of common stock); 3,546 shares of Series J Convertible Preferred Stock (convertible into 3,546,000 shares of common stock); 10,000 shares of Series H Convertible Preferred Stock (convertible into 1,000,000 shares of common stock); 21 shares of Series H2 Convertible Preferred Stock (convertible into 2,100,000 shares of common stock); 11,416 shares of Series K Convertible Preferred Stock (convertible into 11,416,000 shares of common stock); outstanding options and warrants to purchase an aggregate of 34,863,199 shares of common stock; and convertible debt convertible into 19,289,286 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 15g-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 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 $4,800 per month, on a lease extension, signed on December 29, 2015, that expires December 31, 2016, for our corporate office.

On November 1, 2014 we signed a lease for lab space in Medford, MA. We subsequently expanded our space in Medford. The lease expires December 30, 2017 and requires monthly payments of $5,385 subject to annual cost of living increases.

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."

The following table sets forth, for the periods indicated, the high and low sales price and the high and low bids, as applicable, per share of common stock, as reported by the OTC Markets from January 1, 2014 through December 31, 2015.

	Year Ended December 31, 2015	
	High	Low
First Quarter	$0.45	$0.17
Second Quarter	$0.38	$0.20
Third Quarter	$0.32	$0.20
Fourth Quarter	$0.49	$0.20

	Year Ended December 31, 2014	
	High	Low
First Quarter	$0.78	$0.23
Second Quarter	$0.64	$0.32
Third Quarter	$0.40	$0.24
Fourth Quarter	$0.35	$0.13

Authorized Capital

As of December 31, 2015, 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 and 15,000 shares as Series K Convertible Preferred Stock.

As of December 31, 2015, there were 23,004,898 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; Series E Convertible Preferred Stock. As of December 31, 2015 there were 300 shares of Series D Convertible Preferred Stock issued and outstanding and convertible into 750,000 shares of common stock, 86,570 shares of Series G Convertible Preferred Stock issued and outstanding convertible into 865,700 shares of common stock, 10,000 shares of Series H Convertible Preferred Stock issued and outstanding convertible into 1,000,000 shares of common stock, 21 shares of Series H2 Convertible Preferred Stock issued and outstanding convertible into 2,100,000 shares of common stock, 3,546 shares of Series J Convertible Preferred Stock issued and outstanding convertible into 3,546,000 shares of common stock, and 11,416 shares of Series K Convertible Preferred Stock issued and outstanding convertible into 11,416,000 shares of common stock.

Approximate Number of Equity Security Holders

As of December 31, 2015, there were approximately 212 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, 2015, dividends issued or to be issued on convertible preferred stock for the years ended December 31, 2015 and 2014 are outlined in the table below.

Dividends paid in common stock or cash For The Year Ended December 31,			Dividends payable For The Year Ended December 31,		
	2015	2014		2015	2014
Series D	$ -	$ -	Series D	$ -	$ -
Series E	-	-	Series E	-	-
Series G	-	58,268	Series G	1,200	1,200
Series H	-	-	Series H	-	-
Series H2	-	-	Series H2	-	-
Series J	-	24,648	Series J	83,926	83,926
Series K	14,894	-	Series K	170,607	163,733
	$ 14,894	$ 82,916		$ 255,733	$ 248,859

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, 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 and MicroTubes, other processing tubes, and application specific kits (which include consumable products and reagents) together make up our PCT Sample Preparation System, or PCT SPS.

We have experienced negative cash flows from operations with respect to our PCT business since our inception. As of December 31, 2015, we did not have adequate working capital resources to satisfy our current liabilities. Based on our current projections, including equity financing subsequent to December 31, 2015, we believe our current and projected cash resources will enable us to extend our cash for the foreseeable future.

The audit report issued by our independent registered public accounting firm on our consolidated audited financial statements for the fiscal year ended December 31, 2015 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, 2015 states that there is 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, 2015 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 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. Such factors 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.

Management has developed a plan to continue operations. This plan includes continued control on expenses, streamlining operations, and obtaining capital through equity and/or debt financing.

We have entered into various fixed rate convertible debentures ($5M PIPE) throughout 2015 for net proceeds of $4,910,000. We also received approximately $1,400,000 of net proceeds from non-convertible debt lenders of which $600,000 was invested in the $5M PIPE, $746,000 was paid off in 2015, and $154,000 remained due on December 31, 2015.

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. Additional financing may not be available to us on a timely basis, if at all, or on terms acceptable to us. 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.

We currently focus the majority of our resources in the area of biological sample preparation, referring to a wide range of activities that precede scientific analysis performed by scientists worldwide working in biological life sciences research. Within the broad field of biological sample preparation, we focus the majority of our product development efforts in three specific areas: mass spectrometry, forensics, and histology.

Biomarker Discovery - Mass Spectrometry. A biomarker is any substance (e.g., protein) 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 number of laboratory instruments are used to help discover biomarkers; a leader among these is the mass spectrometer. The mass spectrometer is one of the laboratory instruments frequently used to help discover biomarkers.

A mass spectrometer is a laboratory instrument used in the analysis of biological samples, frequently for proteins, in life sciences research. According to a recently published market report by Transparency Market Research (www.transparencymarketresearch.com) "*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 compounded 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 offers 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 using PCT in the sample preparation process. We believe that 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 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 cells 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. 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.

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 four 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 all three of the NIH SBIR Phase II grants awarded to us: one was in the approximate amount of $850,000 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 three of the NIH SBIR Phase I grants and the August 2008 and September 2011 NIH SBIR Phase II grants have been completed.

The 2008 SBIR Phase II grant (2R44GM079059) was awarded to us by the NIH for work in the area of using PCT to extract protein biomarkers, 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 US 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 recently released 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 National Institutes of Health ("NIH"). Entitled "High Pressure Sample Preparation Instrumentation for DNA Sequencing", this grant will help 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.

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.

On January 28, 2016 in a report focused on the exclusive co-marketing agreement between SCIEX and PBI, Emerging Growth LLC indicates the combination of the two company's technologies could result in superior biological insights and discoveries and in rapid and dramatic revenue growth for PBI.

On February 3, 2016 SCIEX and Children's Hospital Medical Research Institute (Sydney, Australia) announced they had joined forces to advance the promise of precision medicine. The partners stated they would benefit from SCIEX's exclusive collaborators, including Pressure BioSciences, and PBI's PCT platform for increased protein quantitation and reproducibility.

On March 14, 2016 the Company announced that it would participate in a SCIEX workshop on new innovations towards industrialized proteomics at the US HUPO scientific conference in Boston.

RESULTS OF OPERATIONS

Year Ended December 31, 2015 as compared with December 31, 2014

Revenue

We had total revenue of $1,797,691, in the year ended December 31, 2015 as compared with $1,374,744 in the prior year, a 31% increase. The increase was due to product sales growth and new government grant supported activities.

Products, Services, and Other. Revenue from the sale of products and services was $1,409,991 in the year ended December 31, 2015 compared with $1,350,150 in the year ended December 31, 2014, a 4.4% increase. Revenue included sales of both PBI and Constant Systems pressure-based products. Sales of instrumentation increased in 2015 by $36,139 or 5%, from $799,472 for FY 2014 to $835,611 for FY 2015. Sales of consumables were $146,408 for the year ended December 31, 2015 compared to $167,380 for the same period in 2014, a decrease of $20,972 or 13%. Products, Services, and Other revenue included $78,743 from non-cash transactions with no non-cash transactions in 2014. Revenue from non-cash transactions was $78,743 in 2015 recognized on the fair value of the assets involved, per ASC 845.

Grant Revenue. During 2015, we recorded $387,700 of grant revenue as compared with $24,594 in 2014. 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 National Institutes of Health (“NIH”). Entitled “High Pressure Sample Preparation Instrumentation for DNA Sequencing”, this. T 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.

Cost of Products and Services

The cost of products and services was $609,054 for the year ended December 31, 2015, compared with $652,438 in 2014. Our gross profit margin on products and services was 66% for FY 2015 vs. 48% for FY 2014. The favorable margin improvement was helped with the sale of preownedPBI Barocycler instruments that we repurchased, refurbished, and then resold at better than usual gross margins. The relationship between the cost of products and services and revenue depends greatly on the mix of instruments we sell, the quantity of such instruments, and the mix of consumable products and instrument accessories that we sell in a given period.

Research and Development

Research and development expenditures were $1,105,295 for 2015 compared to $952,555 in 2014, an increase of $152,740 or 16%. This increase in FY 2015 R&D expenses resulted primarily from additional research activities funded through our SBIR Phase II grant, with the aim to develop a new pressure-based system for the extraction of high quality DNA from samples for analysis. We also added much needed electrical engineering and computer software support to help enhance our entire line of pressure-based instrument systems. In FY 2015, we incurred increased consulting expense due to our on-going collaborations with Key Opinion Leaders in several academic laboratories. Research and development expense also included $50,617 and $30,550 of non-cash, stock-based compensation in 2015 and 2014, respectively.

Selling and Marketing

Selling and marketing expenses were $745,574 in 2015 compared to $721,229 in 2014, an increase of $24,345, or 3%. This increase was primarily due to a more aggressive customer outreach program unveiled in 2015. Selling and marketing expense included $32,704 and $19,792 of non-cash stock based compensation expense in 2015 and 2014, respectively.

General and Administrative

General and administrative costs were $2,902,950 in the year ended December 31, 2015, as compared with $2,386,872 in 2014, an increase of $516,078 or 22%. We increased spending on investor relations and patent/trademark activities, as well as in outside consulting services and other investment relations costs to augment our 2015 fund raising efforts. During the years ended December 31, 2015 and 2014, general and administrative expense included $125,668 and $50,783 of non-cash, stock-based compensation expense, respectively.

Operating Loss

Our operating loss was $3,565,182 for the year ended December 31, 2015 as compared with $3,338,350 for the prior year, an increase of $226,832 or 7%. This increase in operating loss was due primarily to increases in R&D and G&A expenses, and by the award of director and employee stock options, off-set to a certain extent by increases in total revenue and product gross margins.

Other income (expense), net

Interest Expense Net interest expense totaled $4,146,416 for the year ended December 31, 2015 as compared with interest expense of $1,303,129 for the year ended December 31, 2014. In connection with full payments of loans, we accelerated amortization of deferred financing costs and imputed interest against the debt discount on short-term loans relating to the prepayment penalties issued with the loans in 2015.

Other income (expense) net

We recognized $36,879 in expense during 2015, compared to $169,554 of expense from the initial fair value calculation on the conversion option on our convertible debt instruments in 2014.

Gain on extinguishment of embedded derivative liabilities

In connection with full payments of convertible debt, we recorded non-cash gains of $2,555,180 on short-term loans relating to the conversion options issued with the loans in 2015.

Change in fair value of derivative liabilities

During the year ended December 31, 2015, we recorded non-cash expense of $2,222,001 from warrant and conversion option liability revaluation in our consolidated statements of operations due to an increase in the fair value of the derivative warrants and the conversion option liabilities on our debt. This increase in fair value was primarily due to an increase in the price per share of our common stock. During the year ended December 31, 2014, we recorded non-cash income of $198,493 for warrant and conversion option liability revaluation due to a decrease in fair value of the liabilities.

Income Taxes

We did not record an income tax benefit or provision for the years ended December 31, 2015 or 2014.

Net Loss

During the year ended December 31, 2015, we recorded a net loss applicable to common stockholders of $7,438,492 or $(0.36) per share, as compared with $6,251,726 or $(0.44) per share during the year ended December 31, 2014. Although the net loss applicable to common stockholders increased in 2015 due to the amortization to interest expense, the gains relating to the full payment of the loans offset the interest impact. See Note 2 of the accompanying Notes to Consolidated Financial Statements under the “Computation of Loss per Share” heading.

LIQUIDITY AND FINANCIAL CONDITION

As of December 31, 2015, 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 recently completed subscriptions totaling $4,910,000 of a $5 million PIPE through December 31, 2015. As of March 18, 2016, total closed subscriptions in our $5 million PIPE now equal $6,040,000. 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 $5 million in additional capital to fund our three-pronged operational plan, which was designed to help increase revenues and reach profitability, by:

A. implementing a next-generation upgrade to our product line and offering a superior instrument with greater net margins;

B. gaining additional non-dilutive monies from governmental research and development applications, and/or engineering projects; and

C. hiring a small team of sales and marketing persons to target research facilities and academic institutions, and 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 $3,819,746 for the year ended December 31, 2015 as compared with $3,210,578 for the year ended December 31, 2014. Our accounts payable balance was $941,389 as of December 31, 2015, as compared with to $1,035,781 as of December 31, 2014, a decrease of $94,392 for 2015. Accounts payable should continue to become more current as we continue to secure more capital and funds from operations allow for more timely payment of our vendors.

We invested $9,412 in fixed assets during the year ended December 31, 2015 as compared with $7,139 investment in fixed assets in the prior year.

Net cash provided by financing activities for the year ended December 31, 2015 was $3,471,993 as compared with $3,660,248 in the prior year.

In 2015, we raised approximately:

A $5,558,537 in aggregate net proceeds from sales of convertible debentures. In connection with our still open private placement, we raised an aggregate of $4,910,000 and issued senior secured convertible debentures that are convertible into 19,289,286 shares of the Common Stock and also issued warrants to the lenders to purchase an aggregate 8,767,857 shares of the Common Stock, at an exercise price of $0.40 per share, expiring five years after the issuance date. Of the $4,910,000 invested in the private placement, $4,310,000 was received in cash and $600,000 was from the conversion of outstanding principal and interest on convertible promissory notes we issued in 2014.

B Loans in the aggregate amount of approximately $1,257,418 were received during the year and we made payments on new and existing debt of $587,949 and converted $396,919 of debt to equity.

Our common stock is listed on the Over-the-Counter QB market under the ticker 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 terminate in 2016. During the year ended December 31, 2015 and 2014, we incurred approximately $31,301 and $31,835, respectively, 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 must pay us these royalties until the expiration of the patents held by BioSeq in 1998, which we anticipate will be 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 and $2,900 for the years ended 2015 and 2014, respectively.

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*"). 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 2015 or 2014.

Severance and Change of Control Agreements

Mr. Schumacher and Drs. Ting, Lazarev and Lawrence, all 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 executive to become an employee of the Company and 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.

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 2015 and 2014 we incurred $105,169 and $98,600, 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, 2015:

2016	$122,220
Thereafter	64,620
	$186,840

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as of December 31, 2015 and December 31, 2014.

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 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. 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 605, *Revenue Recognition*. Revenue is recognized when realized or when realizable and earned when all the following criteria have been met: persuasive evidence of an arrangement exists; goods were shipped, delivery of service has occurred and risk of loss has passed to the customer; the seller's price to the buyer is fixed or determinable; and collectability is reasonably assured.

Our current instruments, the Barocycler NEP3229 and NEP2320, require a basic level of instrumentation expertise to set-up for initial operation. To support a favorable first experience for our customers, weupon 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. Product revenue related to current Barocycler instrumentation is recognized upon shipment of the unit, or in the case where the customer requests installation and training, the completion of the installation and introductory training process of the instrumentation at the customer location, for domestic and foreign installations. Product revenue related to sales of PCT instrumentation to our foreign distributors is recognized upon shipment through a common carrier. We provide for the expected costs of warranty upon the recognition of revenue for the sales of our instrumentation. Our sales arrangements do not provide our customers with a right of return. Product revenue related to our consumable products such as PULSE Tubes, MicroTubes, and application specific kits is recorded upon shipment through a common carrier. Shipping costs are included in sales and marketing expense. Any shipping costs billed to customers are recognized as revenue.

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

a) The fair value of the asset or service involved is not determinable.

b) The transaction is an exchange of a product or property held for sale in the ordinary course of business for a product or property to be sold in the same line of business to facilitate sales to customers other than the parties to the exchange.

c) The transaction lacks commercial substance.

The Company currently records 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 the Company's 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.

Our transactions sometimes involve multiple elements i.e., products and services. Revenue under multiple element arrangements is recognized in accordance with FASB ASC 605-25 *Multiple-Element Arrangements ("ASC 605").* When vendor specific objective evidence or third party evidence of selling price for deliverables in an arrangement cannot be determined, the Company develops a best estimate of the selling price to separate deliverables, and allocates arrangement consideration using the relative selling price method. Additionally, this guidance eliminates the residual method of allocation. If an arrangement includes undelivered elements that are not essential to the functionality of the delivered elements, we defer the fair value of the undelivered elements with the residual revenue allocated to the delivered elements. Fair value is determined based upon the price charged when the element is sold separately. If there is not sufficient evidence of the fair value of the undelivered elements, no revenue is allocated to the delivered elements and the total consideration received is deferred until delivery of those elements for which objective and reliable evidence of the fair value is not available. We provide certain customers with extended service contracts with revenue recognized ratably over the life of the contract.

Intangible Assets

We have classified as intangible assets, costs associated with the fair value of certain assets of businesses acquired. Intangible assets relate to the remaining value of acquired patents associated with PCT. The cost of these acquired patents is amortized on a straight-line basis over sixteen years. We annually review 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 as of December 31, 2015 concluded they were not impaired.

Long-Lived Assets and Deferred Costs

In accordance with FASB ASC 360-10-05, *Property, Plant, and Equipment*, if indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through the undiscounted future operating cash flows related to the long-lived assets. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the fair value of the asset and record the impairment as a reduction in the carrying value of the related asset and a charge to operating results. While our current and historical operating losses and cash flow are indicators of impairment, we performed an impairment analysis at December 31, 2015 and determined that our long-lived assets were not impaired.

Warrant Derivative Liability

The warrants issued in connection with the registered direct offering of Series D Convertible Preferred Stock (the "Series D Warrants") and issued with the $5 million PIPE convertible debentures (the "Debenture Warrants") are measured at fair value and liability-classified because the Series D Warrants Debenture Warrants contained "down-round protection" and therefore, did not meet the scope exception for treatment as a derivative under ASC 815, *Derivatives and Hedging*. Since "down-round protection" is not an input into the calculation of the fair value of the warrants, the warrants cannot be considered indexed to the Company's own stock which is a requirement for the scope exception as outlined under ASC 815. The estimated fair value of the warrants was determined using the binomial model, resulting in an allocation of the gross proceeds of $283,725 to the warrants issued in the Series D registered direct offering.

In connection with the sales of convertible debentures in 2015, the estimated fair value of the warrants was determined using the binomial model, resulting in an allocation of the gross proceeds of $1,933,375 to the warrants issued with convertible debentures. 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 will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability, whichever comes first.

The down-round protection for the Debenture Warrants and Series D Warrants survives for the life of the Warrants, which end starting in May 2017.

Conversion Option Liability

The Company has signed convertible notes and has 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 will continue to classify the fair value of the conversion options as a liability until the conversion options are exercised, expire or are amended in a way that would no longer require these conversion options to be classified as a liability, whichever comes first. The Company has adopted a sequencing policy that reclassifies contracts (from equity to liabilities) with the most recent inception date first. Thus any available shares are allocated first to contracts with the most recent inception dates.

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

We value our inventories at lower of cost or market. Cost is determined by the first-in, first-out (FIFO) method, including material, labor and factory 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 financing costs associated with our capital raising efforts in our statements of operations. These include amortization of debt issue costs such as cash, warrants and other securities issued to finders and placement agents, and amortization of preferred stock discount created by in-the-money conversion features on convertible debt and allocates the proceeds amongst the securities based on relative fair values or based upon the residual method. 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.

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 Board of Directors and Stockholders of

Pressure BioSciences, Inc. and Subsidiary

South Easton, Massachusetts

We have audited the consolidated balance sheet of Pressure BioSciences, Inc. and Subsidiary (collectively, the "Company") as of December 31, 2015, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' deficit, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Pressure BioSciences, Inc. and Subsidiary as of December 31, 2015, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has a working capital deficit and 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 regarding those matters also are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ MaloneBailey LLP

Houston, Texas
April 5, 2016

Report of Independent Registered Public Accounting Firm

To the Board of Directors of

Pressure BioSciences, Inc. and Subsidiary:

We have audited the consolidated balance sheet of Pressure BioSciences, Inc. and Subsidiary (the "Company") as of December 31, 2014, and the related consolidated statement of operations, changes in stockholders' equity, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Pressure BioSciences, Inc. and Subsidiary as of December 31, 2014, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

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 had recurring net losses and continues to experience negative cash flows from operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters also are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ MARCUM LLP

Boston, Massachusetts

March 31, 2015

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2015 AND 2014

	December 31, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$116,783	$473,948
Accounts receivable	113,256	272,022
Inventories, net of $50,000 reserve at December 31, 2015 and December 31, 2014	1,038,371	850,552
Prepaid income taxes	7,381	7,381
Prepaid expenses and other current assets	213,926	104,204
Total current assets	1,489,717	1,708,107
Investment in available-for-sale equity securities	294,522	-
Property and equipment, net	20,149	36,025
TOTAL ASSETS	$1,804,388	$1,744,132
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable	$941,389	$1,035,781
Accrued employee compensation	176,009	157,347
Accrued professional fees and other	821,088	719,432
Deferred revenue	140,878	27,117
Convertible debt, net of unamortized discounts of $0 and $328,681, respectively	100,000	1,004,513
Other debt, net of unamortized discounts of $3,041 and $0, respectively	151,628	80,480
Warrant derivative liabilities	3,295,976	159,875
Conversion option derivative liabilities	3,940,791	590,341
Total current liabilities	9,567,759	3,774,886
LONG TERM LIABILITIES		
Convertible debt, net of unamortized discounts of $5,223,658 and $0, respectively	177,342	-
Deferred revenue	36,935	28,977
TOTAL LIABILITIES	9,782,036	3,803,863
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' DEFICIT		
Series D Convertible Preferred Stock, $.01 par value; 850 shares authorized; 300 shares issued and outstanding on December 31, 2015 and 2014, respectively (Liquidation value of $300,000)	3	3
Series G Convertible Preferred Stock, $.01 par value; 240,000 shares authorized; 86,570 shares issued and outstanding on December 31, 2015 and 2014, respectively	866	866
Series H Convertible Preferred Stock, $.01 par value; 10,000 shares authorized; 10,000 shares issued and outstanding on December 31, 2015 and 2014, respectively	100	100
Series H2 Convertible Preferred Stock, $.01 par value; 21 shares authorized; 21 shares issued and outstanding on December 31, 2015 and 2014, respectively	-	-

Series J Convertible Preferred Stock, $.01 par value; 6,250 shares authorized; 3,546 shares issued and outstanding on December 31, 2015 and 2014, respectively	36	36
Series K Convertible Preferred Stock, $.01 par value; 15,000 shares authorized; 11,416 shares issued and outstanding on December 31, 2015 and 2014, respectively	114	114
Common stock, $.01 par value; 100,000,000 shares authorized; 23,004,898 and 18,673,390 shares issued and outstanding on December 31, 2015 and 2014, respectively	230,050	186,734
Warrants to acquire common stock	5,416,681	5,253,566
Additional paid-in capital	26,036,733	24,617,564
Accumulated other comprehensive income	(105,025)	-
Accumulated deficit	(39,557,206)	(32,118,714)
Total stockholders' deficit	(7,977,648)	(2,059,731)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$1,804,388	$1,744,132

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, 2015 AND 2014

	For the Year Ended December 31,	
	2015	**2014**
Revenue:		
Products, services, other	$1,409,991	$1,350,150
Grant revenue	387,700	24,594
Total revenue	1,797,691	1,374,744
Costs and expenses:		
Cost of products and services	609,054	652,438
Research and development	1,105,295	952,555
Selling and marketing	745,574	721,229
General and administrative	2,902,950	2,386,872
Total operating costs and expenses	5,362,873	4,713,094
Operating loss	(3,565,182)	(3,338,350)
Other (expense) income:		
Interest expense	(4,146,416)	(1,303,129)
Other expense	(36,879)	(169,554)
Gain on extinguishment of embedded derivative liabilities	2,555,180	-
Change in fair value of derivative liabilities	(2,222,001)	198,493
Total other (expense) income	(3,850,116)	(1,274,190)
Net loss	(7,415,298)	(4,612,540)
Accrued dividends on convertible preferred stock	(23,194)	(143,771)
Deemed dividends on convertible preferred stock	-	(1,495,415)
Net loss applicable to common shareholders	$(7,438,492)	$(6,251,726)
Net loss per share attributable to common stockholders - basic and diluted	$(0.36)	$(0.44)
Weighted average common stock shares outstanding used in the basic and diluted net loss per share calculation	20,726,205	14,264,753

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

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

FOR THE YEARS ENDED DECEMBER 31, 2015 AND 2014

	For the Year Ended December 31,	
	2015	2014
Comprehensive Loss		
Net loss	$(7,415,298)	$(4,612,540)
Other comprehensive loss		
Unrealized loss on marketable securities	(105,025)	-
Comprehensive loss	$(7,520,323)	$(4,612,540)

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT

FOR THE YEARS ENDED DECEMBER 31, 2015 AND 2014

	Series D Preferred Stock		Series G Preferred Stock		Series H Preferred Stock		Series H(2) Preferred Stock		Series J Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
BALANCE, December 31, 2013	300	3	145,320	1,453	10,000	100	-	-	5,088	51
Stock-based compensation	-	-	-	-	-	-	-	-	-	-
Conversion of Series G convertible preferred stock	-	-	(58,750)	(587)	-	-	-	-	-	-
Conversion of Series J convertible preferred stock	-	-	-	-	-	-	-	-	(1,542)	(15)
Conversion of Series K convertible preferred stock	-	-	-	-	-	-	-	-	-	-
Issuance of Series K convertible preferred stock	-	-	-	-	-	-	-	-	-	-
Issuance of common stock for services	-	-	-	-	-	-	-	-	-	-
Exercise of warrants										
Warrant exercise - reset	-	-	-	-	-	-	-	-	-	-
Offering costs for issuance of preferred stock	-	-	-	-	-	-	-	-	-	-
Issuance of warrants	-	-	-	-	-	-	-	-	-	-
Issuance of warrants for services	-	-	-	-	-	-	-	-	-	-
Issuance of stock in lieu of cash for Board of Director fees	-	-	-	-	-	-	-	-	-	-
Deemed dividend associated with beneficial conversion of preferred stock	-	-	-	-	-	-	-	-	-	-
Conversion of debt for commons stock	-	-	-	-	-	-	-	-	-	-
Conversion of preferred stock to common stock	-	-	-	-	-	-	-	-	-	-
Conversion of common stock to Series H2 preferred stock	-	-	-	-	-	-	21	-	-	-
Dividends earned	-	-	-	-	-	-	-	-	-	-
Warrants issued with debt	-	-	-	-	-	-	-	-	-	-
Write off of Series D warrant liability	-	-	-	-	-	-	-	-	-	-
Write off of conversion option	-	-	-	-	-	-	-	-	-	-
Issuance of common stock for dividends paid in kind	-	-	-	-	-	-	-	-	-	-

Net loss	-	-	-	-	-	-	-	-	-	-
BALANCE, December 31, 2014	300	3	86,570	866	10,000	100	21	-	3,546	36
Stock-based compensation	-	-	-	-	-	-	-	-	-	-
Issuance of common stock for services	-	-	-	-	-	-	-	-	-	-
Warrant exercise - reset	-	-	-	-	-	-	-	-	-	-
Issuance of warrants	-	-	-	-	-	-	-	-	-	-
Issuance of warrants for services	-	-	-	-	-	-	-	-	-	-
Conversion of debt for commons stock	-	-	-	-	-	-	-	-	-	-
Dividends earned	-	-	-	-	-	-	-	-	-	-
Unrealized loss on investments, net of tax										
Net loss	-	-	-	-	-	-	-	-	-	-
BALANCE, December 31, 2015	300	3	86,570	866	10,000	100	21	-	3,546	36

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

PRESSURE BIOSCIENCES, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT (CONTINUED)

FOR THE YEARS ENDED DECEMBER 31, 2015 AND 2014

	Series K Preferred Stock		Common Stock		Stock	Additional Paid-In	Accumulated other comprehensive	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	Warrants	Capital	loss	Deficit	Equity
BALANCE, December 31, 2013	4,000	$40	12,024,267	$120,243	$4,267,402	$19,509,921	$-	$(25,866,988)	$(1,967,775)
Stock-based compensation	-	-	-	-	-	101,125		-	101,125
Conversion of Series G convertible preferred stock	-	-	587,500	5,875	-	(5,288)		-	-
Conversion of Series J convertible preferred stock	-	-	1,541,000	15,410	-	(15,395)		-	-
Conversion of Series K convertible preferred stock	(1,099)	(11)	1,099,000	10,990	-	(10,980)		-	-
Issuance of Series K convertible preferred stock	8,176	82	-	-	654,845	1,592,432		-	2,247,359
Issuance of common stock for services	-	-	588,830	5,888	-	208,304		-	214,192
Exercise of warrants			596,658	5,967	-	143,198		-	149,165
Warrant exercise - reset	-	-	3,612,000	36,120	163,654	662,745		-	862,519
Offering costs for issuance of preferred	-	-	-	-	-	(8,000)		-	(8,000)

stock								
Stock exchange with Everest Investments	-	-	-	-	49,599	-	-	49,599
Issuance of warrants for services	-	-	-	-	93,488	-	-	93,488
Issuance of stock in lieu of cash for Board of Director fees	339	3	-	-	24,578	60,169	-	84,750
Deemed dividend associated with beneficial conversion of preferred stock	-	-	-	-	-	1,495,415	(1,495,415)	-
Conversion of debt for commons stock	-	-	510,000					